

# North American Spine Society

Evidence-Based Clinical Guidelines  
for Multidisciplinary Spine Care

## Diagnosis and Treatment of Low Back Pain

Evidence-Based Clinical Guidelines for  
Multidisciplinary Spine Care:  
**Diagnosis & Treatment of Low Back Pain**



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*(does not necessarily imply endorsement)*

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- American Academy of Pain Medicine (AAPM)
- American Association of Neurological Surgeons (AANS)/Congress of Neurological Surgeons (CNS)
- American Society of Anesthesiologists (ASA)
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- Spine Intervention Society (SIS)

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*(does not necessarily imply endorsement)*

- American Academy of Physical Medicine and Rehabilitation (AAPM&R)
- American Physical Therapy Association (APTA)

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Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

## Financial Statement/ Disclosures

This clinical guideline was developed and funded in its entirety by the North American Spine Society (NASS) with the exception that stakeholder societies provided representatives and paid for the travel and accommodation of their representatives to recommendation meetings. All participating authors have disclosed potential conflicts of interest consistent with NASS' disclosure policy (<http://www.spine.org/DisclosurePolicy>). Disclosures of all authors and contributors are listed in the Technical Report associated with this document.

## Comments

Comments regarding this guideline may be submitted to the North American Spine Society at [guidelines@spine.org](mailto:guidelines@spine.org) and will be considered in development of future revisions of the work.

## Endorsements

Letters of endorsement from external societies can be found in the Technical Report associated with this document.

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## Objective

The objective of the *North American Spine Society (NASS) Clinical Guideline for the Diagnosis and Treatment of Low Back Pain* is to provide evidence-based recommendations to address key clinical questions surrounding the diagnosis and treatment of adult patients with nonspecific low back pain. This guideline is based upon a systematic review of the evidence and reflects contemporary treatment concepts for low back pain as reflected in the highest quality clinical literature available on this subject as of February 2016. The goals of the guideline recommendations are to assist in delivering optimum, efficacious treatment and functional recovery from nonspecific low back pain.

## Scope, Purpose and Intended User

This document was developed by the North American Spine Society Evidence-Based Guideline Development Committee with representation from stakeholder organizations as an educational tool to assist practitioners who treat adult patients with nonspecific low back pain. The goal is to provide a tool that assists practitioners in improving the quality and efficiency of care delivered to these patients. The *NASS Clinical Guideline for the Diagnosis and Treatment of Low Back Pain* outlines a reasonable evaluation of patients with nonspecific low back pain and outlines treatment options for adult patients with this condition.

**THIS GUIDELINE DOES NOT REPRESENT A “STANDARD OF CARE,”** nor is it intended as a fixed treatment protocol. It is anticipated that there will be patients who will require less or more treatment than the average. It is also acknowledged that in atypical cases, treatment falling outside this guideline will sometimes be necessary. This guideline should not be seen as prescribing the type, frequency or duration of intervention. Treatment should be based on the individual patient’s need and doctor’s professional judgment and experience. This document is designed to function as a guideline and should not be used as the sole reason for denial of treatment and services. This guideline is not intended to expand or restrict a health care provider’s scope of practice or to supersede applicable ethical standards or provisions of law.

## Patient Population

The patient population for this guideline encompasses adults (18 years or older) with low back pain defined as pain of musculoskeletal origin extending from the lowest rib to the gluteal fold that may at times extend as somatic referred pain into the thigh (above the knee).

## Considerations: Why This Guideline Is Different and How Exclusion of Leg Pain Impacts the Recommendations

NASS typically writes clinical guidelines based on diagnosis. Due to demand and the expertise of NASS spine care specialists, NASS, in this single instance, has opted to address low back pain as a generalized topic rather than a specific diagnosis or code. As a multidisciplinary organization for spine care providers, NASS was uniquely positioned to provide specialty expertise and a real-world perspective on multidisciplinary spine care. It is important to keep in mind that “low back pain” is no more a diagnosis in the spine field than “chest pain” is for cardiology, but rather a generalized patient complaint that can encompass a variety of diagnoses.

Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded leg pain below the knee. Leg pain was excluded in order to address treatment of nonspecific low back pain. For many sections, the inclusion of leg pain in the literature search would have included many specific causes of back pain, including disc herniation and spondylolisthesis, that would have made the focus on nonspecific low back pain more difficult and less clear.

Without the inclusion of leg pain, these guideline recommendations address only a subset of low back pain and its care. The inclusion and exclusion criteria used resulted in the removal of multiple articles that may have influenced overall recommendations for a particular treatment or procedure. Evaluation of a particular treatment or procedure under different clinical circumstances would necessitate a separate evaluation of the evidence.

Due to the time needed to develop a guideline of this size and breadth, some explanation is needed as to the why or why not certain items can be found in the content.

- Although opioids are addressed, it is in a limited fashion. The opioid crisis as we know it today was a phenomenon that reached crisis proportions after the guideline was already in development. In the future, more substantial attention to this issue will be merited.
  - This is the largest clinical guideline NASS has ever undertaken and four years in the making. There were 82 clinical questions and the literature search resulted in more than 45,000 articles. Due
- to the high volume of literature and the labor-intensive nature of the review, literature search dates are spread out in some instances (although most were within the same month). In addition, consideration should be given to the fact that newer research has been published since the literature searches have taken place.
- This document is based on the evidence known at the time of the literature review. However, evidence can be incomplete or immature and recommendations can change in the future where the current evidence is thin, weak, or evolving. NASS' future recommendations for research are a valuable tool when considering these areas.



## Guideline Development

### Methodology

Through objective evaluation of the evidence and transparency in the process of making recommendations, it is NASS' goal to develop evidence-based clinical practice guidelines for the diagnosis and treatment of adult patients with various spinal conditions. These guidelines are developed for educational purposes to assist practitioners in their clinical decision-making processes.

### Multidisciplinary and Multi-Stakeholder Collaboration

With the goal of ensuring the best possible care for adult patients suffering with spinal disorders, NASS is committed to multidisciplinary involvement in the process of guideline development. To this end, NASS has ensured that representatives from research, both operative and non-operative, medical, interventional and surgical spine specialties have participated in the development and review of NASS guidelines. To ensure broad-based representation on this topic, NASS invited representatives from organizations whose members are involved in the care of patients with low back pain to serve on guideline work groups. A more detailed description of stakeholder involvement is included under the "Guideline Development Process" on page 9.

### Evidence Analysis Training of all Guideline Developers

As a condition of participation, all developers completed NASS' Fundamentals of Evidence-Based Medicine Training prior to participating in guideline development. The training includes a series of readings and exercises to prepare guideline developers for systematically evaluating literature and developing evidence-based guidelines. Participants are awarded CME credit upon completion of the course.

### Disclosure of Potential Conflicts of Interest

All participants involved in guideline development have disclosed potential conflicts of interest to their colleagues in accordance with NASS' Disclosure Policy (<https://www.spine.org/DisclosurePolicy>) and their potential conflicts have been documented in the Technical Report associated with this guideline. NASS does not restrict involvement in guidelines based on conflicts as long as members provide full disclosure. Individuals with a conflict relevant to the subject matter were asked to recuse themselves from delib-

eration. Participants have been asked to update their disclosures regularly throughout the guideline development process.

### Levels of Evidence and Grades of Recommendation

NASS has adopted standardized levels of evidence (Appendix A) and grades of recommendation (Appendix B) to assist practitioners in easily understanding the strength of the evidence and recommendations within the guidelines. The levels of evidence range from Level I (high quality randomized controlled trial) to Level V (expert consensus). Grades of recommendation indicate the strength of the recommendations made in the guideline based on the quality of the literature.

#### Grades of Recommendation:

- **A:** Good evidence (Level I studies with consistent findings) for or against recommending intervention.
- **B:** Fair evidence (Level II or III studies with consistent findings) for or against recommending intervention.
- **C:** Poor quality evidence (Level IV or V studies) for or against recommending intervention.
- **I:** Insufficient or conflicting evidence not allowing a recommendation for or against intervention.

Levels of evidence have very specific criteria and are assigned to studies prior to developing recommendations. Recommendations are then graded based upon the level of evidence. To better understand how levels of evidence inform the grades of recommendation and the standard nomenclature used within the recommendations see Appendix C.

Guideline recommendations are written utilizing a standard language that indicates the strength of the recommendation. "A" recommendations indicate a test or intervention is "recommended"; "B" recommendations "suggest" a test or intervention and "C" recommendations indicate a test or intervention "may be considered" or "is an option." "I" or "Insufficient Evidence" statements clearly indicate that "there is insufficient evidence to make a recommendation for or against" a test or intervention. Work group consensus statements clearly state that "in the absence of reliable evidence, it is the work group's opinion that" a test or intervention may be appropriate.

In evaluating studies as to levels of evidence for this guideline, the study design was interpreted as establishing only a potential level of evidence. As an example, a therapeutic study designed as a randomized controlled trial would be considered a potential Level I study. The study would then be further analyzed as to how well the study design was implemented and significant shortcomings in the execution of the study would be used to downgrade the levels of evidence for the study's conclusions. In the example cited previously, reasons to downgrade the results of a potential Level I randomized controlled trial to a Level II study II would include, among other possibilities: an underpowered study (patient sample too small, variance too high), inadequate randomization or masking of the group assignments and lack of validated outcome measures.

In addition, a number of studies were reviewed several times in answering different questions within this guideline. How a given question was asked might influence how a study was evaluated and interpreted as to its level of evidence in answering that particular question. For example, a randomized controlled trial reviewed to evaluate the differences between the outcomes of surgically treated versus untreated patients with lumbar disc herniation with radiculopathy might be a well-designed and implemented Level I therapeutic study. This same study, however, might be classified as providing Level II prognostic evidence if the data for the untreated controls were extracted and evaluated prognostically.

## Guideline Development Process

### Step 1: Recruitment of Guideline Members and Involvement of Stakeholder Representatives

NASS Evidence-Based Guideline Development Committee members were solicited to participate in the guideline development process. NASS also invited stakeholder organizations who participate in the Spine Summit, a multi-stakeholder meeting convened to discuss and collaborate on projects that advance the field of spine care, to nominate representatives from their respective organization to serve on the guideline panel. Additional specialties not represented at the Spine Summit were also solicited to participate in the guideline to ensure broad representation of all specialties directly involved in the care of patients with low back pain. In total, 62 volunteers participated in this effort, including 11 stakeholder societies. Names of guideline panelists are listed on page 2 and disclosures are listed in the Technical Report associated

with this document. The stakeholder groups can also be found on page 3.

NASS spearheaded this guideline effort by providing staff support and financial support, including literature searches, full text articles, webinar/conference capabilities and food and beverage and facility fees for the in-person recommendation meetings. Stakeholder organizations were asked to cover travel and accommodation related expenses for their representative to attend any in-person meetings.

### Step 2: Identification of Work Groups

The guideline panel consists of seven sections: Diagnosis, Imaging, Medical and Psychological Treatment, Interventional Treatment, Physical Medicine and Rehabilitation, Surgical Treatment and Cost-Utility. Stakeholder societies were asked to rank their interest in participating in each section and their representative was placed in their first or second choice. Senior and newer NASS Evidence-Based Guideline Development members were equally placed in work groups to ensure that groups with newer members were balanced with members who have more guideline development experience. Each work group consisted of 7 to 11 members representing multi-disciplinary backgrounds. The guideline panel includes representation from the fields of primary care, psychology, neurosurgery, orthopedic surgery, physical medicine and rehabilitation, physiatry, chiropractic care, physical therapy, anesthesiology, research, and radiology. NASS believes that having multidisciplinary teams involved in the guideline development process helps to minimize inadvertent biases in evaluating the literature and formulating recommendations.

### Step 3: Surveying Patients

To seek patient input to help inform the development of clinical questions, NASS circulated an informal Survey Monkey poll to better understand patients' experiences with low back pain treatment. The survey link was circulated through various websites and social media sites, including NASS' Facebook and Twitter pages; spine-health.com's website, Facebook group and blog; Low-Back Pain Patient Support Group on Facebook; Lower Back Pain Management Support Group on Facebook; and numerous Facebook shares (of the survey link) on consumer and physician profiles. A total of 415 people opened the survey link, including 413 who consented to participate in the survey and 2 who did not participate. The survey included the following questions that allowed for check the box and open-ended responses:

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1. What symptoms made you seek medical attention for your current and/or any past episodes of low-back pain?
2. Please identify the treatment(s) you received for your current and/or any past episodes of low back pain.
3. Based on your treatment experiences for your current and any previous episodes of low back pain, is there anything that you wish your health-care provider shared with you before making your decision to receive treatment?
4. What questions do you recommend that other patients with low back pain ask their providers when seeking a diagnosis and treatment options for low back pain?

#### Step 4: Identification of Clinical Questions

Framing questions to ask in the guideline is critical to the guideline development process. Guideline participants were asked to submit a list of clinical questions pertaining to their assigned section with the patient survey as reference. Members were asked to use the acronym “PICO” when drafting questions. “PICO” serves to guide the development of clinical questions that include all of the necessary components to build a literature search: “P” for the patient/problem; “I” for the intervention or indicator of interest (procedures, therapies, diagnostic tests, exposure, etc.); “C” for comparison and “O” for outcome of interest. The proposed questions were compiled into a master list and circulated to each member for review and comment.

#### Step 5: External Review of Clinical Question Protocol

The draft list of clinical questions was made publicly available on the NASS website for a 4-week public comment period from June 16, 2015 to July 14, 2015. Additionally, stakeholders were invited through email solicitations to comment on the draft questions. In response, 27 individuals and organizations submitted comment letters. Based on feedback, several revisions were incorporated in the guideline definition and clinical question list. After the comment period, an updated clinical question list with summarized changes was posted to the NASS website and circulated to all public comment period reviewers.

#### Step 6: Identification of Search Terms and Parameters

One of the most crucial elements of evidence analysis is the comprehensive literature search. Thorough assessment of the literature is the basis for the re-

view of existing evidence and the formulation of evidence-based recommendations. In order to ensure a thorough literature search, NASS has instituted a Literature Search Protocol (Appendix D) which has been followed to identify literature for evaluation in guideline development. In keeping with the Literature Search Protocol, work group members have identified appropriate search terms and parameters to direct the literature search. Specific search strategies, including search terms, parameters and databases searched, are documented in the Technical Report associated with this document. The guideline definition and inclusion/exclusion criteria are outlined on page 16.

#### Step 7: Completion of the Literature Search

Once each work group identified search terms/parameters, the literature search was implemented by a medical/research librarian at InfoNOW at the University of Minnesota, consistent with the Literature Search Protocol. Following these protocols ensures that NASS recommendations (1) are based on a thorough review of relevant literature; (2) are truly based on a uniform, comprehensive search strategy; and (3) represent the current best research evidence available. NASS maintains a search history in Endnote, for future use or reference.

#### Step 8: Review of Search Results/Identification of Literature to Review

Work group members reviewed all abstracts yielded from the literature search and identified the literature they would review in order to address the clinical questions, in accordance with the Literature Search Protocol (Appendix D).

#### Step 9: Evidence Analysis

Members independently developed evidentiary tables summarizing study conclusions, identifying strengths and weaknesses and assigning levels of evidence. In order to systematically control for potential biases, two or more work group members have reviewed each article selected and independently assigned levels of evidence to the literature using the NASS levels of evidence. Any discrepancies in scoring have been addressed by two or more reviewers. Final ratings are completed at a final meeting or web conference of section workgroup members including the section chair and a guideline co-chair. As a final step in the evidence analysis process, members have identified and documented gaps in the evidence to educate guideline readers about where evidence is lacking and help guide further needed research.

**10** Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

### Step 10: Formulation of Evidence-Based Recommendations and Incorporation of Expert Consensus

Work groups held web-conferences and face-to-face meetings to discuss the evidence-based answers to the clinical questions, the grades of recommendations and the incorporation of expert consensus. Expert consensus was incorporated only where Level I-IV evidence is insufficient and the work group has deemed that a recommendation is warranted. Transparency in the incorporation of consensus is crucial and all consensus-based recommendations made in this guideline very clearly indicate that Level I-IV evidence is insufficient to support a recommendation and that the recommendation is based only on expert consensus.

#### Consensus Development Process

For recommendations with a consensus grading, voting was conducted using a modification of the nominal group technique in which each work group member independently and anonymously ranked a recommendation on a scale ranging from 1 (“extremely inappropriate”) to 9 (“extremely appropriate”). Consensus was obtained when at least 80% of work group members ranked the recommendation as 7, 8 or 9. When the 80% threshold was not attained, up to three rounds of discussion and voting were held to resolve disagreements. If disagreements were not resolved after these rounds, no recommendation was adopted. After the recommendations were established, work group members developed the guideline content, addressing the literature supporting the recommendations.

### Step 11: Internal Review of Draft Guideline

Guideline sections were reviewed by the section work groups that developed them. The full guideline draft was submitted to the guideline co-chairs and NASS Research Council for review and comment. Revisions to recommendations were considered only when substantiated by a preponderance of appropriate level evidence.

### Step 12: External Review of Draft Guideline

Stakeholder societies were invited to comment on the draft guideline during an external review period June–August 2019. Nine of 11 stakeholder societies provided comments. Revisions to recommendations were considered only when substantiated by a preponderance of appropriate level evidence. Responses to external comments are available in the technical

report associated with this guideline. Prior to publication, external stakeholders were invited to be listed as participating or contributing societies.

### Step 13: Submission for Board Approval

Once any evidence-based revisions were incorporated, the drafts were prepared for NASS Board of Directors review and approval. Edits and revisions to recommendations and any other content were considered for incorporation only when substantiated by a preponderance of appropriate level evidence.

### Step 14: Submission for Publication

Following NASS Board approval, the guidelines were slated for publication. No revisions were made after submission for publication, but comments have been and will be saved for the next iteration.

### Step 15: Review and Revision Process

The guideline recommendations will be reviewed every five years by an EBM-trained multidisciplinary team and revised as appropriate after review and assessment of relevant literature published since the development of this version of the guideline or the guideline will be rescinded if it will not be updated.

#### Use of Acronyms

Throughout the guideline, readers will see many acronyms with which they may not be familiar. A glossary of acronyms is available on page 14.

#### Nomenclature for Medical/Interventional Treatment

Throughout the guideline, readers will see that what has traditionally been referred to as “nonoperative,” “nonsurgical,” or “conservative” care is now referred to as “medical/interventional care.” The term medical/interventional is meant to encompass pharmacological treatment, physical therapy, exercise therapy, manipulative therapy, modalities, various types of external stimulators and injections.

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## Glossary

**Acute low back pain:** Within first 6 weeks of person's current LBP episode.<sup>1</sup>

**Chronic low back pain:** Symptoms for current LBP episode present for greater than 12 weeks.<sup>2</sup>

**General fitness program:** Exercise program not focused on specific muscle groups; by definition the goal is to improve the overall general fitness of the patient by using a combination of aerobic conditioning with stretching/strengthening of all major muscle groups.

**Lumbar stabilization exercises:** Focused on facilitating and strengthening specific muscles that directly or indirectly control spinal joint function, especially the abdominal, gluteal and spinal extensor muscle groups.

**Medical/interventional treatment:** The term medical/interventional treatment is used in place of “non-operative,” “conservative,” or “nonsurgical” treatment. It encompasses pharmacological treatment, physical therapy, exercise therapy, manipulative therapy, modalities, various types of external stimulators and injections.

**Nonspecific low back pain:** Pain in which no specific cause or structure can be identified to account for the patient's perceived symptoms.<sup>3</sup>

**Radiculopathy:** Dysfunction of a nerve root associated with pain, sensory impairment, weakness, or diminished deep tendon reflexes in a nerve root distribution.<sup>4</sup>

**Recurrent low back pain:** Symptoms less than 1/2 the days in a year occurring in multiple episodes.<sup>5</sup>

**Sciatica:** Pain radiating down the leg below the knee in the distribution of the sciatic nerve, suggesting nerve root compromise due to mechanical pressure or inflammation. Sciatica is the most common symptom of lumbar radiculopathy.<sup>4</sup>

**Specific low back pain:** Pain that can be linked to a disorder, disease, infection, injury, trauma, or structural deformity. A potential causal relationship can be found between the diagnosis and the pain.<sup>3</sup>

**Spinal manipulative therapy (SMT):** SMT is defined as spinal manipulative therapy, manual therapy, mobilization and high velocity thrusts.

**Subacute low back pain:** Symptoms for current LBP episode present for 6–12 weeks.<sup>1</sup>

**Visceral diseases resulting in back pain:** Pain secondary to diseases of the viscera. *Examples:* endometriosis, prostatitis, aortic aneurysm.<sup>5</sup>

## Red Flag Conditions<sup>4,6-7</sup>

### History

- Cancer
- Unexplained weight loss
- Immunosuppression
- Intravenous drug use
- Urinary tract infection
- Fever
- Significant trauma relative to age
- Bladder or bowel incontinence
- Urinary retention (with overflow incontinence)

### Physical Examination

- Saddle anesthesia
- Loss of anal sphincter tone
- Major motor weakness in lower extremities
- Fever
- Neurologic findings persisting beyond one month or progressively worsening

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## Acronyms

AAQ-II	Acceptance and Action Questionnaire	IV	Intravenous
ADS	Allgemeine Depressions-Skala	K-ODI	Korean Oswestry Disability Index
ALIF	Anterior lumbar interbody fusion	K-SF-36	Korean Short Form-36
AM	Active management	LBP	Low back pain
BDI	Beck Depression Inventory	MDR	Multidisciplinary rehabilitation
BDI-II	Beck Depression inventory-II	MDT	Mechanical diagnosis and therapy
BMI	Body mass index	MMPI	Minnesota Multiphasic Personality Inventory
BMP	Bone morphogenetic protein	MPQ	McGill Pain Questionnaire
BPI	Brief Pain Inventory	MR	Magnetic resonance
CBA	Cognitive behavioral approach	MRI	Magnetic resonance imaging
CBT	Cognitive behavioral therapy	MSPQ	Modified Somatic Perception Questionnaire
CCBT	Contextual cognitive-behavioral therapy	MVK	Modified Von Korff Scale
CEQ	Cognitive Error Questionnaire	NPRS	Numeric Pain Rating Scale
CLBP	Chronic low back pain	NRS	Numerical rating scale
CMDQ	Common Mental Disorders Questionnaire	NSAIDS	Nonsteroidal anti-inflammatory drugs
COX-2	Cyclooxygenase-2	ODI	Oswestry Disability Index
CPAQ	Chronic Pain Acceptance Questionnaire	ODQ	Oswestry Low Back Pain Disability Questionnaire
CPR	Clinical Prediction Rule	OLBPQ	Oswestry Low Back Pain Disability Questionnaire
CT	Computed tomography	PCS	Pain Catastrophizing Scale
DPQ	Dallas Pain Questionnaire	PDI	Pain Disability Index
DD	Disc degeneration	PGADS	Patient Global Assessment of Disease Status
DDS	Descriptor Differential Scale	PGAP	Progressive Goal Attainment Program
DIS	Diagnostic Interview Schedule Version III-R	PGI-I	Patient's Global Impressions of Improvement
DSN	Disc space narrowing	PHIC	Modified Patient Global Impression of Change
ED	Emergency department	PLF	Posterolateral fusion
EEG	Electroencephalogram	PLIF	Posterior lumbar interbody fusion
ESC	End plate signal change	PRI	Pain Rating Index
EMG	Electromyography	PRP	Platelet-rich plasma
ESI	Epidural steroid injection	PSQI	Pittsburgh Sleep Quality Index
FABQ	Fear Avoidance Beliefs Questionnaire	PTSD	Post-traumatic stress disorder
FD	End of First Dose	QALYs	Quality-adjusted life years
FJ	Facet joint	QOL	Quality of life
FJOA	Facet joint osteoarthritis	PENS	Percutaneous electrical nerve stimulation
FJP	Facet joint pain	RCT	Randomized controlled trial
FRI	Function Rating Index	RMDQ	Roland Morris Disability Questionnaire
HADS	Hospital Anxiety and Depression Scale	ROAD	Research on Osteoarthritis/Osteoporosis against Disability
HADS-D Anxiety	Hospital Anxiety and Depression Scale	RTW	Return to work
HILT	High-intensity laser therapy	SCL-90-R	Symptom Checklist
HIZ	High intensity zone	SEBT	Star excursion balance test
HRQOL	Health related quality of life	SF-36	Medical Outcome Study Short Form-36
IAS	Illness Attitude Scale	SFMPQ	Short-Form McGill Pain Questionnaire
IDD	Internal disc disruption		
IDD	Intervertebral Differential Dynamics		
IPQ-R	Revised Illness Perception Questionnaire		
IDET	Intradiscal electrothermal therapy		
IDETA	Intradiscal electrothermal anuloplasty		

SI	Sacroiliac		stimulation
SIJ	Sacroiliac joint	TLIF	Transforaminal lumbar interbody fusion
SIJI	Sacroiliac joint injection		
SIJP	Sacroiliac joint pain	TSE	Transcutaneous spinal electroanalgesia
SIP	Sickness Impact Profile		
SJD	Sacroiliac joint dysfunction	TSK	Tampa Scale for Kinesiophobia
SMT	Spinal manipulative therapy	TTM	Transtheoretical Model
SN	Schmorl's nodes	UK BEAM	UK Back pain Exercise And Manipulation (UK BEAM)
SPECT	Single photon emission computerized tomography	VAS	Visual analog scale
STAXI	State-Trait Anger Expression Inventory	VNS	Visual Numeric Pain Scale
		VO	Vertebral osteophytes
TDR	Total disc replacement	VRS	Verbal rating scale
TENS	Transcutaneous electrical nerve	ZDS	Zung Depression Scale

Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.



## Definition

Low back pain is defined as pain of musculoskeletal origin extending from the lowest rib to the gluteal fold that may at times extend as somatic referred pain into the thigh (above the knee).

## Inclusion Criteria

1. Adult patients aged 18 and older
2. Patients with low back pain limited to somatic referred pain/non-radicular pain limited to above the knee only

## Exclusion Criteria

1. Patients less than 18 years of age
2. Low back pain due to:
  - a. Tumor
  - b. Infection
  - c. Metabolic disease
  - d. Inflammatory arthritis
  - e. Fracture
3. Patients with a diagnosed deformity, including spondylolisthesis, spondylolysis and scoliosis
4. Pain experienced below the knee
5. Extra-spinal conditions (ie, visceral, vascular, genito-urinary)
6. Patients who have undergone prior lumbar surgery
7. Presence of neurological deficit
8. Back pain that is associated with widespread multi-site pain (>2 sites)
9. Pregnancy

Clinical Question	Guideline Recommendation
<p style="text-align: center;"><i>See recommendation sections for supporting text</i></p> <p style="text-align: center;">A=Recommended; B=Suggested; C=May be considered; I=Insufficient or Conflicting Evidence</p>	
Diagnosis	
<p><b>Diagnosis Question 1.</b> In patients with low back pain, are there specific history or physical examination findings that would indicate the structure causing pain and, therefore, guide treatment?</p> <ul style="list-style-type: none"> <li>a. Vertebral body</li> <li>b. Intervertebral disc</li> <li>c. Zygapophyseal joint</li> <li>d. Posterior elements</li> <li>e. Sacroiliac joint</li> <li>f. Muscle/tendon</li> <li>g. Central sensitization</li> </ul>	<p>There is insufficient evidence to make a recommendation for or against the use of innominate kinematics for the assessment of sacroiliac joint pain.</p> <p><b>Grade of Recommendation: I</b></p> <p>There is insufficient evidence to make a recommendation for or against the use of pain localization in predicting response to a diagnostic injection.</p> <p><b>Grade of Recommendation: I</b></p> <p>There is insufficient evidence to make a recommendation for or against the assessment of centralization or peripheralization for the prediction of discography results.</p> <p><b>Grade of Recommendation: I</b></p>
<p><b>Diagnosis Question 2.</b> In patients with low back pain, are there history or physical examination findings that would serve as predictors for the recurrence of low back pain?</p>	<p>There is insufficient evidence to indicate that body mass index (BMI) is a potential predictor of a recurrence of low back pain.</p> <p><b>Grade of Recommendation: I</b></p> <p>It is suggested that history of low back pain is a potential predictor of a recurrence of low back pain.</p> <p><b>Grade of Recommendation: B</b></p>

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<p><b>Diagnosis Question 3.</b> In patients with acute low back pain, are there history or physical examination findings that would predict that an episode will resolve within one month?</p> <p><b>Diagnosis Question 6.</b> What are the patient characteristics that increase or decrease the risk of developing chronic low back pain after an acute episode?</p> <p><b>Diagnosis Question 9.</b> Does a psychological evaluation assist with identifying patients with low back pain who are at risk for developing chronic pain or disability?</p> <p><i>The work group considered these questions together as the vast majority of the literature evaluating the conversion from acute to chronic pain combined various demographic, social, psychological and physical examination findings in predictive models.</i></p>	<p>It is recommended that psychosocial factors and workplace factors be assessed when counseling patients regarding the risk of conversion from acute to chronic low back pain.</p> <p><b>Grade of Recommendation: A</b></p> <p>It is recommended that psychosocial factors be used as prognostic factors for return to work following an episode of acute low back pain.</p> <p><b>Grade of Recommendation: A</b></p> <p>It is recommended that pain severity and functional impairment be used to stratify risk of conversion from acute to chronic low back pain.</p> <p><b>Grade of Recommendation: A</b></p> <p>It is suggested that prior episodes of low back pain be considered a prognostic factor for the conversion from acute to chronic low back pain.</p> <p><b>Grade of Recommendation: B</b></p> <p>There is insufficient evidence to assess sleep quality as a prognostic variable to predict recovery from acute low back pain.</p> <p><b>Grade of Recommendation: I</b></p> <p>There is insufficient evidence to make a recommendation for or against the use of smoking and/or obesity as prognostic factors for the conversion from acute to chronic low back pain.</p> <p><b>Grade of Recommendation: I</b></p>
<p><b>Diagnosis Question 4.</b> In patients with low back pain, what history and/or physical examination findings are useful in determining if the cause is nonstructural in nature and, therefore, guide treatment?</p>	<p>A nonstructural cause of low back pain may be considered in patients with diffuse low back pain and tenderness.</p> <p><b>Grade of Recommendation: C</b></p> <p>There is insufficient evidence to make a recommendation for or against the use of fear avoidance behavior to determine the likelihood of a structural cause of low back pain.</p> <p><b>Grade of Recommendation: I</b></p> <p>There is insufficient evidence to make a recommendation for or against the presence of diffuse back tenderness for the prediction of the presence of disc degeneration on radiographs.</p> <p><b>Grade of Recommendation: I</b></p>

<p><b>Diagnosis Question 5.</b> In patients with low back pain, what elements of the patient's history and findings from the physical examination would suggest the need for diagnostic laboratory studies?</p>	<p>There is insufficient evidence to make a recommendation for or against obtaining laboratory tests to assess for inflammatory disease in patients with sacroiliac joint pain.</p> <p><b>Grade of Recommendation: I</b></p>
<p><b>Diagnosis Question 7.</b> In patients with low back pain, are there specific findings on a pain diagram that help differentiate the structure which is causing pain?</p> <p><b>Diagnosis Question 8.</b> Are there assessment tools or questionnaires that can help identify the cause of acute, subacute or chronic low back pain?</p>	<p>A systematic review of the literature yielded no studies to adequately address these questions.</p>
<p><b>Diagnosis Question 10.</b> Are there history and physical examination findings that would warrant obtaining advanced imaging studies?</p>	<p>A systematic review of the literature yielded no studies to adequately address this question.</p> <p><b>Work Group Consensus Statement:</b></p> <p>In the absence of reliable evidence supporting an absolute indication for advanced imaging based upon history and physical examination in the specifically-defined patient population, it is the work group's opinion that, in patients with severe and intractable pain syndromes who have failed medical/interventional treatment, advanced imaging may be indicated. Subgroups of patients have been shown to have a higher or lower incidence of radiographic abnormalities based upon acuity of low back pain, tenderness to palpation and provocation maneuvers; however, the utility of these findings in guiding treatment is not clear.</p>
<p><b>Imaging</b></p>	
<p><b>Imaging Question 1.</b> What is the association between low back pain and spondylosis on routine radiography?</p>	<p>There is insufficient evidence to make a recommendation for or against an association between low back pain and spondylosis using routine radiography.</p> <p><b>Grade of Recommendation: I</b></p>
<p><b>Imaging Question 2.</b> Is there evidence to support the use of computed tomography (CT) or magnetic resonance imaging (MRI) for the evaluation of low back pain in the absence of x-ray/radiographic abnormality?</p>	<p>A systematic review of the literature yielded no studies to adequately address this question.</p>
<p><b>Imaging Question 3.</b> In patients with low back pain, does duration of symptoms correlate with abnormal findings on imaging?</p>	<p>A systematic review of the literature yielded no studies to adequately address this question.</p>

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<p><b>Imaging Question 4.</b> What is the optimal imaging protocol that should be used in the setting of low back pain?</p> <p><i>4a. Are unique MRI sequences considered preferential or optimal?</i></p>	<p>There is insufficient evidence that unique magnetic resonance imaging (MRI) sequences can be considered preferential or optimal.</p> <p><b>Grade of Recommendation: I</b></p>
<p><i>4b. What is the history and clinical presentation that suggests the use of contrast enhanced imaging in patients with low back pain?</i></p>	<p>A systematic review of the literature yielded no studies to adequately address this question.</p>
<p><i>4c. Is there evidence to support imaging the lumbar spine in an oblique plane?</i></p>	<p>A systematic review of the literature yielded no studies to adequately address this question.</p>
<p><i>4d. What is the value of flexion/extension films in evaluating lower back pain?</i></p>	<p>A systematic review of the literature yielded no studies to adequately address this question.</p>
<p><b>Imaging Question 5.</b> In the absence of red flags, what are the imaging (x-ray, CT or MRI) recommendations for patients with acute or chronic low back pain?</p>	<p>There is insufficient evidence to make a recommendation for or against obtaining imaging in the absence of red flags.</p> <p><b>Grade of Recommendation: I</b></p>
<p><b>Imaging Question 6.</b> Are there imaging findings that correlate with the presence of low back pain?</p>	<p>There is insufficient evidence for or against imaging findings correlating with the presence of low back pain.</p> <p><b>Grade of Recommendation: I</b></p>
<p><b>Imaging Question 7.</b> Are there imaging findings that contribute to decision-making by health care providers to guide treatment?</p>	<p>There is insufficient evidence to determine whether imaging findings contribute to decision-making by health care providers to guide treatment.</p> <p><b>Grade of Recommendation: I</b></p>
<b>Medical and Psychological Treatment</b>	
<p><b>Med/Psych Question 1.</b> Is smoking cessation effective in decreasing the frequency of low back pain episodes?</p>	<p>A systematic review of the literature yielded no studies to adequately address this question.</p>

<p><b>Med/Psych Question 2.</b> In patients with low back pain, is pharmacological treatment effective in decreasing duration of pain, decreasing intensity of pain, increasing functional outcomes of treatment and improving the return-to-work rate?</p> <p>Versus:</p> <p>a. No treatment</p> <p>    i. Risks</p> <p>    ii. Complications</p> <p>b. Cognitive behavioral therapy (CBT) and/or psychosocial intervention alone</p> <p>c. Patient education alone</p>	<p>There is insufficient evidence to make a recommendation for or against the use of anticonvulsants for the treatment of low back pain.</p> <p><b>Grade of Recommendation: I</b></p> <p>Antidepressants are not recommended for the treatment of low back pain.</p> <p><b>Grade of Recommendation: A</b></p> <p>There is insufficient evidence to make a recommendation for or against the use of Vitamin D for the treatment of low back pain.</p> <p><b>Grade of Recommendation: I</b></p> <p>Non-selective NSAIDs are suggested for the treatment of low back pain.</p> <p><b>Grade of Recommendation: B</b></p> <p>There is insufficient evidence to make a recommendation for or against the use of selective NSAIDs for the treatment of low back pain.</p> <p><b>Grade of Recommendation: I</b></p> <p>It is suggested that the use of oral or IV steroids is not effective for the treatment of low back pain.</p> <p><b>Grade of Recommendation: B</b></p> <p>It is suggested that the use of opioid pain medications should be cautiously limited and restricted to short duration for the treatment of low back pain.</p> <p><b>Grade of Recommendation: B</b></p>
<p><b>Med/Psych Question 3.</b> In patients with low back pain, is topical treatment (eg, cream or gel) effective in decreasing duration of pain, decreasing intensity of pain, increasing functional outcomes of treatment and improving the return-to-work rate?</p>	<p>There is insufficient evidence to make a recommendation for or against the use of lidocaine patch for the treatment of low back pain.</p> <p><b>Grade of Recommendation: I</b></p> <p>Topical capsicum is recommended as an effective treatment for low back pain on a short-term basis (3 months or less).</p> <p><b>Grade of Recommendation: A</b></p>
<p><b>Med/Psych Question 4.</b> Following treatment for low back pain, do patients with healthy sleep habits experience decreased duration of pain, decreased intensity of pain, increased functional outcomes and improved return-to-work rates compared to patients with poor sleeping habits?</p>	<p>A systematic review of the literature yielded no studies to adequately address this question.</p>

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<p><b>Med/Psych Question 5.</b> In patients with low back pain, is cognitive behavioral therapy (CBT) and/or psychosocial intervention and/or neuroscience education effective in decreasing duration of pain, decreasing intensity of pain, increasing functional outcomes, decreasing anxiety and/or depression and improving return-to-work rate?</p>	<p>Cognitive behavioral therapy is recommended in combination with physical therapy, as compared with physical therapy alone, to improve pain levels in patients with low back pain over 12 months.</p> <p><b>Grade of Recommendation: A</b></p> <p>Cognitive behavioral therapy in combination with physical therapy, compared to physical therapy alone, is suggested to improve functional outcomes (disability) and return to work in patients with low back pain.</p> <p><b>Grade of Recommendation: B</b></p> <p>There is conflicting evidence to make a recommendation for or against cognitive behavioral therapy for improving depression or anxiety in patients with low back pain.</p> <p><b>Grade of Recommendation: I</b></p>
<p><b>Med/Psych Question 6.</b> In patients with low back pain, does the timing of cognitive behavioral therapy (CBT) and/or psychosocial intervention and/or neuroscience education affect duration of pain, intensity of pain, functional outcomes, anxiety, depression and return-to-work status?</p>	<p>A systematic review of the literature yielded no studies to adequately address this question.</p>
<p><b>Med/Psych Question 7.</b> In patients undergoing interventional or surgical treatment for low back pain, does the addition of cognitive behavioral therapy (CBT) and/or psychosocial intervention add incremental benefit?</p>	<p>There is insufficient evidence to make a recommendation for or against the addition of cognitive behavioral therapy or psychosocial intervention for patients undergoing interventional or surgical treatment for low back pain and whether it would provide incremental benefit.</p> <p><b>Grade of Recommendation: I</b></p>
<p><b>Med/Psych Question 8.</b> Does educating a patient about low back pain improve treatment compliance and outcomes, including duration of pain, intensity of pain, functional outcomes, anxiety, depression and return-to-work status?</p>	<p>There is conflicting evidence to make a recommendation for or against the use of patient education to improve treatment compliance and outcomes, including duration of pain, intensity of pain, functional outcomes, anxiety, depression and return to work status.</p> <p><b>Grade of Recommendation: I</b></p>
<p><b>Med/Psych Question 9.</b> In patients undergoing treatment for low back pain, what is the effectiveness of interventions that address fear-avoidance behaviors?</p>	<p>Treatments targeting fear avoidance combined with physical therapy are recommended compared to physical therapy alone to improve low back pain in the first six months.</p> <p><b>Grade of Recommendation: A</b></p>
<p><b>Med/Psych Question 10.</b> Is active treatment (pharmacological or psychotherapeutic) of anxiety and depression effective in decreasing low back pain?</p>	<p>A systematic review of the literature yielded no studies to adequately address this question.</p>

<p><b>Med/Psych Question 11.</b> What are the psychological factors influencing outcomes, including duration of pain, intensity of pain, functional outcomes and return-to-work status, of low back pain treatment?</p>	<p>It is suggested that kinesiophobia is a negative prognostic factor for predicting response to low back pain treatment.</p> <p><b>Grade of Recommendation: B</b></p>
<p><b>Med/Psych Question 12.</b> In patients with low back pain, what psychosocial/cognitive/emotional or other assessments should be utilized to establish an accurate diagnosis?</p>	<p>A systematic review of the literature yielded no studies to adequately address this question.</p>
<p><b>Med/Psych Question 13.</b> Does nutrition (other than weight reduction) influence the frequency of low back pain episodes?</p>	<p>A systematic review of the literature yielded no studies to adequately address this question.</p>
<b>Physical Medicine and Rehabilitation</b>	
<p><b>PM&amp;R Question 1.</b> In patients undergoing treatment for low back pain, what is the effectiveness of the following in decreasing the duration of pain, decreasing intensity of pain, increasing functional outcomes and improving return-to-work status, as compared with natural history plus or minus medication:</p> <p>a. Acute vs subacute vs chronic</p> <p>i. Patient education and self-directed exercise program</p>	<p>Back school is recommended to provide improvements in pain and function when compared with general medical care, modality care or a simple hand-out at 6-12 months' follow-up for chronic low back pain.</p> <p><b>Grade of Recommendation: A</b></p> <p>There is insufficient evidence that outcomes from a home-based exercise program are different than no care.</p> <p><b>Grade of Recommendation: I</b></p> <p>There is insufficient evidence that a <b>self-directed</b> McKenzie exercise program for acute low back pain results in different outcomes compared to usual medical care.</p> <p><b>Grade of Recommendation: I</b></p> <p>There is insufficient evidence that a monitored pedometer-based exercise program with web-based feedback provides any improvement over pedometer instruction alone.</p> <p><b>Grade of Recommendation: I</b></p>
<p>ii. Physical agents</p> <p>a. (eg, heat, cold)</p>	<p>It is suggested that the use of heat for acute low back pain results in short-term improvements in pain.</p> <p><b>Grade of Recommendation: B</b></p>

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b. (eg, ultrasound)	<p>In patients with chronic low back pain, ultrasound is not recommended to improve functional outcomes.</p> <p><b>Grade of Recommendation: A</b></p> <p>There is conflicting evidence that ultrasound provides immediate pain relief in patients with chronic low back pain.</p> <p><b>Grade of Recommendation: I</b></p>
c. (eg, TENS)	<p>There is conflicting evidence that transcutaneous electrical nerve stimulation (TENS) results in improvement in pain or function at short- to medium-term follow-up.</p> <p><b>Grade of Recommendation: I</b></p>
d. (eg, laser- cutaneous stimulation for purpose of pain modulation)	<p>Laser acupuncture provides no short-term or medium-term benefit over sham treatment for patients with chronic low back pain.</p> <p><b>Grade of Recommendation: A</b></p> <p>It is suggested that the combination of laser therapy (low-level or high level) with exercise provides better short-term relief of <i>pain</i> than either exercise or laser therapy alone.</p> <p><b>Grade of Recommendation: B</b></p> <p>There is conflicting evidence that the combination of laser therapy with exercise provides better short-term improvement in <i>function</i> compared to exercise or laser therapy alone.</p> <p><b>Grade of Recommendation: I</b></p> <p>It is suggested that there is no short-term benefit of laser therapy (low-level or high level) when compared with exercise alone.</p> <p><b>Grade of Recommendation: B</b></p>
e. (eg, traction)	<p>In patients with subacute or chronic low back pain, traction is not recommended to provide clinically significant improvements in pain or function.</p> <p><b>Grade of Recommendation: A</b></p>
f. (eg, dry needling)	<p>There is insufficient evidence for or against the use of dry needling as a treatment option for patients with chronic low back pain.</p> <p><b>Grade of Recommendation: I</b></p>
g. (eg, electrical stimulation)	<p>A systematic review of the literature yielded no studies to adequately address this question.</p>

iii. Acupuncture	<p>In patients with low back pain, there is conflicting evidence that acupuncture provides improvements in pain and function as compared to sham acupuncture.</p> <p><b>Grade of Recommendation: I</b></p> <p>In patients with <b>chronic</b> low back pain, addition of acupuncture to usual care is recommended for short-term improvement of pain and function compared to usual care alone.</p> <p><b>Grade of Recommendation: A</b></p> <p>There is insufficient evidence to draw conclusions regarding the comparative effectiveness of acupuncture techniques.</p> <p><b>Grade of Recommendation: I</b></p>
iv. Bracing <ul style="list-style-type: none"> <li>— Lumbosacral brace</li> <li>— Sacroiliac brace</li> </ul>	<p>There is conflicting evidence that bracing results in improvements in pain and function in patients with subacute low back pain.</p> <p><b>Grade of Recommendation: I</b></p>
v. SMT	<p>For patients with acute or chronic low back pain, spinal manipulative therapy (SMT) is an option to improve pain and function.</p> <p><b>Grade of Recommendation: C</b></p> <p>For patients with acute low back pain, spinal manipulative therapy (SMT) results in similar outcomes to no treatment, medication or modalities. Periodically, short-term improvement is statistically better, but clinical significance is uncertain.</p> <p><b>Grade of Recommendation: A</b></p> <p>For patients with chronic low back pain, there is conflicting evidence that outcomes for spinal manipulative therapy (SMT) are clinically different than no treatment, medication or modalities.</p> <p><b>Grade of Recommendation: I</b></p>

vi. Exercise/physical therapy versus or plus massage	<p>There is insufficient evidence to determine the efficacy of acupressure compared to a standardized multimodal physical therapy.</p> <p><b>Grade of Recommendation: I</b></p> <p>In the long term, it is suggested that the addition of massage to an exercise program provides no benefit when compared to an exercise program alone.</p> <p><b>Grade of Recommendation: B</b></p> <p>There is insufficient evidence that the addition of massage to an exercise program provides short-term relief of pain.</p> <p><b>Grade of Recommendation: I</b></p>
vii. Active stabilization exercise	<p>There is insufficient evidence to make a recommendation for or against lumbar stabilization in patients with chronic low back pain.</p> <p><b>Grade of Recommendation: I</b></p>
viii. McKenzie exercise [includes directional preference, centralization and mechanical diagnosis and therapy (MDT)]	<p>McKenzie method is an option for the treatment of chronic low back pain.</p> <p><b>Grade of Recommendation: C</b></p> <p>There is insufficient evidence that McKenzie method results in different outcomes when compared to a dynamic strengthening program for the treatment of chronic low back pain.</p> <p><b>Grade of Recommendation: I</b></p> <p>There is insufficient evidence that McKenzie method is better or worse than back school for the treatment of chronic low back pain.</p> <p><b>Grade of Recommendation: I</b></p>
ix. Yoga	<p>It is suggested that, in patients with mild chronic low back pain, yoga may offer medium-term improvements in pain and function compared to usual care, although these improvements are not clinically meaningful due to low baseline pain/disability.</p> <p><b>Grade of Recommendation: B</b></p>

x. Aerobic exercise	Aerobic exercise is recommended to improve pain, disability and mental health in patients with nonspecific low back pain at short-term follow-up.  <b>Grade of Recommendation: A</b>  There is insufficient evidence that aerobic exercise improves pain, disability and mental health in patients with nonspecific low back pain at long-term follow-up.  <b>Grade of Recommendation: I</b>
xi. Work hardening or conditioning	In patients with low back pain, work hardening may be considered to improve return to work.  <b>Grade of Recommendation: C</b>  There is insufficient evidence that work hardening is different than an active therapeutic exercise program or guideline-based physical therapy.  <b>Grade of Recommendation: I</b>
<p><b>PM&amp;R Question 2.</b> In patients undergoing treatment for low back pain, what is the appropriate timing, frequency and duration of treatment with:</p> <p>Acute vs. subacute vs. chronic</p> <p>i. Patient education and self-directed exercise program</p> <p>ii. Physical agents</p> <p style="padding-left: 20px;">a. (eg, heat, cold)</p> <p style="padding-left: 20px;">b. (eg, ultrasound)</p> <p style="padding-left: 20px;">c. (eg, TENS)</p> <p style="padding-left: 20px;">d. (eg, laser-cutaneous stimulation for purpose of pain modulation)</p> <p style="padding-left: 20px;">e. (eg, traction)</p> <p style="padding-left: 20px;">f. (eg, dry needling)</p> <p style="padding-left: 20px;">g. (eg, electrical stimulation)</p> <p>iii. Acupuncture</p> <p>iv. Bracing</p> <p style="padding-left: 20px;">— Lumbosacral brace</p> <p style="padding-left: 20px;">— Sacroiliac brace</p>	<p>A systematic review of the literature yielded no studies to adequately address this question.</p>

Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

v. SMT	There is insufficient evidence to determine whether 12 to 18 visits of spinal manipulative therapy (SMT) results in better outcomes than 6 visits for the treatment of low back pain. <b>Grade of Recommendation: I</b>
vi. Exercise/Physical Therapy versus or plus massage	A systematic review of the literature yielded no studies to adequately address this question.
vii. Active stabilization exercise	
viii. McKenzie exercise [includes directional preference, centralization and mechanical diagnosis and therapy (MDT)]	
ix. Yoga	
x. Aerobic exercise	
xi. Work hardening or conditioning	
<b>PM&amp;R Question 3.</b> Are there specific patient or treatment characteristics that predict improved duration of pain, intensity of pain, functional outcomes and return-to-work status with SMT following an episode of low back pain?	There is conflicting evidence that symptoms above the knee, low fear avoidance questionnaire score, at least one hypo-mobile segment, and greater than 35° of internal rotation of the hip are predictive of responding to spinal manipulative therapy (SMT) for patients with acute low back pain. <b>Grade of Recommendation: I</b>  There is insufficient evidence that hyper- or hypo-mobility, patient age, strains and sprains, instability, severe affective distress, relationship with healthcare provider, use of thrust vs nonthrust techniques, pretreatment psychological or socioeconomic status, or number of visits are predictive factors of response to spinal manipulative therapy (SMT). <b>Grade of Recommendation: I</b>
<b>PM&amp;R Question 4.</b> In patients undergoing treatment for low back pain, what are outcomes, including duration of pain, intensity of pain, functional outcomes and return-to-work status, for exercise therapy alone versus exercise with cognitive behavioral therapy (CBT)?	There is conflicting evidence that addition of cognitive behavioral therapy (CBT) to an exercise program results in significant improvement in pain and function compared to exercise alone in patients with chronic low back pain. <b>Grade of Recommendation: I</b>
<b>PM&amp;R Question 5.</b> In patients undergoing treatment for low back pain, what are outcomes, including duration of pain, intensity of pain, functional outcomes and return-to-work status, for a lumbar stabilization exercise program versus a general fitness program?	It is suggested that a specific stabilization exercise program is equivalent to a general exercise program. <b>Grade of Recommendation: B</b>

<p><b>PM&amp;R Question 6.</b> In patients undergoing treatment for low back pain, what are outcomes, including duration of pain, intensity of pain, functional outcomes and return-to-work status, for SMT versus SMT plus active exercise?</p>	<p>It is suggested that the addition of exercise to spinal manipulative therapy (SMT) results in similar outcomes to SMT alone.</p> <p><b>Grade of Recommendation: B</b></p>
<p><b>PM&amp;R Question 7.</b> In patients undergoing treatment for low back pain, what are the outcomes, including duration of pain, intensity of pain, functional outcomes and return-to-work status, for bed rest versus active exercise?</p>	<p>It is suggested that, for patients with acute low back pain, those that exercise more at baseline and use exercise to facilitate recovery are predicted to have better functional outcomes over time than patients who do not exercise or use bed rest to help with recovery.</p> <p><b>Grade of Recommendation: B</b></p> <p>For patients with acute low back pain, it is suggested that advice to remain active within limits of pain compared to short periods of bed rest from 3 to 7 days all result in similar outcomes in pain and function at short- and medium-term follow-up.</p> <p><b>Grade of Recommendation: B</b></p> <p><b>Work Group Consensus Statement:</b> In the absence of reliable evidence for patients with nonspecific back pain, based on abundant data for other spinal disorders that result in back pain, it is the work group's opinion that remaining active is preferred and likely results in better short-term outcomes than does bed rest.</p>
<p><b>PM&amp;R Question 8.</b> In patients with low back pain, does a regular exercise program (or presurgical intervention with exercise, PT, education) prior to lumbar surgery decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate compared to those who don't exercise?</p>	<p>A systematic review of the literature yielded no studies to adequately address this question.</p>
<p><b>PM&amp;R Question 9.</b> In patients with low back pain, does exercise treatment after epidural steroid injections/spinal interventions decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate compared to injections alone?</p>	<p>A systematic review of the literature yielded no studies to adequately address this question.</p>

<p><b>PM&amp;R Question 10.</b> Following surgery for low back pain, are outcomes, including duration of pain, intensity of pain, functional outcomes and return-to-work status, improved with a formal exercise/rehabilitation program versus home instruction plus or minus self-directed exercise program alone?</p>	<p>A systematic review of the literature yielded no studies to adequately address this question.</p>
<p><b>PM&amp;R Question 11.</b> Can a clinical prediction rule determine appropriate indications and predict outcomes, including duration of pain, intensity of pain, functional outcomes and return-to-work status, for exercise for low back pain?</p>	<p>There is insufficient evidence to provide any reliable predictors of outcomes to an exercise program for the treatment of either acute or chronic low back pain.</p> <p><b>Grade of Recommendation: I</b></p>
<p><b>Interventional Treatment</b></p>	
<p><b>Interventional Question 1.</b> In patients with low back pain, do fluoroscopically-guided epidural steroid injections decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate?</p>	<p>There is insufficient evidence to make a recommendation for or against the use of caudal epidural steroid injections in patients with low back pain.</p> <p><b>Grade of Recommendation: I</b></p> <p>There is insufficient evidence to make a recommendation for or against the use of interlaminar epidural steroid injections in patients with low back pain.</p> <p><b>Grade of Recommendation: I</b></p>
<p><b>Interventional Question 2.</b> When evaluating fluoroscopically-guided intra-articular lumbar facet joint injections in patients with acute or chronic low back pain:</p> <p>a. What is the diagnostic utility of this procedure?</p> <p>b. From a therapeutic standpoint, does this procedure decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate?</p>	<p>There is insufficient evidence to make a recommendation for or against the use of patient-reported reproduction of pain during a zygapophyseal joint injection as a predictor of response to dual diagnostic blocks.</p> <p><b>Grade of Recommendation: I</b></p> <p>In patients selected for facet joint procedures using diagnostic criteria of physical exam and a response to a single diagnostic intra-articular injection with 50% relief, it is suggested that intra-articular injection of steroids provides no clinically meaningful improvement at 6 months.</p> <p><b>Grade of Recommendation: B</b></p> <p>In patients selected for facet joint procedures using diagnostic criteria of physical exam and a response to a single diagnostic intra-articular injection with 50% relief, there is insufficient evidence to make a recommendation for or against the use of radiofrequency neurotomy or periarticular phenol injections.</p> <p><b>Grade of Recommendation: I</b></p> <p>There is insufficient evidence to make a recommendation for or against the use of steroid injections into the zygapophyseal joint in patients with chronic back pain and a physical exam suggestive of facet-mediated pain.</p> <p><b>Grade of Recommendation: I</b></p>

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<p><b>Interventional Question 3.</b> In patients with low back pain, do medial branch blocks have a role in defining treatment for low back pain?</p> <p>a. Does duration of pain, intensity of pain, functional outcomes and return-to-work status vary when candidates for neurotomy are determined by single vs comparative medial branch blocks?</p> <p>b. Is there a threshold for the magnitude of relief from diagnostic facet nerve blocks that predict outcomes to neurotomy?</p> <p>c. Does duration of pain, intensity of pain, functional outcomes and return-to-work status vary when candidates for neurotomy are determined by diagnostic facet nerve blocks vs. intra-articular facet joint injections?</p> <p>d. Is there a therapeutic utility of medial branch blocks?</p> <p>e. Does technical accuracy of medial branch blocks (eg, contrast use) affects its validity and effectiveness of subsequent neurotomy?</p>	<p>There is insufficient evidence to make a recommendation for or against the use of SPECT imaging in the diagnosis of zygapophyseal joint pain.</p> <p><b>Grade of Recommendation: I</b></p> <p>There is insufficient evidence to make a recommendation for or against the use of uncontrolled medial branch blocks vs. pericapsular blocks for the diagnosis of zygapophyseal joint pain based on the outcomes of medial branch nerves cryoablation.</p> <p><b>Grade of Recommendation: I</b></p> <p>There is insufficient evidence to make a recommendation for or against the use of cryodenervation for the treatment of zygapophyseal joint pain.</p> <p><b>Grade of Recommendation: I</b></p> <p>There is insufficient evidence to make a recommendation for or against the use of a 50% reduction in pain following medial branch blockade for the diagnosis of zygapophyseal joint pain.</p> <p><b>Grade of Recommendation: I</b></p> <p>Thermal radiofrequency ablation is suggested as a treatment for patients with low back pain from the zygapophyseal joints. The outcomes of this procedure become more reliable when more stringent diagnostic criteria are used. The relief from these ablations is durable for at least six months following the procedure.</p> <p><b>Grade of Recommendation: B</b></p>
<p><b>Interventional Question 4.</b> In patients with low back pain due to lumbar facet joint arthropathy, does fluoroscopically-guided neurotomy decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate?</p>	<p>Thermal radiofrequency ablation is suggested as a treatment for patients with low back pain from the zygapophyseal joints. The outcomes of this procedure become more reliable when more stringent diagnostic criteria are used. The relief from these ablations is durable for at least six months following the procedure.</p> <p><b>Grade of Recommendation: B</b></p>

Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.



<p><b>Interventional Question 5.</b> In patients with low back pain, do fluoroscopically-guided sacroiliac joint injections (SIJI) decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate?</p> <p>a. Does duration of pain, intensity of pain, functional outcomes and return-to-work status vary when candidates for neurotomy are determined by single vs comparative SIJI?</p> <p>b. Is there a benefit to performing lateral branch blocks as compared with intra-articular diagnostic injections as a predictor to response to lateral branch neurotomy?</p> <p>c. Is there a threshold for the magnitude of relief from diagnostic SIJI that predict improvement in duration of pain, intensity of pain, functional outcomes and return-to-work status from SIJ neurotomy?</p>	<p>Intra-articular steroid joint injections may be considered in patients with suspected SI joint pain</p> <p><b>Grade of Recommendation: C</b></p>
<p><b>Interventional Question 6.</b> In patients with pelvic posterior girdle pain relieved temporarily by image guided SIJ injections or lateral branch blocks, does lateral branch neurotomy decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate?</p>	<p>Cooled radiofrequency ablation of the sacral lateral branch nerves and dorsal ramus of L5 may be considered in patients with sacroiliac joint pain diagnosed with dual diagnostic blocks.</p> <p><b>Grade of Recommendation: C</b></p>
<p><b>Interventional Question 7.</b> In patients with low back pain, does spinal cord stimulation decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate?</p>	<p>There is insufficient evidence to make a recommendation for or against the use of spinal cord stimulation as a treatment for low back pain.</p> <p><b>Grade of Recommendation: I</b></p>
<p><b>Interventional Question 8.</b> In patients with low back pain, does continuous delivery of intrathecal opioids decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate and are there risks associated with its use?</p>	<p>A systematic review of the literature yielded no studies to adequately address this question.</p>

<p><b>Interventional Question 9.</b> In patients with low back pain, is provocative lumbar discography more accurate than other diagnostic modalities in identifying the disc as a source of pain?</p>	<p>There is high-level evidence that provocative discography without manometric measurements correlates with pain reproduction in the presence of moderate to severe disc degeneration on MRI/CT discography.</p> <p><b>Grade of Recommendation: A</b></p> <p>There is high-level evidence that provocative discography without manometric pressure measurements correlates with the presence of endplate abnormalities on MRI imaging.</p> <p><b>Grade of Recommendation: A</b></p> <p>Bony vibration provocation may be considered to correlate with the presence of pain in patients who have pain on provocation discography without manometric pressure measurements. There is no correlation with the segmental level of pain.</p> <p><b>Grade of Recommendation: C</b></p> <p>There is insufficient evidence to make a recommendation for or against the use of axial loaded magnetic resonance imaging (MRI) for the diagnosis of low back pain.</p> <p><b>Grade of Recommendation: I</b></p> <p>There is conflicting evidence that pressure controlled provocative discography correlates with nuclear T2 signal intensity on magnetic resonance imaging (MRI) in patients with low back pain.</p> <p><b>Grade of Recommendation: I</b></p> <p>There is conflicting evidence that provocative discography without manometric pressure measurements correlates with the presence of a high-intensity zone (HIZ) on MRI imaging.</p> <p><b>Grade of Recommendation: I</b></p>
<p><b>Interventional Question 10.</b> In patients with low back pain, is anesthetic lumbar discography more accurate than other diagnostic modalities in identifying the disc as a source of pain?</p>	<p>There is insufficient evidence to make a recommendation for or against the use of anesthetic discography.</p> <p><b>Grade of Recommendation: I</b></p>

<p><b>Interventional Question 11.</b> In patients with low back pain, does intradiscal injection decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate?</p>	<p>Intradiscal steroids are suggested to provide short-term improvements in pain and function <i>in patients with Modic changes</i>.</p> <p><b>Grade of Recommendation: B</b></p> <p>There is insufficient evidence that intradiscal steroids provide improvements in pain or function <i>in patients with discogenic low back pain</i>.</p> <p><b>Grade of Recommendation: I</b></p> <p>There is insufficient evidence to make a recommendation for or against the use of intradiscal bone marrow concentrate in patients with discogenic low back pain.</p> <p><b>Grade of Recommendation: I</b></p> <p>There is insufficient evidence to make a recommendation for or against the use of intradiscal platelet rich plasma in patients with discogenic low back pain.</p> <p><b>Grade of Recommendation: I</b></p> <p>There is insufficient evidence to make a recommendation for or against the use of intradiscal Methylene Blue in patients with discogenic low back pain.</p> <p><b>Grade of Recommendation: I</b></p>
<p><b>Interventional Question 12.</b> In patients with low back pain, does intradiscal electrothermal therapy or biacuplasty decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate?</p>	<p>Intradiscal electrothermal annuloplasty is suggested to provide improvements in pain and function at up to two years. This treatment is limited in its effectiveness with roughly 40-50% of patients receiving a 50% reduction in pain.</p> <p><b>Grade of Recommendation: B</b></p> <p>Biacuplasty is an option to produce clinically and statistically significant improvements in pain at 6 months in patients with discogenic low back pain.</p> <p><b>Grade of Recommendation: C</b></p> <p>There is insufficient evidence to make a recommendation for or against the use of percutaneous intradiscal radiofrequency thermocoagulation.</p> <p><b>Grade of Recommendation: I</b></p>
<p><b>Interventional Question 13.</b> In patients with low back pain, do trigger point injections decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate?</p>	<p>There is insufficient evidence to make a recommendation for or against the use of trigger point injections in the treatment of low back pain. The type of injectate does not influence outcomes.</p> <p><b>Grade of Recommendation: I</b></p>

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Surgical Treatment	
<b>Surgical Question 1.</b> In patients with low back pain, does surgical treatment vs medical/interventional treatment alone decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate?	A systematic review of the literature yielded no studies to adequately address this question.
<b>Surgical Question 2.</b> In patients with low back pain, are there predictive factors which determine the benefit of initial treatment with surgical intervention versus initial medical/interventional treatment?	A systematic review of the literature yielded no studies to adequately address this question.
<b>Surgical Question 3.</b> In patients undergoing fusion surgery for low back pain, which fusion technique results in the best outcomes for the following: decreased duration of pain, decreased intensity of pain, increased functional outcomes of treatment and improved return-to-work rate?  a. Posterolateral fusion without internal fixation vs  b. Posterolateral transverse fusion with internal fixation vs  c. Stand-alone (anterior) interbody fusion vs  d. Transforaminal lumbar interbody fusion (TLIF) or posterior lumbar interbody fusion (PLIF) vs  e. Circumferential fusion (anterior interbody, lateral techniques)	There is insufficient evidence to make a recommendation for or against a particular fusion technique for the treatment of low back pain.  <b>Grade of Recommendation: I</b>
<b>Surgical Question 4.</b> In patients undergoing fusion surgery for low back pain, are clinical outcomes, including duration of pain, intensity of pain, functional outcomes and return-to-work status, different for multi-level fusions vs single level fusions?	A systematic review of the literature yielded no studies to adequately address this question.
<b>Surgical Question 5.</b> In patients undergoing fusion surgery for low back pain, does radiographic evidence of fusion correlate with decreased duration of pain, decreased intensity of pain, increased functional outcomes of treatment and improved return-to-work rate?	There is insufficient evidence to make a recommendation regarding whether radiographic evidence of fusion correlates with better clinical outcomes in patients with low back pain.  <b>Grade of Recommendation: I</b>

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<p><b>Surgical Question 6.</b> In patients undergoing fusion surgery for low back pain, does the use of bone growth stimulators (vs fusion alone) decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate?</p>	<p>A systematic review of the literature yielded no studies to adequately address this question.</p>
<p><b>Surgical Question 7.</b> In patients undergoing fusion surgery for low back pain, does the use of BMP (vs fusion alone) decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate?</p>	<p>A systematic review of the literature yielded no studies to adequately address this question.</p>
<p><b>Surgical Question 8.</b> In patients undergoing fusion surgery for low back pain, does the use of minimally invasive techniques decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate compared to open fusion techniques?</p>	<p>A systematic review of the literature yielded no studies to adequately address this question.</p>
<p><b>Surgical Question 9.</b> In patients undergoing surgery for low back pain, do motion preserving systems (disc prosthesis and dynamic stabilization systems treatment) decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate compared to fusion surgery?</p>	<p>A systematic review of the literature yielded no studies to adequately address this question.</p>
<p><b>Surgical Question 10.</b> In patients undergoing surgery for low back pain, do motion preserving systems (disc prosthesis and dynamic stabilization systems) result in lower incidence of symptomatic adjacent segment disease?</p>	<p>A systematic review of the literature yielded no studies to adequately address this question.</p>

<p><b>Surgical Question 11.</b> In patients with low back pain, does fusion treatment decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate compared to treatment with:</p> <ul style="list-style-type: none"> <li>a. Discectomy</li> <li>b. Discectomy plus rhizotomy</li> <li>c. Decompression alone</li> </ul>	<p>A systematic review of the literature yielded no studies to adequately address this question.</p>
<p><b>Surgical Question 12.</b> In patients with low back pain due to sacroiliac joint dysfunction, does sacroiliac joint fusion compared with medical/interventional treatment decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate?</p>	<p>A systematic review of the literature yielded no studies to adequately address this question.</p>
<b>Cost-Utility</b>	
<p><b>Cost-Utility Question 1.</b> Who is the most cost-effective spinal care provider for evaluating patients with low back pain:</p> <ul style="list-style-type: none"> <li>a. Chiropractor vs</li> <li>b. Physical Therapist vs</li> <li>c. Primary Care Provider (including nonphysician providers) vs</li> <li>d. Neurologist vs</li> <li>e. Physiatrist vs</li> <li>f. Spine Surgeon vs</li> <li>g. Anesthesiologists/Pain Medicine Physician vs</li> <li>h. Radiologist</li> </ul>	<p>A systematic review of the literature yielded no studies to adequately address this question.</p>

Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

<p><b>Cost-Utility Question 2.</b> What is the cost-utility of diagnostic imaging studies/workup in the evaluation of low back pain (acute, subacute and chronic), in terms of influencing/altering treatment or in terms of leading to pain reduction and functional improvement?</p> <p>a. X-rays (lumbar standing, lumbar flexion-extension, entire spine)</p> <p>b. CT scan / CT myelogram</p> <p>c. MRI (conventional or dynamic/upright/weight bearing)</p>	<p>There is insufficient evidence to make a recommendation for or against the cost-effectiveness of the use of routine ordering of lumbar spine radiographs for low back pain lasting greater than 6 weeks in the absence of red flags.</p> <p><b>Grade of Recommendation: I</b></p>
<p><b>Cost-Utility Question 3.</b> Does the use of ordering physician-owned diagnostic and treatment facilities affect the cost of low back pain related healthcare services?</p>	<p>A systematic review of the literature yielded no studies to adequately address this question.</p>
<p><b>Cost-Utility Question 4.</b> Are epidural steroid injections (including interlaminar, transforaminal and caudal injections and selective nerve root blocks) more cost-effective in the management of patients with low back pain than other medical/interventional treatments?</p>	<p>A systematic review of the literature yielded no studies to adequately address this question.</p>
<p><b>Cost-Utility Question 5.</b> Is spinal cord stimulation more cost-effective in the management of patients with low back pain than other medical/interventional treatments?</p>	<p>A systematic review of the literature yielded no studies to adequately address this question.</p>
<p><b>Cost-Utility Question 6.</b> Is physical therapy in the management of patients with low back pain more cost-effective than other medical/interventional treatments?</p>	<p>There is insufficient evidence to make a recommendation for or against the cost-utility of physical therapy in the management of low back pain versus other medical/interventional treatments.</p> <p><b>Grade of Recommendation: I</b></p>
<p><b>Cost-Utility Question 7.</b> Is pharmacological management (over-the-counter + prescription medications) for patients with low back pain more or less cost-effective than interventional treatments including physical therapy and injection therapies?</p>	<p>A systematic review of the literature yielded no studies to adequately address this question.</p>
<p><b>Cost-Utility Question 8.</b> Is spinal manipulative therapy in the management of patients with low back pain more cost-effective than other medical/interventional treatments?</p>	<p>There is insufficient evidence to make a recommendation for or against the cost-utility of spinal manipulative therapy for the treatment of low back pain.</p> <p><b>Grade of Recommendation: I</b></p>

<p><b>Cost-Utility Question 9.</b> Is acupuncture-based therapy in the management of patients with low back pain more cost-effective than other medical/interventional treatments?</p>	<p>Acupuncture-based therapy in the management of patients with low back pain is suggested to be cost-effective when compared with other medical/interventional treatments.</p> <p><b>Grade of Recommendation: B</b></p>
<p><b>Cost-Utility Question 10.</b> Are over-the-counter medications only without other medical interventions more cost-effective in the management of patients with low back pain than other medical/interventional treatments?</p>	<p>A systematic review of the literature yielded no studies to adequately address this question.</p>
<p><b>Cost-Utility Question 11.</b> Is cognitive or psychological-based therapy in the management of patients with low back pain more cost-effective than other medical/interventional treatments?</p>	<p>There is conflicting evidence regarding the cost-utility of cognitive or psychological-based therapy in the management of low back pain.</p> <p><b>Grade of Recommendation: I</b></p>
<p><b>Cost-Utility Question 12.</b> In patients with low back pain, is a symptom guided treatment approach using directional preference/centralization matched exercise more cost-effective than usual care (home care vs medication vs. nonspecific physical therapy exercise vs nonspecific physical therapy modalities) long-term at 12 months, 36 months?</p>	<p>There is insufficient evidence to make a recommendation for or against the cost-utility of directional preference based therapy versus alternatives.</p> <p><b>Grade of Recommendation: I</b></p>
<p><b>Cost-Utility Question 13.</b> Is the surgical management (including fusion and lumbar disc replacement and spinal cord stimulators) of patients with low back pain more cost-effective than medical/interventional treatments?</p>	<p>There is insufficient evidence to make a recommendation for or against the cost-utility of surgical therapies versus medical/interventional therapies for low back pain.</p> <p><b>Grade of Recommendation: I</b></p>
<p><b>Cost-Utility Question 14.</b> Is cognitive or psychological-based therapy in the management of patients with low back pain more cost-effective than surgical therapies?</p>	<p>There is insufficient evidence to make a recommendation for or against the cost-utility of cognitive or psychological-based therapies versus surgical therapies in the treatment of low back pain.</p> <p><b>Grade of Recommendation: I</b></p>
<p><b>Cost-Utility Question 15.</b> Are minimally invasive surgical procedures more cost-effective in the management of patients with low back pain than conventional open surgical procedures?</p>	<p>A systematic review of the literature yielded no studies to adequately address this question.</p>
<p><b>Cost-Utility Question 16.</b> Is instrumented lumbar fusion more cost-effective compared to non-instrumented fusion for the treatment of patients with low back pain?</p>	<p>A systematic review of the literature yielded no studies to adequately address this question.</p>

Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.



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## Introduction

This section of the guideline deals with the diagnosis of low back pain (LBP) as defined specifically for this project. As the questions were developed, there were two main focuses. The authors were interested in determining if there were specific patient characteristics that would be useful in identifying structural abnormalities of the spine. The rationale behind this strategy was that structural abnormalities would have specific treatments and the ability to identify such patients early in the process may allow for expedited specific treatment for subgroups of patients. The second emphasis related to identification of patient characteristics that could predict the time course of an episode of back pain. Again, the rationale was to attempt to identify patients at high risk for conversion from an acute episode to a more chronic condition in order to rationally allocate aggressive treatment strategies.

Because back pain is so prevalent, there is an abundance of literature from multiple sources and the panel reviewed thousands of references. Eventually, the references were pruned down to slightly more than 600 selected manuscripts. As the literature was reviewed, several issues arose that require comment. First of all, it is recognized that many assessments of LBP are not necessarily focused on structural abnormalities but may be focused on functional or dynamic characteristics of the pain syndrome. These assessments were not adequately addressed in this section because of the a priori link between assessment and structural abnormality in our question set.

Second, defining the gold standard for a “structural abnormality” as a cause of LBP was extremely problematic. References reporting correlations between different assessment methods, assessment methods and injections, assessment methods and surgery and assessment methods and specific noninvasive therapies were identified. When such studies were well-do-

ne, the results were reported as providing high-quality evidence regarding the correlation between the assessment method and the test or treatment employed as a comparator. For example, a study of patients with tenderness over the sacroiliac joint may correlate well with a positive response to a sacroiliac joint injection. However, with regard to the primary question, the panel could not agree that a “gold standard” exists for the diagnosis of LBP due to the wide range of treatment efficacy when patients are selected for therapies based on a purported “gold standard.” There was uncertainty as to whether the “gold standard” was therefore inaccurate or if the treatment methods based on that standard were simply variably effective. Therefore, with regard to the diagnosis of LBP, the evidence derived from these studies was downgraded.

Third, the majority of the literature dealing with the assessment of patients with LBP includes patients with radicular complaints. Studies were considered for inclusion only if patients with leg pain were excluded or if a subgroup analysis was provided allowing for assessment of only patients without radicular pain/radiculopathy. If, however, patients with radicular complaints were included in a study and a subgroup analysis was not provided, the study did not meet the population targeted by this guideline effort and was discarded. Unfortunately, many well-known and highly-cited papers fall into this latter category.

Fourth, many of the best-designed and best-performed prognosis papers looking at recovery from an acute episode of LBP used return to work (RTW) as their primary outcome measure without an assessment of LBP during the follow-up period. The author panel felt that the use of RTW represented a potentially false endpoint as it relates to the resolution or persistence of LBP. It is recognized that patients may return to

work despite persistent pain and that patients whose pain has resolved may choose not to return to work. For this reason, references that used RTW as the outcome measure without a concomitant assessment of relevant patient-reported outcomes were downgraded with respect to the level of evidence.

Finally, some observations consistently reported by numerous authors were not specifically addressed by the initial question set. The author group felt it appropriate to include statements reflecting such observations where applicable.



**Diagnosis Question 1.** In patients with low back pain, are there specific history or physical examination findings that would indicate the structure causing pain and, therefore, guide treatment?

- a. Vertebral body
- b. Intervertebral disc
- c. Zygapophyseal joint
- d. Posterior elements
- e. Sacroiliac joint
- f. Muscle/tendon
- g. Central sensitization

**There is insufficient evidence to make a recommendation for or against the use of innominate kinematics for the assessment of sacroiliac joint pain.**

**Grade of Recommendation: I**

Adhia et al<sup>1</sup> conducted a single-blinded cross-sectional case-control study to compare the innominate kinematic measures (movement pattern, range of motion and trends of rotation) of participants with LBP of sacroiliac joint (SIJ) origin versus participants with LBP of non-SIJ origin. Participants with LBP  $\geq$  3 months ( $n=122$ ) underwent a clinical examination with valid and reliable noninvasive SIJ symptom provocation tests to be classified as SIJ-positive ( $\geq$  3 familiar symptom reproduction pain provocation tests) or SIJ-negative. The clinical evaluation was followed by innominate kinematic testing by a blinded tester using an electromagnetic palpation-digitization technique. Disability (Modified Oswestry Low Back Pain Disability Questionnaire), level

of physical activity, duration of pain and current intensity of pain per the visual analog scale (VAS) were recorded. Innominate range of motion, movement patterns and trend of rotation were recorded and compared between SIJ-positive and SIJ-negative participants. Results demonstrated that SIJ-positive participants had significantly different innominate movement patterns and trends of rotation, but not innominate ranges of motion. The authors concluded that there was an association between SI joint pain and altered innominate kinematics. This study provides Level III evidence that altered innominate kinematics is associated with 3 out of 5 positive sacroiliac provocation tests and may be considered for the diagnosis of SI joint pain.

**There is insufficient evidence to make a recommendation for or against the use of pain localization in predicting response to a diagnostic injection.**

**Grade of Recommendation: I**

In a retrospective chart review, Depalma et al<sup>2</sup> aimed to estimate the sensitivity, specificity, positive and negative predictive values, diagnostic accuracy and likelihood ratios of positive and negative tests for diagnosing internal disc disruption (IDD), facet joint pain (FJP) or sacroiliac joint pain (SIJP) by use of presence of midline and paramidline LBP. During the clinical evaluation, patients pointed to the most painful LBP with one finger, which was documented as midline (by the spinous processes) or paramidline (more than one fingerbreadth lateral to the midline). Charts of patients with a definitive diagnosis for source of LBP were reviewed and classified as IDD, FJP, or SIJP. In cases of IDD, significantly great percentages of patients reported midline LBP compared to FJP or SIJP and significantly lower percentages of

patients reported paramidline pain compared to FJP or SIJP. The diagnostic accuracy of midline LBP was 83.5% for IDD, 24.1% for FJP and 31.8% for SIJP. The authors concluded that the spine specialist can predict the likely source of the patient's LBP by evaluating the location of LBP as the presence of midline LBP increases the probability of lumbar IDD and reduces the probability of symptomatic FJ and SIJ dysfunction. This study provides Level I evidence that location of pain can predict response to the injection and Level III evidence that the presence of midline LBP increases the probability of lumbar IDD and reduces the probability of symptomatic FJ and SIJ dysfunction. The presence of isolated paramidline LBP increases the probability of symptomatic FJ or SIJ but mildly reduces the likelihood of lumbar IDD.

**There is insufficient evidence to make a recommendation for or against the assessment of centralization or peripheralization for the prediction of discography results.**

**Grade of Recommendation: I**

Donelson et al<sup>3</sup> investigated the relationship between responses of centralization and peripheralization with discographic findings in a prospective blinded study of patients with chronic LBP greater than 3 months. Patients who were scheduled for discography were enrolled in the study (n=63). Participants underwent an initial McKenzie mechanical assessment by a therapist blinded to medical records and were classified as centralizers, peripheralizers, or no change. During discography that immediately followed the assessment, pain response was assessed to disc injection and axial CT was performed on all painful discs. Exact pain reproduction and an abnormal image were criteria for a positive discogram. Of the 31 centralizers, 23 (74%) had a positive discogram; 21 (91%) of those

had a competent annular wall of the positive disc. Of the 16 peripheralizers, 11 (69%) had a positive discogram; 6 (54%) of those had a competent annular wall. Of the 16 with no change upon initial assessment, only 2 (12.5%) had a positive discogram, both with competent annular walls. The authors concluded that the McKenzie assessment process reliably differentiated discogenic versus nondiscogenic pain as well as competent versus incompetent annulus in symptomatic discs. This study provides Level III evidence that patients who centralize or peripheralize pain with McKenzie exercises have a higher incidence of positive discogram than those with no change. Those who centralize have a higher incidence of an intact annulus as compared to those whose pain peripheralized.



### Future Directions for Research

It is recognized that the vast majority of LBP does not have an identifiable structural cause. The term "nonspecific low back pain" provides no biologic basis for LBP nor assistance in clinical decision-making. Therefore, future research should focus on reliably identifying clusters of history and physical examination findings which can classify patients into subgroups to be validated by identifying predictably effective treatments. Further studies of nonspecific LBP are unwarranted.

## References

1. Adhia DB, Milosavljevic S, Tumilty S, Bussey MD. Innominate movement patterns, rotation trends and range of motion in individuals with low back pain of sacroiliac joint origin. *Man Ther.* 2016;21:100-108.
2. Depalma MJ, Ketchum JM, Trussell BS, Saullo TR, Slipman CW. Does the location of low back pain predict its source? *Pm R.* 2011;3(1):33-39.
3. Donelson R, Aprill C, Medcalf R, Grant W. A prospective study of centralization of lumbar and referred pain: a predictor of symptomatic discs and anular competence. *Spine.* 1997;22(10):1115-1122.



**Diagnosis Question 2.** In patients with low back pain, are there history or physical examination findings that would serve as predictors for the recurrence of low back pain?

**There is insufficient evidence to indicate that body mass index (BMI) is a potential predictor of a recurrence of low back pain.**

**Grade of Recommendation: I**

Heuch et al<sup>1</sup> conducted a prospective cohort study to evaluate the relationship between an elevated body mass index (BMI) and probability of experiencing chronic LBP in individuals with and without LBP at baseline. Participants in the Norwegian HUNT 2 study were included for analysis (n=25,450). Participants included those with LBP at baseline (2,669 men and 3,899 women) and without LBP at baseline (8,733 men and 10,149 women). Subjects indicated presence of

LBP >3 months at baseline and after 11 years. Results revealed a significant positive association between BMI and risk of LBP among individuals without LBP at baseline. There was a significant positive association between BMI and LBP recurrence among women. The authors concluded that elevated BMI might predispose to chronic LBP over 11 years. This study provides Level II evidence that increasing BMI is associated with higher reporting of back pain in long-term follow-up in women.

**It is suggested that history of low back pain is a potential predictor of a recurrence of low back pain.**

**Grade of Recommendation: B**

Kääriä et al<sup>2</sup> evaluated symptoms, chronic disorders, low back clinical findings and work absenteeism and their relationship to inpatient hospitalization in a prospective cohort study. Employees of a manufacturing facility in Finland who agreed to participate (n=902) underwent a health examination and completed a questionnaire. Personal data and clinical information, including low back diagnoses, were available through a Finnish Register. Hazard rate ratios of hospitalization due to a low back disorder were analyzed. The authors concluded that predictors of inpatient hospital care for low back disorders included frequent or radi-

ating low back symptoms, chronic low back disorders, back-related work absenteeism and clinical findings in the low back. This study provides Level I evidence that the occurrence of previous episodes of LBP predicts future episodes of LBP.

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LBP at baseline (2,669 men and 3,899 women) and without LBP at baseline (8,733 men and 10,149 women). Subjects indicated presence of LBP >3 months at baseline and after 11 years. Results revealed a significant positive association between BMI and risk of LBP among individuals without LBP at baseline. There was a significant positive association between BMI and

LBP recurrence among women. The authors concluded that elevated BMI might predispose to chronic LBP over 11 years. This study provides Level II evidence that the occurrence of previous episodes of chronic LBP results in greater risk of recurrence of chronic LBP.



### Future Directions for Research

The work group encountered numerous high quality prognostic studies with heterogeneous study populations including patients with leg pain. In order to make useful recommendations, it is recommended that subgroups (ie with or without leg pain) be identified and analyzed separately.

### References:

1. Heuch I, Heuch I, Hagen K, Zwart JA. Body mass index as a risk factor for developing chronic low back pain: a follow-up in the Nord-Trøndelag Health Study. *Spine*. 2013;38(2):133-139.
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**Diagnosis Question 3.** In patients with acute low back pain, are there history or physical examination findings that would predict that an episode will resolve within one month?

**Diagnosis Question 6.** What are the patient characteristics that increase or decrease the risk of developing chronic low back pain after an acute episode?

**Diagnosis Question 9.** Does a psychological evaluation assist with identifying patients with low back pain who are at risk for developing chronic pain or disability?

The work group considered these questions together as the vast majority of the literature evaluating the conversion from acute to chronic pain combined various demographic, social, psychological and physical examination findings in predictive models.

It is recommended that psychosocial factors and workplace factors be assessed when counseling patients regarding the risk of conversion from acute to chronic low back pain.

**Grade of Recommendation: A**

Matsudaira et al<sup>1</sup> studied prospective cohort data from the Japan epidemiological research of Occupation-related Back pain (JOB) study to assess the association between aggravated LBP and psychosocial factors. Participating Japanese workers completed a questionnaire at baseline (n=5,310) and at one-year follow-up (n=3,811) which included information regarding LBP. Of the 1,675 individuals with mild LBP, 43 (2.6%) developed persistent LBP. Using logistic regression, interpersonal stress at work, job satisfaction, depression, somatic symptoms, support from supervisors, previous sick leave due to LBP and family history of LBP with disability were associated with the conversion of mild LBP to persistent LBP. The authors concluded that psychosocial factors are important risk factors for persistent LBP in urban Japanese workers. This study provides Level I evidence that low job satisfaction, lack of support from supervisors, interpersonal stress at home, depression, somatic symptoms and family history of LBP with disability predicted development of persistent LBP related disability. Other risk factors for persistent disability included ergonomic factors such as bending, twisting, lifting and pushing.

Bakker et al<sup>2</sup> evaluated the use of spinal mechanical load as a prognostic factor for the conversion of acute nonspecific LBP to persistent (defined as recurrent and/or chronic) LBP in a prospective cohort study. Subjects with acute LBP <6 weeks were enrolled and underwent a baseline assessment (n=97). A trained evaluator asked each participant to describe daily activities and subsequently recorded posture and spinal load applied (“no load applied”, “loaded”, or “loaded with movement”) on the standardized 24-hour schedule (24HS) form. Participants completed a 6-month follow-up telephone call (n=88) to assess changes in characteristics, mechanical load per the 24HS, and LBP. Sixty percent of the follow-up participants reported persistent LBP. Mechanical load was not a prognostic factor for persistent LBP, but smoking and advanced age were associated with persistent LBP. The authors concluded that mechanical loading of the spine is not predictive for chronicity or recurrent episodes of LBP. This study provides Level I evidence that smoking and advanced age are predictors of conversion of acute to chronic LBP.

Alsaadi et al<sup>3</sup> aimed to evaluate the association between sleep quality and pain intensity in patients with acute LBP using data from an existing randomized controlled trial. Participants from the PACE study received paracetamol or placebo until “recovery from back pain” for up to 4 weeks and recorded outcome data in a weekly diary for 12 weeks. Sleep quality over the past 7 days was assessed using the Pittsburgh Sleep Quality Index (PSQI) and average pain over the last 24 hours was rated using a 10-point numerical rating scale (NRS). A generalized estimating equation model was used with the participants with adequate follow-up data (n=1246). Sleep quality and pain intensity both improved over the 12-week follow-up period; for every 1-point decrease in sleep quality, pain intensity increased by 2.08 points. The authors concluded that sleep quality is related to subsequent pain intensity in patients with acute LBP. This study provides Level I evidence that poor sleep quality associated with acute LBP is a positive predictor for lack of recovery.

Coste et al<sup>4</sup> evaluated the associations between various risk factors and the natural history of acute LBP as well as the impact of LBP on health-related quality of life (HRQOL). Patients with LBP < 72 hours who self-referred to a general practitioner for LBP (n=113) completed a baseline assessment which included a questionnaire on job satisfaction, pain intensity (on a 100-mm VAS), functional disability (Roland Morris Disability Questionnaire) and HRQOL (SF-36). Participants recorded pain intensity and functional disability and had follow-up visits as needed over a 3-month period. Independent associations with delayed recovery included prior low back surgery, higher initial disability, lower SF-36 and temporary compensation status. The authors concluded that work-related factors and initial HRQOL can contribute to the prognosis of LBP. This study provides Level I evidence that prior back disability, high scores on disability questionnaire, temporary disability status and SF-36 general health measure were strong determinants of conversion of acute to chronic LBP.

Foster et al<sup>5</sup> conducted a multicenter prospective cohort study to describe illness perceptions and their associations with clinical outcomes at 6 months in patients with nonspecific LBP. Patients who consulted

a general practice for LBP completed questionnaires that included RMDQ and Revised Illness Perception Questionnaire (IPQ-R) at enrollment (n=1,591) and 6 months (n=810). Patients who expected their back problem to last a long time, who perceived serious consequences and who held weak beliefs in the controllability of their back problem were more likely to have poor clinical outcomes after 6 months. The authors concluded that patient perceptions about their back pain predict clinical outcomes 6 months after consulting their doctor. This study provides Level II evidence that patient expectations at baseline, fear of adverse consequences and perception of lack of control predicted 6-month outcomes.

In a longitudinal cohort study, Fritz et al<sup>6</sup> aimed to determine cut-off values to maximize the predictive ability of nonorganic signs and symptoms in patients with acute LBP and their ability to predict return to work. Patients with work-related LBP < 3 weeks referred for physical therapy completed a questionnaire and underwent a physical examination upon enrollment. A physical therapist gave each participant a score from 0 to 5 based on nonorganic signs present during examination. That number was added to the nonorganic symptom score based on participant questionnaire (0-7) to calculate a nonorganic index. Participants completed the recommended physical therapy, were reevaluated after 4 weeks and were dichotomously categorized as returned to work without restrictions or not. The presence of 2 or more signs, 3 or more symptoms and an index score of 3 or more were the best cut-off values. The areas under the curve ranged from 0.60 to 0.63 which indicate only slightly greater predictive ability than that expected by chance. The authors concluded that the nonorganic tests were not effective screening tools, even with optimal cut-off values. This study provides Level III evidence that nonorganic signs are not a predictor of acute LBP resolution.

Hancock et al<sup>7</sup> prospectively studied data from a randomized controlled trial to develop a simple prognostic rule to help clinicians identify patients with acute LBP. Patients who presented to a general practitioner in Australia with LBP < 6 weeks were enrolled in a randomized controlled trial in which they received placebo versus active spinal manipulative therapy and placebo versus active diclofenac. Prognostic factors were recorded such as average pain over 24 hours, disability, function, gender, age, duration of current episode, number of previous episodes, area of symptoms, segmental mobility, hip internal rotation range, fear of pain (fear avoidance beliefs questionnaire), cata-

strophizing, coping and physiotherapist's prediction score. Recovery was defined as a pain score of 0 or 1 on a 0-10 scale for 7 consecutive days per individual pain diaries. In the eligible sample (n=239), lower than average initial pain intensity, shorter duration of symptoms and fewer episodes were found to be prognostic factors to predict patients who recover quickly. The authors concluded that, although it needs external validation before recommending for clinical use, the simple clinical prediction rule (CPR) can help primary care clinicians identify prognosis better than clinician judgement in terms of days to recovery for patients with acute LBP. In critique of the methodology, the work group downgraded this potential Level I study due to inclusion of patients with radiculopathy; however, an appropriate subgroup multivariate analysis was completed. This study provides Level II evidence that patients with acute LBP who report more severe pain (>7 out of 10), have longer than 5 days duration of pain and who have previous episodes of acute LBP are less likely to recover rapidly from the episode.

Shaw et al<sup>8</sup> aimed to determine if disability risk factors could predict one-month clinical outcomes of functional limitation and return to work in patients with work-related LBP. Enrolled participants (n=568) completed a questionnaire at baseline and after one month that included physical health risks, workplace factors, pain, mood and expectations for recovery. Outcome measures included functional limitation (RMDQ) and return to work. Employer factors and self-ratings of pain and mood better predicted functional improvement and return to work compared to health history or physical examination. The authors concluded that identification and intervention focused on job factors, pain coping strategies and expectations for recovery may improve outcomes. The work group downgraded this potential Level I study due to uncertainty regarding the patient population, specifically regarding radiculopathy. This study provides Level II evidence that risk factors for prolonged disability and the converse of recovery from LBP at 30 days include job circumstances, pain coping strategies and poor expectation for recovery.

In a prospective cohort, Shaw et al<sup>9</sup> assessed the relationship between BMI and pain and function outcomes in work-related LBP. Participants with LBP ≤ 14 days (n=607) reported height, weight, pain, functional limitation and work status at baseline and after one and 3 months. Participants were categorized as normal, overweight or obese based on BMI for data analysis. There were no significant differences in outcomes of pain, functional limitation (RMDQ) or return

to work based on categorization of BMI. The authors concluded that BMI is not a useful prognostic factor for work-related acute or subacute LBP. This study provides Level II evidence that BMI is not predictive of transition to chronicity in the workers compensation population.

Gatchel et al<sup>10</sup> assessed the relationship between psychological characteristics and conversion of acute to chronic LBP. A total of 324 participants with acute LBP  $\leq$  6 weeks completed assessments at baseline including pain and disability (Million VAS), psychopathology (Structured Clinical Interview for DSM-III-R) and Minnesota Multiphasic Personality Inventory (MMPI). After 6 months, patients completed a telephone questionnaire and were categorized as currently working or in training/school ( $n=274$ ), not currently working due to original back injury ( $n=36$ ) or not currently working due to factors other than original back injury ( $n=14$ ; not analyzed in this study). The disabled group had higher self-reported pain and disability, more individuals with a personality disorder and higher scores on Scale 3 of the MMPI. The authors concluded that the presence of these psychosocial variables is associated with injured workers who are likely to convert from acute to chronic LBP. In critique of the methodology, the work group downgraded this potential Level I study due to the inclusion of workers with a history of “chronic back pain” in the original cohort. This study provides Level II evidence that workers with more severe LBP, increased psychological distress and/or personality disorders are more likely to remain off work 6 months after acute episode.

Gatchel et al<sup>11</sup> evaluated the effectiveness of a psychosocial and personality assessment in predicting the transition of acute LBP to chronic pain disability. Participants ( $n=421$ ) with LBP for less than 6 weeks completed assessments including the DSM-III-R Diagnosis, Minnesota Multiphasic Personality Inventory and Million Visual Pain Analog Scale. Return-to-work status was collected at 6- and 12-month follow-up telephone calls. Participants were categorized as currently working or in training/school ( $n=365$ ), not currently working due to original back injury ( $n=29$ ), or not currently working due to factors other than original back injury ( $n=27$ ; not analyzed in this study). Compared to the nondisabled group, the participants not currently working due to the original back injury had higher pain and disability analog scores, higher MMPI Scale 3 scores and proportionately more individuals with workers compensation and personal injury cases. Major psychopathology (depression

and substance abuse) did not precede or cause development of chronic pain disability. The authors concluded that their statistical algorithm to determine a “psychosocial disability factor” can predict patients with acute LBP that will likely develop into chronic disability. The work group downgraded this potential Level I study due to the inclusion of some workers with preexisting chronic LBP in the cohort. This study provides Level II evidence that initial pain and disability MMPI score, female gender and insurance status can predict return to work one year following acute LBP episode.

Reme et al<sup>12</sup> conducted a study to identify clusters of self-reported concerns and expectations in individuals with LBP who would benefit from early intervention. Participants with acute LBP related to work ( $n=496$ ) completed a questionnaire with 11 possible risk factors upon enrollment and a follow-up questionnaire assessing pain, functional limitation and work status after 3 months. Eight of the risk factors had significant associations with the outcomes and were used to create 4 clusters: minimal risk (best functional outcomes), workplace concerns, activity limitations and emotional distress (poorest functional outcomes). The authors concluded that questionnaires that contain pain-related concerns and expectations can be useful to identify patients with LBP who could benefit from early intervention. This study provides Level II evidence that recovery expectations, life impact of pain, organizational support, kinesiophobia, functional limitation, pain catastrophizing, depressive symptoms and pain intensity showed significant associations with functional recovery and return to work. These measures were entered into the cluster analysis. A 4-cluster solution met criteria for cluster separation and interpretability and the 4 clusters were labeled: (a) minimal risk (29 %), (b) workplace concerns (26 %), (c) activity limitations (27%) and (d) emotional distress (19 %). Functional outcomes were best in the minimal risk group, poorest in the emotional distress group and intermediate in the other two groups.

Rolli Salathe et al<sup>13</sup> aimed to identify work-related resources to predict sickness absence in individuals with LBP. Employed individuals with acute (<6 weeks) or subacute (<12 weeks) LBP ( $n=279$ ) completed a questionnaire at baseline and after one year which included the work-related section of the Fear-Avoidance Beliefs Questionnaire (FABQ), life satisfaction, job satisfaction, participation in sports and social support at work. The outcome measure, sickness absence, was self-reported on the



questionnaire as days missed from work due to LBP. Multiple linear regression analysis revealed that life satisfaction, work-related FABQ and sickness absence at baseline were predictors of sickness absence after one year. The authors concluded that life satisfaction was a predictor of sickness absence after one year. This study provides Level III evidence that life satisfaction, job satisfaction and social support decreased sickness absence at baseline and one-year follow-up.

In a prospective cohort study, Shaw et al<sup>14</sup> evaluated the effect of psychiatric diagnoses on the likelihood of transitioning from subacute to chronic LBP. Men presenting to their provider with LBP for 6–10 weeks completed an assessment at baseline (n=140) and after 6 months (n=120) which included a standardized orthopedic evaluation, structured psychodiagnostic interview (Diagnostic Interview Schedule Version III-R [DIS]) and details on pain intensity (Descriptor Differential Scale [DDS]) and Disability (Sickness Impact Profile [SIP]). The outcome of transition to chronic pain was defined as SIP score >10 and DDS score for pain intensity >10 at 6-month follow-up. Men with a diagnosis of major depressive disorder, generalized anxiety, post-traumatic stress disorder (PTSD), or current nicotine dependence had greater risk of transitioning to chronic LBP. The authors concluded that screening for depressive disorder or anxiety disorder may identify individuals with greater risk of transition to chronic LBP. Due to the subacute patient population, the work group determined this study provided Level II evidence that risk of conversion to chronic pain in male patients was significantly elevated in the presence of a lifetime diagnosis of major depression, PTSD and generalized anxiety or a diagnosis of nicotine dependence in the past 6 months.

Turner et al<sup>15</sup> assessed the predictive value of worker demographic, pain, disability and psychosocial variables on 6-month work disability in individuals with work-related LBP. Individuals who submitted a workers' compensation back pain disability claim (n=1,068) completed a telephone interview that addressed pain intensity (on a scale from 0 to 10), disability (RMDQ), catastrophizing (Pain Catastrophizing Scale), recovery expectations, coworker relations, and blame. The outcome measure of work disability was wage replacement compensation for total disability after initially submitting the claim. At 6 months, predictors of disability included age, race, education and baseline pain and disability. High levels of fear-avoidance and low expectations of recovery were independent predictors of 6-month disability. The authors concluded that in the studied population,

risk factors for chronic work disability include high pain and disability, low recovery expectations and fears that work may increase pain or cause harm. The work group initially rated this study as a Level II due to uncertainty regarding the duration of enrollment, but downgraded the level of evidence to a Level III due to the outcome of "not being paid" for return to work. This was felt to introduce an additional false endpoint that may not have been completely dependent upon the resolution of back pain. Therefore, this study provides Level III evidence that workers with lower recovery expectations and greater work fear avoidance at baseline were significantly ( $P < 0.05$ ) more likely to be receiving work disability wage replacement compensation at 6 months.

Melloh et al<sup>16</sup> investigated factors that influence the progression of acute LBP to persistent LBP in an inception cohort study of patients presenting to a health practitioner for acute LBP. Enrolled participants (n=62) completed a questionnaire at baseline and were invited to complete follow-up questionnaires after 3, 6, 12 weeks and 6 months. Predictor variables were combined into three indices: "working conditions," "depression and maladaptive cognitions" and "pain and quality of life." Persistent LBP was defined as an Oswestry Disability Index (ODI) score >10 points after 6 weeks. In the participants who followed up after 6 months (n=53), the index "depression and maladaptive cognitions" (depression, somatization, resigned attitude towards the job, fear-avoidance, rumination, helplessness, catastrophizing and negative expectations on return to work) at baseline was a significant predictor for transition of acute to persistent LBP. The authors concluded that psychological factors at baseline correlated with progression from acute to persistent LBP at 6 months and may be beneficial to add into screening tools. In critique of the methodology, the work group downgraded this potential Level I article due to concerns of select patient population and sample size. This study provides Level II evidence that depression and maladaptive cognitions are a significant risk factor for conversion from acute to chronic LBP at 6 months.

Sewitch et al<sup>17</sup> conducted a secondary analysis of data from a randomized controlled trial on the effectiveness of a back school program in order to find the relationship between psychological factors and recovery from first episode of LBP. Participants (n=134) with a first occurrence of LBP receiving workers' compensation with the inability to work due to LBP completed baseline assessments. Demographics, lifestyle habits, job-related variables, mental health status (per

Psychiatric Symptom Index and General Well Being Scale), functional status (RMDQ) and pain (VAS) were recorded. The outcome of late return to work was defined as return to work > 31 days after enrollment in study; the outcome of compensated recurrence was defined as a subsequent compensated disability due to LBP after initial return to work. Multivariate analysis revealed that lower psychological distress predicted late return to work while higher general well-being,

greater control over emotions, higher aggressiveness and lower anxiety predicted compensated recurrence. The authors concluded that psychological factors do not impact clients with all types of LBP the same way. The work group downgraded this potential Level II study due to nonconsecutive patients and the return-to-work outcome measure. This study provides Level III evidence that history of back pain and psychological level of functioning influences return to work in a workers' compensation population.

**It is recommended that psychosocial factors be used as prognostic factors for return to work following an episode of acute low back pain.**

**Grade of Recommendation: A**

Gatchel et al<sup>10</sup> assessed the relationship between psychological characteristics and conversion of acute to chronic LBP. A total of 324 participants with acute LBP ≤ 6 weeks completed assessments at baseline including pain and disability (Million VAS), psychopathology (Structured Clinical Interview for DSM-III-R) and Minnesota Multiphasic Personality Inventory (MMPI). After 6 months, patients completed a telephone questionnaire and were categorized as currently working or in training/school (n=274), not currently working due to original back injury (n=36) or not currently working due to factors other than original back injury (n=14; not analyzed in this study). The disabled group had higher self-reported pain and disability, more individuals with a personality disorder and higher scores on Scale 3 of the MMPI. The authors concluded that the presence of these psychosocial variables is associated with injured workers who are likely to convert from acute to chronic LBP. In critique of the methodology, the work group downgraded this potential Level I study due to the inclusion of workers with a history of "chronic back pain" in the original cohort. This study provides Level II evidence that workers with more severe LBP, increased psychological distress and/or personality disorders are more likely to remain off work 6 months after acute episode.

Gatchel et al<sup>11</sup> evaluated the effectiveness of a psychosocial and personality assessment in predicting the transition of acute LBP to chronic pain disability. Participants (n=421) with LBP for less than 6 weeks completed assessments including the DSM-III-R Diagnosis, Minnesota Multiphasic Personality Inventory and Million Visual Pain Analog Scale. Return-to-work status was collected at 6- and 12-month follow-up tele-

phone calls. Participants were categorized as currently working or in training/school (n=365), not currently working due to original back injury (n=29), or not currently working due to factors other than original back injury (n=27; not analyzed in this study). Compared to the nondisabled group, the participants not currently working due to the original back injury had higher pain and disability analog scores, higher MMPI Scale 3 scores and proportionately more individuals with workers compensation and personal injury cases. Major psychopathology (depression and substance abuse) did not precede or cause development of chronic pain disability. The authors concluded that their statistical algorithm to determine a "psychosocial disability factor" can predict patients with acute LBP that will likely develop into chronic disability. The work group downgraded this potential Level I study due to the inclusion of some workers with preexisting chronic LBP in the cohort. This study provides Level II evidence that initial pain and disability MMPI score, female gender and insurance status can predict return to work one year following acute LBP episode.

Rolli Salathe et al<sup>12</sup> aimed to identify work-related resources to predict sickness absence in individuals with LBP. Employed individuals with acute (< 6 weeks) or subacute (< 12 weeks) LBP (n=279) completed a questionnaire at baseline and after one year which included the work-related section of the Fear-Avoidance Beliefs Questionnaire (FABQ), life satisfaction, job satisfaction, participation in sports and social support at work. The outcome measure, sickness absence, was self-reported on the questionnaire as days missed from work due to LBP. Multiple linear regression analysis revealed that life satisfaction, work-related FABQ and sickness absence at baseline were predic-

tors of sickness absence after one year. The authors concluded that life satisfaction was a predictor of sickness absence after one year. This study provides Level III evidence that life satisfaction, job satisfaction and social support decreased sickness absence at baseline and one-year follow-up.

Turner et al<sup>15</sup> assessed the predictive value of worker demographic, pain, disability and psychosocial variables on 6-month work disability in individuals with work-related LBP. Individuals who submitted a workers' compensation back pain disability claim (n=1,068) completed a telephone interview that addressed pain intensity (on a scale from 0 to 10), disability (RMDQ), catastrophizing (Pain Catastrophizing Scale), recovery expectations, coworker relations, and blame. The outcome measure of work disability was wage replacement compensation for total disability after initially submitting the claim. At 6 months, predictors of disability included age, race, education and baseline pain and disability. High levels of fear-avoidance and low expectations of recovery were independent predictors of 6-month disability. The authors concluded that in the studied population, risk factors for chronic work disability include high pain and disability, low recovery expectations and fears that work may increase pain or cause harm. The work group initially assigned this study as a Level II due to uncertainty regarding the duration of enrollment, but downgraded the level of evidence to a Level III due to the outcome of "not being paid" for return to work. This was felt to introduce an additional false endpoint that may not have been completely dependent upon

the resolution of back pain. Therefore, this study provides Level III evidence that workers with lower recovery expectations and greater work fear avoidance at baseline were significantly ( $P < 0.05$ ) more likely to be receiving work disability wage replacement compensation at 6 months.

Sewitch et al<sup>17</sup> conducted a secondary analysis of data from a randomized controlled trial of the effectiveness of a back school program in order to find the relationship between psychological factors and recovery from first episode of LBP. Participants (n=134) with a first occurrence of LBP receiving workers' compensation with the inability to work due to LBP completed baseline assessments. Demographics, lifestyle habits, job-related variables, mental health status (per Psychiatric Symptom Index and General Well Being Scale), functional status (RMDQ) and pain (VAS) were recorded. The outcome of late return to work was defined as return to work >31 days after enrollment in study; the outcome of compensated recurrence was defined as a subsequent compensated disability due to LBP after initial return to work. Multivariate analysis revealed that lower psychological distress predicted late return to work while higher general well-being, greater control over emotions, higher aggressiveness and lower anxiety predicted compensated recurrence. The authors concluded that psychological factors do not impact clients with all types of LBP the same way. This study provides Level III evidence that history of back pain and psychological level of functioning influences return to work in a workers' compensation population.

**It is recommended that pain severity and functional impairment be used to stratify risk of conversion from acute to chronic low back pain.**

**Grade of Recommendation: A**

Coste et al<sup>4</sup> evaluated the associations between various risk factors and the natural history of acute LBP as well as the impact of LBP on health-related quality of life (HRQOL). Patients with LBP < 72 hours who self-referred to a general practitioner for LBP (n=113) completed a baseline assessment which included a questionnaire on job satisfaction, pain intensity (on a 100-mm VAS), functional disability (RMDQ) and HRQOL (SF-36). Participants recorded pain intensity and functional disability and had follow-up visits as needed over a 3-month period. Independent associations with delayed recovery included prior low back surgery, higher initial disability, lower SF-36 and temporary compensation status. The authors con-

cluded that work-related factors and initial HRQOL can contribute to the prognosis of LBP. This study provides Level I evidence that prior back disability, high scores on disability questionnaire, temporary disability status and SF-36 general health measure were strong determinants of conversion of acute to chronic pain.

Gatchel et al<sup>10</sup> assessed the relationship between psychological characteristics and conversion of acute to chronic LBP. A total of 324 participants with acute LBP ≤ 6 weeks completed assessments at baseline including pain and disability (Million VAS), psychopathology (Structured Clinical Interview for DSM-III-R)

**50** Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

and Minnesota Multiphasic Personality Inventory (MMPI). After 6 months, patients completed a telephone questionnaire and were categorized as currently working or in training/school (n=274), not currently working due to original back injury (n=36), or not currently working due to factors other than original back injury (n=14; not analyzed in this study). The disabled group had higher self-reported pain and disability, more individuals with a personality disorder and higher scores on Scale 3 of the MMPI. The authors concluded that the presence of these psychosocial variables is associated with injured workers who are likely to convert from acute to chronic LBP. In critique of the methodology, the work group downgraded this potential Level I study due to the inclusion of workers with a history of “chronic back pain” in the original cohort. This study provides Level II evidence that workers with more severe LBP, increased psychological distress and/or personality disorders are more likely to remain off work 6 months after acute episode.

Gatchel et al<sup>11</sup> evaluated the effectiveness of a psychosocial and personality assessment in predicting the transition of acute LBP to chronic pain disability. Participants (n=421) with LBP for less than 6 weeks completed assessments including the DSM-III-R Diagnosis, Minnesota Multiphasic Personality Inventory and Million Visual Pain Analog Scale. Return-to-work status was collected at 6- and 12-month follow-up telephone calls. Participants were categorized as currently working or in training/school (n=365), not currently working due to original back injury (n=29), or not currently working due to factors other than original back injury (n=27; not analyzed in this study). Compared to the non-disabled group, the participants not currently working due to the original back injury had higher pain and disability analog scores, higher MMPI Scale 3 scores and proportionately more individuals with workers compensation and personal injury cases. Major psychopathology (depression and substance abuse) did not precede or cause development of chronic pain disability. The authors concluded that their statistical algorithm to determine a “psychosocial disability factor” can predict patients with acute LBP that will likely develop into chronic disability. The work group downgraded this potential Level I study due to the inclusion of some workers with preexisting chronic LBP in the cohort. This study provides Level II evidence that initial pain and disability MMPI score, female gender and insurance status can predict return to work one year following acute LBP episode.

Costa et al<sup>18</sup> investigated prognostic markers to identify the transition from acute to chronic LBP in an inception cohort study with one-year follow-up in Australia. Patients who initially presented to primary care with acute (<2 weeks) LBP which transitioned to chronic (>3 months) LBP were included in this study (n=406). A telephone interview was conducted at onset of chronic LBP and after 9 and 12 months to assess potential prognostic factors as well as intensity of pain, disability and work status. Participants were considered to be completely recovered when they reported they were pain free, had no disability from back pain and returned to work for 30 consecutive days. Delayed recovery was associated with previous sick leave due to low LBP, high disability levels or pain intensity at onset of chronic LBP, low levels of education, greater perceived risk of persistent pain and birthplace outside of Australia. The authors concluded that the prognosis for individuals with chronic LBP is moderately optimistic; they identified prognostic factors that may make prognosis less favorable. This study provides Level II evidence that patients who do not rapidly recover from acute LBP who are at risk for developing chronic symptoms have: lower education; workers compensation claims; the use of medications; increased disability at acute presentation; previous sick leave for LBP; feelings of depression, tension or anxiety; high pain intensity; morning back stiffness and perception of having a high risk of persistent pain.

Hancock et al<sup>7</sup> prospectively studied data from a randomized controlled trial to develop a simple prognostic rule to help clinicians identify patients with acute LBP. Patients who presented to a general practitioner in Australia with LBP <6 weeks were enrolled in a randomized controlled trial in which they received placebo versus active spinal manipulative therapy and placebo versus active diclofenac. Prognostic factors were recorded such as average pain over 24 hours, disability, function, gender, age, duration of current episode, number of previous episodes, area of symptoms, segmental mobility, hip internal rotation range, fear of pain (fear avoidance beliefs questionnaire), catastrophizing, coping and physiotherapist’s prediction score. Recovery was defined as a pain score of 0 or 1 on a 0–10 scale for 7 consecutive days per individual pain diaries. In the eligible sample (n=239), lower than average initial pain intensity, shorter duration of symptoms and fewer episodes were found to be prognostic factors to predict patients who recover quickly. The authors concluded that, although it needs external validation before recommending for clinical

use, the simple CPR can help primary care clinicians identify prognosis better than clinician judgement in terms of days to recovery for patients with acute LBP. In critique of the methodology, the work group downgraded this potential Level I study due to inclusion of patients with radiculopathy; however, an appropriate subgroup multivariate analysis was completed. This study provides Level II evidence that patients with acute LBP who report more severe pain (>7 out of 10), have longer than 5 days duration of pain and who have previous episodes of acute LBP are less likely to recover rapidly from episode.

Friedman et al<sup>19</sup> investigated whether 5 high-risk variables predict poor functional outcomes in patients presenting to the emergency department (ED) for nontraumatic LBP classified as musculoskeletal. The high-risk variables included baseline functional disability related to LBP, radicular signs, depression, work-related injury or history of chronic or recurrent LBP. In this prospective observational cohort study at a single ED, enrolled participants (n=556) were interviewed prior to ED discharge which included information regarding demographics, duration and symptoms of LBP and the RMDQ. Patients' LBP was categorized as chronic, episodic or rare/never. Participants were contacted at one week (97% follow-up) and three months (92% follow-up) post-discharge to assess the outcome measure of functional limitation per the RMDQ score (score >0 indicating LBP-related functional impairment). A higher baseline RMDQ score and chronic LBP were each associated with LBP-related functional disability at 7-day and 3-month follow-up. Depression, radicular signs and work-injury did not predict functional outcome at either time point. The authors concluded that, in patients presenting to the ED with nontraumatic LBP, those with worse baseline functional impairments and

history of chronic LBP are more likely to have worse short- and long-term functional outcomes. In critique of the methodology, the work group downgraded this potential Level I study due to the short follow-up period. This study provides Level II evidence that high initial disability (RMDQ  $\geq$  17) and a history of previous LBP for 30 straight days predicted lack of recovery at 3 months.

Neubauer et al<sup>20</sup> conducted a prospective cohort study with the objective to develop a short and reliable instrument to predict the chronicity of LBP. Patients presenting to an orthopedic specialist for acute LBP <6 months were invited to participate. Participants completed a questionnaire at enrollment (n=235) and again by mail after 6 months (n=192, 82%) after receiving standard treatment for LBP. Questionnaires covered 167 items including LBP history and pain (VAS), cognitive strategies of pain management, psychosomatic comorbidities, subjective well-being, depressive symptoms (Zung Depression Index), work satisfaction and socio-demographic data. The main outcome measure was chronicity of LBP, defined as presence of LBP after 6 months. Results revealed that pain intensity, tolerance and duration, as well as educational level, pain experienced elsewhere in the body, depression, female gender, catastrophizing thoughts, and feelings of helplessness were strong predictors for the development of chronic LBP. The authors concluded that a questionnaire with these items can predict a patient's risk of developing chronic LBP with a probability of 78%. This study provides Level II evidence that pain intensity and acceptance, response to massage therapy, duration of pain, patient educational level, pain elsewhere in body, depression, female gender, catastrophizing thoughts, and feelings of helplessness predicted conversion to chronic LBP at 6 months.

**It is suggested that prior episodes of low back pain be considered a prognostic factor for the conversion from acute to chronic low back pain.**

**Grade of Recommendation: B**

Coste et al<sup>4</sup> evaluated the associations between various risk factors and the natural history of acute LBP as well as the impact of LBP on health-related quality of life (HRQOL). Patients with LBP <72 hours who self-referred to a general practitioner for LBP (n=113) completed a baseline assessment which included a questionnaire on job satisfaction, pain intensity (on a 100-mm VAS), functional disability (RMDQ) and

HRQOL (SF-36). Participants recorded pain intensity and functional disability and had follow-up visits as needed over a 3-month period. Independent associations with delayed recovery included prior low back surgery, higher initial disability, lower SF-36 and temporary compensation status. The authors concluded that work-related factors and initial HRQOL can contribute to the prognosis of LBP. This study

provides Level I evidence that prior back disability, high scores on disability questionnaire, temporary disability status and SF-36 general health measure were strong determinants of conversion of acute to chronic pain.

Costa et al<sup>18</sup> investigated prognostic markers to identify the transition from acute to chronic LBP in an inception cohort study with one-year follow-up in Australia. Patients who initially presented to primary care with acute (<2 weeks) LBP which transitioned to chronic (>3 months) LBP were included in this study (n=406). A telephone interview was conducted at onset of chronic LBP and after 9 and 12 months to assess potential prognostic factors as well as intensity of pain, disability and work status. Participants were considered to be completely recovered when they reported they were pain free, had no disability from back pain and returned to work for 30 consecutive days. Delayed recovery was associated with previous sick leave due to low LBP, high disability levels or pain intensity at onset of chronic LBP, low levels of education, greater perceived risk of persistent pain and birthplace outside of Australia. The authors concluded that the prognosis for individuals with chronic LBP is moderately optimistic; they identified prognostic factors that may make prognosis less favorable. This study provides Level II evidence that patients who do not rapidly recover from acute LBP who are at risk for developing chronic symptoms have: lower education; workers compensation claims; the use of med-

ications; increased disability at acute presentation; previous sick leave for LBP; feelings of depression, tension or anxiety; high pain intensity; morning back stiffness and perception of having a high risk of persistent pain.

Sewitch et al<sup>17</sup> conducted a secondary analysis of data from a randomized controlled trial of the effectiveness of a back school program in order to find the relationship between psychological factors and recovery from first episode of LBP. Participants (n=134) with a first occurrence of LBP receiving workers' compensation with the inability to work due to LBP completed baseline assessments. Demographics, lifestyle habits, job-related variables, mental health status (per Psychiatric Symptom Index and General Well Being Scale), functional status (RMDQ) and pain (VAS) were recorded. The outcome of late return to work was defined as return to work >31 days after enrollment in study; the outcome of compensated recurrence was defined as a subsequent compensated disability due to LBP after initial return to work. Multivariate analysis revealed that lower psychological distress predicted late return to work while higher general well-being, greater control over emotions, higher aggressiveness and lower anxiety predicted compensated recurrence. The authors concluded that psychological factors do not impact clients with all types of LBP the same way. This study provides Level III evidence that history of back pain and psychological level of functioning influences return to work in a workers' compensation population.

### There is insufficient evidence to assess sleep quality as a prognostic variable to predict recovery from acute low back pain.

#### Grade of Recommendation: I

Alsaadi et al<sup>3</sup> aimed to evaluate the association between sleep quality and pain intensity in patients with acute LBP using data from an existing randomized controlled trial. Participants from the PACE study received paracetamol or placebo until "recovery from back pain" for up to 4 weeks and recorded outcome data in a weekly diary for 12 weeks. Sleep quality over the past 7 days was assessed using the Pittsburgh Sleep Quality Index (PSQI) and average pain over the last 24 hours was rated using a 10-point numerical rating scale (NRS). A generalized estimating equation

model was used with the participants with adequate follow-up data (n=1246). Sleep quality and pain intensity both improved over the 12-week follow-up period; for every 1-point decrease in sleep quality, pain intensity increased by 2.08 points. The authors concluded that sleep quality is related to subsequent pain intensity in patients with acute LBP. This study provides Level I evidence that poor sleep quality associated with acute LBP is a positive predictor for lack of recovery.

There is insufficient evidence to make a recommendation for or against the use of smoking and/or obesity as prognostic factors for the conversion from acute to chronic low back pain.

#### Grade of Recommendation: I

Bakker et al<sup>2</sup> evaluated the use of spinal mechanical load as a prognostic factor for the conversion of acute nonspecific LBP to persistent (defined as recurrent and/or chronic) LBP in a prospective cohort study. Subjects with acute LBP <6 weeks were enrolled and underwent a baseline assessment (n=97). Spinal mechanical load was calculated using the 24HS measurement. Participants completed a 6-month follow-up telephone call (n=88) to assess changes in characteristics, mechanical load per the 24HS and LBP. Sixty percent of the follow-up participants reported persistent LBP. Mechanical load was not a prognostic factor for persistent LBP, but smoking and advanced age were associated with persistent LBP. The authors concluded that mechanical loading of the spine is not predictive for chronicity or recurrent episodes of LBP. This study provides Level I evidence that smoking and advanced age are predictors of conversion of acute to chronic LBP.

In a prospective cohort, Shaw et al<sup>9</sup> assessed the relationship between BMI on pain and function outcomes in work-related LBP. Participants with LBP ≤14 days (n=607) reported height, weight, pain, functional limitation and work status at baseline and after one and 3 months. Participants were categorized as normal, overweight or obese based on BMI for data analysis. There were no significant differences in outcomes of pain, functional limitation (RMDQ) or return to work based on categorization of BMI. The authors concluded that BMI is not a useful prognostic factor

for work-related acute or subacute LBP. This study provides Level II evidence that BMI is not predictive of transition to chronicity in the workers compensation population.

In a prospective cohort study, Shaw et al<sup>14</sup> evaluated the effect of psychiatric diagnoses on the likelihood of transitioning from subacute to chronic LBP. Men presenting to their provider with LBP for 6–10 weeks completed an assessment at baseline (n=140) and after 6 months (n=120) which included a standardized orthopedic evaluation, structured psychodiagnostic interview (Diagnostic Interview Schedule Version III-R [DIS]) and details on pain intensity (DDS) and Disability (Sickness Impact Profile [SIP]). The outcome of transition to chronic pain was defined as SIP score >10 and DDS score for pain intensity >10 at 6-month follow-up. Men with a diagnosis of major depressive disorder, generalized anxiety, post-traumatic stress disorder (PTSD) or current nicotine dependence had greater risk of transitioning to chronic LBP. The authors concluded that screening for depressive disorder or anxiety disorder may identify individuals with greater risk of transition to chronic LBP. Due to the subacute patient population, the work group determined this study provided Level II evidence that risk of conversion to chronic pain in male patients was significantly elevated in the presence of a lifetime diagnosis of major depression, PTSD and generalized anxiety, or a diagnosis of nicotine dependence in the past 6 months.



#### Future Directions for Research

The work group encountered numerous high quality prognostic studies with heterogeneous study populations including patients with leg pain. In order to make useful recommendations, it is recommended that subgroups (ie with or without leg pain) be identified and analyzed separately.

The work group recommends further research on interventions addressing the prognostic factors above and the effect of those interventions on the conversion from acute to chronic LBP.

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**Diagnosis Question 4.** In patients with low back pain, what history and/or physical examination findings are useful in determining if the cause is nonstructural in nature and, therefore, guide treatment?

**A nonstructural cause of low back pain may be considered in patients with diffuse low back pain and tenderness.**

**Grade of Recommendation: C**

Jensen et al<sup>1</sup> assessed the associations between the number of tender points and spinal structural changes as well as psycho-social factors in a cross-sectional study of patients who were sick-listed due to LBP for 3-16 weeks. Participants completed a questionnaire that included information on LBP and the Common Mental Disorders Questionnaire (CMDQ)

and underwent a clinical examination that included a standardized assessment of tender points. Patients were classified as nonspecific LBP without leg pain (n=96), nonspecific radiating pain (n=119), or verified nerve root affection with relevant structural lesion on MRI (n=111). A disc degeneration score was computed based on x-ray findings of disc height

Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.



reductions and patients were classified as “moderate or severe degeneration at minimum one level” or “no or slight degeneration at any level.” Results revealed that many tender points on exam were associated with female sex, psychological distress and widespread pain. Multiple tender points were negatively associated with disc degeneration (DD) and verified root involvement. The authors concluded that the presence of multiple tender points indicates that the pain syndrome is widespread and unlikely due to a specific spinal cause. This study provides Level III evidence that diffuse back tenderness tends to indicate a nonstructural cause.

Coste et al<sup>2</sup> conducted a descriptive cross-sectional study with the aim of developing a clinical and psychological classification of LBP to define treatment protocols. Patients presenting to an outpatient clinic with chief complaint of LBP of any time duration were

included. Participants (n=330) completed a clinical interview (including information on LBP and DSM-III classification) and underwent physical and radiographic examinations. Per DSM-III classification, 136 patients (41.2%) had at least one psychiatric disorder. Diffuse spinal pain, impossibility to assess intensity of pain on a pain scale and pain increased by changing climate, domestic activities or psychological factors were related to the presence of a psychiatric disorder. The authors concluded that LBP should be assessed both physically and psychologically so that an appropriate management may be initiated, which may include psychiatric therapy. This study provides Level II evidence that psychological disorders are common in patients with nonspecific LBP. A combination of diffuse spinal pain, impossibility to assess pain intensity, pain increased by psychological factors, or with changing climate and dysesthesias in the back, indicates a nonorganic syndrome.

### There is insufficient evidence to make a recommendation for or against the use of fear avoidance behavior to determine the likelihood of a structural cause of low back pain.

#### Grade of Recommendation: I

In a prospective cross-sectional study, Lundberg et al<sup>3</sup> aimed to describe the occurrence and association of fear-avoidance variables (pain intensity, kinesiophobia, depression and disability) in patients with specific or nonspecific chronic LBP. Participants with LBP (n=147) were diagnosed as specific (attributable to a specific pathology such as disc herniation, isthmic spondylolisthesis and spinal stenosis) or nonspecific (pain not able to be attributed to a recognizable specific pathology). Upon enrollment, participants completed questionnaires that included information on demographics, pain duration, intensity (VAS), disability (Oswestry Disability Index),

kinesiophobia (Tampa Scale of Kinesiophobia) and depressed mood (Zung Self-Rating Depression Scale). Both groups of patients, with either specific or nonspecific chronic LBP, had elevated fear-avoidance values. All fear-avoidance variables predicted disability in all patients with chronic LBP with the exception of kinesiophobia in those with nonspecific chronic LBP. The authors concluded that pain must be analyzed and treated, in addition to searching for the cause of pain. This study provides Level IV evidence that the presence of fear avoidance behavior does not indicate the absence of a specific structural cause of LBP.

### There is insufficient evidence to make a recommendation for or against the presence of diffuse back tenderness for the prediction of the presence of disc degeneration on radiographs.

#### Grade of Recommendation: I

Jensen et al<sup>1</sup> assessed the associations between the number of tender points and spinal structural changes as well as psycho-social factors in a cross-sectional study of patients who were sick-listed due to LBP for 3-16 weeks. Participants completed a questionnaire that included information on LBP and the CMDQ and underwent a clinical examination that included a standardized assessment of tender points. Patients

were classified as nonspecific LBP without leg pain (n=96), nonspecific radiating pain (n=119), or verified nerve root affection with relevant structural lesion on MRI (n=111). A disc degeneration score was computed based on x-ray findings of disc height reductions and patients were classified as “moderate or severe degeneration at minimum one level” or “no or slight degeneration at any level.” Results revealed that many

tender points on exam were associated with female sex, psychological distress and widespread pain. Multiple tender points were negatively associated with DD and verified root involvement. The authors concluded

that the presence of multiple tender points indicates that the pain syndrome is widespread and unlikely due to a specific spinal cause. This study provides Level III evidence that diffuse back tenderness tends to indicate a nonstructural cause.

### Future Directions for Research

The work group recommends further prospective research evaluating the association between psychological distress and structural abnormalities of the lumbar spine.

### References:

1. Jensen OK, Nielsen CV, Stengaard-Pedersen K. Low back pain may be caused by disturbed pain regulation: a cross-sectional study in low back pain patients using tender point examination. *Eur J Pain*. 2010;14(5):514-522 519p.
2. Coste J, Paolaggi JB, Spira A. Classification of nonspecific low back pain. I. Psychological involvement in low back pain: A clinical, descriptive approach. *Spine*. 1992;17(9):1028-1037.
3. Lundberg M, Frennered K, Hagg O, Styf J. The impact of fear-avoidance model variables on disability in patients with specific or nonspecific chronic low back pain. *Spine*. 2011;36(19):1547-1553.



**Diagnosis Question 5.** In patients with low back pain, what elements of the patient's history and findings from the physical examination would suggest the need for diagnostic laboratory studies?

**There is insufficient evidence to make a recommendation for or against obtaining laboratory tests to assess for inflammatory disease in patients with SI joint pain.**

**Grade of Recommendation: I**

Gupta et al<sup>1</sup> retrospectively reviewed pain history, clinical examination including SIJ provocative tests, laboratory investigations and skeletal imaging to describe the clinical spectrum and propose a diagnostic scheme in patients with LBP due to sacroiliac joint (SIJ) involvement. Of the 61 patients with suspected SIJ problems, 52 had specific SIJ pathology diagnoses; 40 of which had rheumatic conditions and 12 of which had nonrheumatic conditions. The authors concluded

that sacroiliac joint pathology diagnosis was supported by medical history, clinical examination including sacroiliac joint tests, plain radiography and laboratory investigations and that a diagnostic scheme of dividing SIJ pathologies into rheumatic and nonrheumatic conditions in these patients was helpful. This study provides Level IV evidence that, in patients with SI joint pain, laboratory tests should be considered to assess for inflammatory disease.

### Future Directions for Research:

The work group recommends prospective studies of patients with sacroiliac joint pain to define the role of laboratory investigation in the absence of other signs of inflammatory disease.

### References:

1. Gupta AD. Sacroiliac joint pathologies in low back pain. *Journ Back Musculoskel Rehabil*. 2009;22(2):91-97.

*Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.*



**Diagnosis Question 7.** In patients with low back pain, are there specific findings on a pain diagram that help differentiate the structure which is causing pain?

**Diagnosis Question 8.** Are there assessment tools or questionnaires that can help identify the cause of acute, subacute or chronic low back pain?

**A systematic review of the literature yielded no studies to adequately address these questions in this patient population.**



#### Future Directions for Research:

Based upon a review of the available literature, the work group feels that, in the specifically-defined patient population, it is unlikely that pain diagrams are going to elucidate the cause of LBP.



**Diagnosis Question 10.** Are there history and physical examination findings that would warrant obtaining advanced imaging studies?

**A systematic review of the literature yielded no studies to adequately address this question.**

#### Work Group Consensus Statement:

In the absence of reliable evidence supporting an absolute indication for advanced imaging based upon history and physical examination in the specifically-defined patient population, it is the work group's opinion that, in patients with severe and intractable pain syndromes who have failed medical/interventional treatment, advanced imaging may be indicated. Subgroups of patients have been shown to have a higher or lower incidence of radiographic abnormalities based upon acuity of low back pain, tenderness to palpation and provocation maneuvers; however, the utility of these findings in guiding treatment is not clear.



#### Future Directions for Research:

The work group does not have any recommendations for future research on this topic.

## References:

1. Berg L, Hellum C, Gjertsen O, et al. Do more MRI findings imply worse disability or more intense low back pain? A cross-sectional study of candidates for lumbar disc prosthesis. *Skelet Radiol.* 2013;42(11):1593-1602.
2. Elgafy H, Semaan HB, Ebraheim NA, Coombs RJ. Computed tomography findings in patients with sacroiliac pain. *Clin Orthop.* 2001(382):112-118.
3. Graves JM, Fulton-Kehoe D, Jarvik JG, Franklin GM. Early imaging for acute low back pain: one-year health and disability outcomes among Washington State workers. *Spine.* 2012;37(18):1617-1627.
4. Kumar N, Wijerathne SI, Lim WWJ, Barry TWL, Nath C, Liang S. Resistive straight leg raise test, resistive forward bend test and heel compression test: Novel techniques in identifying secondary gain motives in low back pain cases. *Eur Spine J.* 2012;21(11):2280-2286.
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**Imaging Question 1.** What is the association between low back pain and spondylosis on routine radiography?

**There is insufficient evidence to make a recommendation for or against an association between low back pain and spondylosis using routine radiography.**

**Grade of Recommendation: I**

Nemoto et al<sup>1</sup> conducted a longitudinal study to investigate the development of low back pain (LBP) and lumbar degenerative changes. In 1984, 45 Japanese male parachutists, aged 18–19 years, in the Japanese Self Defense Forces were enrolled. None of the participants had a history of LBP, sciatica, neurogenic claudication, or abnormal lumbar spine radiographs at the time of enrollment. In 2009, repeat radiographs were obtained for 40 of the original subjects who then completed an updated questionnaire related to LBP (defined as  $\geq 7$  consecutive days experienced during the year prior to this study), lifestyle habits and number of parachute descents. A single trained observer assessed the radiographs and assigned summary grades to each lumbar spine based on presence and severity of vertebral osteophytes (VOs), disc space narrowing (DSN) and facet joint osteoarthritis (FJOA). The incidence of VOs, DSN, or FJOA was 70%, 48% and 57%, respectively. Mild LBP pain was reported by 60% of subjects. Multivariate analysis demonstrated that an increased risk of VOs was associated with number of parachute descents ( $p=0.025$ ) and DSN ( $p=0.014$ ). No significant association was found between LBP and various factors. However, VO development showed a greater (nonsignificant) odds ratio (OR 3.80, 95% CI 0.95–15.20). The authors concluded that, in young

and radiologically normal parachutists, frequent parachuting descent and newly developed DSN were predictors of VO formation. In critique of the methodology, the work group downgraded the level of evidence of this potential Level III study due to the small sample size. This study provides Level IV evidence that there is an association between vertebral osteophyte formation and incidence of LBP.

Nemoto et al<sup>2</sup> conducted a longitudinal study to investigate the association between LBP and the incidence of newly developed lumbar degenerative changes at middle age. In 1990, 84 Japanese infantry servicemen in the Japanese Self Defense Forces, aged 18 years, were enrolled after confirming normal anteroposterior, lateral and bilateral oblique lumbar spine radiographs. None of the enrolled participants had a history of LBP, sciatica or neurogenic claudication. In 2010, repeat radiographs were obtained for each of the original 84 participants who then also completed an updated questionnaire related to LBP (defined as  $\geq 7$  consecutive days experienced during the year prior to this study) and lifestyle factors. A single trained observer assessed the radiographs and assigned summary grades to each lumbar spine based on presence and severity of vertebral osteophytes (VOs) and DSN.

Mild LBP was reported by 44 subjects (52%). No association between LBP and lifestyle factors such as smoking, sports, alcohol intake or weight gain was demonstrated. Lumbar degenerative changes were found in 52% of the subjects, with DSN and VOs found in 30% and 46% of subjects, respectively. More lumbar spine degeneration was found in subjects with LBP compared to those without LBP. There was a significant correlation between VOs and LBP (OR 3.00, 95% CI 1.23-7.33;  $p=0.013$ ). There was not a significant

association between DSN and LBP. The authors concluded that, in young men without initial radiological abnormalities, there was a significant association between VOs and incidence of mild LBP. In critique of the methodology, the work group downgraded the level of evidence of this potential Level III study due to the small sample size. This study provides Level IV evidence that there is an association between vertebral osteophyte formation and incidence of LBP.

### Future Directions for Research

The work group recommends the development of studies that incorporate a reference standard in patients without other confounding factors such as spondylolisthesis or radiculopathy.

## References

1. Nemoto O, Kitada A, Tsuda Y, Yokobe J, Matsukawa K, Ukegawa Y. A longitudinal study of radiological changes in the lumbar spine in asymptomatic Japanese military young adults. *Eur Orthop Traumatol.* 2012;3(2):135-139.
2. Nemoto O, Kitada A, Naitou S, Tsuda Y, Matsukawa K, Ukegawa Y. A longitudinal study for incidence of low back pain and radiological changes of lumbar spine in asymptomatic Japanese military young adults. *Eur Spine J.* 2013;22(2):453-458.



**Imaging Question 2.** In patients with low back pain, what elements of the patient's history and findings from the physical examination would suggest the need for diagnostic laboratory studies?

A systematic review of the literature yielded no studies to adequately address this question.

### Future Directions for Research

The work group recommends development of studies investigating the use of MRI or CT scans for the evaluation of LBP in the absence of radiographic abnormality.



**Imaging Question 3.** In patients with low back pain, does duration of symptoms correlate with abnormal findings on imaging?

A systematic review of the literature yielded no studies to adequately address this question.



#### Future Directions for Research

The work group recommends development of longitudinal studies that include both clinical and imaging findings.



**Imaging Question 4.** What is the optimal imaging protocol that should be used in the setting of low back pain?

a. Are unique MRI sequences considered preferential or optimal?

**There is insufficient evidence that unique magnetic resonance imaging (MRI) sequences can be considered preferential or optimal.**

**Grade of Recommendation: I**

Lakadamyali et al<sup>1</sup> conducted a retrospective case control study to investigate the relationship between degenerative changes in posterior spinal elements and LBP, as well as to explore the age- and sex-related distribution of those changes on STIR sequence magnetic resonance (MR) images. In the first stage of this two-stage study, the MR images of 372 patients (231 women, 141 men) with LBP without radiculopathy were evaluated after being referred to a radiology department between the years 2000–2004. During the second stage, 249 additional volunteers (123 women, 126 men) without LBP who were referred to the same department for other MRI examinations, formed a control group. Conventional and sagittal STIR sequences were obtained for all subjects. Two experienced radiologists evaluated the lumbar MR images and recorded presence of intervertebral disc degeneration (DD), disc herniation, interspinous ligament degeneration or rupture, facet joint effusion, neocyst formation, intrinsic spinal muscular degeneration and/or subcutaneous edema. Compared to patients

without LBP, patients with LBP had higher incidences of facet joint effusion ( $p=0.0001$ ), interspinous ligament edema ( $p=0.001$  for T12–L1;  $p=0.0001$  for all lumbar levels), neocyst formation ( $p=0.0001$ ) and intrinsic muscle degeneration ( $p=0.0001$ ). The incidences of intervertebral DD, disc herniation, subcutaneous edema and muscle edema were similar in subjects with and without LBP, but increased with age in both groups. Relevant posterior paraspinal changes were better visualized with STIR imaging than routine MRI. The authors concluded that the percentage of posterior paraspinal degenerative change findings was higher in subjects with LBP compared to those without LBP and that the use of the STIR sequence improved the visualization of those changes. This study provides Level III evidence that patients with LBP had significantly higher rates of facet joint effusion, interspinous ligament edema, neocyst formation and paraspinal muscle edema. The incidence of intervertebral DD, disc herniation and subcutaneous edema in persons with and without LBP were similar.



b. What is the history and clinical presentation that suggests the use of contrast enhanced imaging in patients with low back pain?

A systematic review of the literature yielded no studies to adequately address this question.



c. Is there evidence to support imaging the lumbar spine in an oblique plane?

A systematic review of the literature yielded no studies to adequately address this question.



d. What is the value of flexion/extension films in evaluating lower back pain?

A systematic review of the literature yielded no studies to adequately address this question.



#### Future directions for Research

The work group recommends that future imaging studies relative to LBP include subgrouping of relevant populations. In order to assess a specific imaging protocol, the work group recommends a prospective study evaluating patients with and without nonspecific low back pain.

#### Reference

1. Lakadamyali H, Tarhan NC, Ergun T, Cakir B, Agildere AM. STIR sequence for depiction of degenerative changes in posterior stabilizing elements in patients with lower back pain. *AJR Am J Roentgenol.* 2008;191(4):973-979.





**Imaging Question 5.** In the absence of red flags, what are the imaging (x-ray, CT or MRI) recommendations for patients with acute or chronic low back pain?

**There is insufficient evidence to make a recommendation for or against obtaining imaging in the absence of red flags.**

**Grade of Recommendation: I**

One Level II study shows that in the absence of red flags, x-ray does not provide additional benefit at initial consultation. Kerry et al<sup>1</sup> performed a randomized controlled trial (RCT) with an observational arm across 94 general practices in South London and the South Thames region in order to compare outcomes of patients with LBP who were immediately referred for lumbar spine x-ray with those who were not. Over the course of 26 months, patients with LBP, aged 16–64 years, were allocated into a RCT (n=153) or an observational arm (n=506) at the time they consulted their general practitioners. Allocation into these groups was determined by sealed envelope or per the discretion of the individual practitioner. The patients in the RCT group were then randomized into an immediate x-ray referral group (n=73) or no immediate x-ray referral (control) group (n=80). Subjects were included in the final analysis if they completed a questionnaire which included the back-pain specific Roland Morris Disability Questionnaire (RMDQ), the Hospital Anxiety and Depression Scale (HADS) and the short form health survey SF-36 at the time of enrollment,

6 weeks and one year later (response rate at one year was 67%). In the RCT, those who had been immediately referred for radiography had no differences in physical functioning, pain, or disability compared to the control group. However, the subjects in the immediate radiography group scored higher on psychological wellbeing at 6 weeks and one year compared to the control group. Similar findings were observed in the observational study in which, after adjusting for length of back pain episode at presentation, there were no differences in physical outcomes between groups. Those referred for x-ray had lower depression scores at six weeks and one year. The authors concluded that, unless patient anxiety is a major factor, it is not recommended to routinely refer for early x-ray for LBP as it is not associated with improvement of physical functioning, pain or disability. The work group downgraded this potential Level I study due to poor follow-up, significant crossover and potential bias. This study provides Level II evidence that, in the absence of red flags, x-ray does not provide additional benefit at initial consultation.



#### Future directions for Research

The work group recommends studies to evaluate the value of imaging (x-ray, CT or MRI) for patients with acute or chronic LBP in the absence of red flags.

#### Reference

1. Kerry S, Hilton S, Dundas D, Rink E, Oakeshott P. Radiography for low back pain: a randomised controlled trial and observational study in primary care. *Br J Gen Pract.* 2002;52(479):469–474.



## Imaging Question 6. Are there imaging findings that correlate with the presence of low back pain?

**There is insufficient evidence for or against imaging findings correlating with the presence of low back pain.**

**Grade of Recommendation: I**

Carragee et al<sup>1</sup> investigated the association between new and serious LBP episodes with MRI findings of 200 subjects in a 5-year prospective observational study. Working subjects with risk factors for degenerative lumbar disc disease but without a history of clinical LBP episodes underwent a physical examination with plain radiographs, lumbar spine MRI and a detailed interview at enrollment, 6 months and 5 years. The detailed interview included using a visual analog scale (VAS) for LBP intensity, Modified Oswestry Low Back Disability Questionnaire for subjective functional assessment and modified psychometric studies. If a new serious LBP episode with a rating scale intensity  $\geq 6$  for  $\geq 1$  week was reported, MR imaging taken within 6–12 weeks of the episode was compared with baseline images. MR images were assessed by 2 independent blinded examiners. Outcome measures included MR findings (DD, annular disruption, herniation, moderate–severe endplate changes, spinal stenosis or neurologic compression, serious back pain episodes and occupation compensation or disability claims due to LBP. A total of 51 subjects had repeat scans available. The most common progressive findings were disc signal loss, facet arthrosis and endplate changes. Subjects having another MR were more likely to have had baseline psychological distress (OR 2.27, 95% CI 1.15–4.49). Radicular symptoms were the primary reason for three of the repeat scans. Only 2 subjects with primary radicular complaints had new findings of probable clinical significance. The authors concluded that it was highly unlikely that new findings on MRI within 12 weeks of serious LBP represent any new structural change as many of the changes were related to progressive age changes. The work group noted that although there was a subgroup analysis, the mix of back and radicular pain resulted in a small patient population with only LBP. Therefore, the work group downgraded this potential Level II study. This study provides Level III evidence that, in the setting of new back pain, MRI is highly unlikely to detect new structural disease and instead represents existing structural disease.

Cho et al<sup>2</sup> conducted a cross-sectional study to evaluate the prevalence and risk factors of LBP in middle-age and elderly residents of a rural community in South Korea. All participants were a part of the Korean Health and Genome cohort (aged 40–79 years). A total of 1,772 subjects had lumbar spine radiographs available. A single rheumatologist reviewed the radiographs and graded the presence and severity of anterior osteophytes, endplate sclerosis and joint space narrowing using a reference atlas. Each vertebral level was graded using the Kellgren–Lawrence (K–L) grading system. Each subject completed a questionnaire that included information on lifestyle habits and self-report of LBP (current, past 6 months and lifetime) using the 7-item Guttman scale to classify pain intensity. Based on the results, the authors concluded that risk factors associated with either current or lifetime LBP included advanced age, female sex, time spent squatting, presence of osteophytes, joint space narrowing and advanced K–L grading; there was no association between presence of endplate sclerosis and LBP. This study provides Level III evidence that presence of disc space narrowing and osteophytes, but not presence of endplate sclerosis, correlates with LBP.

Lakadamyali et al<sup>3</sup> conducted a retrospective case control study to investigate the relationship between degenerative changes in posterior spinal elements and LBP, as well as to explore the age- and sex-related distribution of those changes on STIR sequence magnetic resonance (MR) images. In the first stage of this 2-stage study, the MR images of 372 patients (231 women, 141 men) with LBP without radiculopathy were evaluated after being referred to a radiology department between the years 2000–2004. During the second stage, 249 additional volunteers (123 women, 126 men) without LBP who were referred to the same department for other MRI examinations, formed a control group. Conventional and sagittal STIR sequences were obtained for all subjects. Two experienced radiologists evaluated the lumbar MR images

and recorded presence of intervertebral DD, disc herniation, interspinous ligament degeneration or rupture, facet joint effusion, neocyst formation, intrinsic spinal muscular degeneration and/or subcutaneous edema. Compared to patients without LBP, patients with LBP had higher incidences of facet joint effusion ( $p=0.0001$ ), interspinous ligament edema ( $p=0.001$  for T12-L1;  $p=0.0001$  for all lumbar levels), neocyst formation ( $p=0.0001$ ) and intrinsic muscle degeneration ( $p=0.0001$ ). The incidences of intervertebral DD, disc herniation, subcutaneous edema and muscle edema were similar in subjects with and without LBP, but increased with age in both groups. Relevant posterior paraspinal changes were better visualized with STIR imaging than routine MRI. The authors concluded that the percentage of posterior paraspinal degenerative change findings was higher in subjects with LBP compared to those without LBP and that the use of the STIR sequence improved the visualization of those changes. This study provides Level III evidence that patients with LBP had significantly higher rates of facet joint effusion, interspinous ligament edema, neocyst formation and paraspinal muscle edema. The incidence of intervertebral DD, disc herniation and subcutaneous edema in persons with and without LBP were similar.

Liu et al<sup>4</sup> conducted a prospective comparative and reliability study in order to develop and evaluate a quantitative assessment of the high-intensity zone (HIZ) on magnetic resonance imaging (MRI) in patients with LBP compared to those without LBP. A total of 72 patients (40 males, 32 females, aged 24–59 years) with LBP for  $\geq 6$  months were enrolled into the symptomatic group (group A). All subjects underwent MRI scanning to confirm absence of potential non-discogenic LBP sources. A total of 79 patients without LBP who presented to the hospital for routine health examinations or minor extremity injuries (44 males, 35 females, aged 23–59 years) were enrolled into an asymptomatic control group (group B). All subjects underwent MR imaging. HIZ was recorded using Picture Archiving and Communication System (Jin YeXiang, Beijing, China). Blinded, experienced radiologists evaluated the images. The incidence of HIZ in symptomatic group A (45.8%) was significantly higher than asymptomatic group B (20.2%) ( $p=0.001$ ). The intensity of the HIZ signal was significantly brighter in symptomatic group A ( $57.55 \pm 14.04\%$ ) compared to asymptomatic group B ( $45.61 \pm 7.22\%$ ) ( $p=0.000$ ). There were no significant differences in area of disc and HIZ nor the area ratio between group A and group B. The authors concluded that HIZ intensity is greater in subjects with LBP compared to those without LBP.

In critique of the methodology, the work group downgraded this potential Level II study as the study arm was retrospective rather than prospective. This study provides Level III evidence that HIZ intensity is greater in patients with LBP compared to controls.

Maatta et al<sup>5</sup> examined the relationship between Modic change (MC) and severe, disabling LBP along with features of DD in a longitudinal cohort study of twins. All subjects completed a comprehensive nurse-led questionnaire related to LBP and underwent lumbar MRI at baseline ( $n=823$ , 95.7% female) and after 10 years ( $n=429$ , 98.1% female). A single blinded observer evaluated all MR images to assess for MC and DD. A second reader evaluated a select subset of images to confirm acceptable inter-rater reliability. Subjects with severe and disabling LBP  $\geq 1$  month were more likely to have MC at baseline (subjects with MC: 35.0% vs. subjects without MC: 16.4%,  $p<0.001$ ) and at follow-up (subjects with MC: 35.1% vs subjects without MC: 20.0%,  $p<0.001$ ). After adjusting for age, BMI, DD and Schmorl's nodes (SN) at baseline, there was a significant association between severe, disabling LBP and MC (OR 1.58, 95% CI 1.04–2.41). The authors concluded that MC is an independent risk factor for episodes of severe and disabling LBP in middle-aged women. In critique of the methodology, the workgroup downgraded this potential Level III study due to poor follow-up. This study provides Level IV evidence that Modic changes are associated with severe disabling back pain.

Riihimaki et al<sup>6</sup> studied the relationship between LBP and lumbar spinal degeneration in concrete workers ( $n=216$ ) and house painters ( $n=201$ ). Each participant completed a self-administered questionnaire (related to occupation history, back accidents and smoking) and a physiotherapist-administered interview related to back symptoms. Demographic information and lumbar radiographs were obtained. A radiologist reviewed the radiographs and recorded the presence of disc space narrowing, vertebral osteophytes (spondylophytes) and endplate sclerosis for each of the lumbar intervertebral spaces using a graded system. Although there was a trend of increasing LBP with increased severity of degeneration, there was no statistical significance. The authors concluded that there was an association between moderate to severe degenerative changes and increased risk of sciatic pain. However, there were no significant correlations between these changes and occurrence of back pain. This study provides Level III evidence that degenerative changes on imaging were not associated with increased risk of the occurrence of nonspecific LBP.

Teraguchi et al<sup>7</sup> examined the associations between LBP and combinations of DD, endplate signal change (ESC) and Schmorl node (SN) in a cross-sectional study of 975 patients (324 men, 651 women, aged 21–97 years) in Japan. Participants were recruited from the Research on Osteoarthritis/Osteoporosis against Disability (ROAD) cohort and included in this study after agreeing to a whole-spine MRI. T2-weighted images were obtained for all subjects used to assess DD, ESC and SN from L1–L2 to L5–S1. A board-certified orthopedic surgeon, who was blinded to the background of the participants, classified the degree of DD and the presence of ESC and/or SN. Kappa analysis to describe intraobserver and interobserver variability was completed for scoring of two orthopedic surgeons for DD, ESC and SN. LBP was diagnosed based on a standardized question asked by board-certified orthopedic surgeons. The overall prevalence of DD alone (30.4%) was highest compared to ESC alone (0.8%), SN alone (1.5%), DD and ESC (26.6%), DD and SN (12.3%), SN and ESC (0.6%) and DD, ESC and SN (19.1%). A combination of DD, ESC and SN was significantly associated with LBP (OR 2.17, 95% CI 1.2–3.9;  $p < 0.01$ ). Additionally, significant associations with LBP were found in a combination of DD, ESC and SN at L1–L2 (OR 6.00, 95% CI 1.9–26.6;  $p < 0.005$ ), L4–L5 (OR 2.56, 95% CI 1.4–4.9;  $p < 0.005$ ) and L5–S1 (OR 2.85, 95% CI 1.1–2.3;  $p < 0.05$ ) as well as a combination of DD and ESC at L3–L4 (OR 2.43, 95% CI 1.5–4.0;  $p < 0.05$ ), L4–L5 (OR 1.82,

95% CI 1.2–2.8;  $p < 0.01$ ) and L5–S1 (OR 1.60, 95% CI 1.1–2.3;  $p < 0.05$ ). The authors concluded that although DD alone is not associated with LBP, a combination of DD and ESC, with or without SN, was significantly associated with LBP. Although there were some limitations to the methodology as only T2 images were available, the work group did not find this sufficient reason to downgrade the study. This study provides Level II evidence that a combination of degenerative changes shows high correlation to LBP.

Wiikeri et al<sup>8</sup> studied the relationship between lumbar DD and LBP in 295 Finnish concrete workers aged 19–64 years. After each participant was radiologically examined, a radiologist and an orthopedic surgeon evaluated each participant's radiograph and graded lumbar DD as none, slight (12%), moderate (23%) or severe (9%). After adjusting for age, there was a weak association between history of LBP and DD ( $p < 0.01$ ). There was also a weak association between history of sciatica and DD ( $p < 0.001$ ). The authors concluded that there is a weak association between lumbar DD and LBP or sciatica, independent of age. This study provides Level IV evidence that lumbar degeneration has a weak correlation with LBP.



### Future directions for Research

The work group recommends separation between radicular pain and LBP groups, inclusion of an asymptomatic reference group and inclusion of a reference standard in a well-powered study.

## References

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**Imaging Question 7.** Are there imaging findings that contribute to decision-making by health care providers to guide treatment?

**There is insufficient evidence to determine whether imaging findings contribute to decision-making by health care providers to guide treatment.**

**Grade of Recommendation: I**

Pneumaticos et al<sup>1</sup> conducted a prospective randomized controlled trial to evaluate the use of bone scintigraphy with single photon emission computed tomography (SPECT) in 47 adult patients (23 men and 24 women) with low back pain who were referred for facet joint injection. The patients were randomized into group A or group B (with a ratio of 2:1 for patients in group A to group B). Bone scanning with SPECT was used for group A. If abnormalities were found, these patients were further categorized into group A1 (n=15) and injections were given at the level of the spine in which facet joint abnormalities were found on the scan. If no abnormalities were found, the patients were categorized into group A2 (n=16) and injections were given at the level originally indicated by the referring physician. Group B (n=16) underwent injections at the level originally indicated by the referring physician, without SPECT bone scanning. All

participants completed a validated pain and function questionnaire before the injection and after 1, 3, and 6 months. There was no significant difference between groups in average pain score at baseline. At one month, 87%, 13%, and 31% of patients in group A1, group A2, and group B, respectively, reported positive improvement in pain. The change in pain score was significantly higher in group A1 than group A2 and group B after one month and 3 months, but there was no difference after 6 months. The authors concluded that bone scintigraphy with SPECT can help identify patients with LBP who have been referred for facet joint injections. In critique of the methodology, the work group downgraded this potential Level I study due to a small sample size. Therefore, this study provides Level II evidence that bone scintigraphy with SPECT can help identify patients with LBP.



### Future directions for Research

The work group recommends designing studies focused on the role of imaging in health care decision-making related specifically to LBP.

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**Med/Psych Question 1.** Is smoking cessation effective in decreasing the frequency of low back pain episodes?

A systematic review of the literature yielded no studies to adequately address this question.



### Future Directions for Research

The work group recommends further population-based observational studies that investigate the association between low back pain (LBP) and smoking. Specifically, a study comparing the frequency of LBP episodes between patients who have quit smoking and those who continue to smoke would be useful.



**Med/Psych Question 2.** In patients with low back pain, is pharmacological treatment effective in decreasing duration of pain, decreasing intensity of pain, increasing functional outcomes of treatment and improving the return-to-work rate?

versus:

- a. No treatment
  - i. Risks
  - ii. Complications
- b. Cognitive behavioral therapy (CBT) and/or psychosocial intervention alone
- c. Patient education alone

Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

## There is insufficient evidence to make a recommendation for or against the use of anticonvulsants for the treatment of low back pain.

### Grade of Recommendation: I

Muehlbacher et al<sup>1</sup> studied the efficacy of topiramate for the treatment of chronic LBP in a randomized, double-blind, placebo-controlled study. Participants with chronic LBP were recruited through advertisements and randomized into the topiramate group (n=48) or placebo group (n=48). Each participant completed the McGill pain Questionnaire (MPQ), State-Trait Anger Expression Inventory (STAXI), Oswestry Low Back Pain Disability Questionnaire (OLBPQ) and SF-36 Health Survey (SF-36) during a face-to-face interview at the time of enrollment and weekly for the duration of the study. After a one-week period in which participants were asked not to use an analgesic or anti-inflammatory medication, they received daily study medication for 10 weeks. The participants in the topiramate group received 50 mg of

topiramate per day which was titrated at 50 mg/week to 300 mg/d by week 6 through week 10. Using an intent-to-treat analysis, the participants in the topiramate group had significantly greater improvements in MPQ ( $p<0.001$ ), STAXI ( $p<0.001$ ), OLBPQ ( $p<0.001$ ) and SF-36 ( $p<0.001$ ) compared to the participants in the placebo group. Adverse events such as severe somnolence, vision problems, psychomotor slowing, memory problems, dizziness, headache and paresthesia were reported, but there were no serious side effects reported. The authors concluded that the study drug is safe and effective in treating chronic LBP. This study provides Level I evidence that topiramate is more effective than placebo for the treatment of chronic LBP over 10 weeks.

## Antidepressants are not recommended for the treatment of low back pain

### Grade of Recommendation: A

Atkinson et al<sup>2</sup> conducted a double-blind randomized controlled trial with head-to-head comparison to evaluate the relative efficacy of noradrenergic and serotonergic antidepressants to treat chronic LBP in patients without depression. Participants aged 21-65 years with chronic LBP  $\geq 6$  months who met study inclusion criteria were enrolled and randomized into groups using a stratified allocation scheme based on presence of radicular pain. Participants in the maprotiline (n=33), paroxetine (n=34) and diphenhydramine hydrochloride active placebo (n=36) groups were instructed to take a single capsule at the same time each day. Each drug dosage was increased every 3 days as tolerated to the maximum range that is used for antidepressant dosage. Participants were interviewed weekly to determine side effects. Pain intensity using the Descriptor Differential Scale (DDS) and mood measures were obtained at enrollment and exit of the study. A total of 20, 22 and 32 participants in the maprotiline, paroxetine and placebo groups, respectively, completed the trial. Based on analyses of participants who completed the trial, the participants had an average pain intensity decrease of 45%, 26% and 27% on maprotiline, paroxetine and placebo, respectively. The participants in the maprotiline group had significantly greater reduction in pain intensity compared to paroxetine ( $p=0.013$ ) and placebo ( $p=0.023$ ). There was no difference in pain intensity

reduction from paroxetine compared to placebo. Using an intent-to-treat analysis, pain intensity reduction was greater with maprotiline compared to paroxetine ( $p=0.028$ ) but not compared to placebo ( $p=0.275$ ). The most frequent adverse events reported were dry mouth, insomnia and sedation. The authors concluded that noradrenergic agents may be more effective analgesic agents than selective serotonergic reuptake inhibitors. In critique of the methodology, the work group downgraded this potential Level I study due to the rapid dose escalation and less than 80% follow-up. This study provides Level II evidence that noradrenergic agents such as maprotiline are associated with greater reductions in LBP compared with selective serotonin reuptake inhibitors in non-depressed patients with chronic LBP.

Dickens et al<sup>3</sup> conducted a randomized controlled trial to determine if paroxetine is more effective at reducing depression and pain than placebo. Patients with LBP (aged 18-65 years) were included in this study, given a placebo for 7 days and then randomized to receive either 20 mg paroxetine (n=44) or placebo (n=48) for the remainder of the study. Assessments were completed after 14, 28 and 56 days ( $\pm 3$  days each). At each assessment, measurements obtained included severity of depressive symptoms using MADRS, diagnosis of depression per DSM-III-R, pain intensity using a

100-mm Visual Analog Scale (VAS) and short-form of the McGill Pain Questionnaire (MPQ), disability using the Oswestry Low Back Pain Disability Questionnaire (ODQ) and health cognitions using the Illness Attitude Scale (IAS). In an intention-to-treat analysis, there were no significant differences in depression symptoms (MADRS), pain intensity (VAS) or disability per Oswestry Disability Index (ODI). However, subjects in the paroxetine group were more likely to reduce their intake of analgesia (n=4) compared to subjects in the placebo group (n=1). In an analysis of patients who took all pills as prescribed and attended all appointments, there were no significant differences between the placebo group (n=34) or paroxetine group (n=27) regarding depression, pain or disability. The authors concluded that paroxetine showed no effects on pain or depression compared to placebo. This study provides Level I evidence that treatment with paroxetine is no better than placebo at 56 days follow-up.

Goodkin et al<sup>4</sup> assessed the efficacy of trazadone hydrochloride for the relief of LBP in a multicenter, randomized controlled trial. Adults with current LBP  $\geq 2$  weeks which had either been continuous  $\geq 1$  year or with at least 2 prior LBP episodes  $\geq 2$  weeks were randomized to receive 50 mg trazadone (n=22) or placebo (n=20) tablets. Participants were instructed to start with one tablet per day and increase at intervals of 3 days as tolerated to a maximum of 4 tablets 3 times a day was reached. A 10-point VAS was used to rate pain every 12 hours at baseline; results were collected at biweekly visits. Additionally, the Beck Depression Inventory (BDI) and Sickness Impact Profile (SIP) were used to assess depressed mood and daily life function, respectively. There were no significant differences in VAS scores between groups. Side effects of constipation, orthostatic hypotension, lightheadedness/dizziness, sedation/lethargy, dry mouth and confusion were reported more frequently in the trazadone group than placebo. The authors concluded that trazadone did not have any significant treat-

ment effects in patients with LBP. This study provides Level II evidence that trazadone HCL is not more effective than placebo/no treatment for chronic LBP in the short-term study.

Skljarevski et al<sup>5</sup> assessed the efficacy of duloxetine for the treatment of chronic LBP in a multicenter, double-blind, randomized controlled trial. Patients with LBP  $\geq 6$  months who met inclusion criteria were enrolled in a one-week screening phase. Eligible participants were then randomized, stratified by reported regular analgesic/NSAID usage, to receive a placebo (n=117) or duloxetine at 20 mg (n=59), 60 mg (n=116), or 120 mg (n=112). During this 13-week treatment phase, participants recorded average 24-hour pain ratings in a daily diary. A total of 267 (66.1%) of participants completed the study. The patients taking 60 mg duloxetine had significantly improved weekly pain from weeks 3 through 11, but not at weeks 12 and 13. The patients receiving duloxetine 60 mg had significantly improved Patient's Global Impressions of Improvement (PGI-I), 24-item Roland-Morris Disability Questionnaire (RMDQ), Brief Pain Inventory (BPI) average pain and BPI average interference. There were no significant differences between groups in occurrence of serious adverse events. Treatment-emergent adverse events included nausea, insomnia, dry mouth, constipation, headache, diarrhea, dizziness, somnolence and fatigue. There were significantly more treatment-emergent adverse events in the 120 mg duloxetine group compared to the placebo. The authors concluded that duloxetine was superior to placebo for pain relief only from weeks 3-11, but was superior to placebo for other secondary measures. In critique of the methodology, the work group downgraded the Level of evidence due to less than 80% follow-up. This study provides Level II evidence that duloxetine has no statistical benefit on pain or function in chronic LBP patients at 12 weeks.



## There is insufficient evidence to make a recommendation for or against the use of Vitamin D for the treatment of low back pain

### Grade of Recommendation: I

In a double-blind randomized clinical trial, Sandoughi et al<sup>6</sup> studied the effect of vitamin D on LBP. Patients aged 18–40 years with chronic LBP >3 months were recruited from a rheumatology clinic and randomized to receive either 50,000 IU vitamin D (n=26) or placebo (n=27) once a week for 8 weeks. All participants were encouraged to exercise at home and were given celecoxib to use as needed (up to 200 mg per day) for back pain. Severity of pain was assessed at baseline and after the 8-week trial using a VAS. At trial com-

pletion, both groups had significant improvements in mean VAS scores and chronic pain with no significant differences between groups. There was no significant difference between groups for usage of celecoxib. The authors concluded that there were no significant differences between vitamin D3 and placebo groups as both improved chronic LBP. This study provides Level II evidence that vitamin D is no more effective than placebo for treatment of chronic LBP.

## Non-selective NSAIDs are suggested for the treatment of low back pain.

### Grade of Recommendation: B

## There is insufficient evidence to make a recommendation for or against the use of selective NSAIDs for the treatment of low back pain

### Grade of Recommendation: I

Birbara et al<sup>7</sup> conducted a double-blind, randomized, placebo-controlled trial across 46 centers in the United States. Adults with LBP for ≥3 months who regularly used an NSAID or acetaminophen for 30 days prior to enrollment were included in this study. They were classified into two groups: LBP without radiation to the extremities or LBP with radiation to extremities but not below the knee and without neurological signs. At enrollment, each participant underwent a physical exam and completed the LBP intensity scale, low back pain bothersomeness scale, Patient Global Assessment of Disease Status (PGADS), Roland-Morris Disability Questionnaire (RMDQ), 27 Hospital Anxiety and Depression Scale (HADS) and the Patient Health Survey (MOS Short Form [SF]-12). If, after a 4–15 day washout period abstaining from their previous use of NSAID or acetaminophen, the patients had a LBP intensity scale score ≥40 mm which increased by at least 10 mm from baseline and a worsened PGADS score by at least 1 point, they remained enrolled. Patients were randomized into one of three groups: 90 mg dose of etoricoxib (n=107), 60 mg dose of etoricoxib (n=103), or placebo (n=109). They were instructed to take the study pill

once daily and return after 1, 2, 4, 8 and 12 weeks to measure vital signs and undergo physical and safety assessments. The completion rates for the placebo, 60 mg etoricoxib and 90 mg etoricoxib groups were 59.6%, 72.8% and 67.3%, respectively. There were no significant differences in results between intent-to-treat and per-protocol analyses. Compared to placebo, both etoricoxib groups had significant improvements in back pain intensity after 4 weeks ( $p \leq 0.001$ ) and 12 weeks ( $p \leq 0.05$ ). Significantly different improvements in RMDQ, LBP bothersomeness scale, PGADS and patient and investigator-global assessment of response to therapy were also observed in both etoricoxib doses compared to placebo after 4 and 12 weeks. There were no significant differences between reported clinical adverse events between the placebo (46.8%), 60 mg etoricoxib (58.3%) and 90 mg etoricoxib (52.3%) treatment groups. Compared to placebo group, the incidence of adverse events that the investigator judged as drug-related was high in the 90 mg etoricoxib group, but not in the 60 mg etoricoxib group. The authors concluded that compared to placebo, etoricoxib once daily provided significant improvement in chronic LBP-related symptoms and

disability after one week, with a maximal effect at 4 weeks, for up to 3 months. This study provides Level I evidence that COX-2 inhibitors at two different doses have a mild effect on chronic LBP. However, this effect did not reach clinical significance as defined as 20 mm improvement on VAS.

Pallay et al<sup>8</sup> evaluated the efficacy and safety of etoricoxib for LBP in a randomized multicenter, double-blind, placebo-controlled trial. Adults aged 18–75 years with LBP >3 months and regularly treated with NSAID or paracetamol for ≥30 days who met inclusion criteria were enrolled in this 12-week study across 46 outpatient centers. After a 4–25 day washout period of analgesic discontinuation, participants were randomized to take once-daily etoricoxib 60 mg (n=109), etoricoxib 90 mg (n=106), or placebo (n=110) using a double-dummy approach. Patients were evaluated and completed questionnaires at baseline and 1, 2, 4, 8 and 12 weeks postrandomization. Outcomes measured included LBP intensity using a 0–100 mm VAS, Roland-Morris Disability Questionnaire (RMDQ), LBP bothersomeness, patient global assessment of disease status and the Patient Health Survey (MOS Short Form [SF]-12). A total of 231 participants completed the study (77 in each group) with over 95% compliance in each group. An intention-to-treat analysis found the etoricoxib 60 mg and 90 mg groups had significantly improved RMDQ scores at 12 weeks and decreased LBP intensity at 4 and 12 weeks compared to the control group. The per-protocol analysis was not significantly different. There were no significant differences in adverse events between groups. The authors concluded that etoricoxib provided relief in LBP symptoms and disability at 1 week, 4 weeks and 3 months. The work group downgraded this potential Level I study due to low follow-up rate, potential bias to responders to NSAIDs and no active comparator in this trial to compare against other NSAIDs. This study provides Level II evidence that etoricoxib can reduce chronic LBP better than placebo for up to three months.

Dreiser et al<sup>9</sup> conducted a multicenter, double-blind, double-dummy, randomized controlled trial to assess the safety and efficacy of diclofenac-K (12.5 mg tablet) compared to placebo and ibuprofen (200 mg) for acute LBP. Patients aged 18–60 years with acute LBP ≥50 mm on a 100 mm VAS were randomized into a 12.5 mg diclofenac-K group (n=124), 200 mg ibuprofen group (n=122), or placebo group (n=126). All participants were instructed to follow a flexible multiple dosing regimen by taking 2 tablets initially, then 1–2 tablets every 4–6 hours, not to exceed 6 tablets per day, while recording frequency of each dosage in a diary. They were given the option to take a rescue medication, paracetamol, which would terminate participation in the trial. Each participant recorded pain (4-point scale) and pain relief (5-point scale) at 30 minutes after initial trial drug and after each hour for 6 hours. The End of First Dose (FD) global assessment of efficacy (5-point scale) was used to assess efficacy after 6 hours, time of rescue medication, or time of remedication. Participants completed a 100-mm VAS and the Eifel algofunctional questionnaire at baseline and at the end of the 7-day trial. Compliance was measured using the diary entries and counting the medication left at the end of the trial. Intent-to-treat analysis was completed. Compared to patients in the placebo group, patients in the diclofenac-K group had significantly greater improvements in total pain relief over the first 3 and 6 hours as well as greater sum of pain intensity differences over 6 hours. Patients in the diclofenac-K group experiences greater pain intensity differences over the first 3 hours compared to both placebo and ibuprofen. Adverse events were similar in the diclofenac-K and ibuprofen groups, but higher in the placebo group. The most frequent adverse events were digestive reports; there were no serious adverse outcomes or deaths. The authors concluded that the flexible multiple dosing regimen of diclofenac-K 12.5 mg is an effective and safe treatment for acute LBP. This paper provides Level I evidence that use of diclofenac in the treatment of acute LBP in the short-term (one week) is safe and effective in the treatment of acute LBP for both pain and disability.

**It is suggested that the use of oral or IV steroids is not effective for the treatment of low back pain.**

**Grade of Recommendation: B**

Eskin et al<sup>10</sup> evaluated the efficacy of oral corticosteroids for the treatment of acute musculoskeletal LBP in the emergency department (ED) in a double-blind randomized controlled trial. Adults in the ED aged 18–55 years with LBP with an intensity  $\geq 5$  out of 10 on a VAS were enrolled. Participants were randomly allocated into the treatment group of 50 mg of prednisone (n=39) or placebo (n=40). Pain was reported using the 10-cm VAS upon ED arrival and discharge. Each patient was discharged home with 4 doses of the study medication (one dose per day). Five to 7 days after discharge, a phone interview was conducted to assess pain on a 3-point verbal rating scale (VRS). At 5 days, there was no statistically-significant difference in the 3-point VRS for pain between groups. No significant side effects were reported during the follow-up telephone call for either groups. The authors concluded that oral corticosteroids did not provide a benefit to ED patients with musculoskeletal LBP. This study provides Level II evidence that oral steroid (prednisone) is not more effective than placebo for acute LBP presenting to an emergency department.

Friedman et al<sup>11</sup> conducted a double-blind randomized controlled trial to test the efficacy of intramuscular methylprednisolone acetate to treat nonradicular LBP one month after discharge from the emergency department (ED). Adults 21–50 years of age with a chief

complaint of nontraumatic LBP upon presentation to the ED were enrolled if inclusion criteria were met after eligibility screening and interview. Only patients with a LBP etiology of twisting or lifting and who had a negative straight leg raise test were included. Participants were randomized into the 160 mg methylprednisolone acetate group (n=44) or placebo (n=43). After the attending physician completed individualized treatment and back pain was controlled to a level acceptable for patient discharge, the subject received an injection of the study drug or placebo. Each participant was discharged with a one-week supply of naproxen (500 mg), oxycodone 5 mg/acetaminophen 325 tablets, a detailed standardized instruction sheet. Subjects were called one week and one month after ED discharge and provided pain rating on an 11-point numerical rating scale (NRS) and a 4-point descriptive scale. A total of 44 and 42 patients in the methylprednisolone and placebo groups were included in final analysis. There were no differences in NRS scores between groups at one week or one month. The authors concluded that parenteral corticosteroids did not provide any benefit for treatment of nonradicular LBP in patients in the ED. This study provides Level II evidence that intravenous steroids are not more effective than placebo for acute LBP presenting to the emergency department.

**It is suggested that the use of opioid pain medications should be cautiously limited and restricted to short duration for the treatment of low back pain.**

**Grade of Recommendation: B**

**Work Group Narrative:** There are limited data that support the short-term effectiveness of opioid pain medication for low back pain. There remain concerns in study design including the role of enriched enrollment and high dropout rates in these trials. The trials also report high rates of adverse events, which may factor into the high dropout rates. As there are few studies evaluating the efficacy and safety of opioids for low back pain beyond 12 weeks and given the concerns associated with the use of opioids with the availability of other effective pharmacologic and nonpharmacologic treatment options, we recommend the cautious use of opioid pain medication in those with low back pain and, when utilized, that a short duration is recommended.

Buynak et al<sup>12</sup> conducted a multicenter, double-blind, randomized controlled trial to evaluate the efficacy and safety of tapentadol extended relief (ER) for the treatment of moderate to severe chronic LBP. Adults with LBP  $\geq$  3 months with a pain intensity  $\geq$  5 out of 11 on a numerical rating scale (NRS) were enrolled in this study. Participants were randomized into the 100–250 mg BID tapentadol ER group (n=321), 20–50 mg BID oxycodone HCl controlled release (CR) group (n=334), or BID placebo group (n=326) and underwent a screening and washout period. During a 3-week double-blind titration period, doses were increased every 3 days, as tolerated, with the assistance of a physician to reach optimal pain relief. Participants were instructed to maintain a steady dose for the duration of the 12-week maintenance trial period if possible. The mean pain intensity was measured using an 11-point NRS throughout the maintenance period and at week 12. A total of 52.2%, 40.5% and 47.6%, of participants completed the study in the tapentadol ER, oxycodone CR and placebo groups, respectively. An intent-to-treat analysis was completed on participants who received at least one dose of their assigned medication in the tapentadol (n=315), oxycodone HCl (n=326), or placebo (n=317) groups. There was a significant reduction in mean pain intensity with tapentadol compared to placebo (least square mean difference vs placebo [95% confidence interval {CI}] -0.8, [-1.22 to -0.47]) at week 12. There was also a significant reduction in mean pain intensity with oxycodone CR compared to placebo (least square mean difference vs. placebo [95%CI], -0.9 [-1.24 to -0.49]) at week 12. Mean pain intensity was significantly reduced throughout the overall maintenance period for both tapentadol ER compared to placebo and oxycodone HCl compared to placebo. The most common adverse events reported in the treatment groups included nausea, constipation, headache, vomiting, dizziness, pruritus and somnolence. Compared to the tapentadol group, the oxycodone HCl group had approximately double the incidence of vomiting, constipation and pruritus as well as higher odds of experiencing constipation or nausea and/or vomiting ( $p < 0.001$ ). Serious adverse events were reported in the placebo group (0.9%), tapentadol ER group (2.2%) and oxycodone CR group (3.4%). Serious adverse events likely related to either of the study drugs included decreased level of consciousness, mental confusion, atrial fibrillation, dizziness and dehydration. The authors concluded that tapentadol ER was effective for relief of moderate to severe chronic LBP over 15 weeks. In critique of the methodology, the work group downgraded this potential Level I article due to less than 80% follow-up.

This study provides Level II evidence that tapentadol improved pain, sleep and physical functioning (BPI scores in patients with chronic LBP compared to placebo and similar to oxycodone CR with improved tolerability [gastrointestinal side effects]).

Cloutier et al<sup>13</sup> conducted a double-blind randomized controlled trial to study the efficacy and safety of controlled release (CR) oxycodone/CR naloxone for the treatment of chronic LBP. Adults with chronic LBP  $\geq$  3 months with a pain intensity of  $\geq 2$  out of a 5-point ordinal scale were enrolled in this study and completed a 2–7 day washout period from period opioid analgesics. Participants were randomly assigned to the study treatment group to receive CR oxycodone/CR naloxone (n=39) or placebo (n=44). Patients attended weekly clinic visits in which the dosage was titrated to the maximum effect with acceptable side effects and maintained that dosage for 4 weeks. After 4 weeks, they received the initial dose again and repeated the same titration period. The 5-point ordinal scale and 100 mm VAS were used to measure pain two times a day in a daily diary. A per-protocol analysis was completed for patients who completed at least 2 weeks in each phase while following protocol (n=54, 65%). Per the per-protocol analysis, the CR oxycodone/CR naloxone group had a significantly greater reduction in mean VAS ( $p=0.0296$ ) and ordinal pain scores ( $p=0.0415$ ) compared to placebo. An intent-to-treat analysis was conducted for participants who had at least one dose and at least one post-randomization data point (n=83). Compared to the placebo group, the CR oxycodone/CR naloxone group had lower, but with no statistical significance, VAS and 5-point ordinal pain scale. There were four serious adverse events during the trial, which were all deemed “not related to study medication.” Other adverse events reported included nausea, constipation, diarrhea, fatigue, somnolence, vomiting, dizziness, dry mouth, upper respiratory tract infection and abdominal pain. There was no difference in the incidence of adverse events between groups. The authors concluded that CR oxycodone/CR naloxone was effective for treatment of moderate to severe chronic LBP in patients who complied with the protocol. In critique of the methodology, the work group downgraded this potential Level I article due to small sample size and less than 80% follow-up. This study provides Level II evidence that opioids help pain control for chronic LBP versus placebo.

Hale et al<sup>14</sup> conducted a multicenter, double-blind, randomized controlled trial to evaluate the efficacy and safety of osmotic-controlled release oral deliv-

ery system (OROS) hydromorphone extended release (ER) in the treatment of moderate to severe chronic LBP in opioid-tolerant patients. After a screening period of <2 weeks, 459 patients with chronic LBP underwent a 2–4 week conversion and titration phase in which they received a dose of hydromorphone ER that was approximately 75% of their previous total daily opioid dose. If they met inclusion criteria, they were then randomized into the hydromorphone ER group (n=134) or placebo group (n=134) and entered the 12-week double-blind treatment phase. The hydromorphone ER group continued to take a fixed dose for the duration of the treatment phase. The placebo group received gradually-reduced doses of hydromorphone ER over 14 days and received placebo only for the duration of the treatment phase. Patients recorded their pain rating using a 10-point numerical rating system (NRS) in a daily diary. Patients were asked to bring their diaries to each follow-up visit. Staff also called patients to monitor safety and compliance in between visits. A total of 49.6% and 33.1% of participants in the hydromorphone ER and placebo group, respectively, completed the 12-week treatment trial. A total of 266 patients were included in the intent-to-treat analysis of the hydromorphone group (n=133) and placebo group (n=133). Over the 12-week treatment phase, the hydromorphone ER group had significantly reduced pain intensity ( $p<0.001$ ), change in weekly patient diary NRS scores ( $p<0.001$ ) and change in office visit NRS scores ( $p<0.05$ ) compared to placebo. The hydromorphone group had a significantly higher proportion of participants (60.6%) who reported at least 30% pain reduction compared to placebo (42.9%). A total of 43 (32.1%) in the placebo group and 36 (26.9%) in the hydromorphone ER group of the double-blind phase reported adverse events that were considered likely to be related to the study medication in the double-blind phase. Adverse events including constipation, sinusitis and arthralgia were reported at a higher rate in the hydromorphone ER group compared to placebo. The authors concluded that hydromorphone ER was safe and effective in opioid-tolerant patients with moderate to severe LBP. In critique of the methodology, the workgroup downgraded the level of evidence of this potential Level I study due to the high drop-out rate, less than 80% follow-up and no validated outcome measures. This study provides Level II evidence that once daily oral hydromorphone ER is more effective than placebo in opioid-experienced patients with chronic lower back pain for up to three months in a randomized withdrawal protocol which tapered both long acting and short acting (rescue opioids) in the placebo group. Functional improvements were noted in the treatment arm per RMDQ.

Lasko et al<sup>15</sup> conducted a double-blind, multicenter, randomized controlled trial to assess the safety and efficacy of an extended-release combination formulation of 75mg tramadol and 650mg paracetamol (DDS-06C) compared to placebo for treatment of LBP. Patients aged 18–80 years with LBP rated as at least 2 out of 4 and 2 out of 11 on intensity rating scales were included in this phase III study. Patients were randomized into DDS-06C (n=141) or placebo group (n=136) and instructed to take 1–2 tablets of the study pill every 10–12 hours for 2.5 hours. They rated their pain intensity (4-point scale) and pain relief (5-point scale) at 0.5 h, 1 h, 1.5 h, 2 h, 4 h, 6 h ( $\pm 30$  min), 26 h ( $\pm 30$  min), 30 h ( $\pm 30$  min), 34 h ( $\pm 30$  min) and 50 h ( $\pm 30$  min). If patients required ongoing treatment at the day 3 follow-up visit, they continued to receive the open-label DDS-06C for 2.5 more days (n=219). Compared to the subjects in the placebo group, the subjects in the DDS-06C group had a significantly greater decrease in pain intensity ( $p=0.038$ ) and greater pain relief ( $p=0.026$ ) during the 50 hour observation period. Adverse events were reported by both the placebo (2.2%) and DDS-06C group (12.1%). Most of the adverse events were mild-to-moderate and considered to be at least possibly related to the treatment. There was one serious adverse event (hospitalization due to exacerbation of back pain) but it was deemed not related to the study medication. The authors concluded that the study drug was superior to placebo for relief of LBP and intensity. This paper provides Level I evidence that tramadol/paracetamol ER can reduce acute LBP better than placebo in the short-term (50 hours).

Lee et al<sup>16</sup> studied the efficacy and safety of tramadol hydrochloride 75-mg/acetaminophen 650-mg extended release tablets (TA-ER) for the treatment of chronic LBP. Adults aged 25–75 years with moderate to severe chronic LBP who met inclusion criteria were enrolled in this multicenter, double-blind, randomized controlled trial. After a 7-day screening period, participants were randomized into the TA-ER group (n=125) or placebo group (n=120) and began a 4-week trial which included a 7-day dose-titration phase. Patients attended regularly-scheduled follow-up visits and rated their average pain intensity using a 6-point VAS, quality of life using the Korean Short Form-36 (K-SF-36) and functionality using the Korean Oswestry Disability Index (K-ODI). A total of 104 and 92 patients in the placebo and TA-ER group, respectively, completed this study. In the full analysis set and the per-protocol analysis, the TA-ER group had a significantly higher percentage of patients with a pain intensity change rate  $\geq 30\%$  compared to the placebo group ( $p<0.05$ ). The patients in the TA-ER

group also had significantly higher pain relief at days 8 and 15, improved general health and higher functional improvements compared to the placebo group. Adverse events were reported more frequently in the TA-ER group compared to the placebo group. No serious adverse events that were believed to be related to the study drug occurred. The authors concluded that TA-ER was safe and effective in treating chronic LBP. In critique of the methodology, the work group downgraded the level of evidence of this potential Level I article due to the short follow-up period and non-stratification of the patients. This paper provides Level II evidence that short-term relief is better with ER tramadol/acetaminophen than no treatment in patients with chronic LBP.

Peloso et al<sup>17</sup> conducted a multicenter, double-blind, randomized, placebo-controlled trial to study the efficacy of tramadol 37.5 mg/acetaminophen 325 mg (tramadol/APAP) for the treatment of LBP. Adults with LBP requiring daily medication > 3 months but otherwise generally healthy were enrolled, completed a washout phase of all pain medication for up to 21 days, were randomized to receive tramadol/APA (n=167) or placebo (n=169) and completed a titration phase. Patients were evaluated and reported pain using a 100 mm VAS, Short-Form McGill Pain Questionnaire (SFMPQ), Roland Morris Disability Questionnaire (RMDQ), Medical Outcome Study Short Form-36 (SF-36) Health Survey and overall medication assessments on days 1, 14, 28, 56 and 91. Patients were given instructions regarding the use of rescue medications and were allowed to maintain physiotherapy if it was started prior to the double-blind portion of the study. A total of 86 and 61 participants completed the study in the tramadol/APAP and placebo groups, respectively. Intention-to-treat analysis found that the participants in the tramadol/APA group had significantly better mean pain VAS, pain relief, RMDQ and SF-36 scores compared to the placebo group. Common adverse events included nausea, dizziness, constipation and somnolence, but there were no serious adverse events thought to be related to the study medication. The authors concluded that the study drug had similar tolerability as other opioids and was effective in pain reduction, physical functioning and quality of life for the treatment of LBP. The work group downgraded the level of evidence due to less than 80% follow-up and other critique of the methodology such as uncertainty regarding blinding, patients may have had other interventions, and pain patients were a selected group with various exclusion criteria. Therefore, this study provides Level II evidence that tramadol/acetaminophen provides better pain relief and functional

improvement than placebo for up to three months.

Ruoff et al<sup>18</sup> assessed the efficacy and safety of tramadol 37.5 mg/acetaminophen 325 mg (tramadol/APAP) for the treatment of LBP in a multicenter, randomized, double-blind, placebo-controlled trial. Patients aged 25-75 years with chronic LBP requiring daily pain medication  $\geq 3$  months who met inclusion criteria were enrolled. Eligible patients completed a 3-week screening and washout period and were then randomized to receive tramadol/APA or placebo. After a 10-day titration period, participants received up to 8 tablets per day. Patients reported their pain using a 100 mm and completed the Pain Relief Rating Scale (PRRS), Short-Form McGill Pain Questionnaire (SF-MPQ), Roland Morris Disability Questionnaire (RMDQ), 36-Item Short-Form Health Survey (SF-36) and overall medication assessment at various time points from day 1-91. A total of 161 and 157 participants were included in the intention-to-treat analysis in the tramadol/APAP and placebo groups, respectively. A total of 91 and 74 participants completed the treatment in its entirety in the tramadol/APAP and placebo groups, respectively. Compared to the placebo group, the tramadol/APAP group had significantly favorable final mean PVA scores ( $p=0.015$ ), PRRS scores ( $p<0.001$ ), SF-MPQ improvements ( $p=0.021$ ), RMDQ score improvements ( $p<0.027$ ) and SF-36 subcategory improvements. Adverse events thought to be related to treatment medication included nausea, somnolence and constipation; there were no treatment-related serious adverse events. The authors concluded that tramadol/APAP was effective for the treatment of chronic LBP and had a favorable safety profile. This study provides Level II evidence that tramadol/acetaminophen is better than placebo for chronic LBP for up to 3 months.

Schiphorst et al<sup>19</sup> conducted a randomized controlled trial to evaluate the efficacy of tramadol/acetaminophen in patients with chronic LBP. Adult patients with chronic LBP >3 months on a wait list for a rehabilitation program were randomized to receive tramadol 37.5 mg/acetaminophen 325 mg capsules (n=25) or placebo (n=25). All participants conducted a wash-out period up to 7 days before beginning a one-week titration phase followed by a steady dose for at least one week. Functional capacity, pain intensity and self-reported disability per the Roland Morris Disability Questionnaire (RMDQ) were measured at baseline and at completion of the two-week trial. One patient in the treatment group was lost to follow-up; a total of 49 patients were included in final analysis. There were no significant differences in outcome measures between

groups. One subgroup (n=10) reported improvements in RMDQ and global pain relief. Side effects such as dizziness, nausea, tiredness, diarrhea and skin rash were reported in both the placebo group (24%) and treatment group (88%). The authors concluded that there were only small nonsignificant treatment effects with tramadol/acetaminophen. The workgroup downgraded the level of evidence from Level I to Level II due to the small sample study, no power analysis, short follow-up and limited generalizability of this exploratory study. This study provides Level II evidence that tramadol/acetaminophen provided similar outcomes to placebo in measures of function in a 2-week study.

Schnitzer et al<sup>20</sup> evaluated the efficacy and safety of tramadol for treatment of moderate chronic LBP in a two-part trial at 26 centers in the United States. Eligible patients aged 25–75 with LBP requiring daily medication  $\geq 3$  months who met inclusion criteria were enrolled in a screening and washout phase for up to 3 weeks. Patients with at least moderate LBP (n=380) then entered a 3-week open-label phase in which they initially received 50 mg tramadol/day which increased to at least 200 mg/day (maximum 400 mg/day) by day 14. If patients tolerated and perceived benefit during the open-label phase, they were enrolled in the 4-week randomized, double-blind, placebo-controlled phase. These participants were randomized to receive tramadol 200–400 mg/day (n=127) or placebo (n=127) with no rescue medication. Patients were in-

structed to continue their current level of exercise but not to initiate any new physiotherapy during the trial. Participants recorded pain according to a 10-cm VAS, pain relief per the pain relief rating scale, LBP details per the short form McGill Pain Questionnaire (SF-MPQ), quality of life per the Roland Morris Disability Questionnaire (RMDQ). Patients were considered to have “therapeutic failure” if they did not experience pain relief for any 24-hour period. A total of 91 and 55 patients completed the entire trial in the tramadol and placebo group, respectively. The time to therapeutic failure was significantly different between groups. The participants in the tramadol group also experienced significantly lower mean pain VAS scores and significantly better SF-MPQ and RMDQ scores. Common adverse events included nausea, dizziness, somnolence and headache. Seventy-eight of the 380 participants in the open-label period discontinued treatment due to adverse events, but <10% experienced each adverse event in the double-blind phase. Four participants in the tramadol group experienced serious adverse events that were deemed possibly or unlikely related to the treatment drug (ie, myocardial infarction, myocardial ischemia, prostate cancer and depression). The authors concluded tramadol was effective for the treatment of chronic LBP in patients who tolerate it well. This study provides Level II evidence that tramadol is better than no treatment at reducing chronic LBP up to 45 days in tramadol responders.



### Future Directions for Research

The work group recommends development of studies that identify specific groups of patients who respond to a particular opioid medication with minimal dependence risk.

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**Med/Psych Question 3.** In patients with low back pain, is topical treatment (eg, cream or gel) effective in decreasing duration of pain, decreasing intensity of pain, increasing functional outcomes of treatment and improving the return-to-work rate?

**There is insufficient evidence to make a recommendation for or against the use of lidocaine patch for the treatment of low back pain.**

**Grade of Recommendation: I**

Gimbel et al<sup>1</sup> assessed the effectiveness and safety of 5% lidocaine patch for the treatment of LBP in an open-label pilot study. Patients with LBP from 5 different centers in the United States were categorized into groups upon enrollment based on duration

of LBP: acute/subacute (3 months), n=21; short-term chronic (3-12 months), n=33; or long-term chronic (12 months), n=77. Participants applied the lidocaine patch to the area of LBP up to 4 times daily for 6 weeks. After 2 weeks, patients were allowed to taper

Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.



off existing analgesic drugs and increase daily lidocaine patches if pain was unacceptable during the taper period. Patients completed the BPI to report pain and quality of life (QOL) at baseline, 2 weeks and 6 weeks. At 2 and 6 weeks, each group had significantly improved pain scores compared to baseline ( $p \leq 0.001$ ). Improvements in QOL were observed in each group from baseline to 2 and 6 weeks. Adverse events reported included skin reactions, lightheadedness and

headache. There were no drug-related serious adverse events reported. The authors concluded that the lidocaine patch 5% resulted in significant improvements in pain intensity and QOL and randomized controlled trials are warranted to further investigate its efficacy and safety for the treatment of LBP. This study provides Level III evidence that treatment with lidocaine patch 5% provided a significant improvement in pain intensity and QOL.

## Topical capsaicin is recommended as an effective treatment for low back pain on a short-term basis (3 months or less).

### Grade of Recommendation: A

Frerick et al<sup>2</sup> conducted a double-blind, randomized, placebo-controlled multicenter study to assess the efficacy and tolerance of capsaicin plaster for the treatment of LBP. A total of 320 patients were randomized to the treatment group which received a 12 x 18 cm capsaicin plaster ( $n=160$ ) or placebo group which received a similar plaster with no active medication ( $n=160$ ). All participants were instructed to apply the plaster to the site of pain for 4–8 hours once daily for 21 days. The Arhus Low Back Rating Scale was used to record patient-reported pain, disability and physical impairment at baseline and days 7 and 21. The global assessments of efficacy by patient and investigator were also recorded at baseline and days 7 and 21. An intent-to-treat analysis included 319 participants (159 in the treatment group and 160 in the placebo group). The treatment group experienced significantly greater reduction in pain (42%) compared to the placebo group (31%). The responder rate ( $\geq 30\%$  pain reduction) was greater in the treatment group (67%) compared to the placebo group (49%). A total of 120 and 129 participants completed the study in the treatment group and placebo group, respectively and were included in the per-protocol analysis. Per-protocol analysis supported the intention-to-treat analysis. Adverse events likely related to capsaicin included excessively severe sensation of heat or erythema. The authors concluded that capsaicin plasters may offer an alternative treatment for LBP. This study provides Level I evidence that capsaicin plaster applied topi-

cally may have short-term benefit for patients with back pain persisting for more than 3 months.

Keitel et al<sup>3</sup> studied the efficacy of capsaicin plaster for the treatment of LBP in a double-blind randomized controlled study. A total of 154 participants were randomized to receive a capsaicin plaster or placebo plaster. Participants placed the plaster at the site of pain for 4–12 hours once daily for 21 days. The Arhus Low Back Rating Scale was used to measure pain and impairment of movement. The global assessments of efficacy and tolerance by participant and physician were recorded at baseline and follow-up. A total of 76 participants in the placebo group and 74 patients in the capsaicin group were included in intention-to-treat analysis. The responder rate ( $\geq 30\%$  pain reduction) was significantly greater in the capsaicin group (60.8%) compared to the control group (42.1%). The participants in the capsaicin group experienced significantly greater reduction in the sum of 3 separate pain scores compared to the placebo group. Common adverse events included local sensation of warmth and itching; more adverse reactions were reported in the treatment group compared to the placebo group. The authors concluded that capsaicin plaster can be used in chronic nonspecific LBP. This study provides Level I evidence that capsaicin plaster provided more analgesia than placebo in a 3-week trial of patients with nonspecific LBP.



### Future Directions for Research

The work group does not have any recommendations for future research on this topic.

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**Med/Psych Question 4.** Following treatment for low back pain, do patients with healthy sleep habits experience decreased duration of pain, decreased intensity of pain, increased functional outcomes and improved return-to-work rates compared to patients with poor sleeping habits?

**A systematic review of the literature yielded no studies to adequately address this question.**



### Future Directions for Research

The work group recommends high quality, prospective studies that utilize sleep logs or other tracking methodologies to evaluate low back treatment outcomes in patients with and without healthy sleep habits.



**Med/Psych Question 5.** In patients with low back pain, is cognitive behavioral therapy (CBT) and/or psychosocial intervention and/or neuroscience education effective in decreasing duration of pain, decreasing intensity of pain, increasing functional outcomes, decreasing anxiety and/or depression and improving return-to-work rate?

**Cognitive behavioral therapy is recommended in combination with physical therapy, as compared with physical therapy alone, to improve pain levels in patients with low back pain over 12 months.**

**Grade of Recommendation: A**

**Cognitive behavioral therapy in combination with physical therapy, compared to physical therapy alone, is suggested to improve functional outcomes (disability) and return to work in patients with low back pain.**

**Grade of Recommendation: B**

**There is conflicting evidence to make a recommendation for or against cognitive behavioral therapy for improving depression or anxiety in patients with low back pain.**

**Grade of Recommendation: I**

*Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.*

Bendix et al<sup>1</sup> compared the rehabilitation outcomes from 3 different therapy approaches to treat LBP in prospective randomized study. A total of 132 patients were randomized into one of 3 groups. Group 1 (n=46) received an intensive multidisciplinary rehabilitation program 39 hours per week for 3 weeks plus an additional 6-hour follow-up session once a week for the following 3 weeks (total of 135 hours). Group 2 (n=43) received active physical training of aerobics, weight training and back education twice weekly for 6 weeks (total of 24 hours). Group 3 (n=43) received a combined psychological and physical therapy program twice weekly for 6 weeks (total of 24 hours). Rehabilitation outcomes such as return-to-work rate, days of sick leave, health-care contacts, pain and disability score and staying physically active were measured at baseline and 4 months after therapy. After 4 months, 40, 31 and 35 patients in Group 1, Group 2 and Group 3, respectively, were available for follow-up. Compared to the participants in Group 2 and Group 3, the participants in Group 1 had significantly improved work-readiness ( $p=0.01$ ), health care contacts ( $p=0.05$ ), pain ( $p\leq 0.001$ ), disability ( $p=0.002$ ) and self-reported physical activity ( $p=0.005$ ). The authors concluded that the multidisciplinary program may be more expensive than a less-intensive program, but is overall economically worthwhile due to savings in sick pay, health care contacts and early retirement pensions. Of note, when psychological interventions were combined with physical training there was an improvement in outcomes related to LBP but the nature of this question did not address physical and psych training together. The work group determined that this study provides Level I evidence that psychological training programs in addition to physical training do not improve functional outcomes compared to physical training alone with regard to LBP.

Dufour et al<sup>2</sup> studied the efficacies of a group-based multidisciplinary biopsychosocial rehabilitation program and an individual intensive therapist-assisted back muscle exercise program. In this randomized controlled trial, patients with chronic LBP >12 weeks were stratified and randomly allocated into the multidisciplinary biopsychosocial rehabilitation program (group A) or the individual exercise program (group B). Each group program ran for 12 weeks. Group A (n=129) received biweekly education from a physiotherapist and occupational therapist along with a total of 75 hours of moderate muscle training exercise which included warm up, stretching, aerobic exercises, strengthening exercises, playing ball games, training in hot water and ball stick training. Group B (n=143) received intensive muscle training exercises,

without stretching or abdominal exercises, guided by a therapist for a total of 22 hours of exercise. Throughout the program, each patient received a total of 12 and 24 hours of therapist assistance in Group A and Group B, respectively. Outcomes were measured at baseline, after 3 months of treatment and at 6, 12 and 24 months. Pain per the VAS, disability per the Roland-Morris Disability Questionnaire (RMDQ), most of the MOS Short-Form Health Survey results and ability to work significantly improved in both groups after treatment using an intent-to-treat analysis as well as an analysis of actual data. There were some minor statistically-significant (but not clinically significant) differences in improvement between groups. A total of 11 patients in each group dropped out due to adverse events such as requirement of surgery, concussion, leg pain, delayed onset muscle soreness, or other reasons unrelated to treatment. The authors concluded that both groups had significantly improved long-term pain and disability scores. This study provides Level I evidence that a biopsychosocial program plus physical training is as effective as an intensive physical exercise program for chronic LBP.

Lamb et al<sup>3</sup> conducted a multicenter randomized controlled trial to compare the clinical and cost-effectiveness of active management with a cognitive-behavioral approach (CBA) versus active management alone (AM) in patients with LBP. Patients with subacute or chronic LBP from 56 different clinical practices in English regions were randomized into either the CBA (n=468) or AM (n=233) group. Both groups received a 15-minute standard best-practice intervention, which included distribution of an educational back book. The CBA group additionally attended 6 professionally led group sessions that covered goal setting, pacing, challenging beliefs, managing pain and improving communication with health professionals. Patients were asked to provide demographic, LBP-associated disability information per the Roland Morris Disability Questionnaire (RMDQ) and pain and disability information per the Modified Von Korff Scale (MVK) through postal questionnaires or telephone surveys (85% follow-up at 12 months). The CBA group experienced significantly greater improvements in mean RMDQ scores at 3 (1.1; 95% CI 0.4 to 1.7), 6 (1.4; 95% CI, 0.7 to 2.1) and 12 months (1.3; 95% CI 0.6 to 2.1). Significantly greater improvements in the CBA group compared to the AM group were also seen in pain per the MVK at 3 (6.8; 95% CI 3.5 to 10.2), 6 (8.0; 95% CI 4.3 to 11.7) and 12 months (7.0; 95% CI 3.2 to 10.7) as well as disability per the MVK at 3 (4.3; 95% CI 0.4 to 12.4), 6 (8.1; 95% CI 4.1 to 12.0) and 12 months (8.4; 95% CO 4.4 to 12.4). The authors con-

cluded that CBA showed long-term effectiveness in treating patients with subacute and chronic LBP. This study provides Level I evidence that cognitive behavioral therapy (CBT) plus active management is better than active management alone in terms of pain and function.

Linden et al<sup>4</sup> assessed the efficacy of CBT for improving pain tolerance compared to a multimodal inpatient orthopedic rehabilitation program alone in patients with LBP in a randomized controlled trial. Patients with LBP >6 months were randomly allocated into an intervention (n=53) or control (n=50) group. All patients received 21 days of inpatient treatment including various therapies, occupational therapy and general patient education sessions on coping. The patients in the intervention group additionally received 3 90-minute CBT group sessions per week focused on stress reduction, problem solving, self-monitoring, pain management, change in dysfunctional cognitions, reduction of avoidance behavior and well-being therapy. Before and after treatment, patients reported fear and avoidance per the Fear Avoidance Beliefs Questionnaire (FABQ), subjective pain per the VAS Pain (VAS-pain), pain-related disability per the Pain Disability Index (PDI) and psychological and psychosomatic complaints per the Symptom Checklist (SCL-90-R). The intervention group experienced significantly greater improvements in VAS-pain ( $p=0.002$ ) and FABQ ( $p<0.001$ ). There were no differences between groups in changes in PDI and SCL scores. The authors concluded that the results of this study support the recommendation that CBT should be a part of the treatment of chronic LBP. This study provides Level I evidence that CBT plus usual care improves short-term pain and disability (over 3 weeks) in chronic LBP patients.

Sullivan et al<sup>5</sup> investigated the physical and psychosocial changes that occur throughout physiotherapy with psychotherapy compared to physiotherapy alone in a retrospective study of 2 matched cohorts. A database of individuals receiving treatment for musculoskeletal conditions was used to systematically identify participants with LBP who were enrolled in the subacute phase of recovery at various clinics. The patients who received physiotherapy plus a Progressive Goal Attainment Program (PGAP) psychotherapy program (n=24) were matched for age, education, duration of sick leave and initial pain severity with patients who received only physiotherapy (n=24). Due to the retrospective design of this study, the patients received therapy per the clinical discretion of each individual therapist; no specific techniques were

described. Participants recorded severity of pain per the McGill Pain Questionnaire (MPQ), pain experience per the Pain Rating Index (PRI) within the MPQ and the severity of their pain per an 11-point numerical rating scale. Function was assessed using a 5-minute walk and finger-to-floor test. Self-perceived disability per the Pain Disability Index (PDI), catastrophic thinking per the Pain Catastrophizing Scale (PCS), fear of re-injury per the Tampa Scale for Kinesiophobia (TSK) and depression per the Beck Depression Inventory-II (BDI-II) were also recorded. Twelve months after treatment termination, participants were contacted by telephone. There were no post-treatment differences in pain intensity, number of pain sites, finger-to-floor test, 5-minute walk distance or self-reported disability. The participants in the physiotherapy + PGAP group had lower MPQ-PRI scores ( $F(1,45)=4.5$ ,  $p<0.05$ ), measures of pain catastrophizing ( $F(1,45)=5.2$ ,  $p<0.05$ ), fear of movement ( $F(1,45)=5.0$ ,  $p<0.05$ ) and depression ( $F(1,45)=23.8$ ,  $p<0.001$ ). The authors concluded that the psychosocial treatment in addition to physiotherapy alone may contribute to more positive outcomes including reductions in psychosocial risk factors for pain and disability in people with LBP. The work group downgraded the level of evidence due to small sample size. This study provides Level II evidence that psychosocial treatment augments the outcomes of physiotherapy in terms of reduction of depression, anxiety and improved return to work.

Turner et al<sup>6</sup> compared the efficacy of cognitive therapy techniques with behavioral treatment in patients with chronic LBP in a randomized controlled study. A total of 102 patients met inclusion criteria and were randomized into a relaxation training (R) group (n=24), cognitive therapy (C) group (n=23), cognitive therapy/relaxation training (CR) group (n=25), or waiting list (WL) group (n=30). Patients in the R group were instructed to use systematic progressive muscle relaxation and imagery. Patients in the C group were trained to identify and counter negative emotions related to pain and stress. The CR group combined the aspects of the R and C group. All training programs were led by psychologists. Measurements including pain intensity using a VAS, pain-related physical and psychosocial dysfunction using the Sickness Impact Profile (SIP), depression using the Beck Depression Inventory (BDI), standardized coding of observer ratings of pain behaviors, and maladaptive cognitions using the Cognitive Error Questionnaire (CEQ) were obtained before treatment and immediately, 6 months and 12 months after treatment. A total of 17, 16, 21 and 18 participants completed the treatment

and post-treatment in the R, C, CR and WL groups, respectively. Pain intensity decreased in all 3 treatment groups and remained improved at 6- and 12-month follow-up. Depressive symptoms and disability improved significantly in all groups, including the WL group. There were no differences in results between treatment groups. The authors concluded that cognitive therapy may be as effective as relaxation training in reducing self-reported LBP; however, neither relaxation training nor cognitive therapy, alone or in combination with each other, is more effective in reducing cognitive errors, depression, disability or pain behavior than a waiting list group. This study provides Level I evidence that CBT, relaxation training alone or in combination improve LBP compared to no treatment; however these modalities compared to no treatment did not improve disability and depression over 12 months as compared to no treatment.

Hampel et al<sup>7</sup> investigated the effects of a multidisciplinary inpatient rehabilitation program with cognitive-behavioral management training for patients with chronic LBP and depressive symptoms. Patients from two different inpatient orthopedic rehabilitation clinics with LBP >6 months and moderate to severe depressive symptoms were assigned to a control group or intervention group. The control group (n=80) received a standard 3-4 week biopsychosocial multidisciplinary rehabilitation program that included medication, physiotherapy, physical applications and group sessions with a psychologist focusing on cognitive-behavioral pain management and muscle relaxation. The intervention group (n=85) received the same rehabilitation program plus additional group therapy sessions focusing on behavioral activation, cognitive restructuring and social skills training from a psychologist. Rehabilitation outcome measures such as days of sick leave, depressive symptoms per the Allgemeine Depressions-Skala (ADS), anxiety per the Hospital Anxiety and Depression Scale (HADS-D Anxiety) and somatization per the Symptom Checklist (SCL-90-R) were assessed at baseline, immediately after rehabilitation and 6, 12 and 24 months after rehabilitation. A total of 40 and 44 participants in the control group and intervention group, respectively, completed the program and were included in the per-protocol analysis. Per both the intention-to-treat and per-protocol analyses, both groups initially showed improvement in depressive symptoms and anxiety, but only the intervention group showed persistent improvement over 24 months. The intervention group had significantly lower depression and anxiety scores at 6 months compared to the control group. The authors concluded

that the intervention rehabilitation program was superior to the standard rehabilitation alone. In critique of the methodology, the workgroup downgraded this potential Level I study due to the small sample size. Therefore, this study provides Level II evidence that adding psychological treatment in people who are depressed with LBP improves their depressive symptoms over the course of a year and improves anxiety at 6 months, but not at 2 years.

Monticone et al<sup>8</sup> conducted a randomized controlled trial pilot study to evaluate the efficacy of a multidisciplinary rehabilitation program with exercise and CBT compared to exercise alone in patients with chronic LBP. Ten patients were randomized into a multidisciplinary treatment program group with psychiatrists, physiotherapists, a psychologist and an occupational therapist in which they received usual-care rehabilitation, spinal stabilizing exercises, and individualized CBT aimed at addressing fear of movement beliefs, catastrophizing, and negative feelings. The control group (n=10) received only usual-care rehabilitation which involved passive spinal mobilization, stretching, muscle strengthening and postural control. Disability per the Oswestry Disability Index (ODI), kinesiophobia per the Italian Tampa Scale of Kinesiophobia (TSK), catastrophizing per the Italian Pain Catastrophizing Scale (PCS), pain rating using a numerical rating scale (NRS), quality of life using the Italian Short Form Health Survey (SF-36), a 6-minute walking test and treatment satisfaction using the global perceived effect (GPE) were assessed at baseline, after the 8-week treatment period and 3 months after the treatment ended. The patients in the treatment group had significant improvements in disability, kinesiophobia, catastrophizing and quality of life in group, time and time-by-group interactions. The authors concluded that this superiority trial revealed that the multidisciplinary rehabilitation program with CBT was superior to exercise alone in patients with chronic LBP. In critique of the methodology, the work group downgraded the level of evidence of this potential Level I study due to the small sample size. Therefore, this paper provides Level II evidence that CBT is better than usual care alone in reducing pain and disability from chronic LBP.

In a multicenter randomized controlled trial, Pincus et al<sup>9</sup> studied the feasibility of contextual cognitive-behavioral therapy (CCBT) compared to physiotherapy alone in patients classified as “avoidant” with LBP. Participants were randomly allocated to the CCBT group (n=45) in which they received up to 8 individual 50-minute sessions with a trained psychologist or the

physiotherapy group (n=44) in which they received up to 8 exercise sessions. Questionnaires were completed at baseline and 3 and 6 months after randomization and included Tampa Scale for Kinesiophobia (TSK), BPI, Chronic Pain Acceptance Questionnaire (CPAQ), Acceptance and Action Questionnaire (AAQ-II), Roland Morris Disability Questionnaire (RMDQ), Hospital Anxiety and Depression Scale (HADS), EuroQol-5D, Modified Patient Global Impression of Change (PHIC) and expectations and satisfaction with treatment. At 6-month follow-up, most outcomes improved for both groups. The CCBT group experienced significantly greater improvements in disability per the RMDQ and pain per the CPAQ. The authors concluded that CCBT is credible and acceptable for patients with LBP and psychological obstacles. In critique, the work group downgraded the level of evidence for this study due to less than 80% follow-up. This study provides Level II evidence that CBT is better than physiotherapy alone in terms of pain and disability at 6 months.

Schiltenswolf et al<sup>10</sup> studied the efficacy of biopsychosocial treatment compared to biomedical therapy alone in patients with subacute LBP in a randomized controlled clinical trial. Participants were randomized into either the conventional biomedical therapy (MT) group (n=31) or the biopsychosocial treatment (BT) group (n=33). All participants received 6 hours of treatment per day for 15 days over the course of 3 weeks. The MT group received physiotherapy, group therapy in water, workout, passive interventions such as massage and physical therapy and education on stretching, strengthening and improving mobility and body control. The BT group received the same biomedical therapy as the MT group, but additionally received additional psychotherapy and relaxation therapy 3 and 4 times per week, respectively. Questionnaires were completed at baseline, immediately after the 3-week therapy program and at 6-month follow-up. At each time point, pain was assessed using a numeric rating scale (NRS), mobility per the finger-floor-test, torque of abdominal muscles, functional capacity per the Hannover Functional Status Questionnaire-Back (FFbH-R), depressive dysfunction (CES-D) and sick leave data according to the patient's insurance company. A total of 32 (97%) and 29 (94%) participants completed the post-treatment evaluation at 3 weeks in the BT and MT groups, respectively. Both groups experienced improvement in pain intensity and functional capacity of the back (FFbH-R) after 3 weeks, but the BT group experienced significantly greater improvements at 6 months compared to the MT group. The BT group required significantly less sick leave (912 days of leave) with 13 out of 22 (59%) not requiring

further sick leave due to LBP compared to the MT group (2,228 days of leave) with 2 out of 20 (10%) not requiring further sick leave due to LBP. The authors concluded that a biopsychosocial treatment program for patients with LBP is beneficial in improving pain, functional status and work performance compared to conventional biomedical therapy alone. The work group downgraded this potential Level I article due to small sample size and less than 80% follow-up. This study provides Level II evidence that CBT can decrease sick leave (improve return to work) as well as pain and depression compared to control treatment.

Smeets et al<sup>11</sup> conducted a randomized controlled trial to compare active physical, cognitive-behavioral therapy (CBT) and a combined treatment for chronic LBP compared to a wait list control group. Participants with LBP >3 months from three different rehabilitation centers were randomized into the Active Physical Treatment group (APT), CBT group, Combined Treatment group, or Waitlist group (WL). The APT group (n=53) received aerobic training, individually adjusted based on heart rate and perceived exertion, along with strengthening exercises. The participants in the CBT group (n=58) did not receive strength or aerobic exercises but gradually increased daily activity level using operant behavioral graded activity training and participated problem solving training (PST) with a trained psychologist or social worker to help reach their goals and modify dysfunctional beliefs related to LBP. The Combined Treatment group (n=61) received the same training as the APT group and the PST portion of the CBT group. Each treatment group received 10 weeks of treatment. The WL group (n=51) was offered individual treatment after 10 weeks. Each participant completed a questionnaire at baseline, immediately after treatment and 6 and 12 months after treatment to measure functional limitation per the Roland Morris Disability Questionnaire (RMDQ), pain and severity of complaints using a 100-mm VAS, depression per the Beck Depression Inventory, global assessment of overall results using an ordinal scale and treatment satisfaction using a 100-mm VAS. A total of 52, 55, 55 and 50 participants were available for analysis immediately after the 10-week treatment period in the APT, CBT, Combined Treatment and WL groups, respectively. For various reasons such as rejection of treatment or non-LBP-associated medical or psychological problems, some of those participants did not complete sufficient training. A total of 83% completed the appropriate APT sessions, 78% and 76% had sufficient GA and PST sessions (respectively) in the CBT group and 72% and 62% had sufficient physical training and GA/PST (respectively). Using an

intention-to-treat analysis, RMDQ, pain and severity of complaints significantly improved in all three treatment groups compared to the WL group. The authors concluded that all 3 treatment groups were more effective than the wait list group, but were not statistically significantly different from each other. The work group downgraded this potential Level I study due to

a follow-up rate less than 80%. This study provides Level II evidence that CBT is better than control (no treatment), but not better than physical treatment alone in terms of pain and disability at 10 weeks.



### Future Directions for Research

The work group recommends future studies that clearly identify what types of psychosocial interventions (eg, CBT, neuroscience education), in what frequency and what combination is most effective for the treatment of LBP.

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**Med/Psych Question 6.** In patients with low back pain, does the timing of cognitive behavioral therapy (CBT) and/ or psychosocial intervention and/or neuroscience education affect duration of pain, intensity of pain, functional outcomes, anxiety, depression and return-to-work status?

**A systematic review of the literature yielded no studies to adequately address this question.**



#### Future Directions for Research

The work group recommends that future studies of cognitive behavioral therapy should also include timing and duration of this treatment.



**Med/Psych Question 7.** In patients undergoing interventional or surgical treatment for low back pain, does the addition of cognitive behavioral therapy (CBT) and/or psychosocial intervention add incremental benefit?

**There is insufficient evidence to make a recommendation for or against the addition of cognitive behavioral therapy or psychosocial intervention for patients undergoing interventional or surgical treatment for low back pain and whether it would provide incremental benefit.**

**Grade of Recommendation: I**

Rolving et al<sup>1</sup> conducted a randomized clinical trial to evaluate the cost-effectiveness of a CBT intervention compared to usual care in patients undergoing lumbar spinal fusion surgery (LSF). Patients with chronic LBP scheduled for LSF who met inclusion criteria were randomly allocated into a control group (n=31) or CBT group (n=59). All participants received usual care of the LSF operation and rehabilitation 3 months post-surgery. The CBT group received additional preoperative CBT intervention to address pain-coping strategies. Quality-adjusted life years (QALYs) were calculated based on EQ-5D scores; a societal viewpoint was adapted to calculate costs. There was no

difference in the overall cost between groups, but the CBT group had a statistically-significantly more favorable QALY than the control group at one-year follow-up (0.071 QALY, 95% CI: 0.001-0.139, p=0.045). Compared to the control group, the CBT group experienced greater reductions in disability per the Oswestry disability index (ODI) at 3 months (p=0.003) and 6 months (p=0.047) but not at one year (p=0.082). The authors concluded that preoperative CBT was more effective and cost-neutral in the treatment of LSF surgery. This study provides Level I evidence that, in patients undergoing lumbar fusion, the addition of CBT improves function at 3 and 6 months but not at one year.





### Future Directions for Research

The work group recommends future studies to evaluate whether the addition of cognitive behavioral therapy or psychosocial intervention add incremental benefit in patients undergoing interventional or surgical treatment for LBP.

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**Med/Psych Question 8.** Does educating a patient about low back pain improve treatment compliance and outcomes, including duration of pain, intensity of pain, functional outcomes, anxiety, depression and return-to-work status?

**There is conflicting evidence to make a recommendation for or against the use of patient education to improve treatment compliance and outcomes, including duration of pain, intensity of pain, functional outcomes, anxiety, depression and return-to-work status.**

**Grade of Recommendation: I**

Cherkin et al<sup>1</sup> evaluated the relative effectiveness of physical therapy, chiropractic manipulation and an educational booklet for the treatment of LBP in a randomized controlled trial. Adults with LBP (n=321) were randomized to receive one of the three treatments for one month and recorded bothersomeness of symptoms on an 11-point scale along with a 24-point Roland Disability Scale. There were no significant differences in outcomes between the chiropractic and physical therapy group; both groups reported slight and insignificantly less severe symptoms than the educational booklet group after treatment. The authors concluded that the effects of physical therapy and chiropractic manipulation had similar effects and costs and were marginally better than the effects of the educational booklet. This study provides Level I evidence that patient education did not improve outcomes compared to standard care.

In a randomized controlled trial, Basler et al<sup>2</sup> evaluated the effect of counseling based on the Transtheoretical Model (TTM) in elderly patients with LBP. Elderly participants with LBP (n=170) received

10 20-minute physiotherapy sessions. Prior to each session, the experimental group (n=86) received an additional 10 minutes of TTM-based counseling while the placebo group (n=84) received an ultrasound treatment with an inactivated device. There were no significant differences in outcomes such as duration of physical activity, functional capacity, or range of motion between groups after treatment. The authors concluded that a TTM-based motivation program is not superior to placebo in the treatment of LBP. This study provides Level II evidence that, in older adults with chronic LBP, education combined with physical therapy did not improve outcomes at 6 months when compared to physical therapy alone.

Berwick et al<sup>3</sup> conducted a randomized prospective trial to compare the effects of an educational pamphlet against a single 4-hour back school psychoeducational session with or without a one-year program encouraging self-management for the treatment of LBP. A total of 222 participants were randomized into one of the 3 treatment groups. There were no significant differences between groups in pain or functional

status at 3, 6, or 12 months after enrollment. The authors concluded that a short version of back school, with or without follow-up reinforcement, is not likely to affect pain and disability in patients with LBP. This study provides Level II evidence that the addition of back school does not improve pain reduction as compared to usual care for acute LBP.

Cecchi et al<sup>4</sup> conducted a randomized trial to compare treatments for LBP. Patients with LBP (n=210) were randomized to receive spinal manipulation (4-6 20-minute sessions once-a-week), back school with group exercise and education/ergonomics (15 one-hour sessions for 3 weeks), or individual physiotherapy with exercise, passive mobilization and soft-tissue treatment (4-6 20-minute sessions once per week). Pain and function were assessed by Pain Rating Scale and Roland Morris Disability Questionnaire, respectively, at 3, 6 and 12 months. The authors concluded that spinal manipulation provided functional improvement and more pain relief compared to back school or individual physiotherapy. This study provides Level II evidence that spinal manipulation therapy has greater treatment effect than either physical therapy or back school in improving disability.

In order to assess the effectiveness of routine physiotherapy compared with advice on remaining active, Frost et al<sup>5</sup> conducted a randomized controlled trial of 286 patients with LBP. Although the patients in the physiotherapy group reported greater perceived benefit, there were no significant differences in scores of the Oswestry disability index, Roland and Morris disability questionnaire, or SF-36 12 months after enrollment. The authors concluded that routine physiotherapy was no more effective than one session of assessment and advice from a physiotherapist. This study provides Level II evidence that routine physiotherapy for mild to moderate LBP is no more effective than a session with a physiotherapist that includes advice.

Hsieh et al<sup>6</sup> conducted a randomized trial to compare the effectiveness of back school, joint manipulation, myofascial therapy and combined joint manipulation and myofascial therapy with 200 patients with LBP. Participants received the assigned treatment for 3 weeks. Pain per a visual analog pain scale and activity per the Roland-Morris activity scale were recorded at baseline, immediately after treatment and 6 months. There were no statistically significant differences found between groups at either time point. The authors concluded that back school was as effective as joint manipulation, myofascial therapy or a combi-

nation of the two for treatment of subacute LBP. This study provides Level II evidence that back school was no more effective than standard treatment.

In a multicenter randomized controlled trial, Johnson et al<sup>7</sup> evaluated the effect of a group exercise and education program for the treatment of LBP. All participants (n=234) received an educational booklet and audio-cassette with advice on self-management of LBP. Participants were randomized into a 6-week interventional program (n=116) consisting of 8 2-hour group sessions with exercise and education delivered using a CBT approach or a control group (n=118) which did not receive any additional intervention. The intervention group showed only a small but nonsignificant effect at reducing pain and disability compared to the control group at 12-month follow-up. The authors concluded that the intervention program produces only modest effects in reducing LBP and disability over a one-year period. This study provides Level II evidence (moderate) that exercise with CBT approach is no more effective than education with booklets alone.

Karjalainen et al<sup>8</sup> conducted a multicenter randomized controlled trial to study the effectiveness of a mini-intervention with or without an additional worksite visit compared to usual care for treatment of LBP. The patients in the mini-intervention group (n=56) received consultations with a physician and physiotherapist which included education, encouragement of physical activity and exercise planning. The worksite visit group (n=51) received the same treatment, but had an additional visit with a physiotherapist, nurse and physician at each participant's workplace to ensure and encourage proper adoption of the previous instructions. The patients in the usual care group (n=57) received a leaflet on back pain and were treated by their general practitioners. There were no significant differences in pain intensity, perceived disability or health-related quality of life between groups at 3, 6, 12 or 24 months. The authors concluded that the mini-intervention is an effective treatment for subacute LBP. This study provides Level II evidence that mini-intervention does not appear to be more effective than worksite visit or usual care.

Leclaire et al<sup>9</sup> evaluated the efficacy of a back school program compared to physiotherapy alone for the treatment of LBP in a randomized controlled trial. Participants were randomized to receive daily physiotherapy (n=86) or back school with daily physiotherapy plus 3 90-minute education sessions at weeks 0, 1 and 8 (n=82). There were no differences

between groups in terms of time off work for LBP, duration of recurrences in the year after enrollment, level of pain, spinal mobility, active straight-leg raising, or functional disability per the Oswestry or Roland-Morris scales at post-treatment, 6-month, or 12-month follow-up. The authors concluded that back school did not reduce time to return to work or the number or duration of recurrences of LBP after one year. This study provides Level II evidence that back school does not improve outcomes of physiotherapy for treatment of acute LBP in workers.

In a randomized controlled trial, Magalhaes et al<sup>10</sup> compared the effectiveness of graded activity and physiotherapy for the treatment of LBP. Participants were randomly assigned to groups and received individual sessions twice a week for 6 weeks. The graded activity group (n=33) included moderate intensity treadmill walking, brief education and strength exercises. The physiotherapy group (n=33) included strengthening, stretching and motor control. There were no significant differences in pain (Pain Numerical Rating Scale) or disability (Roland-Morris Disability Questionnaire) between groups after 6 weeks. The authors concluded that graded activity and physiotherapy have similar effects for patients with chronic LBP. This study provides Level II evidence that graded activity and physiotherapy exercises have similar beneficial effects in patients with chronic LBP.

Ribeiro et al<sup>11</sup> conducted a randomized controlled trial to evaluate the effectiveness of a 4-week back school program for the treatment of LBP. Patients randomized into the intervention group (n=29) received 5 one-hour group sessions of back school which included education, exercise and relaxation. Participants in the control group (n=31) had weekly medical visits without education. There were no significant differences between the groups in pain (pain visual analogical scale), functional status (Roland-Morris Disability Questionnaire), anxiety or depression at 30, 60 or 120 days after enrollment. The authors concluded that the back school program was ineffective in improving quality of life domains, pain, functional status, anxiety and depression. This study provides Level II (weak) evidence that back school is no more effective than meeting with the provider to talk about their pain.

Sparkes et al<sup>12</sup> conducted a randomized controlled trial to assess the effectiveness of an evidence-based booklet, *The Back Book*, for the treatment of LBP. After referral from a general practitioner to a spinal pain clinic, participants were randomized into an inter-

vention group who received *The Back Book* (n=33) or a control group who did not receive the booklet (n=29). At the time of the initial appointment at the spinal pain clinic, there were no significant differences between groups in pain (VAS) or disability (Roland Morris Disability questionnaire). The authors concluded that *The Back Book* may not be suitable if used alone for the treatment of LBP. In critique of the methodology, the work group downgraded this potential Level I study due to the small sample size without a power analysis reported. Therefore, this study provides Level II (weak) evidence that *The Back Book* is not effective when given in isolation.

Göhner et al<sup>13</sup> studied the effects of a cognitive-behavioral training program for the treatment of patients with LBP. Patients were enrolled in an exercise plus a CBT program (n=25) or exercise only program (n=22) for 6-8 weeks. Although there were significant differences in self-efficacy, perceptions and frequency of exercise, there were no differences regarding pain intensity between groups immediately after the program or 3 or 6 months post-treatment. The authors concluded that the CBT program is an effective tool to enable patients with LBP to follow treatment recommendations. This study provides Level III evidence that the addition of CBT enhances treatment compliance but does not improve pain outcomes with exercise therapy for LBP.

In a randomized controlled trial, Cherkin et al<sup>14</sup> evaluated the effects of two educational interventions for the treatment of LBP compared to a control group. Patients received usual care (n=98) or an educational booklet with (n=103) or without (n=98) a 15-minute session with a clinic nurse who reviewed the booklet, answered questions, provided encouragement and assisted with goal development related to exercise. Outcomes of satisfaction with care, perceived knowledge, participation in exercise, functional status, symptom relief and health care use were assessed at 1, 3, 7 and 52 weeks after the intervention. Although the participants in the nurse intervention group reported greater satisfaction and perceived knowledge, there were no significant differences between groups in terms of functional status, health care use or worry. The authors concluded that the educational interventions had no impact on symptoms, function, disability, or health care use. In critique of the methodology, the work group downgraded the Level of evidence due to nonmasked reviewers and patients. This study provides Level II evidence that patient education did not improve outcomes compared to standard care.

DuBois et al<sup>15</sup> studied the efficacy of a rehabilitation-oriented coaching intervention compared to a usual care control group for the treatment of LBP. In a randomized controlled trial, patients allocated to the intervention group (n=252) received medical advice during a disability evaluation during the first, second and third month of sick leave. Patients randomized to the control group (n=257) received a brief disability evaluation during the third month of sick leave without medical advice. Results revealed that the patients in the intervention group had a statistically significantly higher return-to-work rate at one year. The authors concluded that a disability evaluation should include reassurance and advice about LBP. This study provides Level I evidence that combined counseling and disability evaluation by a medical adviser results in a higher return-to-work rate due to a lower sick leave recurrence than disability evaluation alone.

Durmus et al<sup>16</sup> evaluated the effectiveness of an exercise program with or without back school for the treatment of LBP in a randomized controlled trial. Subjects (all female) participated in 60 minutes of exercise therapy 3 times a week for 3 months. The intervention group (n=61) received back school education in addition to exercise therapy while the control group (n=60) only participated in the exercises. Both groups showed improvements in outcomes after therapy. Compared to the control group, the intervention group had significantly greater improvements for pain (per the VAS and pain disability index), pain and disability according to the Oswestry Disability Questionnaire, trunk and knee muscle strength, endurance and walking performance. The authors concluded that back school increases the effectiveness of exercise programs for the treatment of LBP. This paper provides Level I evidence that, in females, back school in combination with specific exercise programs was more effective than specific exercise therapy alone in patients with chronic LBP.

Van den Hout et al<sup>17</sup> aimed to evaluate the supplemental value of problem-solving therapy when added to behavioral graded activity for the treatment of LBP in a randomized controlled trial. The participants in the intervention group (n=45) received behavioral graded therapy, group education and CBT focusing on problem solving for application in daily life. The control group (n=39) received behavioral graded activity and group education without problem-solving therapy. The participants in the intervention group had fewer days of sick leave in the second half-year after intervention. The authors concluded that there was value in adding problem-solving therapy to behavioral graded

activity for the treatment of LBP. This study provides Level I evidence that the addition of problem-solving therapy to behavioral graded activity had supplemental value in employees with non-specific LBP.

In a cluster randomized trial, Albaladego et al<sup>18</sup> investigated the efficacy of a short education and physiotherapy program for the treatment of LBP. All participants received advice, drug treatment and potential diagnostic procedures as part of usual care for LBP. The control group (n=109) additionally received a booklet and group education session on healthy nutrition habits. The Education Group (n=139) was given *The Back Book* with a corresponding education session. The Education + Physiotherapy Group (n=100) received the same education as the Education Group in addition to an additional booklet and education session on postural hygiene and 4 one-hour group sessions focusing on relaxation techniques, stretching, active exercises and encouragement to continue those movements at home. Compared to the control group, participants in both intervention groups had significantly greater improvements in disability per the Roland Morris Questionnaire and pain per the VAS. The authors concluded that the short education program added to usual care of patients with LBP leads to small improvements in disability, pain and quality of life. This study provides Level II evidence that physical therapy plus a short education program improves outcomes compared to physical therapy alone at 6 months.

Friedrich et al<sup>19</sup> conducted a randomized controlled trial to evaluate the effect of an exercise and motivational program in the treatment of LBP. Participants were randomly assigned to the control group (n=49) with standard exercise or the motivational intervention group (n=44) with exercise combined with extensive counseling, information and reinforcement techniques. Pain (according to a 101-point numerical scale), disability (per a 13-question questionnaire) and working ability were measured at 3.5 weeks, 4 months, 12 months and 5 years. The intervention group had greater improvements in disability at all time points and greater decrease in pain at 5 years. Improvement in working ability was only found in the intervention group. The authors concluded that the combined exercise and motivation group was superior to the standard exercise program. This study provides Level II evidence that a motivational program (ie, educational program) improves the outcome of exercise treatment for LBP in terms of function, pain and various other factors included in the cumulative effects at 5 years.

Heymans et al<sup>20</sup> conducted a randomized controlled

trial to assess the effectiveness of a low-intensity and high-intensity back school compared to usual care for workers who were sick-listed due to LBP. The participants in the usual care group (n=103) received advice to continue normal activities as much as possible. The participants in the low-intensity group (n=98) participated in 4 sessions of exercise (90 minutes) plus education (30 minutes) each week for 4 weeks. The participants in the high-intensity group (n=98) participated in 2 one-hour exercise sessions per week for 8 weeks. Sick leave was recorded throughout the study along with pain intensity (VAS) and functional status (Roland Morris Disability Questionnaire) at baseline and 3 and 6 months. The authors concluded that the low-intensity back school was most effective in reducing work absence, functional disability and kinesiophobia. This study provides Level II evidence of the positive effects on work absence for a low-intensity back school compared with the effects of a high-intensity back school and usual care during six months follow-up, in workers sick-listed for subacute nonspecific LBP. Treatment effects on the secondary outcomes functional status, kinesiophobia and perceived recovery were borderline significant at 3 and 6 months, also in favor of the low-intensity back school. Differences between groups concerning pain relief were small and not statistically significant.

Indahl et al<sup>21</sup> studied the long-term effects of an education program for treating LBP in a controlled clinical trial. Subjects in the intervention group (n=245) participated in a “mini back school” which focused on an explanation of back pain and encouragement to decrease fear about LBP. Subjects in the control group (n=244) were not called in for an examination and were treated in the conventional medical system. There were fewer recurrences of sick days for the patients in the intervention group compared to control group. The authors concluded information designed to reduce fear and increase light activity may help reduce long-term disability in patients with LBP. This study provides Level II evidence (moderate) that education to reduce fear may improve return-to-work status.

Pengel et al<sup>22</sup> compared the effectiveness of a physiotherapist-directed exercise program, advice or both for the treatment of LBP in a randomized controlled trial. Participants (n=259) were randomized into one of 4 groups: exercise (individualized progressive therapy guided by a physiotherapist) and advice (graded return to normal activity encouraged by a physiotherapist), exercise and sham advice, sham exercise and advice, or sham exercise and

sham advice. Pain (scale, 0-10), function (Patient-Specific Functional Scale), global perceived effect (11-point scale), disability (Roland-Morris Disability Questionnaire), number of health care contacts and depression (Depression Anxiety Stress Scales-21) were measured at 6 weeks and 12 months. When combined, exercise and advice had greater effects at 6 weeks for all outcomes, but had greater effects only on function at 12 months. The authors concluded that exercise and advice were more effective for the treatment of LBP compared to placebo at 6 weeks, with greater effects observed when the two were combined. This study provides Level II evidence that exercise and advice were slightly better than exercise alone at 12 months follow-up in terms of function for treatment of subacute LBP.

Tavafian et al<sup>23</sup> conducted a randomized controlled trial to assess the effect of a health education program, “Back School Programme,” on quality of life in patients with LBP. Female participants with LBP were randomized into the intervention group (n=50) to receive a physician evaluation followed by a 4-day, 5-session health education program or a control group (n=52) to receive only the initial physician evaluation and standard care. Quality of life was measured using the Short Form Health Survey (SF-36) at baseline and at three months follow-up. The intervention group had significantly better outcomes. The authors concluded that the “Back School Programme” might improve the quality of life over 3 months in patients who experience chronic LBP (CLBP). In critique of the methodology, the work group downgraded this potential Level I study due to lack of generalizability. This study provides Level II evidence that Back School was more effective than a control nonintervention population of female patients with CLBP in this short-term study.

Zhang et al<sup>24</sup> conducted a randomized controlled trial to compare the effects of a 12-week exercise program with health education on active management and postural hygiene compared to exercise alone for the treatment of LBP. Participants were randomized to receive education plus exercise (n=25) or exercise alone (n=24) and recorded pain, disability (Oswestry Disability Index), muscle endurance and quality of life (SF-36) at baseline and immediately after treatment. Pain, disability and SF-36 results were significantly better in the health education group compared to the exercise-only group. This study was downgraded from Level I due to small sample size and provides Level II evidence that health education provides additional benefits over and above lumbar exercise alone

for improving the pain, disability and health-related quality-of-life of young patients (aged 18–30 years) with chronic LBP.

In a randomized controlled trial, Basler et al<sup>25</sup> assessed the effects of medical treatment plus cognitive-behavioral treatment in the treatment of LBP. The participants in the intervention group (n=36) received usual medical treatment plus 12 weekly 2.5-hour cognitive-behavioral treatment sessions focusing on education, relaxation, modified thoughts and feelings, enhancement of pleasant activities and training of good postural habits. The control group (n=40) received medical treatment only. The intervention group experienced less pain, better pain control, more pleasurable activities, less avoidance, less catastrophizing and reduced disability compared to the medical treatment only group. The authors concluded that the cognitive-behavioral treatment added to medical care resulted in better outcomes compared to medical treatment alone. This study provides Level III evidence that a treatment package of cognitive-behavioral and standard care is more effective than standard care alone.

Castagnoli et al<sup>26</sup> compared the effects of global postural reeducation (GPR) to standard physical therapy (PT) for the treatment of LBP. All subjects received educational booklets and a home exercise program. The PT group (n=45) received an individualized treatment guided by a physiotherapist while the GPR group (n=45) were subjected to a postural assessment in which postures were selected to correct identified muscle imbalances. Both groups received 15 sixty-minute sessions twice weekly. Both groups experiences improvement in pain and function at discharge (15 working days after enrollment), but only the GPR group sustained those improvements at 12 months after discharge. The authors concluded that GPR and PT both result in short-term improvements in function and pain; GPR may have longer lasting effects compared to PT. This study provides Level III evidence that patients who received global postural reeducation still reported statistically significant pain relief compared to baseline and a lower frequency of pain.

Gremaux et al<sup>27</sup> conducted a randomized study to evaluate the effect of education workshops added to spa therapy for the treatment of LBP. Participants were randomized into the intervention group (n=188) to receive 3 90-minute education sessions in addition to thermal therapy for 3 weeks or the control group (n=172) to receive usual thermal therapy and non-standardized verbal information. Both groups

had significant reductions in physical fear-avoidance beliefs (FABQ), disability and pain, with a significantly greater reduction in FABQ in the intervention group only. The authors concluded that standardized education workshops during spa therapy reduce the effect of fear-avoidance beliefs and relieve pain in patients with LBP. The work group downgraded the Level of evidence for this study in critique of the methodology due to nonmasked reviewers and patients. This study provides Level II evidence that the addition of patient education improves the outcomes of spa therapy for LBP.

Iles et al<sup>28</sup> compared the effects of telephone coaching in addition to physiotherapy with physiotherapy alone for the treatment of LBP in a randomized trial. Participants were randomized into the intervention group (n=15) to receive 5 sessions of telephone coaching or the control group (n=15) to receive physiotherapy alone. The coaching group had significantly greater scores for function (Patient Specific Functional Scale) and recovery expectation. The authors concluded that the addition of telephone coaching to physiotherapy improved activity and recovery expectation. This study provides Level III evidence (weak) that telephone coaching may improve patient-specific functional outcomes in patients with chronic LBP.

Jaromi et al<sup>29</sup> hypothesized that nurses with LBP would have significantly decreased pain intensity levels and improved body posture after completing a program with ergonomics training and education (Back School) once a week for 6 weeks compared to a control group receiving passive physiotherapy once a week for 6 weeks. Although both groups showed improvement in pain intensity immediately after therapy, the Back School group (n=56) had significantly better improvements at 6 months and one year compared to the control group (n=55). The authors concluded that Back School results in significant improvements in pain intensity and posture in nurses who are experiencing chronic lower back pain. This study provides Level III evidence that, in working nurses with chronic LBP, the addition of back school to passive physical therapy results in a significantly better result at one year than physical therapy alone.

Paolucci et al<sup>30</sup> conducted a randomized controlled trial to evaluate the effect of a Back School program in the treatment of LBP. The intervention group (n=29) participated in a 4-week multidisciplinary Back School program with education and exercise while the control group (n=21) received medical assistance

only. Significant improvements in quality of life (SF-36), disability (Waddell Disability Index and Oswestry Disability Index) and pain (VAS) were observed in the intervention group. Additional mental component improvements in the SF-36 were observed in the patients in the intervention group who had at least one scale elevation in Minnesota Multiphasic Personality Inventory-II (MMPI-II) scores. The authors concluded that Back School has positive effects in patients with at least one scale elevation of MMPI-II. The work group downgraded the level of evidence of this study due to small sample size. This study provides Level II evidence for the effectiveness of back school.

Burton et al<sup>31</sup> conducted a randomized controlled trial to study the effects of a novel educational

booklet on patients' beliefs on LBP and functional outcomes. Patients with LBP received *The Back Book* with evidence-based information and advice (n=53) compared to a traditional booklet control group (n=50). The participants who received *The Back Book* had significant improvements in beliefs about physical activity at 2 weeks, 3 months and one year. There were no statistically significant differences between groups in pain or disability. The authors concluded that carefully selected information and advice on LBP can have a positive effect on outcomes for individuals with LBP. This study provides Level II evidence that patient education can improve function but not pain up to 3 months following usual treatment for LBP.



### Future Directions for Research

The work group recommends future studies to evaluate whether the inclusion of patient education impacts LBP treatment compliance and outcomes.

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**Med/Psych Question 9.** In patients undergoing treatment for low back pain, what is the effectiveness of interventions that address fear-avoidance behaviors?

**Treatments targeting fear avoidance combined with physical therapy are recommended compared to physical therapy alone to improve low back pain in the first 6 months.**

**Grade of Recommendation: A**

George et al<sup>1</sup> conducted a multicenter randomized controlled trial to compare physical therapy to fear-avoidance-based physical therapy in patients with acute LBP. Eligible patients were randomized into one of 2 groups to receive either standard physical therapy (n=32) or fear-avoidance-based physical therapy (n=34). All participants received education and

a one-hour individualized treatment with exercise prescriptions and progressions while recording home participation in a diary. The participants in the fear-avoidance-based physical therapy group additionally received specific education with fear-avoidance model principles and a graded exercise program with positive reinforcement. At baseline, 4 weeks after treat-

Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.



ment and 6 months after treatment, each participant completed a questionnaire that addressed disability per the Oswestry Disability Questionnaire (ODQ), pain intensity on a scale from 0 to 10 and fear-avoidance beliefs per the Fear-Avoidance Beliefs Questionnaire (FABQ). Using an intention to treat analysis, disability and pain intensity improved in both groups. The fear-avoidance beliefs significantly improved in the fear-avoidance therapy group and were significantly lower than the standard therapy group at both follow-up time points. The authors concluded that patients with elevated fear-avoidance beliefs at baseline experienced less disability with fear-avoidance treatment compared to standard treatment; however, those with reduced fear-avoidance fared worse with an increase in fear-avoidance with the fear-avoidance-based physical therapy. The work group downgraded this potential Level I study due to recruitment and small sample size. This study provides Level II evidence that fear avoidance-based physical therapy can improve outcomes more than standard physical therapy for treatment of acute LBP in patients with elevated fear-avoidance on screening questionnaire. Screening would be indicated as a blanket approach and would not work well without screening for fear avoidance.

George et al<sup>2</sup> later conducted another multicenter randomized controlled trial to compare physical therapy to physical therapy combined with graded exercise or graded exposure in patients with acute and subacute LBP. Eligible patients were randomized into a treatment-based classification (TBC) physical therapy group (n=36), TBC plus graded activity/exercise (GA) group (n=37), or TBC with graded exposure (GX) group (n=35). The participants in the TBC group received education and an individualized treatment. The participants in the GA group received treatment similar to the TBC group but augmented with gradually increased activity according to pain tolerance. The participants in the GA group first completed a questionnaire to indicate existing fear (such as lifting more than 20 pounds) which the therapist used to guide gradually-progressing activities to improve movements related to that goal. Questionnaires were administered at baseline, 4 weeks and 6 months which collected demographic information, disability per the Oswestry Disability Questionnaire (ODQ), fear-avoidance beliefs per the Fear-Avoidance Beliefs Questionnaire (FABQ) and pain catastrophizing per the Pain Catastrophizing Scale (PCS). Additionally, a blinded physical therapist used the physical impairment scale (PIS) at baseline and 4 weeks to quantify physical impairment. A total of 26, 22 and 24 participants com-

pleted the 6-month follow-up in the TBC, GA and GX groups, respectively. All groups experienced improvement in ODQ scores; however, there were no significant differences in improvements between groups. All groups had an improvement in FABQ scores; both TBC and GX showed significant decreases in pain-related fear ( $p < 0.01$ ). Intention to treat analyses showed similar results as the completers-only analyses. The authors concluded that in patients with LBP, adding GA or GX to TBC was not effective for improving outcomes. This study provides Level I evidence that treatment-based classification physical therapy supplemented with graded activity or graded exposure was not effective for improving outcomes related to the development of chronic LBP

Monticone et al<sup>3</sup> conducted a randomized, parallel-group, superiority-controlled trial to evaluate the efficacy of a CBT-based multidisciplinary program on perceived disability, kinesiophobia, pain and QoL in patients with nonspecific chronic LBP. Patients with LBP for >3 months were randomized to receive a program with exercise and CBT (n=45) or an exercise-only program (n=45). All participants received training on a 60-minute exercise program that involved active and passive spine mobilization, muscle strengthening and stretching and postural control twice a week for a 5-week instructive phase and were instructed to continue twice-weekly sessions independently for a year. The participants in the exercise and CBT (experimental) group additionally received a 60-minute CBT session under the supervision of a clinical psychologist once a week for 5 weeks followed by one session per month for a year. All participants completed questionnaires at baseline, after the 5-week instructive phase and then at 12 and 24 months. Questionnaires measured disability per the Roland-Morris Disability Questionnaire (RMDQ), fear-avoidance behaviors per the Tampa Scale for Kinesiophobia (TSK), pain using an 11-point numerical rating scale (NRS) and QoL per the Short-Form (36) Health Survey (SF-36). No patients dropped out during this study. The patients in the experimental group experienced significant improvements in RMDQ, TSK, NRS and SF-36 scores ( $p < 0.001$  for all). The authors concluded that the CBT and exercise program was superior to the program with exercise alone in reducing disability, fear-avoidance beliefs and pain and enhancing the quality of life of patients with chronic LBP. This study provides Level I evidence that cognitive behavior therapy specifically targeting FAB can improve outcomes of treatment for chronic LBP better than exercise alone for the first year.

Woods et al<sup>4</sup> conducted a randomized controlled trial to evaluate the effectiveness of a graded in vivo exposure (GivE) therapy program on improving self-efficacy and reducing fear, avoidance, emotional distress, perceived pain and perceived disability in patients with LBP. A total of 85 participants met inclusion criteria after recruitment through advertisement, had a score  $\geq 38$  on the Tampa Scale for Kinesiophobia (TSK) and were randomized into one of 3 groups: GivE (n=36), graded activity (n=25) and wait-list control (n=22). At baseline, each participant completed a questionnaire which included functional ability per the Pain Disability Index (PDI), ratings of pain and psychological factors per the Hospital Anxiety and Depression Scale (HADS), McGill Pain Questionnaire-Short Form (SF-MPQ), Pain Self-Efficacy Questionnaire (PSEQ), TSK, Fear Avoidance Belief Questionnaire (FABQ), short form of Pain Anxiety Symptoms Scale (PASS-20), Pain Catastrophising Scale (PCS) and the Working Alliance Inventory – Client Form (WAI). Participants in both treatment groups received 8 individualized 45-minute therapy sessions over the course of four weeks. The participants in the graded activity group received therapy from a Registered Physiotherapist along with positive reinforcement.

The participants in the GivE group received education about the cognitive-behavioral perspective on fear-avoidance and its consequences in addition to the same treatment as the graded activity group. The wait-list control group was offered participation at a later time. A total of 15, 13 and 16 participants completed the GivE, graded activity and wait-list control therapy programs, respectively. Per an intention-to-treat analysis, there were no significant differences in outcomes between GivE and graded activity. However, participants in the GivE group had significant improvements on the TSK ( $p = .011$ ), FABQ ( $p = .020$ ), PCS ( $p = .010$ ), HADS ( $p = .010$ ) and SF-MPQ ( $p = .030$ ) compared to the wait-list control group. With a complete case analysis, participants in the GivE group had significantly greater improvement in PSEQ ( $p=0.028$ ), TSK ( $p=0.008$ ), FABQ ( $p=0.027$ ) and PASS-20 ( $p=0.027$ ) compared to the graded activity group. The work group determined this study provides Level I evidence that graded activity exposure, targeted towards decreasing fear avoidance behavior compared to standard treatment or no treatment, can improve outcomes in patients with chronic LBP.



### Future Directions for Research

The work group recommends longer-term follow-up studies (one year or greater) to determine longitudinal benefits of treatments targeting fear avoidance.

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**Med/Psych Question 10.** Is active treatment (pharmacological or psychotherapeutic) of anxiety and depression effective in decreasing low back pain?

A systematic review of the literature yielded no studies to adequately address this question.



#### Future Directions for Research

The work group recommends consideration of a clinical trial to assess whether active treatment of depression or anxiety can improve back pain.



**Med/Psych Question 11.** What are the psychological factors influencing outcomes, including duration of pain, intensity of pain, functional outcomes and return-to-work status, of low back pain treatment?

It is suggested that kinesiophobia is a negative prognostic factor for predicting response to low back pain treatment.

**Grade of Recommendation: B**

Foster et al<sup>1</sup> conducted a prospective cohort study across 8 general practices to evaluate the association between psychological factors at the time of presentation of LBP as well as the psychological factors that predict clinical outcomes after 6 months. A total of 1,591 patients with LBP completed a questionnaire at baseline which included the Roland and Morris Disability Questionnaire (RMDQ) and questions related to sociodemographics and psychological factors. After 6 months, 810 patients completed the same questionnaire. At baseline, there were associations between RMDQ scores and 18 out of 20 of the psychological factors; the strongest correlations were found in perceptions of consequences (IPQ-R), depression (HADS) and pain self-efficacy (PSEQ). At 6 months, acute/chronic timeline, illness identity, perceptions of personal control and pain self-efficacy were significantly predictive of LBP outcomes (RMDQ) using a reduced multivariate model (n=761). The authors concluded that patients who experience these four psychological factors are more likely to have poor clinical outcomes. The work group determined that this study provides Level III evidence that perception of personal con-

trol, illness identity and pain self-efficacy were psychological factors that were predictive of outcomes of LBP treatment.

Helmhout et al<sup>2</sup> evaluated relationship of improvement of chronic LBP and baseline individual factors, pain-related factors, work-related psychosocial factors and psychological factors in a prospective cohort study of data from three randomized controlled trials. A total of 273 military employees, predominantly male, were recruited by a general practitioner or military advertisements. Each participant completed a questionnaire at baseline which included functional disability per the Roland-Morris Disability Questionnaire (RMDQ), details of LBP complaints (duration and pain radiation), fear of movement per the Tampa Scale for Kinesiophobia (TSK), psychological distress per the General Health Questionnaire (GHQ), perceived social and coworker support and degree of physical activity. Six months after treatment, participants completed the same questionnaire again along with perceived improvement (0-100%) or the Global Perceived Effect (GPE). Improvement was defined by

improvement of  $\geq 30\%$  on the RMDQ and an improvement of  $\geq 20\%$  of self-perceived improvement or a GPE score of “completely recovered” or “much improved.” Significant associations were found between long-term LBP improvement and RMDQ score of 4-7 (OR 2.29), RMDQ score  $\geq 11$  (OR 2.53) and TSK score (OR 0.97) at baseline. The authors concluded that individuals with a high level of baseline disability and fear avoidance behavior are at risk for poor long-term recovery from LBP and may need additional cognitive behavioral treatment. This study provides Level II evidence that kinesiophobia can negatively influence the outcomes of LBP treatment.

Keeley et al<sup>3</sup> conducted a prospective cohort study to assess the predictive relationship between both social and psychological factors at baseline with physical health-related quality of life (HRQoL) and health service utilization in patients with mechanical LBP. At baseline, each participant (n=108) completed a questionnaire that included demographic information, details of back pain, anxiety and depression symptoms per the Hospital Anxiety and Depression Scale (HADS), beliefs about the relationship between physical activity and LBP per the Fear-Avoidance Be-

liefs Questionnaire (FABQ) and social stress per the Life Events and Difficulties Schedule (LEDS). Physical HRQoL was measured at baseline and 6 months after initial assessment using the UK version of the 36-item Short-Form Health Survey (SF-36) Physical Component Score (PCS). Health care utilization was measured for 6 months after initial assessment using the Client Socio-Demographic and Service Receipt Inventory (CSSRI). At 6-month follow-up, baseline variables found to have a statistical significant prediction of physical HRQoL included duration of pain (standardized regression coefficient  $\beta=0.18$ ,  $p=0.04$ ), HADS score ( $\beta=0.27$ ,  $p=0.003$ ) and back pain related social difficulties ( $\beta=0.42$ ,  $p<0.0005$ ). Fear Avoidance Beliefs about work (Incident Rate Ratio [IRR]=1.02,  $p=0.009$ ), back pain related social difficulties (IRR=1.16,  $p=0.03$ ) and perceived cause of pain (IRR=1.46,  $p=0.03$ ) were independent predictors of number of health care contacts. The authors concluded that anxiety, depression, fear avoidance beliefs relating to work and back pain-related stresses are predictors of physical HRQoL and number of health care utilization contacts. This study provides Level III evidence that SF-36 scores improved in patients without fear avoidance behavior before treatment.



### Future Directions for Research

The work group recommends development of registries that collect information regarding psychological factors that can influence low back pain and quantitative analysis of this information.

### References

1. Foster NE, Thomas E, Bishop A, Dunn KM, Main CJ. Distinctiveness of psychological obstacles to recovery in low back pain patients in primary care. *Pain*. 2010;148(3):398-406.
2. Helmhout PH, Staal JB, Heymans MW, Harts CC, Hendriks EJ, Bie RA. Prognostic factors for perceived recovery or functional improvement in non-specific low back pain: secondary analyses of three randomized clinical trials. *Eur Spine J*. 2010;19(4):650-659.
3. Keeley P, Creed F, Tomenson B, Todd C, Borglin G, Dickens C. Psychosocial predictors of health-related quality of life and health service utilisation in people with chronic low back pain. *Pain*. 2008;135(1-2):142-150.



**Med/Psych Question 12.** In patients with low back pain, what psychosocial/cognitive/emotional or other assessments should be utilized to establish an accurate diagnosis?

**A systematic review of the literature yielded no studies to adequately address this question.**



#### Future Directions for Research

The work group recommends that future studies on the evaluation and management of LBP specifically identify psychological assessment that facilitate diagnostic accuracy.



**Med/Psych Question 13.** Does nutrition (other than weight reduction) influence the frequency of low back pain episodes?

\* This question focuses on healthy eating, nutrition/diet and not weight reduction.

**A systematic review of the literature yielded no studies to adequately address this question.**



#### Future Directions for Research

The work group recommends systematic evaluation of the role of nutrition and nutraceuticals in the management of LBP.

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**Follow-up rule for evidentiary review:** Follow-up must be at least 6 weeks after active treatment for study to be included unless otherwise noted



**PM&R Question 1.** In patients undergoing treatment for low back pain, what is the effectiveness of the following in decreasing the duration of pain, decreasing intensity of pain, increasing functional outcomes and improving return-to-work status, as compared with natural history plus or minus medication:

**PM&R Question 2.** In patients undergoing treatment for low back pain, what is the appropriate timing, frequency and duration of treatment with:

- a. Acute versus subacute versus chronic
  - i. patient education and self-directed exercise program

### Q1 Recommendations:

**Back school is recommended to provide improvements in pain and function when compared with general medical care, modality care or a simple handout at 6-12 months' follow-up for chronic low back pain.**

**Grade of Recommendation: A**

### Q1 Evidence Summary:

In a randomized controlled trial of patients with chronic low back pain (LBP), Durmus et al<sup>1</sup> evaluated the effectiveness of the addition of back school to a modified exercise program. Participants were randomized to receive an exercise program with back school (n=61) or exercise alone (n=60) 3 days a week for 3 months. Pain (Visual Analog Scale, VAS) and disability (Oswestry Disability Questionnaire) were recorded at baseline, immediately after treatment and at 6-month follow-up. The participants who received back school in addition to exercise had significantly

greater improvements in pain and disability. The authors concluded that modified exercise programs can be used to treat chronic LBP and that the addition of back school can further increase the effect. This study provides Level I therapeutic evidence that the addition of low back school to an exercise program improves pain and function at 6 months.

Hurri et al<sup>2</sup> evaluated the effect of a Swedish-type back school in patients with chronic LBP in a randomized controlled trial. Female patients with LBP for at least

12 months were invited to participate and randomized into a treatment group (n=95) or control group (n=93). Patients in the treatment group completed 6 60-minute exercise and education sessions over three weeks plus 2 additional 60-minute review classes after 6 months. The control group received written materials and otherwise continued regular follow-up healthcare services. Pain (VAS and low back pain index), disability (Oswestry Disability Questionnaire), spinal mobility and strength, and length of sick leave were recorded at baseline and at 6- and 12-month follow-up. The treatment group experienced significantly greater improvements in pain, disability and mobility compared to the control group at 12-month follow-up. The authors concluded that patients with chronic or recurrent LBP may get relief of subjective symptoms from back school. This study offers Level I therapeutic evidence that for women with nonspecific chronic LBP, a back school regimen of education and exercise 6 times in 3 weeks and reviewed with 2 sessions at 6 months improves pain and disability at 6 months compared to education booklet controls. Though clinically meaningful improvements were only seen for pain at 6 months; the intervention group did not have improvements in sick leave or other medical treatment.

Jaromi et al<sup>3</sup> conducted a randomized controlled trial to assess the effectiveness of a spine training program (Back School) in nurses with chronic LBP. Participants randomized to the control group (n=55) received passive physiotherapy once a week for 6 weeks. The intervention group (n=56) received ergonomics training and an educational Back School program. Pain intensity (VAS) and body posture (Zebris biomechanical motion analysis) were recorded at baseline, immediately after treatment and at 6- and 12-month

follow-up. The participants in the intervention group had significantly greater improvements in back pain intensity at both follow-up points and significantly greater improvement in back posture. The authors concluded that back school, including active physical therapy methods, can significantly improve pain intensity and body posture in nurses with LBP. This study provides Level I therapeutic evidence that for health care workers with nonspecific chronic LBP, back school one time per week for 6 weeks is effective at decreasing pain at the end of treatment, 6- and 12-month follow-up. Passive PT in the same study showed improvement in pain only at the end of treatment. The results retained clinically meaningful levels at 6 and 12 months for the treatment group as compared to the control group.

In a randomized controlled trial, Morone et al<sup>4</sup> evaluated the effects of a multidisciplinary back school program in patients with chronic LBP. Patients with LBP for at least 3 months were randomized to participate in 4 weeks of either a multidisciplinary Back School program with education and exercises (n=44) or a control group with medical assistance (n=29). Quality of life (Short Form 36), disability (Waddell Disability Index and Oswestry Disability Index) and pain perceptions (VAS) were recorded at baseline, after treatment completion and at 3- and 6-month follow-up. The Back School participants had significantly greater improvements in quality of life, disability and pain perception. The authors concluded that the Back School program investigated can be an effective treatment in people with chronic nonspecific LBP. This study provides Level I therapeutic evidence that a back school program can improve quality of life, disability and pain in nonspecific chronic LBP compared to supportive medical care control.

**There is insufficient evidence that outcomes from a home-based exercise program are different than no care.**

**Grade of Recommendation: I**

Kuukkanen et al<sup>5</sup> conducted a randomized controlled trial and 5-year follow-up to evaluate the long-term effectiveness of a home exercise program in relieving pain and improving function in patients with chronic LBP. Participants with LBP for at least 3 years were randomized into a home exercise group (n=29) or control group with no exercise (n=28). LBP intensity (Borg CR-10 scale) and function (Oswestry Disability

Index) were recorded at baseline and at 5-year follow-up. LBP intensity and function improved in both groups after 3 months; pain intensity remained significantly lower in the home exercise group compared to the control group at 5-year follow-up. The authors concluded that supervised, controlled home exercises can reduce LBP over 5 years. This study was downgraded to Level II due its small sample and provides

**102** Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

therapeutic evidence that, in patients with low-level baseline pain and disability, a home exercise program provides pain improvements at 5-year follow-up. There was no statistically significant difference in function as compared with no treatment.

In a multicenter, randomized controlled trial, Shirado et al<sup>6</sup> evaluated the effectiveness of home-based exercise on pain, dysfunction and quality of life (QOL) in Japanese individuals with chronic LBP. Participants were randomized to a treatment group to complete trunk muscle strengthening and stretching exercises (n=103) or a control group to be treated with nonsteroidal anti-inflammatory drugs (n=98). Pain intensity (VAS) and dysfunction (Japan Low back pain Evaluation Questionnaire and Roland-Morris Disability

Questionnaire, RMDQ) were recorded at baseline, after treatment and at 6- and 12-month follow-up. Both groups experienced improvement in pain and dysfunction; however, the exercise treatment group had a statistically significantly greater improvement in function (95% confidence interval for the difference of median of change ratio was from -0.33 to 0.00). The authors concluded that the home-based exercise program was more effective than nonsteroidal anti-inflammatory drugs in Japanese patients with chronic LBP. This study offers Level I therapeutic evidence that a home-based program with frequent physician oversight resulted in significantly better function and similar pain outcomes at one year compared to nonsteroidal anti-inflammatory drugs.

**There is insufficient evidence that a *self-directed* McKenzie exercise program for acute low back pain results in different outcomes compared to usual medical care.**

**Grade of Recommendation: I**

In a randomized controlled trial, Underwood et al<sup>7</sup> examined the effectiveness of teaching back exercises based on the McKenzie approach in addition to usual care for acute LBP. Patients with acute LBP for less than 28 days were randomized to attend a group back class (n=35) or receive conventional management (n=40). Disability (Oswestry disability score) and pain (VAS) were recorded at baseline and 4, 8, 12 and 52 weeks after study enrollment. There were no

differences in the primary outcome measures for pain or disability between groups. The authors concluded that the back class was not effective compared to conventional care. The sample size was small and the study was underpowered. This study provides Level II therapeutic evidence that there is no difference in pain or disability scores in patients with acute LBP treated with a McKenzie exercise program compared to usual care.

**There is insufficient evidence that a monitored pedometer-based exercise program with web-based feedback provides any improvement over pedometer instruction alone.**

**Grade of Recommendation: I**

Krein et al<sup>8</sup> conducted a randomized controlled trial to determine whether a pedometer-based internet-mediated program can reduce disability due to chronic back pain. After trial enrollment, veterans with nonspecific chronic back pain received a pedometer. The intervention group (n=111) also received access to a website with walking goals, feedback, motivational messages and social support, while the control group (n=118) did not. Disability (Roland Morris Disability Questionnaire) was recorded at baseline and at 6-

and 12-month follow-up. The results showed slight improvement in the intervention group. This was statistically significant at 6 months but not at one year and in neither case was the difference clinically meaningful. This study provides Level I evidence that a walking program resulted in improved function, but the addition of internet based instruction and motivation did not make a clinically meaningful difference in improvement.



**Q2 Evidence Summary:**

A systematic review of the literature yielded no studies to adequately address this question.

**Q1&2 Future Directions for Research**

The work group recommends development of additional studies to corroborate or dispute the existing evidence base. Opportunities exist for technology-assisted exercise monitoring.

**PM&R Questions 1 & 2.**

- ii. Physical agents (eg, heat, cold, ultrasound, electrical stimulation, laser, dry needling, traction, TENS)
  - a. heat/cold

*Note: 6-week follow-up rule does not apply*

**Q1 Recommendation:**

It is suggested that the use of heat for acute low back pain results in short-term improvements in pain.

**Grade of Recommendation: B**

**Q1 Evidence Summary:**

Dehghan and Farahbod<sup>9</sup> studied the efficacy of thermotherapy and cryotherapy added to pharmacologic treatment in a randomized trial of patients with LBP. Patients with LBP for less than one month received 500 mg naproxen twice daily and were randomized to receive additional thermotherapy (hot water bag), cryotherapy (ice), or naproxen only (n=29 in each group) for one week. Pain (McGill Pain Questionnaire) was recorded at baseline and on the 3rd, 8th and 15th day after enrollment. Pain significantly reduced in the thermotherapy and cryotherapy groups by the second visit; the thermotherapy group had significantly greater reductions than the cryotherapy group. The authors concluded that thermotherapy and cryotherapy are effective in the short-term to help reduce pain in patients with acute LBP. This study provides Level II evidence that addition of heat or cold to an NSAID results in improved outcomes for pain compared to NSAID alone for acute back patients at 3 weeks.

Kettenman<sup>10</sup> et al conducted a randomized controlled trial to determine the efficacy of heat therapy in

patients with LBP. Patients with LBP for less than 3 months were randomized to the intervention group with heat-wrap therapy for at least 4 hours a day for 4 consecutive days (n=15) or control group without heat therapy (n=15). Both groups received nonsteroidal anti-inflammatory drugs (NSAIDs) to use as needed. Subjective reports of sleep, well-being and pain intensity (Pain, Sleep and Stress Questionnaire) were recorded in a patient diary and the power of frequency bands in the spontaneous electroencephalogram (EEG) were recorded on days 2 and 4. The patients in the heat therapy group reported significantly improved pain, less stressful everyday situations and sleep. EEG-recordings in the heat group indicated reduced arousal as evidenced by decreased power in frequency bands. The authors concluded that heat therapy resulted in improved pain, psychophysical measures and objective measures that suggest acute therapeutic relaxation. This study provides Level II evidence that addition of heat therapy to NSAIDs results in better pain scores than NSAIDs alone in patients with acute back pain at 4-week follow-up.

In a randomized controlled trial, Mayer<sup>11</sup> et al investigated the effect of combining continuous low-level heat wrap therapy with directional preference-based exercises on functional outcomes in patients with acute LBP. Patients with LBP for less than 3 months were randomized to receive 5 consecutive days of heat wrap therapy alone (n=25), exercise alone (n=25), heat wrap plus exercise (n=24) or a control group booklet (n=26). Functional improvement (0–200 Rating of Perceived Capacity–Spine), disability (Roland–Morris Disability Questionnaire) and pain (6–point verbal rating scale) were recorded at baseline and day 2, 3 and 7 follow-ups. The combination of heat wrap plus exercise resulted in significantly greater improvements in function, disability and pain relief compared to each individual treatment or control. The authors concluded that a combination of heat wrap therapy with directional preference-based exercise is more effective for the treatment of LBP compared to either intervention alone or control treatment (booklet). This study provides Level II evidence that heat and exercise together result in better pain scores than heat or exercise alone in patients with acute back pain at 7-day follow-up.

Nadler et al<sup>12</sup> aimed to determine the efficacy of continuous low-level heat wrap therapy for the treatment of acute nonspecific LBP in a randomized, parallel, single-blind, placebo-controlled, multicenter clinical trial. Patients with acute LBP for less than 3 months were randomized to receive 3 consecutive days of heat wrap therapy for 8 consecutive hours per day (n=95), oral placebo (n=96), oral ibuprofen (n=12) or unheated back wrap (n=16) after being stratified by baseline pain and gender. Pain (0–5-point verbal response scale), muscle stiffness (numeric rating scale), lateral trunk flexibility and disability (Roland–Morris Disability Questionnaire) were recorded over the course of the 3-day treatment and 2 days of follow-up. The patients in the heat wrap group had significantly greater pain relief, less muscle stiffness, increased flexibility and reduced disability. The authors concluded that continuous low-level heat wrap therapy was effective for the treatment of acute, nonspecific LBP. This study provides Level II evidence that heat wrap results in better pain and disability scores as compared to oral placebo in patients with acute back pain. Heat wrap results in better pain scores than placebo heat wrap or NSAIDs.

Nadler et al<sup>13</sup> studied the safety and efficacy of eight hours of continuous overnight low-level heat wrap therapy for the treatment of LBP in a randomized, single-blind, placebo-controlled, multicenter clin-

ical trial. Patients with LBP for less than 3 months were randomized to receive 3 consecutive days of heat wrap therapy (n=33), oral placebo (n=34), unheated wrap (n=5) or oral ibuprofen (n=4) after being stratified for baseline pain and gender. Morning pain relief (0–5-point verbal response scale), daytime pain relief, extended pain relief, muscle stiffness, lateral trunk flexibility, and disability (Roland–Morris Disability Questionnaire) were recorded on days 2 through 4. All outcomes were significantly improved in the heat wrap group. The authors concluded that use of a heat wrap overnight resulted in improved pain relief, less muscle stiffness and disability and improved flexibility sustained more than 48 hours after treatment completion. This study provides Level II evidence that overnight heat wrap results in better pain and disability scores as compared to oral placebo in patients with acute back pain.

Shakoor et al<sup>14</sup> investigated the effects of deep heat therapy for the treatment of patients with chronic LBP. Patients with LBP for more than 3 months were randomized to receive nonsteroidal anti-inflammatory drugs (NSAIDs) and short-wave diathermy (n=50) or NSAIDs and placebo short-wave diathermy (n=52). Pain intensity, disability and physical impairment were assessed using the Lettinen Test Scores and VAS. Both groups experienced improvements, with significantly greater improvements in the short wave diathermy group compared to the placebo group at weeks 3 and 6. The authors concluded that although both interventions may be beneficial for the treatment of LBP, treatment with short wave diathermy added to NSAID use may be more beneficial than NSAID use alone. This study provides Level II evidence that diathermy, exercise and NSAIDs results in nonsignificant improvement in VAS scores at 6 weeks relative to sham, exercise and NSAIDs for treatment of chronic LBP.

Tao et al<sup>15</sup> conducted a randomized controlled trial to study the effects of an education program with or without heat wrap therapy in patients with acute LBP. Patients with work-related LBP for less than 3 months were randomized to receive back therapy education and pain management (n=18) or back therapy education, pain management and 3 consecutive days of 8-hour heat therapy (n=25). Pain intensity, pain relief and disability were recorded at baseline, 4 times per day for the 3-day treatment period and 4 and 14 days after enrollment. The patients in the heat wrap group had significantly reduced pain intensity, increased pain relief and improved disability scores during and after treatment. In critique, the work group down-

graded this potential Level I study due to small sample size. This study provides Level II evidence that heat

wrap significantly reduced pain intensity, increased pain relief and improved disability scores compared to placebo.

## Q2 Evidence Summary:

A systematic review of the literature yielded no studies to adequately address this question.



### Q1&2 Future Directions for Research

The work group does not have any recommendations for future research on this topic.



### PM&R Questions 1 & 2.

- ii. Physical agents (eg, heat, cold, ultrasound, electrical stimulation, laser, dry needling, traction, TENS)
- b. ultrasound

## Q1 Recommendations:

In patients with chronic low back pain, ultrasound is not recommended to improve functional outcomes.

Grade of Recommendation: A

There is conflicting evidence that ultrasound provides immediate pain relief in patients with chronic low back pain.

Grade of Recommendation: I

## Q1 Evidence Summary:

Durmus et al<sup>16</sup> investigated the effects of phonophoresis and ultrasound therapy in patients with chronic LBP. Patients with LBP for at least 3 months were randomized to the control group to receive exercise only (n=20), ultrasound plus exercise (n=20), or phonophoresis plus exercise (n=20), 3 days a week for 6 weeks. Pain (VAS), disability (Oswestry Disability Questionnaire and pain disability index), walking performance, depression (Beck Depression Inventory scores), quality of life (SF-36), and muscle strength and endurance were recorded before and after treatment. All groups had improvements in outcomes. The ultrasound and phonophoresis groups had statistically significant greater improvements in pain, walking performance and extensor muscle strength compared to the control group, although not necessarily clinically

important improvement. The authors concluded that both ultrasound and phonophoresis were effective treatments for patients with chronic LBP. Baseline impairment was mild and sample size was small. This study provides Level II therapeutic evidence that, in patients with LBP, addition of ultrasound therapy to exercise program provides questionable immediate clinically-important reduction in pain, but not disability compared to exercise alone.

Ebadi et al<sup>17</sup> compared the effect of exercise plus continuous versus placebo ultrasound in patients with chronic LBP in a randomized controlled trial. Patients with nonspecific chronic LBP were randomized to receive 10 treatment sessions, 3 times per week (every other day) for 4 weeks of continuous ultrasound

**106** Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

(n=25) or placebo ultrasound (n=25). All participants were instructed to perform a semi-supervised exercise program consisting of stretching and strengthening exercises daily during the trial and for one month after treatment. Functional disability (Functional Rating Index) and global pain (VAS) were among the outcomes measured upon enrollment, after treatment and after one-month follow-up. Intention-to-treat analysis found that both groups experienced improved function and pain. The Time x Group inter-

actions for pain and function were not statistically significant. The main effect of Group on Functional Rating Index was significant. The authors concluded that continuous ultrasound added to an exercise program improved function, lumbar range of motion and endurance time. This study provides Level I therapeutic evidence that, in patients with LBP, there is no difference in pain and function between ultrasound plus exercise compared to placebo ultrasound.

## Q2 Evidence Summary:

**A systematic review of the literature yielded no studies to adequately address this question.**



### Q1&2 Future Directions for Research

The work group does not have any recommendations for future research on this topic.



### PM&R Questions 1 & 2.

- ii. Physical agents (eg, heat, cold, ultrasound, electrical stimulation, laser, dry needling, traction, TENS)
- c. Transcutaneous Electrical Nerve Stimulation (TENS)

## Q1 Recommendation:

**There is conflicting evidence that transcutaneous electrical nerve stimulation (TENS) results in improvement in pain or function at short- to medium-term follow-up.**

**Grade of Recommendation: I**

## Q1 Evidence Summary:

Herman et al<sup>18</sup> conducted a randomized controlled trial to evaluate the effectiveness of a standard exercise program with or without transcutaneous electrical nerve stimulation (TENS) in patients with industry-related acute LBP. Patients with LBP from a work-related injury with a duration of 3-10 weeks were randomized to receive TENS (n=29) or placebo stimulation (n=29) in addition to an exercise program. Disability (Roland-Morris disability questionnaire) and pain (VAS) were recorded before and after each treatment session and 4 weeks after enrollment. Return to work was assessed at 5 weeks and 6 months after enrollment. There were no significant differences in outcomes between groups. The authors concluded that there were no additional benefits of TENS

when added to an exercise program. This study was limited by significant number of dropouts. This study provides Level II evidence that there are no additional benefits from TENS when added to exercise treatment for industrial-related LBP.

In a randomized controlled trial, Weiner et al<sup>19</sup> studied the effectiveness of percutaneous electrical nerve stimulation (PENS) for the treatment of chronic LBP. Patients with LBP for at least 3 months were randomized to receive twice-weekly PENS (n=17) or sham PENS (n=17) in addition to physical therapy for 6 weeks. Pain intensity (McGill Pain Questionnaire) and disability (Roland-Morris Back Pain Disability Questionnaire) were assessed at baseline, immediately after the 6-week treatment period and after 3 months.

The patients who received PENS had statistically significant reductions in pain intensity and disability at both follow-up points, while the sham PENS group did not. The study was limited by a small sample size. This study provides Level II evidence that percutaneous electrical nerve stimulation added to an exercise program resulted in significant improvement in pain and function at 3 months in geriatric patients with chronic LBP.

Weiner et al<sup>20</sup> investigated the effectiveness of percutaneous electrical nerve stimulation (PENS) for the treatment of chronic LBP in a randomized controlled trial. Patients with chronic LBP were randomized to receive one of 4 treatments twice weekly for 6 weeks: PENS (n=50), control-PENS (n=50), PENS plus general conditioning and aerobic exercise (n=50), or control-PENS plus general conditioning and aerobic exercise (n=50). Control-PENS consisted of brief electrical stimulation. Pain (McGill Pain Questionnaire) and disability (Roland Morris Questionnaire) were recorded at baseline, within one week of completing the intervention and 6 months after completing the intervention. All groups experienced improved pain and disability at 6 months. The authors concluded that the exact dose of electrical stimulation required for analgesia cannot be determined. This study provides Level I evidence that PENS and a modified PENS as the sham resulted in significant improvements in pain and function that did not improve with exercise in a geriatric population with chronic LBP at 6 months follow-up, although the addition of exercise did seem to improve fear avoidance in particular.

Deyo et al<sup>21</sup> compared the effect of transcutaneous electrical nerve stimulation (TENS), a program of stretching exercises, or a combination of both for the treatment of chronic LBP. Patients with LBP for at least 3 months were randomized to receive TENS (n=36), sham TENS (n=36), TENS plus exercises (n=37), or sham TENS plus exercises (n=36). Patients assigned to TENS received instructions for home-use of at least 3 45-minute TENS sessions per day. Patients allocated to receive exercise received instructions for a daily structured exercise sequence, adding one new exercise each day. Functional status (modified Sickness Impact Profile), self-reported activity level, pain (ordinal and VAS for pain, improvement and frequency) pain scale) and physical measures were recorded at baseline, after 2 and 4 weeks of therapy and 2-month follow-up after completion of the trial. There were no significant differences in outcomes in those who received TENS and no interactive effect of TENS with exercise. The authors concluded that TENS is no more

effective than placebo and adds no additional benefit to exercise alone. This study provides Level I therapeutic evidence that TENS does not provide improvement in pain in patients with chronic LBP.

In a randomized double-blind crossover study, Jarzem et al<sup>22</sup> compared transcutaneous electrical nerve stimulation (TENS) to sham therapy in patients with chronic LBP. Patients with LBP for at least 3 months were randomized to receive TENS followed by 2 treatments of sham TENS (n=25) or sham treatment followed by 2 treatments of conventional TENS (n=25). Pain tolerance (VAS) and physical measurements were recorded upon enrollment and within an hour after each treatment. There were significant improvements in pain and physical measurements after TENS compared to sham treatment. These measurements were usually done within an hour of treatment. Durable effects from treatment were not evaluated. The authors concluded that TENS significantly reduces pain and improves physical performance on the studied measurements and should be considered for short-term pain relief. This study offers Level I therapeutic evidence that TENS provides immediate relief in patients with chronic LBP.

Marchand et al<sup>23</sup> aimed to compare the effect of transcutaneous electrical nerve stimulation (TENS), placebo-TENS and no treatment in patients with chronic LBP. Patients with LBP for more than 6 months were allocated into one of 3 groups using a pseudo-random assignment to control for sex, weight, diagnosis and pain severity. Patients presented to the clinic twice weekly for ten weeks to receive TENS (n=14), placebo-TENS (n=12), or no treatment (n=16). Pain intensity and unpleasantness (VAS) were recorded before and after each treatment, as well as every two hours at home during 3-day periods before treatment, 1 week after treatment and 3 and 6 months after treatment. Both TENS and placebo-TENS reduced pain intensity and unpleasantness. TENS reduced pain intensity significantly more than placebo-TENS immediately after treatment sessions and one week after sessions, but not 3 months or 6 months after. The authors concluded that TENS should be used as a short-term treatment as part of a multidisciplinary program for LBP. In critique of the methodology, this potential Level I study was downgraded due to small sample size. This study provides Level II therapeutic evidence that TENS provides immediate term pain relief in patients with chronic LBP.

Thompson et al<sup>24</sup> conducted a double-blind randomized controlled trial to study the effect of transcuta-

neous spinal electroanalgesia (TSE) in patients with LBP. Patients with LBP for greater than one year were randomized to blindly receive a single 20-minute treatment of TSE (n=29) or sham treatment (n=29). Pain (VAS) was recorded every day of the week prior to and following treatment as well as immediately before and after the treatment session. There were no significant differences in pain scores between TSE and sham after treatment. The authors concluded that a single 20-minute treatment of TSE does not signifi-

cantly impact pain in patients with LBP. This technique has some similarity to TENS, but can be run at higher frequencies. This study is limited by the fact that patients received only one dose. This study provides Level I therapeutic evidence that a single dose of transcutaneous spinal electroanalgesia did result in short-term pain relief when compared to placebo in patients with chronic LBP.

## Q2 Evidence Summary:

**A systematic review of the literature yielded no studies to adequately address this question.**



### Q1&2 Future Directions for Research

The work group recommends randomized clinical trials with long-term follow-up looking at the benefits of TENS compared to exercise/physical therapy, or the addition of TENS to usual care of LBP.



### PM&R Questions 1 & 2.

- ii. Physical agents (eg, heat, cold, ultrasound, electrical stimulation, laser, dry needling, traction, TENS)
- d. Laser (Cutaneous stimulation for purpose of pain modulation)

## Q1 Recommendations:

**Laser acupuncture provides no short-term or medium-term benefit over sham treatment for patients with chronic low back pain.**

**Grade or Recommendation: A**

## Q1 Evidence Summary:

Glazov et al<sup>25</sup> studied the effect of laser acupuncture for the treatment of chronic LBP in a double blind randomized controlled trial. Patients with LBP for at least three months were randomized to receive 5-10 treatments (0.2 Joules/point) of laser acupuncture (n=50) or sham control (n=50). All treatments were provided by a single blinded investigator. Pain (VAS) and disability were recorded at baseline and at the end of the 6-week treatment period and pain was also evaluated at 6 months follow-up after completion along with a global assessment. Baseline pain (5.2 to 6.2) and disability scores (25 to 35) were moderate. Forty-five out of 50 patients in each group were evaluated at the final follow-up. All participants experienced improvements in outcomes, but there were no significant dif-

ferences between groups. Improvements were modest and not clinically important for functional scores. The authors concluded that laser acupuncture does not have a specific effect for the treatment of chronic LBP. This study offers Level I therapeutic evidence that for patients with chronic and moderately severe LBP, laser acupuncture provides no benefit over sham treatment at short-term follow-up.

Glazov et al<sup>26</sup> later conducted another double-blind controlled trial to investigate the effect of different doses of laser acupuncture in reducing pain and disability in patients with chronic LBP. Patients with LBP for at least 3 months were randomized to receive one session per week for 8 weeks of high-dose (0.8 Joules/

point) laser acupuncture (n=48), low-dose (0.2 Joules/point) laser acupuncture (n=48) or sham (0 Joules/point) laser acupuncture (n=48). Treatment was provided by experienced general practitioners at six different general practices. Pain (Numerical Pain Rating Scale) and disability (Oswestry Disability Inventory) were recorded at baseline, one and 6 weeks into the treatment period and 6 months post-treatment. Pain was also recorded 12 months post treatment. Baseline

pain (means 4.9 to 5.3) and function (mean ODI 26 to 27) scores were moderate. Final analysis was done for 42, 40 and 45 patients respectively. All groups experienced improvements in pain and disability, but there were no differences in outcomes between groups. Improvements in function were statistically significant, but not clinically important. This study offers Level I therapeutic evidence that laser acupuncture provides no short- or medium-term benefit over sham treatment in patients with moderately severe chronic LBP.

**It is suggested that the combination of laser therapy (low-level or high-level) with exercise provides better short-term relief of *pain* than either exercise or laser therapy alone.**

**Grade of Recommendation: B**

**There is conflicting evidence that the combination of laser therapy with exercise provides better short-term improvement in *function* compared to exercise or laser therapy alone.**

**Grade of Recommendation: I**

**It is suggested that there is no short-term benefit of laser therapy (low-level or high-level) when compared with exercise alone.**

**Grade of Recommendation: B**

Alayat et al<sup>27</sup> compared the effect of high-intensity laser therapy (HILT) in patients with chronic LBP in a randomized controlled trial. Patients in the male section of a single rehabilitation department with LBP for at least one year were randomized to receive twelve 15-minute sessions over 4 weeks of HILT plus a home exercise program to be completed twice daily for 4 weeks (n=28), placebo laser plus exercise (n=24), or HILT alone (n=20). Range of motion, pain (VAS), functional disability (Roland Morris Disability Questionnaire and Modified Oswestry Disability Questionnaire) were recorded at baseline, after the 4-week treatment period and at 12-week follow-up from the start of treatment. All groups experienced improved pain and disability, with no significant differences in disability between groups. The HILT plus exercise group experienced a clinically meaningful and statistically significantly greater decrease in pain compared to the HILT only group. The authors concluded that HILT combined with exercise is more effective than HILT or exercise alone for the treatment of chronic LBP. The study is limited by potential problems with compliance with home exercise program and its short duration of follow-up (8 weeks after conclusion of treatment). This study offers Level I therapeutic evidence that combination of high-intensity laser therapy (HILT) plus exercise provides short-term increased pain relief and function as compared to HILT

or home exercise alone. Home exercise alone provides increased pain relief but no difference in function over HILT alone.

Djavid et al<sup>28</sup> conducted a randomized trial to investigate the effect of low-level laser therapy for the treatment of chronic LBP. Patients referred to a single occupational medicine department with LBP for at least 12 weeks were randomized to receive laser therapy (n=20), laser therapy plus exercise (n=21) or placebo laser therapy plus exercise (n=20). The exercise program consisted of a home program of strengthening, stretching, mobilizing and stabilization exercises. Laser therapy was performed twice weekly for 6 weeks. Pain severity (VAS), range of motion and disability (Oswestry Disability Index) was recorded at baseline, immediately following the 6-week treatment period and 6 weeks after completion of the trial. Baseline disability was moderate (ODI low 30s). There were 8 dropouts and no power analysis was done for sample size. There were no significant differences in outcomes between laser therapy alone and exercise plus sham. At 12 weeks (6 weeks following conclusion of treatment), the laser therapy plus exercise group had significantly improved pain, range of motion and disability compared to the exercise plus sham group. The authors concluded that low-level laser therapy plus exercise is more beneficial than exercise plus sham.

**110** Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

The study was downgraded for small effect size and small sample size. This study provides Level II therapeutic evidence that, at short-term follow-up, laser plus exercise provided more pain relief and improved

disability compared to exercise plus sham laser. There is no short-term benefit of low-level laser alone as compared to exercise plus sham laser.

## Q2 Evidence Summary:

**A systematic review of the literature yielded no studies to adequately address this question.**



### Q1&2 Future Directions for Research

The work group recommends that current studies be supported by larger sample sizes with longer follow-up.



### PM&R Questions 1 & 2.

- ii. Physical agents (eg, heat, cold, ultrasound, electrical stimulation, laser, dry needling, traction, TENS)
- e. Traction

## Q1 Recommendation:

**In patients with subacute or chronic low back pain, traction is not recommended to provide clinically significant improvements in pain or function.**

**Grade of Recommendation: A**

## Q1 Evidence Summary:

Borman, et al<sup>29</sup> conducted a randomized controlled study to determine the efficacy of traction in the treatment of LBP. Patients with LBP for at least 6 weeks were randomized to receive ten sessions of standard physical therapy of heat, ultrasound and active exercise (n=21) or standard physical therapy with conventional lumbar traction (n=21). Disability (Oswestry Disability Index) and pain (VAS) were recorded at baseline, at the end of the intervention and 3-month follow-up. Both groups experienced improvement in pain and disability after treatment, with no significant differences between groups. The authors concluded that traction has no specific effect on standard physical therapy. The work group downgraded this potential Level I study during critique of the methodology due to small sample size and for 35% of participants receiving another treatment during the 3-month follow-up period. This study provides Level II evidence that there was no efficacy in adding traction to a standard physical therapy protocol of passive and active intervention.

Diab et al<sup>30</sup> investigated the effect of lumbar extension traction on pain, function and whole spine sagittal balance in patients with chronic LBP. Patients with LBP for greater than three months were randomly allocated to a control group (n=40) to receive stretching exercises and infrared radiation or a traction group (n=40) to receive 3 sessions a week of lumbar extension traction for 10 weeks in addition to the same stretching exercises and infrared radiation. Pain (Back Pain Rating Scale), disability (Oswestry Disability Index) and radiological spine sagittal balance parameters were recorded at baseline, after the 10-week treatment period and 6-month follow-up. Their primary measure was radiographic outcomes. There were significant differences in pain and disability at 6-month follow-up, but not immediately after the 10-week treatment period. However, the actual change in lordosis was 4° and sacral slope 1° with substantial overlap in standard deviations. Mean ODI scores (32 and 31) and pain scores (6 and 5.5) revealed moderate severity. There were improvements in both



groups and while statistically different, the differences do not appear to be clinically important. The authors concluded that the addition of lumbar extension to stretching exercises and infrared radiation resulted in improvements in spine sagittal balance parameters, pain and disability. This study provides Level I evidence that extension traction added to an exercise program and infrared heat to treat patients with chronic LBP with moderate pain and disability results in statistically better but clinically insignificant improvement in pain and disability at 6-month follow-up.

Schimmel et al<sup>31</sup> conducted a randomized controlled trial to study the effect of adding Intervertebral Differential Dynamics (IDD) therapy to standard graded activity program for the treatment of chronic LBP. Patients with LBP for more than 3 months were randomized to receive sham therapy (n=29) or IDD Ther-

apy which included intermittent traction sessions in the AccuSPINA device (n=31). During the first 6 weeks, all participants received 20 sessions of their assigned sham or IDD Therapy. A standard graded activity program was added after two weeks for both groups and consisted of one-hour sessions twice weekly for 12 weeks. Pain (100-mm VAS), disability (Oswestry Disability Index), quality of life (SF-36) and fear of movement (Tampa Scale for Kinesiophobia) were recorded upon enrollment and 2, 6 and 14 weeks after initiation of the treatment. Improvements in outcomes were seen in both groups. The authors concluded that the addition of intermittent, mechanical traction added to standard graded activity is not effective. This study provides Level I evidence that the addition of intermittent traction with the AccuSPINA device versus sham when coupled with graded activity does not result in improved pain or disability scores in patients with chronic LBP at short-term follow-up.

## Q2 Evidence Summary:

A systematic review of the literature yielded no studies to adequately address this question.



### Q1&2 Future Directions for Research

The work group does not have any recommendations for future research on this topic.



### PM&R Questions 1 & 2.

- ii. Physical agents (eg, heat, cold, ultrasound, electrical stimulation, laser, dry needling, traction, TENS)
- f. Dry needling

## Q1 Recommendation:

There is insufficient evidence for or against the use of dry needling as a treatment option for patients with chronic low back pain.

Grade of Recommendation: I

## Q1 Evidence Summary:

Gunn et al<sup>32</sup> conducted a clinical trial to evaluate the effect of dry needling in patients with chronic LBP. Patients (men only) with LBP for at least 12 weeks were randomized to receive standard therapy plus dry needling 1-2 times per week at muscle motor points

(n=29) or standard therapy alone (n=27). Standard therapy included physiotherapy, exercise and occupational therapy. Pain and work status were classified as 0 (no improvement), + (some improvement), ++ (good improvement) or +++ (total improvement). The patient's status was recorded at baseline, at time of discharge, 12 weeks post-discharge and again when

**112** Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

contacted at the time of writing the report (12–61 weeks, average 27.3 weeks). The group that received dry needling in addition to standard therapy significantly improved compared to standard therapy alone at time of discharge and both follow-up points. The authors concluded that the addition of dry needling to standard care seems justified for the treatment of chronic LBP in patients with myofascial pain. In critique, study outcome measures are poorly defined and not validated. Sample size was small without pow-

er analysis. This was a mix of subacute patients with symptoms present for as little as 12 weeks combined with patients that had symptoms for years, with a mean of 27 weeks. Lastly the randomization was constrained to randomization in blocks of 2. Due to flaws in randomization methodology, the study started as a Level II design and was downgraded to Level III. This study offers Level III therapeutic evidence that, in patients with LBP, addition of dry needling to a comprehensive exercise program results in greater improvement than exercise alone.

### Q2 Evidence Summary:

**A systematic review of the literature yielded no studies to adequately address this question.**



#### Q1&2 Future Directions for Research

The work group recommends undertaking high quality studies evaluating effectiveness of dry needling.



#### PM&R Questions 1 & 2.

- ii. Physical agents (eg, heat, cold, ultrasound, electrical stimulation, laser, dry needling, traction, TENS)
- g. Electrical Stimulation

### Q1 Evidence Summary:

**A systematic review of the literature yielded no studies to adequately address this question.**

### Q2 Evidence Summary:

**A systematic review of the literature yielded no studies to adequately address this question.**



#### Q1&2 Future Directions for Research

The work group does not have any recommendations for future research on this topic.



**PM&R Questions 1 & 2.**  
**iii. Acupuncture**

**Q1 Recommendations (*sham acupuncture*):**

**In patients with low back pain, there is conflicting evidence that acupuncture provides improvements in pain and function as compared to sham acupuncture.**

**Grade of Recommendation: I**

**Q1 Evidence Summary (*sham acupuncture*):**

Carlsson et al<sup>33</sup> conducted a blinded placebo-controlled study to investigate the effect of needle acupuncture on long-term relief of chronic LBP. Patients with LBP for at least 6 months were randomized to receive needle acupuncture (n=34) or placebo stimulation using a disconnected transcutaneous electrical nerve stimulation stimulator (n=16) once weekly for 8 weeks plus 2 additional treatments over a 6-month follow-up. Pain intensity (VAS), analgesic intake, quality of sleep and activity level were recorded in a diary. An independent blinded observer completed a global assessment at 1, 3 and 6 months after treatment. A significantly greater proportion of the patients in the acupuncture group had improved global assessments at 1- and 6-month follow-up. There were significant improvements in mean weekly pain scores, return to work, quality of sleep and analgesic intake in the acupuncture group compared to the placebo group. The authors concluded that needle acupuncture provides long-term pain-relieving effect in some patients with chronic nociceptive LBP. Due to the small sample size of the study, the level of evidence was downgraded. This potential Level I study offers Level II therapeutic evidence that, in patients with chronic LBP, acupuncture was associated with improvement in return to work, quality of sleep and analgesic intake at 6 months compared to placebo; acupuncture was associated with statistically significant, but not clinically meaningful, improvement in pain at 6 months compared to placebo.

Kerr et al<sup>34</sup> investigated the effect of acupuncture for the treatment of chronic LBP in a randomized controlled trial. Patients with LBP for more than 6 months were randomized to receive acupuncture therapy (n=30) or placebo transcutaneous electrical nerve stimulation (n=30) for 6 weeks. Pain (McGill Pain Questionnaire and VAS), quality of life (SF-36)

and range of motion were recorded at baseline, after completion of the 6-week treatment and 6 months after treatment. Both groups had improvements in all outcomes (with the exception of McGill Pain Questionnaire in the placebo group). The authors concluded that there were no significant differences between acupuncture therapy and placebo. In critique, less than 80% of patients completed follow-up and there was concern for Type II error due to small sample size. Due to these reasons, the work group downgraded the level of evidence for this study. This potential Level I study provides Level II therapeutic evidence that, in patients with chronic LBP, there were no differences in pain and function between acupuncture and placebo at 6 months.

Vas et al<sup>35</sup> conducted a multicenter randomized controlled trial to investigate the efficacy of acupuncture in patients with acute nonspecific LBP. Patients with their first episode of LBP, with a duration of less than 2 weeks, were randomized into one of 4 groups: conventional treatment alone (n=70), conventional treatment plus acupuncture (n=68), conventional treatment plus sham acupuncture (n=68), or conventional treatment plus placebo acupuncture (n=69). Conventional treatment consisted of posture recommendations, analgesics, nonsteroidal anti-inflammatory drugs and myorelaxant drugs). Each acupuncture group received 5 20-minute sessions over a 2-week period. Disability (Roland Morris Disability Questionnaire), pain intensity (VAS), occupational disability, LBP persistence, appearance of LBP and patient-perceived improvement were recorded at baseline and at 3, 12 and 48 weeks. All 3 acupuncture groups (true acupuncture, sham and placebo) improved significantly more than conventional treatment alone; but there were no significant differences between the acupuncture groups. The authors concluded that acupuncture is not

**114** Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

better than sham or placebo acupuncture. This study offers Level I therapeutic evidence that, in patients with acute LBP, acupuncture, sham acupuncture, placebo acupuncture and conventional treatment provide similar functional outcomes at 48 weeks follow-up.

Cho et al<sup>36</sup> conducted a randomized sham-controlled clinical trial to study the effect of individualized acupuncture for the treatment of chronic LBP. Patients with LBP for at least three months were randomized to receive twice-weekly sessions of individualized acupuncture (n=65) or sham acupuncture (n=65). LBP bothersomeness (VAS), pain intensity (VAS), disability (Oswestry Disability Index), general health status (Short-Form-36) and depression (Beck Depression Inventory) were recorded at baseline and at 3- and 6-month follow-ups. Disability, depression and general health status improved in both groups with no differences between groups. LBP intensity and bothersomeness improved significantly more in the individualized acupuncture group than the sham group. The authors concluded that acupuncture is more effective in reducing LBP bothersomeness and intensity compared to sham acupuncture in patients with chronic LBP. This study provides Level I therapeutic evidence that, in patients with LBP, acupuncture is more effective than sham acupuncture for pain relief at 6 months with no difference for function or depression.

Cherkin et al<sup>37</sup> compared the effectiveness of individualized acupuncture, standardized acupuncture, simulated acupuncture and usual care for the treatment of chronic LBP. Patients with LBP for at least 3 months were randomized to receive 10 15-20 minute sessions over 7 weeks of individualized acupuncture with no limits on number of needs, depth of insertion or needle manipulation (n=157), standardized acupuncture

(n=158), simulated acupuncture using a toothpick in a needle guide tube (n=162), or usual care per the discretion of their physician (n=161). Back-related dysfunction (Roland-Morris Disability Questionnaire) and symptom bothersomeness were recorded at baseline and after 8, 26 and 52 weeks. All 3 acupuncture groups had significantly greater improvement in mean dysfunction scores at 8 weeks compared to usual care. The authors concluded that individualizing acupuncture does not affect therapeutic benefits. This study provides Level I therapeutic evidence that, in patients with LBP, acupuncture and sham acupuncture provide statistically significant, but not clinically meaningful, improvement in function.

In a randomized controlled trial, Haake et al<sup>38</sup> studied the effect of acupuncture for reducing chronic LBP compared to conventional therapy or sham acupuncture. Patients with LBP for at least six months were randomized to receive 10 30-minute sessions of verum acupuncture (n=387), sham acupuncture avoiding all verum points or medians (n=387) or guideline-based conventional therapy including exercise or physiotherapy sessions with a physician or physiotherapist (n=388). Pain (Von Korff Chronic Pain Grade Scale) and functional status (Hanover Functional Ability Questionnaire) were assessed at baseline and 1.5, 3 and 6 months after start of treatment. Both the verum and sham acupuncture groups had greater improvements than the conventional therapy, with no differences between verum and sham acupuncture. The authors concluded that verum and sham acupuncture improved LBP for at least 6 months with greater effectiveness than conventional therapy. This study provides Level I therapeutic evidence that, in patients with LBP, acupuncture and sham acupuncture result in improved pain and function at 6 months compared to guideline-based conventional therapy (physical therapy).

**Q1 Recommendations (usual care):**

In patients with **chronic** low back pain, addition of acupuncture to usual care is recommended for short-term improvement of pain and function compared to usual care alone.

Grade of Recommendation: A

**Q1 Evidence Summary (usual care):**

In a randomized controlled trial, Haake et al<sup>38</sup> studied the effect of acupuncture for reducing chronic LBP compared to conventional therapy or sham acupuncture. Patients with LBP for at least 6 months were randomized to receive 10 30-minute sessions of verum acupuncture (n=387), sham acupuncture avoiding all verum points or medians (n=387), or guideline-based conventional therapy including exercise or physiotherapy sessions with a physician or physiotherapist (n=388). Pain (Von Korff Chronic Pain Grade Scale) and functional status (Hanover Functional Ability Questionnaire) were assessed at baseline and 1.5, 3 and 6 months after start of treatment. Both the verum and sham acupuncture groups had greater improvements than the conventional therapy, with no differences between verum and sham acupuncture. The authors concluded that verum and sham acupuncture improved LBP for at least 6 months with greater effectiveness than conventional therapy. This study provides Level I therapeutic evidence that, in patients with LBP, acupuncture and sham acupuncture result in improved pain and function at 6 months compared to guideline-based conventional therapy (physical therapy).

Witt et al<sup>39</sup> compared the effectiveness and cost of acupuncture in addition to routine care for chronic LBP in a randomized controlled trial and nonrandomized cohort. Patients with LBP for more than 6 months were randomized to receive up to 15 sessions of acupuncture in addition to routine medical care (n=1,549) or routine medical care alone (n=1,544). Patients who did not agree to participate in the RCT were enrolled in a nonrandomized acupuncture group (n=8,537). Back function (Hannover Functional Ability Questionnaire), pain (Low Back Pain Rating Scale) and quality of life (SF-36) were assessed at baseline and after 3 and 6 months. Back function, back pain and quality of life improved significantly more in the acupuncture group compared to the control group at 3-month follow-up. The cost-effectiveness analysis revealed that acupuncture was relatively cost-effective. The authors concluded that acupuncture added to routine care was associated with clinical improvements. This study provides Level

I therapeutic evidence that, at 3 months, acupuncture shows improvement in pain and function compared to routine care (routine care not defined); these results were not sustained at 6 months.

Yeung et al<sup>40</sup> conducted a randomized controlled trial to investigate the effect of electro-acupuncture added to exercise for the treatment of chronic LBP. Patients with LBP for at least 6 months were randomized to receive one hour per week of a standard group exercise program (n=26) or the same exercise program plus 12 sessions of electro-acupuncture (n=26) for 4 weeks. Pain (Numerical Rating Scale), disability (Aberdeen LBP scale), range of motions and isokinetic strength were assessed at baseline, immediately after treatment and at one- and 3-month follow-up. The patients who received the additional electro-acupuncture had significantly better pain and disability scores compared to those who had exercise only. The authors concluded that the addition of electro-acupuncture to exercise might be an effective treatment for chronic LBP. This study provides Level I therapeutic evidence that, at 3 months, in patients with LBP, electro-acupuncture added to an exercise program improves pain and function better than an exercise program alone.

Yun et al<sup>41</sup> aimed to determine if Hegu acupuncture is more effective than standard acupuncture and if both forms of acupuncture are more effective than medical care alone for the treatment of chronic LBP. Patients with back pain for at least three months were randomized to receive 18 treatments of Hegu acupuncture (n=64), standard acupuncture (n=60), or usual care only (n=63) over 7 weeks. Hegu acupuncture involved inserting and drawing back the needle in different directions before inserting straight to the de qi point compared to standard acupuncture in which the acupuncturist inserted the needle straight to the de qi point. The participants in the usual care did not receive any treatment but were allowed to continue any care recommended by their own physicians. Back-related dysfunction (Roland-Morris Disability Questionnaire) and pain (VAS) were recorded at baseline and at 8 and 48 weeks after enrollment. The

**116** Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

Hegu acupuncture group had greater improvements in dysfunction and pain scores compared to the standard acupuncture group at both follow-up points. Both acupuncture groups had greater improvements in dysfunction and pain compared to the usual care group at both follow-up points. This study provides Level I therapeutic evidence that, at 48 weeks, Hegu

acupuncture is associated with statistically significant improvements in pain and disability compared to standard acupuncture and provide statistically significant improvements in pain and disability compared to usual care. These improvements are small and may not be clinically significant.

### Q1 Recommendation (acupuncture technique):

There is insufficient evidence to draw conclusions regarding the comparative effectiveness of acupuncture techniques.

Grade of Recommendation: I

### Q1 Evidence Summary (acupuncture technique):

Ceccherelli et al<sup>42</sup> compared the effect of superficial and in-depth insertion of acupuncture needs in treatment of chronic LBP in a randomized double-blind study. Patients with lumbar myofascial pain for more than three months were randomized to receive 8 sessions of acupuncture using either a 2 mm depth (n=21) or deep placement into the muscular tissue (n=21). Pain intensity (McGill Pain Questionnaire) was recorded at baseline, after the 6-week treatment period and at 3-month follow-up. The patients who received deep acupuncture had significantly greater pain reduction compared to the superficial insertion at 3-month follow-up. The authors concluded that deep stimulation has better pain relief effects compared to superficial stimulation. This study offers Level I therapeutic evidence that, in patients with LBP, deep acupuncture provided more pain relief at 3 months compared to superficial acupuncture.

Pach et al<sup>43</sup> conducted a randomized controlled trial to compare the effectiveness of standardized and individualized acupuncture for the treatment of chronic LBP. Patients with LBP for at least 3 months were randomized to receive 10–15 sessions of standardized acupuncture (n=78) or individualized acupuncture based on diagnosis (n=72) over 8 weeks. Pain (VAS) was recorded in a daily diary. Both groups had improvement in pain severity over 8 weeks, with no differences in the area under the curve for pain severity from baseline to end of week 8. The authors concluded that individualized acupuncture was not superior to standard acupuncture. This study offers Level I therapeutic evidence that, in patients with LBP, outcomes for standard and individualized acupuncture are equivalent. This study offers Level IV therapeutic evidence that acupuncture results in significant pain relief.

Shin et al<sup>44</sup> compared the effect of bee venom acupuncture and sham control for the treatment of chronic LBP. Patients with LBP for at least 3 months were randomized to receive twice-weekly treatments of bee venom acupuncture (n=30) or sham control of normal saline injection (n=30) for four weeks. Pain intensity (VAS), disability (Oswestry Disability Questionnaire) and quality of life (SF-36) were recorded at baseline, at each treatment session and 4- and 12-month follow-up after completion of treatment. Both groups had significant improvement in pain intensity, disability and quality of life at all follow-up points with no significant differences between groups in disability or quality of life. At the 7th and 8th treatment sessions, the participants in the bee venom acupuncture group had significantly greater pain relief compared to the control group, but there were no differences at 4- or 12-month follow-up. Adverse events such as pruritus and other skin reactions occurred but resolved without medical intervention. The authors concluded that bee venom acupuncture is effective in treating chronic LBP. This study provides Level I therapeutic evidence that, in patients with LBP, bee venom acupuncture and saline acupuncture are equally effective in pain relief similar at 3 months' follow-up.

Yun et al<sup>41</sup> aimed to determine is Hegu acupuncture is more effective than standard acupuncture and if both forms of acupuncture are more effective than medical care alone for the treatment of chronic LBP. Patients with back pain for at least three months were randomized to receive 18 treatments of Hegu acupuncture, standard acupuncture, or usual care only over seven weeks. Hegu acupuncture involved inserting and drawing back the needle in different directions before inserting straight to the de qi point compared to stan-

standard acupuncture in which the acupuncturist inserted the needle straight to the de qi point. The participants in the usual care did not receive any treatment but were allowed to continue any care recommended by their own physicians. Back-related dysfunction (Roland-Morris Disability Questionnaire) and pain (VAS) were recorded at baseline and at 8 and 48 weeks after enrollment. The Hegu acupuncture group had greater improvements in dysfunction and pain scores compared to the standard acupuncture group at both follow-up points. Both acupuncture groups had greater

improvements in dysfunction and pain compared to the usual care group at both follow-up points. This study provides Level I therapeutic evidence that, at 48 weeks, Hegu acupuncture is associated with statistically significant, but not clinically meaningful, improvements in pain and disability compared to standard acupuncture; both types of acupuncture provide statistically significant, but not clinically meaningful improvements in pain and disability compared to usual care.

## Q2 Evidence Summary:

**A systematic review of the literature yielded no studies to adequately address this question.**



### Q1&2 Future Directions for Research

The work group does not recommend the undertaking of additional studies. It appears that additional high-level studies will not change recommendations.



## PM&R Questions 1 & 2.

### iv. Bracing

- Lumbosacral brace
- Sacroiliac brace

## Q1 Recommendation:

**There is conflicting evidence that bracing results in improvements in pain and function in patients with subacute low back pain**

**Grade of Recommendation: I**

## Q1 Evidence Summary:

Calmels et al<sup>45</sup> investigated the effects of an elastic lumbar belt for the treatment of LBP in a multicenter, randomized controlled trial. Patients with a current LBP episode lasting 1-3 months were randomly assigned to receive a lumbar belt (n=102) or to a control group instructed not to wear any type of lumbar belt (n=95). Participants who received the lumbar

belt were instructed to wear the belt every day for the duration of the 3-month trial. Pain (VAS), functional capacity (EIFEL scale, French version of the Roland-Morris scale) and number of days of medical consumption were recorded at baseline and on day 30, 60 and 90. The lumbar belt group had statistically significant improvements in pain, functional capacity

**118** Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

and medication consumption. The authors concluded that the addition of a lumbar belt can improve the functional status, pain level and pharmacologic consumption in patients with subacute LBP. Although the differences between groups were statistically significant, in critique, the work group deemed the results clinically insignificant. This study offers Level I therapeutic evidence that, in patients with subacute LBP, there does not appear to be a clinically significant difference in pain and function at 3 months between wearing a nonrigid lumbar corset and medication.

Oleske et al<sup>46</sup> conducted a multicenter randomized clinical trial to compare the effectiveness of a back support lumbar corset plus education versus education alone in patients with LBP. Patients with work-related LBP were randomized to receive education plus the back support corset (n=222) or education alone (n=211). LBP frequency and bothersomeness (numerical rating scale), disability (Oswestry Back Pain Disability Questionnaire), physical health (SF-12), mental health and work time were recorded at follow-up and after 1, 2, 6 and 12 months. Both groups experienced improvements in pain, disability, neurogenic symptoms and physical health over 12 months. The back support plus education group had a lower likelihood of LBP recurrence, but otherwise there were no differences in outcomes between groups. The authors concluded that the back support

may prevent recurrence of work-related LBP when added to education. This study provides Level I therapeutic evidence that, in patients with subacute LBP, the addition of lumbar corset to education does not result in decreased pain and disability compared to education alone at one year.

Doran and Newell<sup>47</sup> investigated the effectiveness of four different treatment options in patients with LBP. Participants were randomly assigned to receive at least 2 sessions of manipulation per week (n=98), at least 2 sessions of physiotherapy per week (n=104), corset applied on the first day of the trial (n=93), or 2 paracetamol tablets every 4 hours (n=100). Patients completed questionnaires to report whether their pain was worse, unchanged, improved or completely relieved at the end of the 3-week trial, 3 weeks after the conclusion of the trial, 3 months after enrollment and one year after enrollment. The authors concluded that there were no significant differences between any of the 4 studied interventions. In critique, no validated outcomes were included in this study and outcome data is limited. Due to these reasons, the work group downgraded this study. This potential Level I study provides Level II therapeutic evidence that, in patients with acute LBP, SMT, physiotherapy, medication and corset resulted in similar improvements up to 3 months.

## Q2 Recommendation:

**A systematic review of the literature yielded no studies to adequately address this question.**



### Q1&2 Future Directions for Research

The work group recommends comparative effectiveness studies using bracing in patients with chronic LBP.





## PM&R Questions 1 & 2. v. Spinal manipulative therapy (SMT)

*Work Group Narrative: The majority of SMT literature involves the centralization phenomenon which is commonly seen in patients with leg pain. This review examined only evidence in the sub-set of patients without radiating pain. Additional literature discussing clinical benefits from SMT for the treatment of LBP including radiating pain were not included in our systematic review. Therefore, a definitive statement of SMT in all patients with LBP cannot be made.*

### Q1 Recommendations:

**For patients with acute or chronic low back pain, spinal manipulative therapy (SMT) is an option to improve pain and function.**

**Grade of Recommendation: C**

**For patients with acute low back pain, spinal manipulative therapy (SMT) results in similar outcomes to no treatment, medication or modalities. Periodically, short-term improvement is statistically better, but clinical significance is uncertain.**

**Grade of Recommendation: A**

**For patients with chronic low back pain, there is conflicting evidence that outcomes for spinal manipulative therapy (SMT) are clinically different than no treatment, medication or modalities.**

**Grade of Recommendation: I**

### Q1 Evidence Summary:

In a randomized control trial, Dougherty et al<sup>48</sup> evaluated the effectiveness of spinal manipulative therapy (SMT) in older veterans with chronic LBP compared to a sham intervention. Veterans at least 65 years of age with LBP for at least 3 months were randomly allocated to groups to receive SMT (n=69) or sham intervention (n=67) twice weekly for 4 weeks. Pain (VAS, SF-36 pain subscale), disability (Oswestry Disability Index) and physical function (SF-36 subscale, Timed Up and Go) were recorded at baseline and after 5 and 12 weeks. Both groups experienced improvements in pain and disability at 5 and 12 weeks. Disability improved significantly more in the SMT group compared to the control group. The authors concluded that SMT resulted in greater improvement in disability but not pain at 12 weeks. This study offers Level I therapeutic evidence that, in patients with chronic LBP, there were similar improvements in pain when comparing SMT to sham. There was statistically significant im-

provement in function in the SMT group. However, it is uncertain as to whether these functional improvements were clinically significant.

Haas et al<sup>49</sup> conducted a randomized controlled trial in patients with chronic LBP to identify the dose-response relationship between visits to a chiropractor for SMT and treatment outcomes and to compare treatment outcomes of manipulation versus light massage. Four hundred patients with non-specific LBP for at least 3 months were prescribed 18 sessions with a chiropractor (three times a week for six weeks). Participants were randomized to receive either 0, 6, 12 or 18 sessions of SMT (n=100 in each group). The chiropractor provided light massage for the remaining sessions that did not include SMT. Pain and disability (modified Von Korff pain and disability scales) were recorded at baseline and throughout a 52-week follow-up period. Pain and disability improved in all

**120** Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

groups and was sustained for 52 weeks. The greatest treatment effects were found from 12 sessions of SMT. The authors concluded that 12 SMT visits had modest effects on chronic LBP outcomes compared to the other dose levels, but the difference was not well distinguished. This study offers Level I therapeutic evidence that, in patients with LBP, spinal manipulative therapy is associated with statistically significant improvement in pain compared to light massage. However, it is uncertain whether this was clinically significant. Regarding frequency, this study offers Level I therapeutic evidence that 12–18 visits of SMT were statistically better than 6 visits at 12-week follow-up; no difference between doses at one-year follow-up. Again, the differences were small and the clinical significance was uncertain.

In a placebo controlled randomized trial, Hancock et al<sup>50</sup> evaluated the effectiveness of nonsteroidal anti-inflammatory drugs (NSAIDs), spinal manipulative therapy (SMT), or combination of NSAIDs and SMT for the treatment of acute LBP. Patients presenting to their general practitioner with LBP were randomized into one of 4 groups: diclofenac 50 mg twice daily and placebo SMT (n=60); SMT and placebo drug (n=60); diclofenac 50 mg twice daily and SMT (n=60); or double placebo (n=60) until recovery or up to 4 weeks. The primary outcome of “days to recovery” was recorded as the first pain-free day and the first of 7 consecutive days with a pain score of 0 or 1. There were no significant differences in days to recovery between groups. The authors concluded that the addition of diclofenac or spinal manipulative therapy do not improve recovery in patients with acute LBP already receiving first-line care. This study offers Level I therapeutic evidence that, in patients with acute LBP, there was no difference in resolution of pain between spinal manipulative therapy, NSAIDs and placebo.

Hoiriis et al<sup>51</sup> compared chiropractic adjustments and muscle relaxants to sham treatment and placebo in a randomized controlled trial of patients with subacute LBP. Patients with LBP for 2–6 weeks were randomly allocated into one of 3 groups: chiropractic adjustments with placebo medicine (n=50), muscle relaxants with sham adjustments (n=53) or placebo medicine with sham adjustments (n=53). Primary outcomes of pain (VAS), disability (Oswestry Disability Questionnaire) and depression (Modified Zung Depression Scale) were assessed at baseline, 2 weeks and 4 weeks. Patients at baseline had mild pain and disability. The chiropractic group had greater pain improvement compared to the control group and greater improvement in a secondary outcome of Global Im-

pression of Severity compared to all groups. There were no significant differences between groups in other outcomes. The authors concluded that chiropractic treatment was more beneficial than placebo in reducing pain. This study offers Level I therapeutic evidence that, in patients with acute LBP and mild baseline disability, there was statistically better improvement in pain with SMT, while improvements in function were otherwise similar relative to medication and sham groups at 4 weeks. However, the differences across groups were small and it is uncertain whether these improvements in pain were clinically significant.

Juni et al<sup>52</sup> conducted a randomized controlled trial in patients with subacute LBP to evaluate the efficacy of SMT as an addition to standard care compared to standard care alone. Patients with acute LBP for less than four weeks were randomized to receive standard care of general advice and paracetamol, diclofenac or dihydrocodeine as required (n=52) or standard care plus SMT (n=52). Pain (11-point box scale) and analgesic use were recorded throughout the 2-week trial and at 6-month follow-up. There were no significant differences in pain or analgesic use between groups. The authors concluded that SMT is not likely to reduce pain in patients with acute LBP. This study provides Level I therapeutic evidence that, in patients with acute LBP, there were no differences in pain and function between SMT and medication at up to 6 months follow-up.

Schneider et al<sup>53</sup> conducted a randomized controlled trial in patients with acute or subacute LBP to evaluate manual thrust manipulation compared to mechanical-assisted manipulation and manipulation compared to usual medical care. Patients with LBP of less than 12 weeks duration were randomized into one of three groups for 4 weeks: twice-weekly manual-thrust manipulation (n=37), twice-weekly mechanical-assisted manipulation (n=35), or 3 visits of usual medical care (n=35). Disability (Oswestry LBP Disability Index) and pain (numeric pain rating scale) were recorded at baseline, after 4 weeks of treatment and at 3- and 6-month follow-up. The participants who received manual-thrust manipulation had significantly greater improvements in disability and pain compared to the machine-assisted manipulation and usual medical care at 4 weeks. There was a greater proportion of responders (30–50% reduction in Oswestry LBP Disability Index score) in the manual-thrust manipulation compared to machine-assisted manipulation or usual medical care. The authors concluded that manual-thrust manipulation

provides greater short-term improvements in pain and disability compared to usual medical care or machine-assisted manipulation. This study offers Level I therapeutic evidence that, in patients with acute LBP, manual based SMT had significantly greater improvement in pain and function compared to mechanical assisted manipulation or usual care at 4 weeks follow-up, but not at 3 months.

In patients with chronic LBP, Senna et al<sup>54</sup> conducted a randomized controlled trial to compare SMT to sham SMT. Patients with LBP for at least 6 months were randomized to one of 3 groups: 12 treatments of sham SMT over one month (n=40), 12 treatments of SMT over one-month followed by no treatment for 9 months (n=27) or 12 treatments of SMT over one month with “maintenance spinal manipulation” every 2 weeks for the following 9 months (n=26). Pain (VAS), disability (Oswestry disability questionnaire), generic health status (SF-36) and back-specific patient satisfaction were recorded at baseline and after one, 4, 7 and 10 months. After one month, both of the SMT groups had significantly lower pain and disability compared to the sham SMT group. At 10 months, only the maintenance SMT group had improvements in pain and disability. The authors concluded that SMT is effective for the treatment of LBP and suggested maintenance manipulation for long-term benefits. In critique, less than 80% of patients completed follow-up. Due to this potentially confounding factor, the work group downgraded the level of evidence for this study. This potential Level I study provides Level II therapeutic evidence that, in patients with chronic LBP, pain and function showed more improvement in group with maintained SMT than in the group with nonmaintained SMT or sham SMT at all time frames after one month.

In a placebo and sham randomized controlled trial, Von Heymann et al<sup>55</sup> evaluated the effectiveness of spinal high-velocity low-amplitude manipulation compared to treatment with a nonsteroidal anti-inflammatory drug. Patients with LBP for less than 48 hours were randomized to receive spinal manipulation therapy (SMT) and placebo drug (n=37), sham SMT and 50 mg tablets diclofenac three times a day (n=38), or sham SMT and placebo drug (n=25). Physical disability (Roland Morris Disability Questionnaire), function (SF-12), pain (VAS) off-work time and rescue medication usage were recorded at baseline, 7–9 days after randomization and 12-week follow-up. Both intervention groups had better outcomes than the placebo group. The manipulation group experienced faster and more distinct reduction

in pain and disability compared to the diclofenac group. There were no adverse effects, harm or unexpected untoward events in either group. The authors concluded that SMT was significantly better than diclofenac and placebo in the treatment of LBP. This study offers Level I therapeutic evidence that, in patients with acute LBP, SMT resulted in statistically significant short-term (9 days) improvement in pain compared to medication. The clinical significance was uncertain. The two groups were similar at medium-term follow-up.

In a randomized control trial, Grunnesjo et al<sup>56</sup> evaluated muscle stretching, manual therapy and steroid injections in addition to staying active in patients with acute and subacute LBP. Participants were randomized into one of 4 groups: “stay active” care only (n=35), “stay active” and muscle stretching (n=36), “stay active, muscle stretching and manual therapy (n=42), or “stay active,” muscle stretching, manual therapy and steroid injections (n=47). The “stay active” care included some active physical therapies in addition to encouragement to stay physically active. Quality of life measurements (The Gothenburg Quality of Life instruments) were recorded at baseline, after 5 weeks of treatment and at the end of the 10-week trial. There was a significant trend for increasing well-being as additional modalities were added. The authors concluded that additional effects were seen as additional treatment modalities were added. This study offers Level I therapeutic evidence that, in patients with LBP, addition of manual therapy to staying active and stretching had similar effects on quality of life compared to staying active and stretching alone at 10 weeks.

Licciardone et al<sup>57</sup> conducted a randomized controlled study to determine the efficacy of osteopathic manipulative treatment for the treatment of LBP. Patients with LBP for at least 3 months were randomized to receive 7 visits over 5 months of osteopathic manipulative treatment (n=46), sham manipulation (n=23), or usual care only (n=20). Pain (VAS), self-reported health status (SF-36 Health Survey), disability (Roland-Morris Disability Questionnaire), lost work/school days and satisfaction of care were recorded. Follow-up was completed after one month (n=82), 3 months (n=71) and 6 months (n=66). There were no significant differences in outcomes between osteopathic manipulative treatment compared to sham manipulation; both manipulation groups experienced benefits compared to no intervention. The authors concluded that both osteopathic manipulative treatment and sham manipulation provide benefits com-

pared to usual care alone in patients with chronic LBP. In critique, the work group downgraded this study from Level I to Level II due to less than 80% follow-up. This study provides Level II therapeutic evidence that, in patients with subacute LBP, osteopathic manipulation provides no benefit in pain or disability compared with sham manipulation and that both provide statistically significant, but not clinically meaningful, improvements when compared with no care.

Cambron et al<sup>58</sup> compared pain and disability outcomes in patients with chronic LBP who received flexion distraction chiropractic care or physical therapy in a randomized clinical trial. Patients with LBP > 3 months were randomly assigned to receive flexion distraction chiropractic care using flexion distraction (n=123) or a physical therapy program of strength, flexibility and cardiovascular exercises with the goal of strengthening the trunk muscles (n=112). Both treatment programs were 4 weeks with 2-4 sessions per week. Patients reported pain (VAS) and dysfunction (Roland Morris) at baseline and one-month follow-up questionnaire. Both groups experienced improvements in pain and disability; however, the pain scores were significantly lower in the chiropractic group compared to the physical therapy group. The authors concluded that flexion distraction was more effective in reducing pain than the studied physical therapy program. This study offers Level I therapeutic evidence that, in patients with chronic LBP, SMT provides similar improvement in pain and function compared to an exercise program at one year follow-up. It offers Level IV evidence that SMT results in improved pain and function.

Cecchi et al<sup>59</sup> compared the effect of spinal manipulation, back school and individual physiotherapy on pain and disability outcomes in a randomized trial of patients with chronic LBP. Patients were randomized to receive 15 one-hour sessions of back school (group exercise, education/ergonomics) over the course of 3 weeks (n=70), 15 one-hour sessions of individual physiotherapy (exercise, passive mobilization and soft-tissue treatment) over the course of 3 weeks (n=70), or 4-6 20-minute sessions of spinal manipulation per week for 4-6 weeks (n=70). Participants recorded pain (Pain Rating Scale) and disability (Roland Morris Disability Questionnaire) at baseline, discharge and follow-up at 3, 6 and 12 months. All patients experienced improvement in pain and disability at discharge and 12-month follow-up. Function, pain recurrences and drug intake were significantly reduced compared to back school or physiotherapy. The authors concluded that spinal manipulation resulted

in better improvements in pain and function compared to back school or individual physiotherapy. This study provides Level I therapeutic evidence that, in patients with LBP, SMT results in statistically significant improvement in pain and functional compared to multimodal physical therapy (baseline scores indicate mild pain). However, it is uncertain if these improvements are of clinical significance. It offers Level IV evidence that SMT results in improved pain and function.

Cherkin et al<sup>60</sup> evaluated the different outcomes after patients with acute LBP received the McKenzie method of physical therapy, chiropractic manipulation or an educational booklet. Patients who still had LBP 7 days after an initial visit to the primary care practitioner were randomized to receive up to 8 sessions in a one-month period of McKenzie method of physical therapy (n=133), up to 8 sessions in a one-month period of chiropractic manipulation (n=122), or an educational booklet only (n=66). Patients reported LBP bothersomeness (11-point scale) and dysfunction (Roland Disability Scale). There were no statistically and clinically significant differences between groups. The authors concluded that the McKenzie method of physical therapy and chiropractic manipulation resulted in similar outcomes in patients with LBP and were only marginally better than the educational booklet intervention. This study offers Level I therapeutic evidence that, in patients with LBP, there were no statistical differences in functional outcomes between educational booklet, SMT and McKenzie exercise at 12 weeks. It offers Level IV evidence that SMT results in improved pain and function.

Doran and Newell<sup>47</sup> investigated the effectiveness of four different treatment options in patients with acute LBP. Participants were randomly assigned to receive at least 2 sessions of manipulation per week (n=98), at least 2 sessions of physiotherapy per week (n=104), corset applied on the first day of the trial (n=93) or two paracetamol tablets every 4 hours (n=100). Patients completed questionnaires to report whether their pain was worse, unchanged, improved, or completely relieved at the end of the 3-week trial, 3 weeks after the conclusion of the trial, 3 months after enrollment and one year after enrollment. The authors concluded that there were no significant differences between any of the four studied interventions. In critique, no validated outcomes were included in this study and outcome data is limited. Due to these reasons, the work group downgraded this study. This potential Level I study provides Level II therapeutic evidence that, in patients with acute LBP, SMT, phys-

iotherapy, medication and corset resulted in similar improvements up to 3 months.

In a randomized controlled trial, Enix et al<sup>61</sup> aimed to compare chiropractic care and physical therapy as treatments for chronic LBP in geriatric patients. Participants aged 60–85 years with LBP were randomized to receive 6 weeks (12–18 sessions) of either chiropractic care (n=61) or physical therapy (n=57). Patients completed pain questionnaires at baseline, at the end of the 6-week trial and 6 weeks after trial completion (week 12). Both groups experienced significant improvements in pain. The authors concluded that there were no differences in pain outcomes between groups at 6- or 12-week follow-up. This study offers Level I therapeutic evidence that, in geriatric patients with chronic LBP, physical therapy and SMT resulted in similar improvement in pain relief at 6 weeks' follow-up (baseline scores indicate mild pain). It offers Level IV evidence that SMT results in improved pain and function.

Hemmila et al<sup>62</sup> conducted a randomized controlled trial to compare the effectiveness of bone-setting, light exercise therapy and physiotherapy in patients with LBP greater than 7 weeks. Patients were randomly allocated into groups to receive up to 10 sessions of bone-setting (n=45), light exercise therapy (n=35) or physiotherapy (n=34) over 6 weeks. Disability (Oswestry Disability Questionnaire) was recorded at baseline and one-year after treatment. Disability improved more in the bone-setting group. The authors concluded that traditional bone-setting was more effective than exercise or physiotherapy for pain and disability related to LBP. However, baseline disability was low and the bone setting group had slightly worse baseline scores on average than the comparison groups. Overall improvements were small across all groups and although the net improvement in the bonesetting group was statistically greater, it is uncertain whether this had clinical significance. In addition, inclusion criteria included pain beyond 7 weeks, but the duration of pretreatment pain beyond that is unknown as is the balance of pain duration across

patients in each group. If there is substantial heterogeneity in pain duration across groups, this could bias the outcomes as well. This study provides Level I therapeutic evidence that, in patients with subacute or chronic LBP and mild baseline disability, SMT, physiotherapy and exercise result in similar improvements in function at one year. It offers Level IV evidence that SMT results in improved pain and function.

Hurwitz et al<sup>63</sup> compared outcomes related to LBP in patients who received medical or chiropractic care with or without physical modalities or physical therapy in a multicenter randomized controlled trial. Participants had back pain ranging from 3 weeks to greater than one year. Distribution based on chronicity was reasonably similar. In general, about 40% had pain for less than 3 months at onset of treatment and the other 60% had pain greater than 3 months, with 45 to 49% of the total having pain for greater than a year. Patients were randomly assigned to receive chiropractic care with physical modalities (n=172), chiropractic care without physical modalities (n=169), medical care with physical therapy (n=170), or medical care without physical therapy (n=170). Physical modalities included heat or cold therapy, ultrasound and/or electrical muscle stimulation. Physical therapy included heat or cold therapy, ultrasound, electrical muscle stimulation, soft tissue and joint mobilization, traction, supervised therapeutic exercise and/or strengthening and flexibility exercises. Disability (Roland-Morris Low-Back Disability Questionnaire) and pain (numerical rating scale) were recorded at baseline and 2, 6, 26, 52 and 78 weeks after enrollment. A total of 610 (90%) completed follow-up after 18 months. Results revealed small, clinically insignificant differences in pain and disability outcomes. The authors concluded that there were no clinically meaningful differences in outcomes between medical and chiropractic care without physical therapy or modalities, besides a difference in patient perception. This study provides Level I therapeutic evidence that, in patients with LBP of variable duration, SMT, SMT with modalities, routine medical care and medical care with physical therapy produced similar improvements in pain and function at 18 months follow-up.

**Question 2 Recommendation:**

There is insufficient evidence to determine whether 12 to 18 visits of spinal manipulative therapy (SMT) results in better outcomes than 6 visits for the treatment of low back pain.

Grade of Recommendation: Grade I

**Question 2 Evidence Summary:**

Haas et al<sup>49</sup> conducted a randomized controlled trial in patients with chronic LBP to identify the dose-response relationship between visits to a chiropractor for spinal manipulative therapy (SMT) and treatment outcomes and to compare treatment outcomes of manipulation versus light massage. Four hundred patients with nonspecific LBP for at least 3 months were prescribed 18 sessions with a chiropractor (three times a week for six weeks). Participants were randomized to receive either 0, 6, 12 or 18 sessions of SMT (n=100 in each group). The chiropractor provided light massage for the remaining sessions that did not include SMT. Pain and disability (modified Von Korff pain and disability scales) were recorded at baseline and throughout a 52-week follow-up period. Pain and disability improved in all groups and was sustained for

52 weeks. The greatest treatment effects were found from 12 sessions of SMT. The authors concluded that 12 SMT visits had modest effects on chronic LBP outcomes compared to the other dose levels, but the difference was not well distinguished. This study offers Level I therapeutic evidence that, in patients with LBP, spinal manipulative therapy is associated with statistically significant improvement in pain compared to light massage. However, it is uncertain whether this was clinically significant. Regarding frequency, this study offers Level I therapeutic evidence that 12-18 visits of SMT were statistically better than 6 visits at 12-week follow-up; no difference between doses at 1-year follow-up. Again, the differences were small and the clinical significance was uncertain.

**Q1&2 Future Directions for Research**

Despite multiple studies, there is still uncertainty regarding the benefits of SMT for both acute and chronic LBP. There is significant heterogeneity across studies that contribute to uncertainty as well. There are opportunities for further well-designed studies to determine the efficacy of SMT in the treatment of LBP.



## PM&R Questions 1 & 2.

### vi. Exercise/PT Exercise/Physical Therapy vs or plus Massage

#### Q1 Recommendations:

There is insufficient evidence to determine the efficacy of acupressure compared to a standardized multimodal physical therapy.

Grade of Recommendation: I

In the long term, it is suggested that the addition of massage to an exercise program provides no benefit when compared to an exercise program alone.

Grade of Recommendation: B

There is insufficient evidence that the addition of massage to an exercise program provides short-term relief of pain.

Grade of Recommendation: I

#### Q1 Evidence Summary:

Hsieh et al<sup>64</sup> compared efficacy of acupressure with that of usual care hospital based physical therapy for treating patients with chronic LBP. Patients received treatment for 4 weeks in both groups. Pain scores were evaluated in 56 and 65 patients studied at 6 months with 82% follow-up. This was a randomized study with one provider for the acupressure. At 6-month follow-up, there was significant reduction in pain in the acupressure group compared to physical therapy. This study provides Level I evidence that acupressure results in significantly greater relief of pain than usual care hospital based physical therapy at medium-term follow-up in patients with chronic LBP.

Hsieh et al<sup>65</sup> compared efficacy of acupressure with that of standardized out patient physical therapy for treating patients with chronic LBP. This was a randomized study with one provider for the acupressure. At 6 months, with 84% follow-up, there was significant improvement in pain and disability scores in the acupressure group compared to physical therapy. This study provides Level I evidence that acupressure results in significantly greater improvement in pain and function than standardized outpatient physical therapy at medium-term follow-up in patients with chronic LBP.

These two studies by Hsieh et al provided high quality evidence favoring acupressure over physical therapy. However, the acupressure was administered by one provider in both studies and concerns for external validity demand corroborating results by other providers to verify efficacy.

Kankaanpa et al<sup>66</sup> conducted a randomized trial to compare efficacy of active rehabilitation to a passive control group consisting of heat and massage. There were 54 patients total with 91% follow-up at one year. These patients had mild disability at baseline. At one year, the active group showed more improvement in pain and disability scores. This study was downgraded for small sample size, inability to mask groups and the relatively low baseline disability scores. It provides Level II evidence that active rehabilitation results in greater improvement in LBP relative to heat and massage at one year.

Little et al<sup>67</sup> compared the effectiveness of Alexander technique lessons, massage therapy and exercise advice with behavioral counseling for the treatment of chronic or recurrent back pain. Patients with LBP for at least 3 months were randomized to receive normal care (n=144), massage (n=147), 6 Alexander tech-

nique lessons (n=144) or 24 Alexander technique lessons (n=144). Half of each group randomly received an exercise prescription with behavioral counseling. Disability (Roland Morris disability score) and number of days in pain were recorded at baseline, three months and one year. Disability in the group that received exercise and lessons in the Alexander technique decreased while those who received massage had no effect on disability. This study provides Level II evidence that massage produced no long-term clinically meaningful effects compared to usual care.

In a prospective study, Zhang et al<sup>68</sup> aimed to determine the effectiveness of Chinese massage added to core stability exercises for the treatment of LBP. The inclusion criteria are not clearly stated in terms of acuity. It is implied that these were probably acute or

subacute episodes, but this is uncertain. These patients were randomized to receive Chinese massage combined with core stability exercises (n=46) or Chinese massage alone (n=46). Pain (VAS) and disability (Oswestry disability index) were assessed at baseline and after 2 and 8 weeks. Recurrence of LBP was evaluated after one year, but definition of recurrence was not clearly stated. Both groups experienced improvements in pain and disability with no differences between groups after 2 weeks. After 8 weeks, pain and disability were significantly lower in the exercise and massage group compared to the massage-only group. The massage-only group had a significantly higher recurrence rate compared to the massage and exercise group based on phone interview one year later. This study provides Level II evidence that exercise is more effective than massage.

## Q2 Evidence Summary:

A systematic review of the literature yielded no studies to adequately address this question.



### Q1&2 Future Directions for Research

The work group recommends high-level studies on acupuncture versus exercise across multiple centers.





## PM&R Questions 1 & 2.

### vii. Active stabilization exercise

#### Q1 Recommendation:

**There is insufficient evidence to make a recommendation for or against lumbar stabilization in patients with chronic low back pain.**

**Grade of Recommendation: I**

#### Q1 Evidence Summary:

Moussouli et al<sup>69</sup> investigated the effects of an isometric and isotonic stabilization exercise program on health-related quality of life in a study of women with chronic LBP. Women with LBP for at least 6 months were randomized to receive 4 60-minute sessions per week of isometric stabilization exercises (n=13), isotonic stabilization exercises (n=13), or no exercise (n=13). Health-related quality of life (SF=36) was assessed upon enrollment, immediately after the four-week treatment period and 9-months after treatment termination. The patients in the isometric stabilization group had significant improvements in pain and vitality at treatment-termination that was maintained for 9 months. The authors concluded that isometric stabilization exercises reduce pain and enhance vitality for at least 9 months in women with chronic LBP. The study's small sample size was the primary factor in downgrading the level of evidence. This potential Level I study offers Level II therapeutic evidence that use of an isometric stabilization program improves functional outcomes in women with chronic LBP at 9 months relative to a dynamic stabilization exercise program or no exercise at all.

Lomond et al<sup>70</sup> compared the effects of trunk stabilization versus a movement system impairment exercise strategy to treat patients with chronic LBP. Their premise is that LBP arises at least in part due to impaired postural coordination. Patients with LBP for at least 6 months were randomized to a 10-week physical therapy program consisting of either stabilization (n=29) or movement system impairment exercises (n=29). Pain (Numeric Pain Index) and function (Oswestry Disability Index) were assessed 11 weeks and 6 months after treatment initiation along with EMG function to assess postural reeducation. Both groups experienced improvements in pain and function at 6-month follow-up. The detailed data reporting focused on EMG and muscle reeducation changes. There is one sentence that mentions comparable improve-

ment in pain and disability scores although it suggests these improvements are modest and maybe not clinically meaningful. The authors concluded that stabilization treatment does not preferentially improve treatment outcomes in patients with LBP. The study had no power calculation and the sample size was small. They also did not report the details of the pain and disability scores. This study offers Level IV therapeutic evidence exercise improves pain and disability in patients with LBP and Level II evidence that trunk stabilization and movement system impairment exercises result in similar outcomes for pain and disability with no improvement voluntary postural adjustment mechanisms in patients with LBP.

Ganesh et al<sup>71</sup> investigated the effectiveness of the star excursion balance test (SEBT) grid training for the treatment of chronic LBP. Patients with mechanical LBP for at least three months were randomized to receive 5 sessions per week for 4 weeks of diagnosis-specific interventions, core muscles strengthening and muscle training using the SEBT grid (n=30) or diagnosis-specific interventions, core muscle strengthening and stationary cycling (n=30). Disability (Oswestry Disability Index), strength and endurance (pressure-biofeedback unit) were assessed at baseline and at 4 and 16 weeks. Both groups had improvement in disability, strength and endurance with better improvement in the SEBT group compared to the conventional exercises. Although both programs resulted in improvement, the authors concluded that core muscle strengthening using a SEBT grid is more effective than conventional exercise programs. This study provides Level I therapeutic evidence that the addition of star excursion balance test and training to a diagnosis-specific intervention and core muscle strengthening improves functional outcomes at short-term follow-up when compared with a cycling program using the same exercise program. Baseline disability for this study was modest (low 20 scores on Oswestry Disability prior to treatment).

**128** Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

**Q2 Evidence Summary:**

A systematic review of the literature yielded no studies to adequately address this question.

**Q1&2 Future Directions for Research**

The work group recommends undertaking randomized controlled trials with long-term follow-up evaluating the benefits of stabilization exercise in patients with LBP.

**PM&R Questions 1 & 2.**

viii. McKenzie exercise (includes directional preference, centralization and mechanical diagnosis and therapy [MDT])

*Work Group Narrative: The majority of McKenzie literature involves the centralization phenomenon which is commonly seen in patients with leg pain. This review examined only evidence in the subset of patients without radiating pain. Additional literature discussing clinical benefits from McKenzie for the treatment of LBP including radiating pain were not included in our systematic review. Therefore, a definitive statement of McKenzie in all patients with LBP cannot be made.*

**Q1 Recommendations:**

**McKenzie method is an option for the treatment of chronic low back pain.**

**Grade of Recommendation: C**

**There is insufficient evidence that McKenzie method results in different outcomes when compared to a dynamic strengthening program for the treatment of chronic low back pain.**

**Grade of Recommendation: I**

**There is insufficient evidence that McKenzie method is better or worse than back school for the treatment of chronic low back pain.**

**Grade of Recommendation: I**

**Q1 Evidence Summary:**

Petersen et al<sup>72</sup> conducted a randomized controlled trial to compare the effect of a McKenzie-based exercise program versus a strengthening exercise program in patients with subacute or chronic LBP. Patients with LBP for at least 8 weeks were randomized to be treated with the McKenzie method (n=132) or with a dynamic strength training program (n=128) for 8 weeks in a clinic followed by 2 weeks at home. A total of 260 patients were randomized. Follow-up was 71%

(90/132) in the McKenzie group and 67% (86/128) in the dynamic exercise group. Pain (Manniche's Low Back Pain Rating Scale) and disability (15-item disability scale) were recorded at baseline, after completion of the treatment program and 2 and 8 months after termination of the treatment. The participants in the McKenzie group had significantly greater reduction of disability compared to the strengthening program at 2-month follow-up. At 8-month follow-up,

Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

there were no differences in pain or disability between groups. The authors concluded that the McKenzie method and intensive dynamic strengthening training are equally effective for the treatment of subacute or chronic LBP. This Level I study was downgraded because a substantial percent of patients were lost to follow-up. This provides Level II evidence that, at 8 months, there is no difference between pain and disability scores between strength training and a McKenzie based exercise program in patients with CLBP. This also provides Level IV evidence that an exercise program results in significant improvement in pain and disability for patients with chronic LBP.

In a one-year follow-up to the Petersen et al<sup>72</sup> randomized controlled trial, Petersen et al<sup>73</sup> reported the long-term outcomes of the McKenzie-based exercise program and strengthening exercise program. This is the same study as above, but slightly longer follow-up and with evaluation of prognostic factors. They were able to retrieve additional patients with data on 93% at 14 months, versus the 70% follow-up at the 8-month mark. There were no differences in functional status, pain level, work status or use of health care services at 14-month follow-up between the 2 groups. Again there was significant improvement in pain and disability scores that was of questionable clinical importance. In the McKenzie group, there was a 7-point improvement in the ODI from 36 to 29 and a 9 point improvement in the other group from 39 to 30. A total of 665 reported poor outcomes on reduction of disability and 75% poor reduction of pain. There were similar modest improvements in pain scores. Outcomes were most correlated with low expectations for future work ability, lack of compliance with ex-

ercise program and lower initial baseline scores. The authors concluded that poor long-term outcomes can be explained by various patient-related factors which seemed to be stronger determinants of outcomes than the exercise programs studied. This study offers Level I therapeutic evidence that, at 14 months, there is no difference between pain and disability scores between strength training and a McKenzie based exercise program in patients with chronic LBP.

Garcia et al<sup>74</sup> aimed to compare the effectiveness of Back School and the McKenzie method for patients with chronic nonspecific LBP. Patients with LBP for at least 3 months were randomized to receive one session per week for 4 weeks of either a group-based Back School (n=74) or individual McKenzie treatment (n=74). All participants were also instructed to complete exercises at home daily. The care provider of both groups was certified by the McKenzie Institute of Brazil and the outcome assessor received two months of McKenzie training from the McKenzie-certified therapist. Pain intensity (numerical rating scale) and disability (Roland-Morris Disability Questionnaire) were assessed at baseline and 1, 3 and 6 months after randomization. Participants in the McKenzie group had statistically greater improvements in disability at one month but not 6 months compared to the Back School group. The authors concluded that the McKenzie method was slightly more effective than Back School for disability, but not for pain intensity in participants with chronic LBP. This study provides Level I therapeutic evidence that, at 6-month follow-up, the McKenzie method provides slight disability benefit as compared to the back school method though pain improvements are similar and modest at this time point. Both result in improvement, although clinical importance is debatable.

## Q2 Evidence Summary:

A systematic review of the literature yielded no studies to adequately address this question.



### Q1&2 Future Directions for Research

The work group recommends high-level studies on McKenzie/MDT for axial back pain utilizing certified MDT clinicians.



PM&R Questions 1 & 2.  
ix. Yoga

**Q1 Recommendation:**

It is suggested that, in patients with mild chronic low back pain, yoga may offer medium-term improvements in pain and function compared to usual care, although these improvements are not clinically meaningful due to low baseline pain/disability.

Grade of Recommendation: B

**Q1 Evidence Summary:**

In a randomized controlled trial, Aboagye et al<sup>75</sup> compared the cost-effectiveness of medical yoga versus evidence-based exercise therapy and self-care advice for nonspecific LBP. In a 6-week treatment period, participants were randomly assigned to participate in group medical yoga twice a week (n=52), individual standardized strength exercise therapy twice weekly (n=52), or a booklet of self-care advice and advice to stay active (n=55). Health-related quality of life (EQ-5D) was assessed at baseline, 6 weeks, 6 and 12 months. Follow-up response rates were 89% for yoga, 69% for exercise and 63% for self-care advice. At 12-month follow-up, participants in the yoga group who adhered to the recommended protocol had statistically significantly better HRQOL ( $0.79 \pm 0.14$ ) compared to self-care advice ( $0.75 \pm 0.23$ ), but there was no difference when comparing to exercise therapy. The authors concluded that 6 weeks of adherence to uninterrupted medical yoga therapy is cost-effective for early treatment of nonspecific LBP. During critical appraisal, the work group downgraded the level of evidence of this study due to less than 80% follow-up. In addition, the authors did not clearly define the nature of the inclusion criteria. These appear to be patients with nonspecific back pain, but acuity is not stated and baseline severity appears to be mild. Implication would be that these were patients with relatively acute back pain. This potential Level I study offers Level II therapeutic evidence that there was no difference in health outcomes between treatment groups for patients receiving yoga relative to an alternative exercise program, although both were better than self-care in patients with uncertain acuity of LBP.

Tilbrook et al<sup>76</sup> conducted a multicenter randomized controlled trial to examine the effectiveness of yoga for treatment of chronic or recurrent LBP. Patients

with LBP received a back pain education booklet and were randomized to participate in 12 yoga classes over 3 months (n=156) or usual care (n=157). Back function (Roland-Morris Disability Questionnaire), pain (Aberdeen Back Pain Scale), pain self-efficacy (Pain Self-Efficacy Questionnaire) and general health measures were recorded at baseline and after 3, 6 and 12 months. These patients had mild disability at baseline. The yoga group had better back function at all 3 follow-up points. Pain and general health scores were similar between groups. The authors concluded that a 12-week yoga program had greater improvements in back function compared to usual care in adults with chronic or recurrent LBP. This study provides Level I therapeutic evidence that, in patients with LBP of mild severity, yoga is associated with greater improvements in disability at one year compared to usual care.

Williams et al<sup>77</sup> compared the effects of Iyengar yoga therapy versus education in a randomized controlled trial of patients with nonspecific chronic LBP. Patients with LBP for more than 3 months were randomized to receive a 16-week period of Iyengar yoga (n=30) or education (n=30). Functional disability (Pain Disability Index), pain intensity (Short Form-McGill Pain Questionnaire), pain medication usage, pain-related attitudes and behaviors, and spinal range of motion were assessed before and after the interventions and at 3-month follow-up. Of the 60 participants enrolled, 42 (70%) completed the study. The yoga group had significant reduced pain intensity, functional disability and pain medication usage at 3-month follow-up. The authors concluded that Iyengar yoga therapy results in improvement in medical and functional LBP-related outcomes in patients with mild chronic LBP. In critique, small sample size and less than 80% follow-up were factors in downgrading the level of evidence for this study. In addition, it is not-

ed that this group of patients had chronic LBP that was mild in severity at baseline. This potential Level I study offers Level II therapeutic evidence that, in patients with LBP of mild severity, yoga may decrease disability at 3 months compared to self-directed standard medical care. It also resulted in significant improvement in pain, although these improvements were clinically very small, at least in part due to the relatively low starting scores at baseline.

Williams et al<sup>78</sup> conducted a randomized controlled trial to compare the effects of yoga and standard medical care in patients with chronic LBP. Patients with LBP for greater than 3 months were randomized to a yoga group (n=43) or control group of standard medical care (n=47). Yoga participants completed a 24-week program of biweekly yoga classes. Disability (Oswestry Disability Questionnaire), pain (VAS), depression (Beck Depression Inventory) and pain med-

ication usage were recorded upon enrollment, after 12 weeks, upon completion of the program (24 weeks) and 6-month follow-up. The yoga group experienced significantly greater functional disability, pain intensity and depression improvements compared to the usual care group at 24 weeks. The authors concluded that yoga results in improved functional disability, pain intensity and depression in adults with chronic LBP. Patient follow-up was less than 80%; therefore, the work group downgraded this study from Level I to Level II. Again, it is noted that this group of patients had chronic LBP that was mild in severity at baseline. This study provides Level II therapeutic evidence that yoga provides significant improvements in pain and disability at 6 months compared to standard care. Again, at least in part due to low starting scores at baseline, the magnitude of these improvements were small.

## Q2 Evidence Summary:

**A systematic review of the literature yielded no studies to adequately address this question.**



### Q1&2 Future Directions for Research

There is an opportunity to look at the efficacy of yoga in populations with higher baseline pain and disability.



**PM&R Questions 1 & 2.**  
x. Aerobic exercise

**Q1 Recommendations:**

**Aerobic exercise is recommended to improve pain, disability and mental health in patients with nonspecific low back pain at short-term follow-up.**

**Grade of Recommendation: A**

**There is insufficient evidence that aerobic exercise improves pain, disability and mental health in patients with non-specific low back pain at long-term follow-up.**

**Grade of Recommendation: I**

**Q1 Evidence Summary:**

Murtezani et al<sup>79</sup> conducted a randomized controlled trial to study the effectiveness of high-intensity aerobic exercise for the treatment of chronic LBP. Patients with LBP for at least 3 months were randomized to receive 3 30- to 45-minute sessions per week of supervised aerobic exercise based on individual heart rate zones (n=50) or passive modalities such as interferential current, transcutaneous electrical nerve stimulation, ultrasound and heat without any form of physical activity (n=51) for 12 weeks. LBP intensity (VAS), disability (Oswestry Low Back Pain Disability Questionnaire), fingertip-to-floor distance and psychosocial factors were assessed upon enrollment and after 12 weeks. The exercise group had significant improvements in pain intensity, disability and anxiety/depression at 12 weeks. The authors concluded that high-intensity aerobic exercise reduces pain, disability and psychological strain in patients with chronic LBP. This study offers Level I therapeutic evidence that, in patients with LBP, aerobic exercise resulted in better pain and functional outcomes compared to passive modalities at short-term follow-up.

In a randomized controlled trial, Cuesta-Vargas et al<sup>80</sup> evaluated the effect of the addition of deep water running to standard general practice compared to general practice alone for the treatment of LBP. Patients with LBP for at least three months were randomized to receive general practice plus three 30-minute sessions of deep water running per week (n=29) or general practice alone (n=29) for 15 weeks. General practice involved a physician's consultation and educational booklet. Disability (Spanish version of Roland Morris Disability Questionnaire), pain (VAS) and general

health (SF-12) were recorded at baseline and at 4, 6 and 12 months. Both groups had improvements. The deep-water running group had significantly greater improvements in pain and disability compared to general practice alone. The authors concluded that the addition of deep water running to general practice was more effective than general practice alone in patients with nonspecific chronic LBP. This study provides Level I therapeutic evidence that, in patients with LBP, the addition of aerobic exercise to an education program compared to an education program alone resulted in significant improvement in pain, disability and mental health at 12-month follow-up.

Chatzitheodorou et al<sup>81</sup> aimed to evaluate the effects of high-intensity aerobic exercise in patients with chronic musculoskeletal LBP. Patients with LBP for at least 6 months were randomized to receive a high-intensity aerobic exercise program 3 times per week (n=10) or passive modalities without physical activity (n=10) for 12 weeks. Pain (McGill Pain Questionnaire), disability (Roland-Morris Disability Questionnaire), psychological strain (Hospital Anxiety and Depression Scale) and cortisol concentrations (ng/mL) were recorded before and after the 12-week treatment period. Participants in the exercise group had significant reductions in pain, disability and psychological strain while the subjects who received passive modalities did not experience any changes. The authors concluded that high-intensity exercise improved pain, disability and psychological strain in subjects with chronic LBP, but did not improve serum cortisol concentrations. Although the sample size was small, statistically significant differences were found between patient groups. This study offers Lev-

el I therapeutic evidence that, at 12-week follow-up, high intensity aerobic exercise decreases pain, disability and anxiety/depression compared to passive modalities in patients with chronic LBP.

Tritilanunt et al<sup>82</sup> evaluated the efficacy of an aerobic exercise and health education program for the treatment of chronic LBP. Patients with LBP for at least three months were randomly assigned to participate in an aerobic exercise program (n=36) or a lumbar flexion exercise program (n=36). Health education was included in both programs. Pain (VAS), anthropometric and biochemical characteristics were re-

corded before and after the 12-week treatment period. The aerobic exercise group had significantly greater improvements in pain compared to the lumbar flexion group. The authors concluded that the aerobic exercise and education program is useful and can be a treatment option for patients with chronic LBP. This study provides Level I therapeutic evidence that, in patients with chronic LBP, aerobic exercise decreases pain more than lumbar flexion exercise and both exercise treatments resulted in significant reduction in pain.

## Q2 Evidence Summary:

**A systematic review of the literature yielded no studies to adequately address this question.**



### Q1&2 Future Directions for Research

The work group recommends randomized controlled trials with long-term follow-up looking at the benefits of aerobic exercise.



**PM&R Questions 1 & 2.**  
xi. Work hardening or conditioning

**Q1 Recommendations:**

**In patients with low back pain, work hardening may be considered to improve return to work.**

**Grade of Recommendation: C**

**There is insufficient evidence that work hardening is different than an active therapeutic exercise program or guideline-based physical therapy.**

**Grade of Recommendation: I**

**Q1 Evidence Summary:**

Bendix et al<sup>83</sup> conducted a randomized controlled trial to investigate the effectiveness of a comprehensive functional restoration program versus an intensive outpatient physical training program for the treatment of chronic LBP. Patients with chronic LBP were randomized to receive functional restoration (n=64) or outpatient intensive physical training (n=74). The functional restoration program involved physical training, ergonomic training and behavioral support for 39 hours per week for 3 weeks. The outpatient intensive physical training program consisted of 1.5 hours of training 3 times per week for 8 weeks. Patients were assessed at baseline and at one-year follow-up. There were no statistically significant differences in work capability, sick leave, health care contacts, back pain, leg pain or self-reported activities of daily living outcomes between groups. The authors concluded that functional restoration program was superior to the physical training program only in terms of overall assessment, but no other outcomes. This study provides Level I therapeutic evidence that, in patients with LBP, functional restoration and outpatient intensive training provide equivalent results for sick leave, back pain and function at one year.

Sang et al<sup>84</sup> evaluated the effectiveness of a work hardening program for the treatment of LBP. Patients with a work-related back injury who were unable to work and referred to the occupational therapy department were enrolled in a 12-week work hardening program (n=32). The program consisted of muscle stretching, lifting capacity training, carrying capacity training and work tolerance training based on the overload training principle. Participants completed two to three 90-minute sessions per week for 12 weeks. Return to work was recorded during a 3-month follow-up via

telephone. Seventy-five percent of the participants who completed the program had returned to work by 3-month follow-up. The authors concluded that since this rate was similar to other studies, the overloading principle should be used to design work hardening programs. This study offers Level IV therapeutic evidence that work hardening is associated with return to sedentary-to-medium work in 75% patients with LBP.

Casso et al<sup>85</sup> conducted a prospective study to investigate the return-to-work status one year after a physical reconditioning program in manual laborers with chronic LBP. Patients with LBP and absent from work for at least 3 months (n=125) completed a 3-week inpatient program consisting of 6 hours of group treatment per day, 5 days a week. Participants and their physicians were sent a follow-up questionnaire one year after completion of the program. Of the 109 patients who had a job available to them at the time of completion of the program, 90 (81.6%) were considered capable of returning to work full- or part-time. After one year, 57 (52.3%) patients were working and 52 patients were on disability leave (47.7%). The authors concluded that the reconditioning program had positive effects on return-to-work status after one year. This study offers Level IV therapeutic evidence that an intensive recondition program results in return to part-time or full-time work in about 80% at the end of training program and about 50% at one-year follow-up.

Beaudreuill et al<sup>86</sup> evaluated the effectiveness of a functional restoration program for patients with chronic LBP in a prospective study with one-year follow-up. Patients absent from work due to LBP for at



least three months (n=39) were enrolled in a functional restoration program. The program consisted of physician counseling, physical exercises, aerobic activity, manual handling and lifting techniques, muscle strengthening on machines, stretching and relaxation for a total of 5.5 hours per day, 5 days a week, for 5 weeks. One year after completion of the program, 25 (64%) patients had returned to work and the number of sick leave days significantly decreased compared to the year before the program. The authors concluded that the functional restoration program was effective. This study offers Level IV therapeutic evidence that, in patients with LBP, work hardening improves return-to-work rate.

Luk et al<sup>87</sup> aimed to study the effectiveness of a multidisciplinary rehabilitation program for patients with chronic LBP. Patients with LBP for at least three months (n=65) were enrolled in a 14-week multidisciplinary rehabilitation program consisting of physical conditioning, work conditioning and work readiness. LBP intensity (VAS), self-perceived disability (Oswestry Disability Questionnaire Index), range of motion, isoinertial performance of the trunk muscles and depression were recorded at baseline, week 7 and 14 and month 6. Twenty-eight (51.8%) of the 54 patients who completed the 6-month follow-up assessments returned to work. Pain significantly improved in both groups at 6-month follow-up. Disability improved significantly more in those who returned to work compared to those who did not. The authors concluded that this rehabilitation program improved physical functioning and ability to return to work. This study provides Level IV therapeutic evidence that 14-week work hardening program resulted in about 50% return-to-work (RTW) rate, improved functional scores only in those that RTW and improved pain scores regardless of RTW. RTW was predicted 74% of the time. All patients that returned to work were on sick leave at entry.

Roche et al<sup>88</sup> performed a multicenter prospective randomized controlled study to compare the short-term effectiveness of active individual therapy and a functional restoration program for the treatment of LBP. All patients were unable to work at the time of enrollment. Patients with chronic LBP were randomized to receive 5 weeks of either a functional restoration program (n=68) or active individual therapy (n=64). The functional restoration program consisted of 25 hours per week of isotonic muscular-strengthening exercises and endurance exercises increasing progressively throughout the program, referral to a psychologist and dietary advice. The active individual therapy con-

sisted of 3 hours per week of flexibility training, pain management, stretching and proprioception exercises plus instructions to complete exercises at home for 50 minutes twice a week. Trunk flexibility, endurance, pain severity (VAS) and impact of pain on quality of life (Dallas Pain Questionnaire, DPQ) such as daily activities, work and leisure activities, anxiety and depression and social interest were recorded at baseline and upon completion of the 5-week program. All outcomes improved in both groups with the exception of endurance in the active individual therapy group. Pain intensity and DPQ scores for daily activities and work and leisure were similar between groups. Other outcomes improved significantly greater in the functional restoration program compared to the active individual therapy group. The authors concluded that low-cost ambulatory active individual therapy is effective and the main advantage of a functional restoration program is improved endurance. This study offers Level I therapeutic evidence that work hardening may be slightly better than active exercise program in improving quality of life and RTW in patients with CLBP currently unable to work. This study also provides Level IV therapeutic evidence that an active to intensive exercise program results in improvement in quality of life and RTW.

Sivan et al<sup>89</sup> investigated the effect of a 3-week functional restoration program on functional and vocational outcomes in patients with chronic LBP. Patients with LBP for at least 6 months were enrolled in an intense rehabilitation program 5 days a week for 3 weeks totaling 100 hours. The program consisted of physical training (aerobics, hydrotherapy, back exercises) and psychological and occupational training (education, CBT, relaxation techniques, recreational activities, group counseling). Functional status (Oswestry Disability Index, ODI and Roland Morris Disability Questionnaire, RM) and impact on work status were assessed at baseline and at least one year after completion of the program (n=118). Functional status (ODI and RM) and work status significantly improved. The authors concluded that this functional restoration program improves the functional and vocational status of patients with chronic LBP. Approximately 1/3 of patients were lost to follow-up. This study offers Level IV therapeutic evidence that, for patients with CLBP and impaired ability to work, an intensive exercise program results in improved RTW and functional outcome scores after 2 years.

Van der Roer et al<sup>90</sup> conducted a multicenter pragmatic randomized controlled trial to study the efficacy of an intensive group training protocol for the

**136** Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

treatment of nonspecific chronic LBP. Patients with LBP for less than 12 weeks from 49 different primary care practices were randomly assigned to an intensive group training protocol (n=60) or physiotherapy according to the Dutch guidelines for LBP (n=54). The intensive group training protocol included 10 individual sessions and 20 group sessions of exercise therapy, back school and operant-conditioning behavioral principles with a goal to return to normal daily activities. Functional disability (Roland Morris disability questionnaire), pain intensity (numerical rating scale), perceived recovery and sick leave due to LBP were recorded at baseline and after 6, 13, 26 and 52 weeks. Intention-to-treat and per-protocol analyses revealed no significant differences between groups at

one-year follow-up. The authors concluded that the intensive group training protocol was not more effective than usual physiotherapy for chronic LBP. In critique, the study's sample size was small and less than 80% of patients completed follow-up. Due to these reasons, the work group downgraded the study from Level I to Level II. This is also a less chronic population than other studies with symptoms present less than 12 weeks. This study provides Level II therapeutic evidence that an intensive group training protocol involving exercise, education and behavioral principles was no more effective than PT done per the Dutch guidelines at one-year follow-up of patients with chronic LBP. This was true for functional outcomes (RM), pain and fear avoidance.

## Q2 Evidence Summary:

A systematic review of the literature yielded no studies to adequately address this question.



### Q1&2 Future Directions for Research

The work group recommends undertaking high quality clinical and cost-effectiveness studies comparing work hardening to other forms of occupational rehabilitation.

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Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

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**PM&R Question 3.** Are there specific patient or treatment characteristics that predict improved duration of pain, intensity of pain, functional outcomes and return-to-work status with SMT following an episode of low back pain?

*Definition: SMT defined as spinal manipulative therapy, manual therapy, mobilization, and high velocity thrusts*

**Recommendations:**

**There is conflicting evidence that symptoms above the knee, low fear avoidance questionnaire score, at least one hypomobile segment, and greater than 35° of internal rotation of the hip are predictive of responding to spinal manipulative therapy (SMT) for patients with acute low back pain.**

**Grade of Recommendation: I**

Flynn et al<sup>1</sup> prospectively studied a cohort of patients with LBP in order to develop a clinical prediction rule (CPR) to identify patients with LBP who are likely to improve with spinal manipulation. Patients referred to physical therapy for LBP (n=71) underwent an initial standardized examination and reported pain (11-point scale), disability (Modified Oswestry Disability Questionnaire) and beliefs about activity (Fear-Avoidance Beliefs Questionnaire). A therapist performed spinal manipulation on all patients during an initial session. Participants reported disability and attended a second treatment session 2-4 days after the initial session. If disability improvement was >50%, the study participant was ended due to success in treatment. If disability improvement was <50%, the participant attended one final treatment session after 2-4 days. Patients were also instructed to complete pelvic tilt range of motion exercise and maintain usual activity levels within pain limits. Statistical analyses aimed to determine the association between individual variables from the initial examination and categorization of successful treatment. Thirty-two patients were classified as having successful treatment. A CPR was developed using 5 variables: <16-day duration of symptoms, at least one hip with >35° of internal rotation, hypomobility with lumbar spring testing, FABQ work subscale score <19 and no symptoms distal to the knee. The authors concluded that patients with LBP who are likely to respond to spinal manipulation can be identified before treatment. This study offers Level II prognostic evidence that, in patients with LBP receiving SMT and exercise, the following clinical predictors are associated with 50% improvement for function within one week: symptoms less than 16 days, symptoms above the knee, low fear avoidance questionnaire score, at least one hypomobile seg-

ment, greater than 35° of internal rotation of the hip; presence of more predictors associated with increased likelihood of responding to treatment.

Childs et al<sup>2</sup> aimed to validate the spinal manipulation CPR developed by Flynn et al<sup>1</sup> in a multicenter randomized controlled trial. Patients who were referred to physical therapy for LBP were randomly assigned to receive exercise alone (n=61) or exercise plus manipulation (n=70). All participants completed questionnaires to measure pain (11-point pain-rating scale), Fear-Avoidance Beliefs Questionnaire (FABQ) and Oswestry Disability Questionnaire (ODQ) and were assessed by a physical therapist using the CPR. To be considered positive on the CPR, patients had to have at least 4 out of 5 of the following: duration of current episode of LBP <16 days, no symptoms distal to the knee, FABQ work subscale score <19 points, ≥1 hypomobile segment in the lumbar spine, ≥ one hip with >35° of internal rotation range of motion. Participants were invited for follow-up after one week, 4 weeks and 6 months. Patients who received manipulation had greater improvements in disability and pain than those who received exercise alone. The patients who were positive on the rule and received manipulation had greater improvement in disability and pain at all follow-up points compared to patients who were negative on the rule and received manipulation. The authors concluded that the CPR could be used to assist with decision-making in patients with LBP. This study offers Level II prognostic evidence that, in patients with LBP receiving SMT and exercise, the following clinical predictors are associated with 50% improvement for function within one week: symptoms less than 16 days, symptoms above the knee, low fear avoidance questionnaire score, at least one hy-

*Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.*

pomobile segment, greater than 35° of internal rotation of the hip; presence of more predictors associated with increased likelihood of responding to treatment.

Dougherty et al<sup>3</sup> conducted a randomized controlled trial to evaluate a modified CPR for spinal manipulative therapy (SMT) in patients with chronic LBP. Patients with chronic LBP were screened using a modified version of Flynn et al's<sup>1</sup> CPR and were categorized as positive or negative. They were then randomized to receive SMT (n=92) or active exercise therapy (n=89) twice weekly for 4 weeks. Active exercise therapy included directional preference exercises, lumbar stabilization, general flexibility and specific training exercises. To be considered positive on the modified CPR, patients had to have at least 3 out of the following: pain proximal to the knee, internal hip rotation of greater than 35°, hypomobility of one or greater lumbar segments and FABQ work subscale score of less than 19. Participants completed questionnaires at baseline and after 5, 12 and 24 weeks which included pain intensity (VAS), SF-36, disability (Oswestry Disability Index), patient satisfaction and patient expectation. Both groups experienced improvements in pain and disability after treatment. There were no significant differences in outcomes between therapy groups or based on classification on the modified CPR. The authors concluded that the modified CPR cannot be used to determine which patients would benefit more from SMT. This study offers Level I prognostic evidence that, in patients with chronic LBP receiving SMT, the following clinical predictors are not associated with a substantially different pain and functional outcome: symptoms above the knee, low fear avoidance questionnaire score, at least one hypomobile segment and greater than 35° of internal rotation of the hip.

Hancock et al<sup>4</sup> conducted a multicenter randomized controlled trial in Sydney, Australia to investigate the use of the CPR developed by Flynn et al<sup>1</sup> in patients with LBP presenting to outpatient general practice clinics. Patients who presented to a general practitioner with LBP <6 weeks received usual care (reassurance, advice to remain active and avoid bed rest and prescription of paracetamol) and were randomized into one of four treatment arms. Patients were randomized to receive either diclofenac or placebo and further randomized to receive SMT or placebo. Since neither SMT nor diclofenac were found to significantly reduce time to recovery from pain, both placebo SMT groups were considered the control group and both active SMT groups were considered the intervention group for the purpose of this study. During initial evaluation, each patient was classified using the CPR; at least 4 out of

5 criteria were necessary to be classified as positive. The participants in the intervention group (n=120) received up to 12 treatments of SMT over 4 weeks. The participants in the intervention group (n=120) received sham ultrasound for the same duration of time. Pain (11-point scale) and disability (24-point Roland Morris disability questionnaire) were recorded at 1, 2, 4 and 12 weeks. Patients who were classified as positive on the CPR had greater improvements in pain and disability regardless of treatment. There were no significant interaction effects in pain or disability between treatment groups and prediction rule classification. The authors concluded that the CPR validated by Childs et al<sup>2</sup> was not generalizable to patients in the primary care setting. This study provides Level II prognostic evidence that, in patients with acute LBP receiving SMT, the following clinical predictors were not found to be associated with improvements for pain and function: symptoms less than 16 days, symptoms above the knee, low fear avoidance questionnaire score, at least one hypomobile segment, greater than 35° of internal rotation of the hip; presence of more predictors associated with increased likelihood of responding to treatment

Hallegraeff et al<sup>5</sup> assessed the efficacy of manipulative therapy in a multicenter randomized controlled trial. Patients with acute nonspecific LBP who met three factors of the CPR (duration of symptoms <16 days, no pain distal of the knee, age >35 years)<sup>1</sup> were randomized into one of 2 treatment arms. The intervention group (n=31) received 4 sessions of manipulative therapy along with physical therapy (low intensity endurance exercises). The control group (n=33) received physical therapy alone. Pain (VAS), disability (Oswestry Disability Low Back Pain Questionnaire) and mobility (Sit-and-Reach Test) were recorded at baseline and after 2.5 weeks of treatment. The patients who received manipulation therapy had a greater improvement in disability compared to the control group, but there were no significant differences in pain or mobility. The authors concluded that although there were statistically significant interaction effects for disability and sex, these had low effect size and there were no significant effects for pain or mobility. This study provides Level I prognostic evidence that the addition of manipulative therapy added benefit over physical therapy alone for improving disability. However, it did not support that the two-factor CPR was predictive of responders (predictive variables include: duration of symptoms less than 16 days, no pain distal to the knee and age greater than 35 years).

**There is insufficient evidence that hyper- or hypo-mobility, patient age, strains and sprains, instability, severe affective distress, relationship with healthcare provider, use of thrust vs. non-thrust techniques, pretreatment psychological or socioeconomic status, or number of visits are predictive factors of response to spinal manipulative therapy (SMT).**

**Grade of Recommendation: I**

Cook et al<sup>6</sup> aimed to evaluate the predictive value of prognostic variables in outcomes in patients with LBP in a secondary analysis of a multicenter randomized controlled trial (RCT). All participants received manual therapy for 2 visits, either thrust (n=76) or non-thrust (n=73). The results of the RCT found no differences between thrust or nonthrust techniques. Outcome measures included disability per the Oswestry Disability Index (ODI), Numeric Pain Rating Scale (NPRS), total visits and report of rate of recovery. Predictive values included body mass index (BMI), NPRS at baseline, ODI at baseline, Fear-Avoidance Beliefs Questionnaire (FABQ) work subscale at baseline, CPR for spinal manipulation (presence of at least 4 of the following: no pain below knee, symptom duration <16 days, FABQ-W score <19, 1+ hips with internal rotation range of motion >35° and 1+ hypomobile lumbar segment), duration of symptoms (weeks), age, irritability, diagnosis and allocation to thrust versus nonthrust technique. Logistic and linear regression modeling were used to create predictive models and find significant explanatory power for the outcome variables. A positive CPR at baseline was present in all 4 models. The authors concluded that the CPR was prognostic for all outcome measures. This study offers Level II prognostic evidence that, in preselected patients with LBP, CPR is a predictor of success for treatment with SMT; factors included meeting the CPR, age, strains and sprains, instability, irritability, ODI score on first visit, duration of symptoms and met numerical pain rating scale score on first visit.

In a retrospective analysis of data from a randomized controlled trial, Cecchi et al<sup>7</sup> aimed to identify predictors of response to various interventions for chronic LBP. Patients with chronic LBP were randomly assigned to receive back school (n=68), individual physiotherapy (n=68) or spinal manipulation (n=69). Participants were classified as nonresponders to therapy if their changes in Roland Morris Disability score improved by less than <2.5 after treatment. Potential predictors of response, including demographics, baseline disability and pain intensity and life satisfaction, were analyzed using multivariable backward logistic regression to predict the probability of non-

response to treatment. The authors concluded that a lower baseline Roland Morris Disability score predicted nonresponse for physiotherapy, but not for spinal manipulation. This study provides Level II prognostic evidence that there are no predictive factors for success with SMT.

Cook et al<sup>8</sup> analyzed data from a multicenter randomized clinical trial to determine if changes in pain during or between sessions of manual therapy were associated with outcomes in patients treated for LBP. Participants (n=100) had been randomized to receive thrust or nonthrust manipulation, along with a home exercise program. Patients reported pain (Numerical Pain Rating Scale), disability (Oswestry Disability Questionnaire) and rate of recovery (0-100%) at baseline, after two sessions and at discharge. Functional recovery was defined as ≥50% reduction in Oswestry Disability Index (ODI). The authors concluded that a change of ≥2 points on the 11-point scale is associated with functional recovery at discharge. This study offers Level II prognostic evidence that, in preselected patients with LBP treated with SMT, a 2-point reduction in pain score after the second visit predicts a higher likelihood of functional improvement.

In a secondary analysis of data from a prospective, multicenter, randomized controlled trial (RCT), Donaldson et al<sup>9</sup> studied outcomes in patients with LBP who were matched, unmatched, or indifferent to their preference of thrust versus nonthrust manual therapy intervention. Prior to randomization, patients indicated their preference of an exercise program plus two sessions of either thrust or nonthrust manual therapy. As part of the RCT, 77 participants were allocated to thrust manipulation and 77 participants were allocated to nonthrust manipulation. Outcomes of disability (Oswestry Disability Index), pain perception (11-point Numerical Pain Rating Scale), care intensity, fear-avoidance behaviors (FABQ) and perception of extent of recovery were measured. There were no statistically significant differences in any of the outcomes between patient preference groups. The authors concluded that there were no statistical differences in disability or pain in patients who were matched, unmatched, or indifferent to their assigned



intervention. This study provides Level II prognostic evidence that, in patients with LBP, patient preference for specific manipulation technique did not affect outcomes.

Fritz et al<sup>10</sup> investigated the value of posterior-anterior mobility testing for predicting disability outcomes in patients with LBP in a randomized controlled trial. Participants underwent an initial assessment with posterior-anterior mobility testing and were classified as presence or absence of hypomobility and hypermobility. Participants were randomized to receive an intervention of manipulation (n=70) or stabilization exercise (n=61) for 4 weeks. Disability (Oswestry Disability Questionnaire) was recorded upon study enrollment and after the 4-week treatment. Three-way repeated measures analyses of variance were performed to assess interaction effects of mobility categorization and intervention on change in disability. The authors concluded that patients with LBP and hypomobility had better outcomes with manipulation while those with hypermobility were more likely to benefit from stabilization exercise. This study offers Level I prognostic evidence that patients with hypomobility had better functional outcomes when receiving SMT and those with hypermobility had better functional outcomes when receiving exercise.

Haas et al<sup>11</sup> conducted a randomized controlled trial to evaluate the effect of number of spinal manipulation treatment visits with or without physical modalities on pain and disability outcomes in patients with LBP. Patients were randomized to a treatment intervention of spinal manipulation only or spinal manipulation plus physical modalities (soft tissue therapy, hot packs, electrotherapy, or ultrasound). Patients were randomly assigned number of visits per week (1, 2, 3, or 4) for 3 weeks. Pain intensity and disability (Modified Von Korff Scales) were recorded. There were no significant effects of treatment intervention type. There were significant effects of number of treatment sessions per week (3–4 sessions per week) on pain and disability at 4 weeks. The authors concluded that relief was substantial for patients receiving 3 to 4 sessions per week for 3 weeks. This study offers Level II prognostic evidence that, in patients with LBP who receive SMT, the optimal number of treatments is 3 to 4 times a week for 3 weeks.

Hoehler et al<sup>12</sup> investigated the predictive value of a modified Minnesota Multiphasic Personality Inventory (MMPI) for response to spinal manipulation in patients with acute or chronic LBP. Patients referred for spinal manipulative therapy (n=90) complet-

ed questionnaires and a modified version of MMPI. They reported improvement in pain immediately after treatment and again several days later (reported as much better, somewhat better, no change, somewhat worse or much worse). Other variables such as age, sex and duration of pain were also included in analysis to study predictive value. Immediately after treatment, there were no significant correlations between psychological measures and extent of relief. Several days after treatment, the percentage of patients reporting improvement was lower; lack of improvement was associated with hypochondriasis, hysteria and functional LBP. The authors concluded that underlying psychosomatic factors may predispose the condition to recur. This study provides Level III prognostic evidence that MMPI scores indicating hysteria, hypochondriasis or higher LBP scores are associated with recurrence of pain after manipulation and not associated with immediate response to SMT.

In an analysis of data from a randomized controlled trial, Niemisto et al<sup>13</sup> investigated the predictive value of sociodemographic data for response to treatment for chronic (>3 months) LBP. Patients were randomized to receive spinal manipulation therapy (SMT), exercise and physician consultation (n=102) or physician consultation only (n=102). Questionnaires were completed to record potential risk factors such as sociodemographics, characteristics of LBP, disability, quality of life, work ability, psychological variables (Modified Somatic Perception Questionnaire) and physical activity at work. Patients were clustered into groups based on improvement in pain intensity (VAS) and disability (Oswestry Questionnaire) at one-year follow-up. Results indicated that severe affective distress was a risk factor for poor response to SMT. Risk factors for poor response to the physician consultation approach included >25-day sick leave during the previous year, poor life control and generalized somatic symptoms. The authors concluded that psychosocial differences are important determinants for treatment outcomes. This study offers Level II prognostic evidence that, in patients with LBP, severe affective distress is associated with a poor response to treatment outcome with SMT.

Underwood et al<sup>14</sup> conducted an analysis of the UK Back Pain Exercise And Manipulation (UK BEAM) Trial to identify characteristics predictive of response to treatment of LBP. The UK BEAM Trial (n=1334) found that compared treatment packages of spinal manipulation (up to 8 sessions over 12 weeks), manipulation plus exercise (6 weeks manipulation and 6 weeks of exercise) and exercise alone (9 group class-

es over 12 weeks) against usual care, including *The Back Book*. Disability (Roland Morris Disability Questionnaire), back pain beliefs (Fear Avoidance Beliefs Questionnaire), psychological state (Distress and Risk Assessment Method), treatment expectations and other demographic characteristics were obtained before randomization and at 3-month and one-year follow-up. None of the studied baseline characteris-

tics predicted response (disability per Roland Morris Disability Questionnaire) to treatment. The authors concluded that there were no characteristics that predicted response to the UK BEAM treatment packages. This study offers Level II prognostic evidence that, in patients with subacute LBP receiving SMT, there were no predictors (including pain duration) for response to treatment.



### Future Directions for Research

1. There has been a lot of work done to look at the CPR for response to acute LBP developed by Flynn et al<sup>1</sup>, with conflicting results. It is possible that a large randomized controlled trial with specific attention to subgroups may identify certain populations that are responders, as there have been conflicting outcomes to date.
2. There is very little work done for clinical predictors in chronic LBP. In addition, there have been several well conducted studies looking at response to thrust versus nonthrust, mobility versus stability, socioeconomic and psychological factors and number of visits. Repeated high quality studies looking at these questions could be useful for generating higher levels of recommendations either for or against.

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Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.



**PM&R Question 4.** In patients undergoing treatment for low back pain, what are outcomes, including duration of pain, intensity of pain, functional outcomes and return-to-work status, for exercise therapy alone versus exercise with cognitive behavioral therapy (CBT)?

### Recommendation:

**There is conflicting evidence that addition of cognitive behavioral therapy (CBT) to an exercise program results in significant improvement in pain and function compared to exercise alone in patients with chronic low back pain.**

**Grade of Recommendation: I**

Steenstra et al<sup>1</sup> conducted a randomized controlled trial to assess the effectiveness of graded activity as part of a return-to-work (RTW) program for patients with LBP. Patients enrolled in a multistage RTW program who were absent from work greater than 8 weeks due to LBP were randomized to receive graded activity (n=55) or usual care treatment according to Dutch occupational physician guidelines for LBP (n=57). All these patients were treated initially from 2 to 6 weeks following injury in a pain management program and failed. The graded activity used an operant-conditioning behavioral approach in 2 one-hour sessions per week for a maximum of 26 sessions and ended when the participant fully returned to work. Outcome measures included severity of pain, functional status, total number of days on sick leave during follow-up and the number of days off work until first RTW for more than 28 days. Graded activity prolonged RTW and did not improve pain or functional status. The authors concluded that graded activity was not effective for any of the outcome measures. This study offers Level I evidence that, in patients with LBP, graded activity is not effective for improving return to work, disability, or pain compared to usual care according to Dutch guideline care.

Lindstrom et al<sup>2</sup> studied the effectiveness of graded activity to restore occupational function in patients with LBP. Blue-collar workers with subacute, nonspecific, mechanical LBP, absent from work for at least 8 weeks due to LBP were randomized to the graded activity group (n=51) or control group (n=52). The graded activity program used an operant-conditional behavioral approach based on measurements of functional capacity and a workplace visit while the control group continued to be traditionally treated by their regular physicians. The patients in the graded activity group returned to work significantly earlier than those in the control

group. The authors concluded that the patients with subacute, nonspecific, mechanical LBP in the graded activity group had faster restoration of occupational function and reduced long-term sick leave compared to those who received traditional care. This study provides Level I therapeutic evidence that, in patients with subacute LBP, a graded activity program is associated with decreased health care utilization, increased return to work and decreased sick leave at 2 years as compared to usual care.

Johnson et al<sup>3</sup> conducted a multicenter randomized controlled trial to study the effect of a group exercise and education program on pain and disability in patients with persistent LBP, as well as its cost-effectiveness and whether patient preference influences outcomes. Patients who had LBP persisting 3 months after initial consultation to one of 9 family medical practices in the United Kingdom were randomized into an intervention or control group. The control group (n=118) received an educational booklet and audio-cassette along with usual care. The intervention group (n=116), in addition to the same resources as the control group, received 8 2-hour group sessions over 6 weeks that included exercise and education from a physiotherapist using a cognitive behavioral therapy (CBT) approach. All participants were sent a questionnaire that measured pain severity (100-mm VAS), disability (Roland-Morris Disability Questionnaire) and general health (EQ-5D) at 3, 9 and 15 months postrandomization and at 6 and 12 months post-treatment. Twelve months post-treatment, 196 subjects (84%) completed follow-up. Both groups had significant improvements in pain and disability, but there were no significant differences between groups. The incremental cost-effectiveness ratio was \$8,650 per quality adjusted life year. Patients in the intervention group who had expressed a preference for the intervention before randomization had significant improvements in pain

**146** Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

and disability compared to those in the intervention group who had initially expressed a preference for the control group. The authors concluded that the intervention with exercise and education with CBT had only a small effect in reducing LBP and disability over a one-year period. However, they recommended further investigation regarding the impact of patient preference for treatment on outcomes. This study offers Level I therapeutic evidence that, in patients with LBP, addition of group-exercise-based CBT produces no meaningful improvement at 15 months compared to educational pack alone unless patients had preference for treatment.

In a parallel-group, randomized, superiority controlled study, Monticone et al<sup>4</sup> investigated the effect of a CBT-based multidisciplinary intervention program targeted against fear-avoidance beliefs in patients with chronic (>3 months) LBP. Patients referred to a specialized rehabilitation institute in Italy for chronic LBP were randomized to receive the intervention treatment with exercise or exercise alone. Both groups participated in 2 60-minute exercise sessions per week for 5 weeks and were encouraged to continue home exercise twice weekly for a year. The intervention group (n=45) additionally received a 60-minute CBT session each week for 5 weeks plus a 60-minute session with a psychologist once per month for a year. The control group (n=45) did not receive any resources in addition to the exercise program alone. Participants were asked to complete questionnaires pretreatment, immediately post-treatment and 12- and 24-months post-treatment that measured disability (Roland-Morris Disability Questionnaire), fear-avoidance behaviors (Tampa Scale for Kinesiophobia), pain (numerical rating scale) and the Short-Form Health Survey. All participants completed the follow-up. Results revealed significant improvements in all outcomes in the intervention group while the control group experienced no significant changes. The authors concluded that the multidisciplinary program was superior to the exercise program in reducing disability, fear-avoidance beliefs and pain and enhancing the quality of life of patients with chronic LBP for at least one year after the conclusion of the intervention. This study offers Level I therapeutic evidence that CBT via a psychologist with exercise results in significant improvement in pain, function and fear-avoidance behaviors at one year versus exercise alone.

Vibe Fersum et al<sup>5</sup> aimed to compare the effect of classification-based cognitive functional therapy versus traditional manual therapy and exercise on

pain and disability outcomes in patients with LBP. Participating patients with chronic LBP (>3 months) in outpatient practices in a Norwegian university town were randomized into an intervention group or control group. The participants in the intervention group (n=62) received 12 weeks of individualized sessions that included a cognitive component, specific movement exercises to normalize maladaptive movement behaviors identified, integration of daily functional activities that the patient had been avoiding and a physical activity program. The participants in the control group (n=59) underwent joint mobilization or manipulation per best current practice and were instructed to complete general exercises or motor control exercises at home. Follow-up questionnaires included perceived function (Oswestry Disability Index), pain (Pain Intensity Numerical Rating Scale), anxiety and depression (Hopkins Symptoms Checklist), fear-avoidance beliefs (Fear-Avoidance Beliefs Questionnaire), total lumbar spine range of motion, patient satisfaction, sick-leave days and care-seeking. A total of 51 and 43 participants completed follow-up assessments in the intervention and control groups, respectively. The patients in the intervention group had clinically- and statistically-significantly greater improvements in disability and pain intensity compared to the control group. The authors concluded that the classification-based cognitive functional therapy resulted in superior outcomes compared to traditional manual therapy and exercise in patients with chronic LBP. In critique, less than 80% of study patients completed follow-up. Due to this reason, the work group downgraded the level of evidence for this study. This potential Level I study provides Level II therapeutic evidence that physical therapy based cognitive functional therapy provides improvements in pain, function and fear-avoidance behaviors at 1 year compared to standard physical therapy.

Friedrich et al<sup>6</sup> conducted a randomized controlled trial to investigate the long-term effect of a combined exercise and motivation program versus exercise alone on disability outcomes in patients with chronic (>4 months) LBP in Austria. All participants completed a questionnaire at baseline to measure disability (13-item questionnaire by Greenough and Fraser), pain intensity (101-point numerical rating scale) and working ability. The participants randomized to the control group (n=49) were prescribed ten 25-min exercise sessions with follow-up assessments at 3.5 weeks (73.5%), 4 months (83.7%), 12 months (71.4%) and 5 years (61.2%). In addition to the same exercise prescription, the participants randomized

to the intervention group (n=44) also received extensive counseling, reinforcement techniques from the therapist and encouragement to post a treatment contract and complete an exercise diary. The intervention group had follow-up at 3.5 weeks (86.4%), 4 months (97.7%), 12 months (77.3%) and 5 years (59.1%). Disability scores improved in both groups at all follow-up points, but the cumulative effect in the intervention group was more than twice than the control group. The patients in the intervention group experienced a steady decrease in pain intensity from baseline to 5-year follow-up while the control group only had a decrease in pain intensity from baseline to 4-month follow-up. The authors concluded that the combined exercise and motivation program was superior to exercise alone. In critique, follow-up of less than 80% was a factor in downgrading the level of evidence for this study from Level I to Level II. This study provides Level II therapeutic evidence that the addition of a motivational program to an exercise program provides improvements in pain and working ability at one year compared to exercise alone.

Monticone et al<sup>7</sup> investigated the effect of a multidisciplinary rehabilitation program compared to usual care on outcomes in patients with chronic LBP in a randomized controlled pilot study. Patients with chronic LBP (>3 months) were randomly assigned to the intervention group or a control group to receive usual care. The control group (n=10) participated in rehabilitation with passive spinal mobilization, stretching, muscle strengthening and postural control. The participants in the intervention group (n=10) participated in a multidisciplinary program including spinal stabilizing exercises and CBT in addition to usual care. Participants completed a questionnaire to measure disability (Oswestry Disability Index), kinesiophobia (Tampa Scale for Kinesiophobia), catastrophizing (Pain Catastrophizing Scale), pain (Pain Numerical Rating Scale) and quality of life (Short-

Form Health Survey) at baseline, immediately after the 8-week trial and 3-months post-treatment. The authors concluded that the multidisciplinary program with CBT and exercise was superior to exercise alone in reducing disability, kinesiophobia, catastrophizing and enhancing quality of life in patients with chronic LBP. Due to the small sample size, the work group downgraded this potential Level I study. This study provides Level II evidence that CBT plus stabilization exercise plus usual care is better than usual care alone at 3 months' follow-up for patients with chronic LBP.

Sahin et al<sup>8</sup> conducted a randomized controlled trial to compare outcomes in patients with chronic LBP who participated in a program with exercise, physical therapy and back school (n=75) compared to exercise and physical therapy alone (n=75). The back school program, taught by a physiatrist, included education on the function of the back, life skills and discussion of problems and problem-solving skills. All participants completed questionnaires to measure pain (VAS) and functional status (Oswestry Low Back Pain Disability Questionnaire) at baseline, immediately after the 2-week trial and 3 months after treatment. Both groups experienced improvements in pain and functional status immediately after treatment. At 3-month follow-up, the participants who participated in back school had significantly greater improvements in pain and functional status compared to those who participated in exercise and physical therapy alone. The authors concluded that, in patients with chronic LBP, the addition of back school was more effective than exercise and physical treatment alone. This study provides Level I evidence that, in patients with chronic LBP, pain and disability scores improved for both PT plus exercise group as well as PT plus exercise combined with CBT. At 3-month follow-up, the addition of CBT resulted in statistically significant but not clinically significant improvement compared to the group without CBT.



### Future Directions for Research

There were several high-quality studies with heterogeneity across outcome measures, cohorts of patients and types of interventions. It is clear that in some cases, CBT offered a distinct benefit. Future research will need to focus on details of comparative effectiveness study design to identify the specific variables that contribute to success.

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**PM&R Question 5.** In patients undergoing treatment for low back pain, what are outcomes, including duration of pain, intensity of pain, functional outcomes and return-to-work status, for a lumbar stabilization exercise program versus a general fitness program?

*Definition: Lumbar stabilization exercises are focused on facilitating and strengthening specific muscles that directly or indirectly control spinal joint function, especially the abdominal, gluteal and spinal extensor muscle groups. General fitness programs are not focused on specific muscle groups; by definition the goal is to improve the overall general fitness of the patient by using a combination of aerobic conditioning with stretching/strengthening of all major muscle groups.*

### Recommendation:

**It is suggested that a specific stabilization exercise program is equivalent to a general exercise program.**

**Grade of Recommendation: B**

Aluko et al<sup>1</sup> conducted a preliminary randomized controlled trial to compare outcomes in patients with LBP completing regular trunk exercises with or without additional core stability exercises. Thirty-three patients with LBP for ≤6 weeks were randomized to receive regular core stability exercises (n=17) or regular exercise plus 8 specific stabilization exercises (n=16)

for 6 weeks. Trunk sagittal acceleration (Lumbar Motion Monitor), pain (pain VAS) and disability (Roland Morris Disability Questionnaire) were measured at baseline, 3 weeks, 6 weeks and 3 months. Outcomes improved in both groups, but there were no statistical differences between groups. The authors concluded that the addition of specific core stability ex-

Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

ercises does not provide additional benefits for acute LBP compared with exercise alone at short-term follow-up. Due to the small sample size, the work group downgraded this study. This potential Level I study offers Level II therapeutic evidence that, compared to general exercise program, stabilization adds no benefit in terms of pain or disability.

Koumantakis et al<sup>2</sup> compared outcomes in patients with subacute or chronic back pain after completing an exercise program with versus without additional stabilization exercises in a randomized controlled trial. Patients with recurrent nonspecific back pain were randomized into an exercise-only group (n=26) or stabilization-enhanced exercise group (n=29). All participants received *The Back Book* along with twice weekly 45–60 minute sessions and encouraged to repeat the assigned exercises at home for 30 minutes 3 times per week. Outcomes of pain (Short-Form McGill Pain Questionnaire), disability (Roland-Morris Disability Questionnaire) and cognitive status (Pain Self-Efficacy Questionnaire, Tampa Scale of Kinesiophobia, Pain Locus of Control Scale) were recorded at baseline, immediately after intervention and 3-months after intervention. All outcomes improved with times in both groups. Disability improved significantly more in the general exercise group compared to the stabilization-enhanced group. Otherwise, there were no statistically significant differences in outcomes between groups. The authors concluded that the addition of stabilization exercises do not appear to provide additional benefit to patients with subacute or chronic LBP without spinal instability. In critique, the sample size is small and less than 80% of patients completed follow-up. In addition these are a mixture of subacute and chronic patients that are not subgrouped and the distribution across interventions is uncertain. Due to these reasons, the work group downgraded the study from Level I to Level II. This study provides Level II therapeutic evidence that a general exercise and stabilization program results in similar pain relief and functional improvement in patients with low baseline disability.

Unsgaard-Tondel et al<sup>3</sup> compared outcomes of motor control exercises, sling exercises and general exercises for the treatment of LBP in a randomized controlled trial. Patients with chronic nonspecific LBP (n=109) were randomized to one of 3 intervention groups: low-load ultrasound-guided motor control exercises (n=36), high-load sling exercises (n=36), or general exercises (n=37). All participants received an educational booklet on LBP, were encouraged to stay active in their daily lives and participated in their assigned

therapy once a week for 8 weeks. Outcomes included pain (Numeric Pain Rating Scale), self-reported activity limitation (Oswestry Disability Index), function (Fingertip-to-Floor Test) and fear-avoidance beliefs and were recorded at baseline, after treatment and at one-year follow-up. There were no significant differences in outcomes between groups. The authors concluded that there is no evidence of benefits of the studied motor control exercises or sling exercises compared to general exercises for chronic LBP. In critique of the methodology, the work group downgraded this potential Level I study due to the small sample size without power analysis and overall mild disability at baseline. This study provides Level II evidence that Pilates as a form of stabilization exercise are equal to general exercise program for patients with chronic LBP and relatively low-level baseline disability.

Mostagi et al<sup>4</sup> aimed to compare pain and functionality outcomes of Pilates versus general exercise in patients with chronic LBP in a randomized controlled trial. Patients with non-specific chronic LBP were randomized to participate in Pilates (n=11) or general exercise (n=11) twice weekly for 8 weeks. Outcome measures of pain (VAS), functionality (Quebec Back Pain Questionnaire) and flexibility (kinematic analysis measuring the hip joint angle) were measured at baseline, immediately after treatment and after three-month follow-up. Follow-up rate was 91%; 77% of patients were included in analysis. The participants in the general exercise group had improved functionality at both follow-up time points compared to baseline. There were no significant pain or functionality differences between groups otherwise. The authors concluded that there were no differences in pain and functionality after patients with chronic LBP completed general exercise versus Pilates, but the subjects in the Pilates group had increased functionality and flexibility. The work group downgraded this study due to small sample size and less than 80% follow-up. This study provides Level II evidence that Pilates is equivalent to general exercise program for patients with chronic LBP.

Rasmussen-Barr et al<sup>5</sup> tested the hypothesis that stabilizing treatment has more long-term effectiveness than manual treatment for patients with LBP in a randomized trial. Patients with LBP greater than 6 weeks were randomized to receive 6 weeks of either stabilizing training (n=22) or manual therapy (n=20). Stabilizing training consisted of training on how to activate and control deep abdominal and lumbar multifidus muscles. Manual therapy included a combination of muscle stretching, traction, soft tissue mobili-

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zation and mobilization of thoracic and upper lumbar segments if needed. Pain (VAS), general health (VAS), functional disability (Oswestry Low-Back Pain Questionnaire) and perceived difficulty (Disability Rating Index) were measured at baseline (n=42), after treatment (n=41) and at 3-month follow-up (n=33) and 12-month follow-up (n=31). Pain and disability improved in both groups. While there was a small differ-

ence favoring stabilization, this was not clinically significant. In critique, this study had a small sample size and less than 80% follow-up. Due to these reasons, the work group downgraded this study. This potential Level I study provides Level II therapeutic evidence that, in patients with subacute and chronic LBP, SMT and stabilization exercise provide similar improvements in pain and function at one year.



### Future Directions for Research

There were several high quality studies with heterogeneity across outcome measures, cohorts of patients and types of interventions. Future research will need to focus on details of comparative effectiveness study design to identify the specific variables that contribute to success.

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**PM&R Question 6.** In patients undergoing treatment for low back pain, what are outcomes, including duration of pain, intensity of pain, functional outcomes and return-to-work status, for SMT versus SMT plus active exercise?

### Recommendation:

**It is suggested that the addition of exercise to SMT results in similar outcomes to SMT alone.**

**Grade of Recommendation: B**

Researchers for the UK BEAM Trial <sup>1</sup> compared outcomes in patients with LBP who received treatment of “best care” alone or with additional exercise classes, spinal manipulation, or manipulation followed by ex-

ercises. Patients had back pain for at least 4 weeks. In this multicenter pragmatic randomized trial, participants (n=1334) were randomized into four groups: the “best care” group (n=338) to receive active manage-

Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.



ment and *The Back Book*, the exercise program group (n=310) with up to nine community classes over 12 weeks in addition to “best care,” the spinal manipulation group (n=353) with 8 sessions over 12 weeks in addition to “best care,” or the combined group (n=333) which included 6 weeks of manipulation and 6 weeks of exercise in addition to “best care.” Disability (Roland Morris disability questionnaire) was recorded at baseline and at 3- and 12-month follow-up. All groups experienced improvement in disability scores at all time-points. The authors concluded that “relative to ‘best care’ in general practice, manipulation followed by exercise achieved a moderate benefit at three months and a small benefit at 12 months; spinal manipulation achieved a small to moderate benefit at 3 months and a small benefit at 12 months; and exercise achieved a small benefit at 3 months but not 12 months.” Due to less than 80% follow-up, the work group downgraded this study from Level I to Level II. Length of symptoms prior to treatment beyond 4 weeks was unknown. Therefore the final results were evaluated over an unknown duration of baseline chronicity. This study offers Level II therapeutic evidence that, in patients with LBP, educational booklet, educational booklet plus exercise, educational booklet plus manipulation alone, and educational booklet plus manipulation and exercise provide similar improvements in pain and function at one year (baseline scores indicate mild disability).

In a randomized controlled trial, Hsieh et al<sup>2</sup> assessed the effectiveness of back school, joint manipulation, myofascial therapy and combined joint manipulation and myofascial therapy in patients with subacute LBP. Patients with LBP for more than 3 weeks but less than 6 months were randomly allocated into one of four treatment groups for 3 weeks: back school (n=48), joint manipulation (n=49), myofascial therapy (n=51), or combined joint manipulation and myofascial therapy (n=52). Pain (VAS) and Roland-Morris activity scales were assessed at baseline, immediately after the 3-week treatment period and 6 months after completion of treatment. All groups had improvements in outcomes immediately after treatment – with no differences between groups. The authors concluded that back school or combined joint manipulation and myofascial therapy were as effective as joint manipulation or myofascial therapy alone for the treatment of subacute LBP. The inclusion criteria are a weakness in this study, as the outcomes of patients with pain ranging from 3 weeks to 6 months can be substantially variable, although in this case it did not seem to make any difference. This study offers Level I therapeutic evidence that, in patients with LBP from 3 weeks to 6 months, myofascial therapy, joint manipulation, combination therapy (myofascial and joint manipulation) and back school provided similar improvement in pain and function at 6 months.



### Future Directions for Research

There is a need for well-conducted studies to evaluate the benefit of SMT alone compared to SMT and exercise in the treatment of LBP.

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**PM&R Question 7.** In patients undergoing treatment for low back pain, what are the outcomes, including duration of pain, intensity of pain, functional outcomes and return-to-work status, for bed rest versus active exercise?

### Recommendations:

**It is suggested that, for patients with acute low back pain, those that exercise more at baseline and use exercise to facilitate recovery are predicted to have better functional outcomes over time than patients who do not exercise or use bed rest to help with recovery.**

**Grade of Recommendation: B**

**For patients with acute low back pain, it is suggested that advice to remain active within limits of pain compared to short periods of bed rest from 3 to 7 days all result in similar outcomes in pain and function at short- and medium-term follow-up.**

**Grade of Recommendation: B**

### Work Group Consensus Statement:

In the absence of reliable evidence for patients with nonspecific back pain, based on abundant data for other spinal disorders that result in back pain, it is the work group's opinion that remaining active is preferred and likely results in better short-term outcomes than does bed rest.

Oleske et al<sup>1</sup> evaluated the effect of personal, medical and job factors on recovery from work-related low back disorders in an observational longitudinal study. Active employees at 2 automotive plants with a work-related low back disorder were included in the study (n=352). Participants completed a structured interview related to LBP, health habits, job factors and medical interventions at enrollment and at 1, 2, 6 and 12 months afterwards. From the interview, 106 items were selected as independent variables and compared with the dependent variable of recovery from LBP (Oswestry Disability Questionnaire). Better recovery was associated with lower stress levels and exercise outside of work. Cigarette smoking and bedrest were associated with higher disability levels. The authors concluded that personal modifiable factors are major influences in the recovery from work-related, low back disorders. This study provides Level II evidence that more exercise at baseline is a prognostic factor for better improvement than bedrest to help recovery.

Hagen et al<sup>2</sup> conducted a randomized controlled study to evaluate the effect of a light mobilization program

on the duration of sick leave. Patients who were on sick leave 8–12 weeks due to LBP were randomized to a control group (n=220) to receive conventional primary health care or an intervention group (n=237). The intervention group was invited to a spine clinic for an approximately 3-hour visit with a physician and physiotherapist. Participants in the intervention group were encouraged to remain active and were given additional information about LBP and radiographs. All participants completed questionnaires at 3, 6 and 12 months. At all 3 time points, a greater percentage of the intervention group had returned to full-duty work compared to the control group. The authors concluded that early intervention, information and recommendations to stay active significantly reduced sick leave for patients with LBP. This study provides Level II evidence that, in subacute LBP patients (8 to 12 weeks LBP), one visit offering reassurance and encouragement to increase activity level versus a regular primary care visit resulted in significantly more patients who returned to work at one year.

Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

Rozenberg et al<sup>3</sup> conducted a randomized controlled trial to compare LBP outcomes after 4 days of bed rest versus normal daily activity. Patients with acute LBP or an acute-on-chronic episode of LBP with current symptoms for <72 hours were randomized into two treatment groups. Patients in the bed rest group (n=137) were encouraged to stay in bed for at least 16 hours of a 24-hour day for 4 days. Patients in the normal activity group (n=140) were instructed to continue normal daily activity as able and to spend no more than 12 hours per 24-hour day in bed. Medical treatment was otherwise the same across groups; physical therapy, bracing and chiropractic care were not allowed in either group for 3 months during the trial. Outcomes were measured with the VAS and Eifel index (French version of Roland Morris) plus a global assessment score. A total of 277 out of 281 patients were analyzed with intention-to-treat analysis, which satisfied power calculation. Compliance rates were 72% and 90% in the bed rest and usual activity groups, respectively. At one week and 3 months, both groups improved, with no significant difference in pain or function scores. The authors concluded that normal activity is at least equivalent to bed rest. This study provides Level I evidence that, for patients with acute LBP of less than 3 days in duration, implementation of bed rest for 4 days versus usual care results in similar outcomes for pain and function at short- and medium-term follow-up.

Wiesel et al<sup>4</sup> aimed to objectively analyze the roles of bedrest and medication for the treatment of LBP. Two

hundred male basic combat trainees (average age 23 years) were randomly allocated to an experimental group or control group in a 3-section study. The first part of the study focused on bedrest (n=80); the second and third parts focused on medication treatment (n=45 and n=75). During the first section of the study, all participants described their pain at baseline and were given a quantifiable score each day. The experimental group was admitted to the hospital for bedrest treatment until their LBP subsided. The control group was assigned restricted-duty without exercise, but entailed standing on their feet. The primary outcome was return to full duty which occurred when pain was resolved and physical exam had returned to normal. The bed rest group returned to duty significantly faster than the ambulatory group (6.6 days in the bed rest group compared to 11.8 days in the light duty group). The authors concluded that bedrest, as compared with ambulation, will decrease the amount of time lost from work by 40% to 50%; decrease discomfort by 60%; and, in combination with analgesic medication, will further decrease the amount of pain. In critique of the methodology, the workgroup downgraded this potential Level I study due to the use of non-validated outcome measures and an unrealistic form of bed rest used (hospitalization). This study provides Level II evidence that bed rest, in the form of hospitalization, results in sooner return to full duty than treatment with light duty in young male combat trainees. Outcomes by 2 weeks appeared to be the same.



### Future Directions for Research

The work group recommends future randomized controlled trials to evaluate the effect of bed rest on LBP

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**PM&R Question 8.** In patients with low back pain, does a regular exercise program (or presurgical intervention with exercise, PT, education) prior to lumbar surgery decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate compared to those who don't exercise?

A systematic review of the literature yielded no studies to adequately address this question.



#### Future Directions for Research

The work group recommends future randomized controlled trials to assess if prehabilitation compared to usual activity affects outcomes of lumbar spine surgery.



**PM&R Question 9.** In patients with low back pain, does exercise treatment after epidural steroid injections/spinal interventions decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate compared to injections alone?

A systematic review of the literature yielded no studies to adequately address this question.



#### Future Directions for Research

The work group recommends that high-level studies be performed evaluating the outcomes of interventional spine procedures alone versus interventional spine procedures in combination with physical therapy/exercise.



**PM&R Question 10.** Following surgery for low back pain, are outcomes, including duration of pain, intensity of pain, functional outcomes and return-to-work status, improved with a formal exercise/rehabilitation program versus home instruction plus or minus self-directed exercise program alone?

A systematic review of the literature yielded no studies to adequately address this question.



#### Future Directions for Research

The work group recommends comparative effectiveness research, preferably prospective, but even retrospective, to define value of post-op rehab for LBP.



**PM&R Question 11.** Can a clinical prediction rule determine appropriate indications and predict outcomes, including duration of pain, intensity of pain, functional outcomes and return-to-work status, for exercise for low back pain?

#### Recommendation:

**There is insufficient evidence to provide any reliable predictors of outcomes to an exercise program for the treatment of either acute or chronic low back pain.**

**Grade of Recommendation: I**

Underwood et al<sup>1</sup> conducted an analysis of the UK Back pain Exercise And Manipulation (UK BEAM) Trial to identify characteristics predictive of response to treatment of LBP. The UK BEAM Trial (n=1334) found that compared treatment packages of spinal manipulation (up to 8 sessions over 12 weeks), manipulation plus exercise (6 weeks manipulation and 6 weeks of exercise) and exercise alone (9 group classes over 12 weeks) against usual care, including *The Back Book*. Disability (Roland Morris Disability Questionnaire), back pain beliefs (Fear Avoidance Beliefs Questionnaire), psychological state (Distress and Risk Assessment Method), treatment expectations and other demographic characteristics were obtained before randomization and at 3-month and one-year follow-up. None of the studied baseline characteristics predicted response (disability per Roland Morris Disability Questionnaire) to treatment. The authors

concluded that there were no characteristics that predicted response to the UK BEAM treatment packages. This study offers Level II prognostic evidence that, in patients with subacute LBP receiving SMT, there were no predictors (including pain duration) for response to treatment.

Cecchi et al<sup>2</sup> prospectively enrolled patients with chronic LBP to be treated with an exercise program devised by a physical therapist based on the individual assessment of each patient. Six sessions were provided along with education and the patients were encouraged to continue with a home exercise program. At one year, 211 of 225 patients were contacted for follow-up and evaluated for predictors of improvement. The only predictive factor of functional outcome at discharge was less intense pain at baseline assessment. At one-year follow-up, younger age, better baseline mental

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health, no history of prior treatment and low drug use predicted higher long-term response rates. This is a Level I prognostic study to indicate that in patients with chronic LBP, short-term favorable response to

an exercise program is predicted by less intense pain at baseline. Younger age, better mental health, no prior history of treatment and lower drug use predict better long-term functional outcomes at one year.



### Future Directions for Research

Establishing clinical predictors to exercise for the treatment of LBP would be very practical and useful for both the patient and provider. Prospective trials or post hoc reviews of registry data could be used to improve our understanding of these predictors. Great care will need to be taken in study design to ensure that LBP is defined in a consistent, measurable and evaluable manner and that homogeneous exercise programs are developed and applied across studies to improve the strength of the evidence.

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**Interventional Question 1.** In patients with low back pain, do fluoroscopically-guided epidural steroid injections decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate?

**There is insufficient evidence to make a recommendation for or against the use of caudal epidural steroid injections in patients with low back pain.**

**Grade of Recommendation: I**

Southern et al<sup>1</sup> investigated the efficacy of fluoroscopic caudal epidural steroid injections for the treatment of chronic lumbar discogenic pain. Patients with chronic low back pain (LBP) with evidence of disc pathology without stenosis (n=97) received at least one fluoroscopically-guided caudal epidural injection with 12 mg of betamethasone and 8 cc of 0.5% lidocaine. Disability (Roland Morris Disability Questionnaire, RMDQ), pain (Visual Numeric Pain Scale, VNS) and patient satisfaction (North American Spine Society, NASS, patient satisfaction questionnaire) were assessed before and after the injection. Eighty-four patients were included in follow-up analysis. Patients were classified as procedure failure (if a discography

and/or surgery was needed after injection) or success (score of 1-2 on NASS patient satisfaction, >50% reduction in VNS and >2-point change in RMDQ score). After at least one year, 19 patients were classified as successes and 65 as failures. Patient satisfaction was 45%. The patients classified as successes had significantly lower baseline pain scores. The authors concluded that patient satisfaction exceeds reported rate of efficacy of fluoroscopically-guided caudal epidural steroid injections in patients with chronic lumbar discogenic pain. This study provides Level IV evidence that roughly 20% of patients with chronic discogenic LBP will experience at least 50% reduction in pain following caudal epidural steroid injections.

**158** Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

**There is insufficient evidence to make a recommendation for or against the use of interlaminar epidural steroid injections in patients with low back pain.**

**Grade of Recommendation: I**

Lee et al<sup>2</sup> conducted an observational study to determine the effect of a fluoroscopic interlaminar epidural steroid injection (ESI) for axial LBP. Patients with LBP (n=81) at a single facility received an interlaminar ESI and followed-up within the first month and again 1-2 years later via telephone interview. The procedure was classified as effective if the patient's reported pain score was reduced by >50%. Sixty-three of 81 procedures were considered effective at short-term follow-up. Thirty-seven (37%) reported greater than

6 months' symptom relief. There were no significant outcome predictors. The authors concluded that the therapeutic trial of a fluoroscopic interlaminar ESI was effective for axial LBP. This study provides Level IV evidence that interlaminar epidural steroid injections in patients with LBP can be expected to provide patient-reported pain relief in roughly 40% of patients at 6 months or greater. Ninety percent of these patients received one or two ESI.



### Future Directions for Research

The work group had no additional recommendations for future research on this topic.

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2. Lee JW, Shin HI, Park SY, Lee GY, Kang HS. Therapeutic trial of fluoroscopic interlaminar epidural steroid injection for axial low back pain: effectiveness and outcome predictors. *AJNR Am J Neuroradiol*. 2010 Nov;31(10):1817-23.



**Interventional Question 2.** When evaluating fluoroscopically-guided intra-articular lumbar facet joint injections in patients with acute or chronic low back pain:

- a. What is the diagnostic utility of this procedure?
- b. From a therapeutic standpoint, does this procedure decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate?

**There is insufficient evidence to make a recommendation for or against the use of patient-reported reproduction of pain during a zygapophyseal joint injection as a predictor of response to dual diagnostic blocks.**

**Grade of Recommendation: I**

Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.



Schwarzer et al<sup>1</sup> investigated the relationship between pain provocation and the analgesic response in lumbar zygapophyseal joint blocks. Patients with LBP for greater than 3 months underwent at least one intra-articular, fluoroscopically-guided injection of lidocaine into the zygapophyseal joints. Ten minutes after injection, each patient was asked to perform previously painful movements and rate the pain as “worse,” “no change,” “partial,” “definite” or “complete” relief. If the pain relief was less than complete, the same procedure was completed using the next segmental level. Two weeks later, confirmatory blocks using 0.5% bupivacaine were completed for each patient and classi-

fied as a positive response if the patient experienced >50% improvement in pain (VAS). Analysis of the 203 joints revealed that reproduction of pain correlated with either definite or complete relief of pain after a single analgesic block, only with liberal criteria. The authors concluded that the validity of pain provocation alone as a criterion standard in patients undergoing diagnostic lumbar zygapophyseal joint blocks should be questioned. This study provides Level I evidence that pain reproduction during a zygapophyseal joint injection is not predictive of the zygapophyseal joint as the pain generator. The positive predictive value was 16%.

**In patients selected for facet joint procedures using diagnostic criteria of physical exam and a response to a single diagnostic intra-articular injection with 50% relief, it is suggested that intra-articular injection of steroids provides no clinically meaningful improvement at 6 months**

**Grade of Recommendation: B**

Carette et al<sup>2</sup> conducted a randomized controlled study to investigate the effectiveness of corticosteroid injections into the facet joints to treat chronic LBP. Patients with LBP for at least 6 months who reported immediate pain relief after a diagnostic injection of local anesthetic into the facet joints were randomized to receive 20 mg methylprednisolone acetate (n=49) or isotonic saline (n=48) under fluoroscopic guidance. Pain severity (Visual Analog Scale [VAS] and McGill pain questionnaire), back mobility and limitation of function (modified Sickness Impact Profile) were recorded one, 3 and 6 months after injection. There were no statistically significant differences between groups after one and three months. The methylprednisolone group had greater improvements in pain and disability after 6 months, but the differences were reduced when concurrent interventions were taken into account. The authors concluded that injecting methylprednisolone acetate into the facet joints is of little value in the treatment of patients with chronic LBP. This study provides Level II evidence that, in patients selected for facet joint injections with steroid using a single diagnostic intra-articular block with 50% relief, the outcome of pain relief is similar in the steroid group to the saline group.

In a double-blind randomized controlled trial, Lakemeier et al<sup>3</sup> compared the effectiveness of intra-articular facet joint steroid injections and radiofrequency denervation for the treatment of chronic LBP. Patients with LBP for at least 24 months who had hypertrophy of the facet joints L3/L4-5/S1 on magnetic resonance imaging and experienced at least 50% pain reduction after a test injection of local anesthetics were included in this study. Participants were randomized to receive radiofrequency denervation (n=27) or intra-articular steroid infiltration (n=29). Participants completed the RMDQ, VAS and Oswestry Disability Index at baseline and after 6 months. Both groups had improvements with no significant differences between groups. This study provides Level II evidence that, in patients who receive a 50% reduction in pain with a single intra-articular facet joint injection of local anesthetic, intra-articular steroids provide similar results to a radiofrequency ablation. Neither provides clinically meaningful improvements at 6 months.

**In patients selected for facet joint procedures using diagnostic criteria of physical exam and a response to a single diagnostic intra-articular injection with 50% relief, there is insufficient evidence to make a recommendation for or against the use of radiofrequency neurotomy or periarticular phenol injections.**

**Grade of Recommendation: I**

In a double-blind randomized controlled trial, Lakemeier et al<sup>3</sup> compared the effectiveness of intra-articular facet joint steroid injections and radiofrequency denervation for the treatment of chronic LBP. Patients with LBP for at least 24 months who had hypertrophy of the facet joints L3/L4-5/S1 on magnetic resonance imaging and experienced at least 50% pain reduction after a test injection of local anesthetics were included in this study. Participants were randomized to receive radiofrequency denervation (n=27) or intra-articular steroid infiltration (n=29). Participants completed the RMDQ, VAS and Oswestry Disability Index at baseline and after 6 months. Both groups had improvements with no significant differences between groups. This study provides Level II evidence that, in patients who receive a 50% reduction in pain with a single intra-articular facet joint injection of local anesthetic, intra-articular steroids provide similar results to a radiofrequency ablation. Neither provides clinically meaningful improvements at 6 months.

Schulte et al<sup>4</sup> aimed to investigate the clinical improvement after a standard facet joint injection therapy protocol and determine the best time for repet-

itive injection therapy. Patients with chronic LBP diagnosed with lumbar facet joint syndrome (n=39) were treated with a standardized protocol of fluoroscopically-guided injection therapy. Patients who reported at least 50% reduction of pain after initial injection of 1 ml crystalline prednisolone acetate (50 mg) mixed with 2 ml lidocaine (1%) received an injection using only lidocaine and phenol solution (5%, 1 ml each joint) the next day. Participants completed questionnaires that contained the pain disability index, Macnab criteria (excellent, good, fair or poor) and VAS for pain at baseline and after 6 months. Pain was reduced up to 6 months. Patients reported as excellent or good by 62% of patients after 1 month, 41% of patients after three months and 36% of patients after six months. The authors concluded that facet joint injection therapy using a standardized protocol is safe, effective and easy to perform and recommended repetitive injection after 3 months. This study provides Level IV evidence that, in patients who receive a 50% reduction in pain with a single periarticular facet joint injection of local anesthetic and steroids, periarticular injection of phenol produced excellent to good response using Macnab criteria and roughly half of patients reported a poor outcome at 6 months.

**There is insufficient evidence to make a recommendation for or against the use of steroid injections into the zygapophyseal joint in patients with chronic back pain and a physical exam suggestive of facet-mediated pain.**

**Grade of Recommendation: I**

Chaturvedi et al<sup>5</sup> evaluated the efficacy of facet joint infiltrations for the treatment of chronic LBP. Patients with LBP for greater than 3 months (n=44) received facet joint injections under fluoroscopic guidance (n=39) or CT guidance (n=5). Pain was assessed one hour after the procedure and at 1, 4, 12 and 24 weeks. Significant pain relief was reported after one hour (81.8%), one week (86.3%), 4 weeks (93.3%), 12 weeks (85.7%) and 24 weeks (62.5%). The authors concluded that the minimally invasive facet nerve block was

safe, resulted in long-term success rates over 60% and should be considered an alternative treatment for non-radicular back pain. This study provides Level IV evidence that, in patients with greater than 3 months of LBP and symptoms and physical exam suggestive of facet-mediated pain, intra-articular steroid injections into the facet joints produces significant pain relief in 90% of patients at 12 weeks and 2/3 of patients at 24 weeks. Roughly 15% of patients required more than one injection.



### Future Directions for Research

1. The work group recommends future randomized controlled trials of various facet joint interventions including therapeutic injections and radiofrequency neurotomy in patients diagnosed with facet joint pain using dual diagnostic blocks with 80% relief.
2. The work group recommends, in patients with suspected facet mediated pain, more than one comparison trial between outcomes of patients undergoing dual diagnostic blocks with a single local anesthetic versus dual diagnostic blocks with local anesthetics with different durations of action and pain relief commensurate with the local anesthetic used.

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**Interventional Question 3.** In patients with low back pain, do medial branch blocks have a role in defining treatment for low back pain?

- a. Does duration of pain, intensity of pain, functional outcomes and return-to-work status vary when candidates for neurotomy are determined by single vs comparative medial branch blocks?
- b. Is there a threshold for the magnitude of relief from diagnostic facet nerve blocks that predict outcomes to neurotomy?
- c. Does duration of pain, intensity of pain, functional outcomes and return-to-work status vary when candidates for neurotomy are determined by diagnostic facet nerve blocks vs intra-articular facet joint injections?
- d. Is there a therapeutic utility of medial branch blocks?
- e. Does technical accuracy of medial branch blocks (eg, contrast use) affects its validity and effectiveness of subsequent neurotomy?

**There is insufficient evidence to make a recommendation for or against the use of SPECT imaging in the diagnosis of zygapophyseal joint pain.**

**Grade of Recommendation: I**

Ackerman et al<sup>1</sup> compared the effectiveness of intra-articular and medial branch nerve blocks in patients with LBP with single-photon emission computed

tomography (SPECT)-positive lumbar facet joints. Patients with nonradicular LBP who were lumbar facet joint SPECT-positive were randomized to

receive intra-articular (n=23) or medial branch nerve blocks (n=23) with lidocaine and triamcinolone. Pain (Numeric Pain Intensity Score) and disability (Oswestry Disability Index Score) were measured after the injection and after 12 weeks. The intra-articular group experienced significantly greater improvements in pain and disability. The authors concluded that intra-articular lumbar facet joint injections are more effective than medial branch nerve blocks in SPECT-positive patients. In critique of the methodology, the work group downgraded this potential Level I study as

the diagnostic utility of SPECT imaging was negated by injecting bilateral joints and/or bilateral medial branch blocks in every patient. This study provides Level II evidence that, in patients with LBP and positive SPECT imaging showing uptake in the facet joint, intra-articular injection of steroid provides at least a 50% reduction in pain in roughly 60% of patients and steroid injection around the medial branch nerves provides at least a 50% reduction in pain in roughly 25% of patients.

### There is insufficient evidence to make a recommendation for or against the use of uncontrolled medial branch blocks vs. pericapsular blocks for the diagnosis of zygapophyseal joint pain based on the outcomes of medial branch nerves cryoablation.

#### Grade of Recommendation: I

Birkenmaier et al<sup>2</sup> aimed to compare the predictive value of uncontrolled medial branch blocks versus pericapsular blocks for predicting successful outcomes of cryodenervation. Patients with LBP for at least 3 months were randomized to receive medial branch blocks or pericapsular blocks. The patients who had a positive response ( $\geq 50\%$  improvement in LBP for at least 3 hours) were enrolled in the study (n=13 in each group). Percutaneous medial branch cryodenervation was performed, under fluoroscopic guidance, with local anesthesia and 1% mepivacaine by use of a Lloyd Neurostat 2000. Pain (VAS), limitation of activity (Macnab) and overall satisfaction were recorded at baseline and after 2 and 6 weeks as well as

3 and 6 months. Patients who received diagnostic medial branch blocks had statistically significantly better pain relief at 6 weeks and 3 months compared to those who received pericapsular blocks. The authors concluded that, although both blocks worked, uncontrolled medial branch blocks are superior to pericapsular blocks in selecting patients for facet joint cryodenervation. From a diagnostic perspective, this study provides Level III evidence that a single medial branch block is a better predictor of an outcome of pain relief following cryodenervation of the medial branch nerves than a pericapsular local anesthetic injection.

### There is insufficient evidence to make a recommendation for or against the use of cryodenervation for the treatment of zygapophyseal joint pain.

#### Grade of Recommendation: I

Birkenmaier et al<sup>2</sup> aimed to compare the predictive value of uncontrolled medial branch blocks versus pericapsular blocks for predicting successful outcomes of cryodenervation. Patients with LBP for at least 3 months were randomized to receive medial branch blocks or pericapsular blocks. The patients who had a positive response ( $\geq 50\%$  improvement in LBP for at least three hours) were enrolled in the study (n=13 in each group). Percutaneous medial branch cryodenervation was performed, under fluoroscopic guidance, with local anesthesia and 1% mepivacaine by use of a Lloyd Neurostat 2000. Pain (VAS), limitation of activity (Macnab) and overall satisfaction were

recorded at baseline and after 2 and 6 weeks as well as 3 and 6 months. Patients who received diagnostic medial branch blocks had statistically significantly better pain relief at 6 weeks and 3 months compared to those who received pericapsular blocks. The authors concluded that, although both blocks worked, uncontrolled medial branch blocks are superior to pericapsular blocks in selecting patients for facet joint cryodenervation. From a therapeutic perspective, this study provides Level IV evidence that cryodenervation of the medial branch nerves in patients with LBP selected using a single medial branch block patients noted a 66% reduction in pain at 6 months.

**There is insufficient evidence to make a recommendation for or against the use of a 50% reduction in pain following medial branch blockade for the diagnosis of zygapophysial joint pain.**

**Grade of Recommendation: I**

Kaplan et al<sup>3</sup> conducted a randomized controlled trial to investigate the effectiveness of conventional medial branch blocks for zygapophysial joint pain. In the first phase, healthy, asymptomatic adults with no history of lumbar pain (n=18) received a fluoroscopically-guided intra-articular zygapophysial joint injection of contrast until pain was elicited. Participants recorded pain (VAS) immediately after pain was elicited, every hour for the first 6 hours and every day for 7 days. In the second phase of this study, the participants who incurred pain provocation that lasted less than 48 hours were randomly allocated to receive medial branch nerve injections with 2.0% lidocaine (n=10) or saline (n=5). Thirty minutes after injection, the participants underwent the same joint injection that elicited pain the previous week and recorded pain in the same manner. All patients who received saline medial branch injections experienced pain on repeat capsular distention. Of the individuals who received 2% lidocaine medial branch blocks, eight felt no pain. The authors concluded that the 2% lidocaine was significantly more effective on anesthetization of the zygapophysial joint when uptake was avoided during these injections. The workgroup felt that this type of study was not adequately described in the defined Levels of Evidence Table and, as a consensus, rated

this as Level I. This study provides Level I evidence that medial branch blockade with local anesthetic effectively anesthetizes the zygapophysial joint. Venous uptake may negatively affect the response to medial branch blockade.

Rocha et al<sup>4</sup> studied the prevalence of LBP after controlled medial branch blocks in a prospective, controlled, diagnostic study. Patients with chronic LBP for at least 3 months underwent a saline injection followed by a controlled medial branch block (0.5 ml of lidocaine at 2%, without epinephrine). Pain (VAS) was recorded before and after the injection. Patients who reported >50% improvement of pain after the blockade (n=54) were included in follow-up after one day, one week and one, 2 and 3 months. After 3 months, 18 participants (33%) experienced return of lumbar pain. The authors concluded that patient diagnosis with a controlled medial branch block was effective but not associated with any demographic variables. This study provides Level IV evidence that, in patients undergoing medial branch blocks, using a cutoff of a 50% pain reduction, 2/3 of the patients who responded to this block will have continued reduction in pain 3 months after the block.

**Thermal radiofrequency ablation is suggested as a treatment for patients with low back pain from the zygapophysial joints. The outcomes of this procedure become more reliable when more stringent diagnostic criteria are used. The relief from these ablations is durable for at least 6 months following the procedure.**

**Grade of Recommendation: B**

Kaplan et al<sup>3</sup> conducted a randomized controlled trial to investigate the effectiveness of conventional medial branch blocks for zygapophysial joint pain. In the first phase, healthy, asymptomatic adults with no history of lumbar pain (n=18) received a fluoroscopically-guided intra-articular zygapophysial joint injection of contrast until pain was elicited. Participants recorded pain (VAS) immediately after pain was elicited, every hour for the first 6 hours and every day for 7 days. In the second phase of this study, the participants who incurred pain provocation that lasted less than 48 hours were randomly allocated to receive medial branch nerve injections with 2.0% lidocaine

(n=10) or saline (n=5). Thirty minutes after injection, the participants underwent the same joint injection that elicited pain the previous week and recorded pain in the same manner. All patients who received saline medial branch injections experienced pain on repeat capsular distention. Of the individuals who received 2% lidocaine medial branch blocks, 8 felt no pain. The authors concluded that the 2% lidocaine was significantly more effective on anesthetization of the zygapophysial joint when uptake was avoided during these injections. The workgroup felt that this type of study was not adequately described in the defined Levels of Evidence Table and, as a consensus, rated this as

Level I. This study provides Level I evidence that medial branch blockade with local anesthetic effectively anesthetizes the zygapophyseal joint. Venous uptake may negatively affect the response to medial branch blockade.

Nath et al<sup>5</sup> conducted a randomized controlled study to determine the effectiveness of percutaneous radiofrequency zygapophysial joint neurotomy in patients with lumbar zygapophysial joint pain. Patients with LBP for at least 2 years who had at least 80% pain relief after controlled medial branch blocks were randomized to receive an active treatment with 2 mL of bupivacaine (n=20) or sham with the same procedure without radiofrequency (n=20). The degree and duration of pain (VAS) was recorded every hour for 6 hours after the injection, the following day and 6-month follow-up. The active treatment group had significantly greater improvements in pain, quality of life, analgesic consumption and global perception of improvement compared to the sham group. The authors concluded that radiofrequency facet denervation can be used as a treatment for chronic LBP in carefully-selected patients. This study provides Level I evidence that, in patients undergoing dual diagnostic comparative medial branch blocks with 80% relief, radiofrequency ablation of the medial branch nerves provides clinically and statistically significant improvements in pain, quality of life variables and analgesic consumption compared to sham at 6 months.

Van Kleef et al<sup>6</sup> investigated the effectiveness of percutaneous radiofrequency denervation of the lumbar zygapophysial joints in the treatment of LBP originating from the lumbar zygapophysial joints. Patients with LBP for at least one year who had a positive response to a diagnostic nerve blockade were randomized to receive a 60-second 80°C radiofrequency lesion of the dorsal ramus of the segmental nerve roots L3-L5 (n=15) or a control group of the same procedure without radiofrequency current (n=16). Physical impairment, global perceived effect, pain (VAS) and disability (Oswestry disability scale) were recorded before the treatment and 8 weeks after treatment. Success was defined as  $\geq 50\%$  pain reduction on global perceived effect and  $\geq 2$ -points reduction on the VAS scale. The radiofrequency group experiences statistically significantly greater improvements in pain, global perceived effect and disability. There were more successes in the radiofrequency group at 3, 6 and 12 months compared to the sham group. The authors concluded that radiofrequency lumbar zygapophysial joint denervation significantly reduces pain and functional disability on a short-term and long-term basis

in a select group of patients with chronic LBP. In critique of the methodology, the work group downgraded this potential Level I study due to poor inclusion criteria and no concealment prior to randomization. This study provides Level II evidence that, in patients who have at least a 50% reduction in pain from diagnostic medial branch blocks, radiofrequency ablation provides better improvements in pain and functional outcomes than sham.

Civelek et al<sup>7</sup> compared the effectiveness of facet joint injections and facet joint radiofrequency denervation in patients with chronic LBP. Patients with LBP who did not respond to conservative treatment and diagnosed with lumbar facet syndrome were randomized to receive a facet joint injection (n=50) or facet joint radiofrequency denervation at 80°C temperature for 120 seconds (n=50). The facet joint injection consisted of a medial branch block of the posterior primary ramus with 1 cc of methyl-prednisolone acetate (40 mg) (diluted with 1 cc SF) combined with 2 cc bupivacaine hydrochloride (diluted with 2 cc SF). Pain (NVS), patient satisfaction (NASS) and general health status (EQ-5D) were recorded at baseline as well as 3, 6 and 12 months. The patients who received facet joint radiofrequency denervation experienced statistically significantly greater improvements in pain at one, 6 and 12 months. The authors concluded radiofrequency denervation should be used for the treatment of chronic LBP if pain recurs or if pain relief is not experienced after the first line facet joint injection. In critique of the methodology, the work group downgraded this potential Level I study due to poor selection criteria for facet joint pain. This study provides Level II evidence that, in patients without diagnostic blocks with suspected facet pain, radiofrequency ablation shows better improvements in pain at 6 months and 1 year when compared with a medial branch steroid injection.

Kroll et al<sup>8</sup> conducted a prospective, randomized, double-blind study to compare the efficacy of continuous radiofrequency thermocoagulation with pulsed radiofrequency in the treatment of lumbar facet syndrome. Patients were randomly allocated to receive continuous radiofrequency thermocoagulation at 80°C for 75 seconds (n=13) or pulsed radiofrequency at 42°C with a pulse duration of 20 ms and pulse rate of 2 Hz for 120 seconds (n=13). Pain (VAS) and disability (Oswestry Low Back Pain and Disability Questionnaire) were assessed at baseline and after 3 months. There were no significant differences between groups in relative percentage of improvement in pain or disability. The patients in the

continuous radiofrequency thermocoagulation group experienced significant improvement in pain and disability over time while the pulsed radiofrequency group did not experience any significant changes over time. The authors concluded that continuous radiofrequency resulted in greater improvement over time compared to pulsed radiofrequency. In critique, the work group downgraded this potential Level I study due to lack of follow-up and small sample size. This study provides Level II evidence that thermal radiofrequency ablation produces clinically and statistically significant improvements in pain and function at 3 months when compared with pulse radiofrequency.

Tekin et al<sup>9</sup> compared the effectiveness of conventional radiofrequency and pulsed radiofrequency denervation to medial branches of dorsal rami in the treatment of facet joint pain. Patients with chronic LBP for more than six months who responded to a diagnostic medial branch block (0.3 mL lidocaine 2%) with greater than 50% pain reduction on VAS were enrolled. Participants were randomly allocated into a control group to receive local anesthetic (n=20), or treatment groups to receive 80°C conventional radiofrequency group (n=20), or 2 Hz pulsed radiofrequency (n=20). Pain (VAS) and disability (Oswestry Disability Index) were recorded before and after the procedure as well as 6 months and one year after the procedure. Pain and disability improved immediately after the procedure in all groups, with lower scores in both treatment groups compared to the control group. The decrease in pain was maintained at 6- and 12-month follow-ups in the conventional radiofrequency group, but not the pulsed radiofrequency denervation group. The authors concluded that both treatments were safe and effective, but conventional radiofrequency resulted in long-lasting facet joint pain relief. In critique of the methodology, the work group downgraded this potential Level I study due to poor inclusion criteria. This study provides Level II evidence that, in patients diagnosed with facet pain using a single medial branch block and 50% relief, thermal radiofrequency ablation provides statistically significant improvements in pain and function when compared to pulsed radiofrequency ablation and sham.

In a double-blind randomized controlled trial, Lakemeier et al<sup>10</sup> compared the effectiveness of intra-articular facet joint steroid injections and radiofrequency denervation for the treatment of chronic LBP. Patients with LBP for at least 24 months who had hypertrophy of the facet joints L3/L4-5/S1 on magnetic resonance imaging and

experienced at least 50% pain reduction after a test injection of local anesthetics were included in this study. Participants were randomized to receive radiofrequency denervation (n=27) or intra-articular steroid infiltration (n=29). Participants completed the RMDQ, VAS and Oswestry Disability Index at baseline and after 6 months. Both groups had improvements with no significant differences between groups. This study provides Level II evidence that, in patients who receive a 50% reduction in pain with a single intra-articular facet joint injection of local anesthetic, intra-articular steroids provide similar results to a radiofrequency ablation. Neither provides clinically meaningful improvements at 6 months.

In a double-blind randomized controlled trial, Leclaire et al<sup>11</sup> evaluated the efficacy of percutaneous radiofrequency articular facet denervation for the treatment of LBP. Patients with LBP for more than 3 months and positive response after fluoroscopically-guided intra-articular facet injections were enrolled. Participants were randomized into a treatment group to receive fluoroscopically-guided percutaneous radiofrequency articular facet denervation (n=36) or control group to receive sham therapy of the same procedure without denervation (n=34). Pain (VAS) and disability (Oswestry and RMDQ scales) were recorded at baseline and after 4 and 12 weeks. The treatment group had significantly greater improvement in RMDQ scores compared to the control group at 4 weeks, with no differences in Oswestry or VAS. There were no differences between groups at 12 weeks in any outcomes. The authors concluded that radiofrequency facet joint denervation may provide short-term improvement in functional disability in patients with chronic LBP, but the efficacy has not been established. In critique of the methodology, the work group downgraded this potential Level I study due to poor inclusion criteria. This study provides Level II evidence that patients who reported relief from their back pain within one week of an intra-articular steroid injection and undergo radiofrequency ablation with the active tip of the needle placed perpendicular to the nerve, report no improvement in pain at 3 and 12 months when compared with sham RF.

MacVicar et al<sup>12</sup> investigated the effectiveness of lumbar medial branch radiofrequency neurotomy for the treatment of chronic LBP. Patients who experienced complete relief of pain after controlled diagnostic medial branch blocks (n=106) were treated with radiofrequency neurotomy performed by 2 trained practitioners. Pain relief of 80-100% for at least 6 months with complete return to work and return to activities

of daily living without need for further health care was classified as a successful outcome. Successful outcomes were achieved in 58% and 53% of patients at two different practices. The authors concluded that lumbar radiofrequency neurotomy can be an effective treatment for chronic back pain when performed in a rigorous manner in appropriately-selected patients. The study provides Level IV evidence that the majority of patients selected by comparative lumbar facet

nerve blocks for radiofrequency neurotomies have 80–100% relief from their LBP with the restoration of activities and no other health care for a median duration of 15 months. Further, patients that experienced successful relief from their LBP after the first radiofrequency neurotomies will likely experience a similar response to repeat radiofrequency neurotomies for the same condition.



### Future Directions for Research

The work group recommends randomized controlled trials comparing the response to medial branch radiofrequency ablation outcomes to various diagnostic methods of diagnosing zygapophyseal joint pain, including intra-articular facet joint injections and medial branch blocks with varying response rates using different local anesthetics.

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**Interventional Question 4.** In patients with low back pain due to lumbar facet joint arthropathy, does fluoroscopically-guided neurotomy decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate?

**Thermal radiofrequency ablation is suggested as a treatment for patients with low back pain from the zygapophysial joints. The outcomes of this procedure become more reliable when more stringent diagnostic criteria are used. The relief from these ablations is durable for at least 6 months following the procedure.**

**Grade of Recommendation: B**

Nath et al<sup>1</sup> conducted a randomized controlled study to determine the effectiveness of percutaneous radiofrequency zygapophysial joint neurotomy in patients with lumbar zygapophysial joint pain. Patients with LBP for at least 2 years who had at least 80% pain relief after controlled medial branch blocks were randomized to receive an active treatment with 2 mL of bupivacaine (n=20) or sham with the same procedure without radiofrequency (n=20). The degree and duration of pain (VAS) was recorded every hour for 6 hours after the injection, the following day and 6-month follow-up. The active treatment group had significantly greater improvements in pain, quality of life, analgesic consumption and global perception of improvement compared to the sham group. The authors concluded that radiofrequency facet denervation can be used as a treatment for chronic LBP in carefully-selected patients. This study provides Level I evidence that, in patients undergoing dual diagnostic comparative medial branch blocks with 80% relief, radiofrequency ablation of the medial branch nerves provides clinically and statistically significant improvements in pain, quality of life variables and analgesic consumption compared to sham at 6 months.

Van Kleef et al<sup>2</sup> investigated the effectiveness of percutaneous radiofrequency denervation of the lumbar zygapophysial joints in the treatment of LBP originating from the lumbar zygapophysial joints. Patients with LBP for at least one year who had a positive response to a diagnostic nerve blockade were randomized to receive a 60-second 80°C radiofrequency lesion of the dorsal ramus of the segmental nerve roots L3-L5 (n=15) or a control group of the same procedure without radiofrequency current (n=16). Physical impairment, global perceived effect, pain (VAS) and disability (Oswestry disability scale) were recorded before the treatment and eight weeks after treat-

ment. Success was defined as  $\geq 50\%$  pain reduction on global perceived effect and  $\geq 2$ -points reduction on the VAS scale. The radiofrequency group experiences statistically significantly greater improvements in pain, global perceived effect and disability. There were more successes in the radiofrequency group at 3, 6 and 12 months compared to the sham group. The authors concluded that radiofrequency lumbar zygapophysial joint denervation significantly reduces pain and functional disability on a short- and long-term basis in a select group of patients with chronic LBP. In critique of the methodology, the work group downgraded this potential Level I study due to poor inclusion criteria and no concealment prior to randomization. This study provides Level II evidence that, in patients who have at least a 50% reduction in pain from diagnostic medial branch blocks, radiofrequency ablation provides better improvements in pain and functional outcomes than sham.

Civelek et al<sup>3</sup> compared the effectiveness of facet joint injections and facet joint radiofrequency denervation in patients with chronic LBP. Patients with LBP who did not respond to conservative treatment and diagnosed with lumbar facet syndrome were randomized to receive a facet joint injection (n=50) or facet joint radiofrequency denervation at 80°C temperature for 120 seconds (n=50). The facet joint injection consisted of a medial branch block of the posterior primary ramus with 1 cc of methyl-prednisolone acetate (40 mg) (diluted with 1 cc SF) combined with 2 cc bupivacaine hydrochloride (diluted with 2 cc SF). Pain (Visual Numeric Pain Scale), patient satisfaction (NASS) and general health status (EQ-5D) were recorded at baseline as well as 3, 6 and 12 months. The patients who received facet joint radiofrequency denervation experienced statistically significantly greater improvements in pain at 1, 6 and 12 months. The au-

thors concluded radiofrequency denervation should be used for the treatment of chronic LBP if pain recurs or if pain relief is not experienced after the first line facet joint injection. In critique of the methodology, the work group downgraded this potential Level I study due to poor selection criteria for facet joint pain. This study provides Level II evidence that, in patients without diagnostic blocks with suspected facet pain, radiofrequency ablation shows better improvements in pain at 6 months and one year when compared with a medial branch steroid injection.

Kroll et al<sup>4</sup> conducted a prospective, randomized, double-blind study to compare the efficacy of continuous radiofrequency thermocoagulation with pulsed radiofrequency in the treatment of lumbar facet syndrome. Patients were randomly allocated to receive continuous radiofrequency thermocoagulation at 80°C for 75 seconds (n=13) or pulsed radiofrequency at 42°C with a pulse duration of 20 ms and pulse rate of 2 Hz for 120 seconds (n=13). Pain (VAS) and disability (Oswestry Low Back Pain and Disability Questionnaire) were assessed at baseline and after 3 months. There were no significant differences between groups in relative percentage of improvement in pain or disability. The patients in the continuous radiofrequency thermocoagulation group experienced significant improvement in pain and disability over time while the pulsed radiofrequency group did not experience any significant changes over time. The authors concluded that continuous radiofrequency resulted in greater improvement over time compared to pulsed radiofrequency. In critique, the work group downgraded this potential Level I study due to lack of follow-up and small sample size. This study provides Level II evidence that thermal radiofrequency ablation produces clinically and statistically significant improvements in pain and function at 3 months when compared with pulse radiofrequency.

Tekin et al<sup>5</sup> compared the effectiveness of conventional radiofrequency and pulsed radiofrequency denervation to medial branches of dorsal rami in the treatment of facet joint pain. Patients with chronic LBP for more than 6 months who responded to a diagnostic medial branch block (0.3 mL lidocaine 2%) with greater than 50% pain reduction on VAS were enrolled. Participants were randomly allocated into a control group to receive local anesthetic (n=20), or treatment groups to receive 80°C conventional radiofrequency group (n=20), or 2 Hz pulsed radiofrequency (n=20). Pain (VAS) and disability (Oswestry Disability Index) were recorded before and after the procedure

as well as 6 months and one year after the procedure. Pain and disability improved immediately after the procedure in all groups, with lower scores in both treatment groups compared to the control group. The decrease in pain was maintained at 6- and 12-month follow-ups in the conventional radiofrequency group, but not the pulsed radiofrequency denervation group. The authors concluded that both treatments were safe and effective, but conventional radiofrequency resulted in long-lasting facet joint pain relief. In critique of the methodology, the work group downgraded this potential Level I study due to poor inclusion criteria. This study provides Level II evidence that, in patients diagnosed with facet pain using a single medial branch block and 50% relief, thermal radiofrequency ablation provides statistically significant improvements in pain and function when compared to pulsed radiofrequency ablation and sham.

In a double-blind randomized controlled trial, Lakemeier et al<sup>6</sup> compared the effectiveness of intra-articular facet joint steroid injections and radiofrequency denervation for the treatment of chronic LBP. Patients with LBP for at least 24 months who had hypertrophy of the facet joints L3-4, L4-5, L5-S1 on magnetic resonance imaging and experienced at least 50% pain reduction after a test injection of local anesthetics were included in this study. Participants were randomized to receive radiofrequency denervation (n=27) or intra-articular steroid infiltration (n=29). Participants completed the RMDQ, VAS and Oswestry Disability Index at baseline and after 6 months. Both groups had improvements with no significant differences between groups. This study provides Level II evidence that, in patients who receive a 50% reduction in pain with a single intra-articular facet joint injection of local anesthetic, intra-articular steroids provide similar results to a radiofrequency ablation. Neither provides clinically meaningful improvements at 6 months.

In a double-blind randomized controlled trial, Leclaire et al<sup>7</sup> evaluated the efficacy of percutaneous radiofrequency articular facet denervation for the treatment of LBP. Patients with LBP for more than 3 months and positive response after fluoroscopically-guided intra-articular facet injections were enrolled. Participants were randomized into a treatment group to receive fluoroscopically-guided percutaneous radiofrequency articular facet denervation (n=36) or control group to receive sham therapy of the same procedure without denervation (n=34). Pain (VAS) and disability (Oswestry and RMDQ scales) were recorded at baseline and after 4 and 12 weeks. The treatment

group had significantly greater improvement in Roland-Morris scores compared to the control group at 4 weeks, with no differences in Oswestry or VAS. There were no differences between groups at 12 weeks in any outcomes. The authors concluded that radiofrequency facet joint denervation may provide short-term improvement in functional disability in patients with chronic LBP, but the efficacy has not been established. In critique of the methodology, the work group downgraded this potential Level I study due to poor inclusion criteria. This study provides Level II evidence that patients who reported relief from their back pain within one week of an intra-articular steroid injection and undergo radiofrequency ablation with the active tip of the needle placed perpendicular to the nerve, report no improvement in pain at 3 and 12 months when compared with sham radiofrequency denervation.

MacVicar et al<sup>8</sup> investigated the effectiveness of lumbar medial branch radiofrequency neurotomy for the

treatment of chronic LBP. Patients who experienced complete relief of pain after controlled diagnostic medial branch blocks (n=106) were treated with radiofrequency neurotomy performed by 2 trained practitioners. Pain relief of 80–100% for at least 6 months with complete return to work and return to activities of daily living without need for further health care was classified as a successful outcome. Successful outcomes were achieved in 58% and 53% of patients at 2 different practices. The authors concluded that lumbar radiofrequency neurotomy can be an effective treatment for chronic back pain when performed in a rigorous manner in appropriately-selected patients. The study provides Level IV evidence that the majority of patients selected by comparative lumbar facet nerve blocks for radiofrequency neurotomies have 80–100% relief from their LBP with the restoration of activities and no other health care for a median duration of 15 months. Further, patients that experienced successful relief from their LBP after the first radiofrequency neurotomies will likely experience a similar response to repeat radiofrequency neurotomies for the same condition.



### Future Directions for Research

The work group does not have any recommendations for future research on this topic.

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**Interventional Question 5.** In patients with low back pain, do fluoroscopically-guided sacroiliac joint injections (SIJI) decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate?

- Does duration of pain, intensity of pain, functional outcomes and return-to-work status vary when candidates for neurotomy are determined by single vs. comparative SIJI?
- Is there a benefit to performing lateral branch blocks as compared with intra-articular diagnostic injections as a predictor to response to lateral branch neurotomy?
- Is there a threshold for the magnitude of relief from diagnostic SIJI that predict improvement in duration of pain, intensity of pain, functional outcomes and return-to-work status from SIJ neurotomy?

### Intra-articular steroid joint injections may be considered in patients with suspected SI joint pain Grade of Recommendation: C

Chakraverty et al<sup>1</sup> reported hospital audit results on the outcomes of patients who underwent spinal injection and interventional procedures for presumed facet joint or sacroiliac joint pain. Retrospective chart audits were performed of patients with chronic LBP from 7 different hospitals. Patients were diagnosed with either intra-articular facet joint injections, medial branch blocks, or intra-articular sacroiliac joint injections. Pain was recorded using a VAS; pain relief of at least 50% indicated response to the diagnostic procedure. Patients were treated with lumbar facet injection (n=42), medial branch block (n=10), intra-articular sacroiliac injection with local anesthesia (n=52), intra-articular facet injection with corticosteroid (n=34), radiofrequency denervation of medial branch (n=38), intra-articular sacroiliac injection with corticosteroid (n=33), or sacroiliac ligament prolotherapy (n=19). Thirty percent of patients who received an intra-articular corticosteroid injection reported greater than 50% pain relief at 6-month follow-up. The authors concluded that both radiofrequency denervation and sacroiliac prolotherapy showed good long-term outcomes at one year. There appears to be a continuing role for intra-articular corticosteroid injections. Sacroiliac ligament prolotherapy is worthy of further study. This study provides Level IV evidence that patients with mechanical LBP who receive a 50%

reduction in pain following a diagnostic sacroiliac joint injection may experience up to 6 months of at least 50% improvement from their LBP following SIJI of local anesthetic and corticosteroid.

Cusi et al<sup>2</sup> investigated the effectiveness of prolotherapy in the treatment of deficient load transfer of the sacroiliac (SI) joint. Patients diagnosed with persistent suboptimal stability of the SI joint with LBP for at least 6 months were enrolled (n=25). Participants underwent three injections of prolotherapy with 6 weeks between each injection. Disability (Roland-Morris) and pain (Quebec Back Pain Disability Scale) were reported 24 hours before each injection and one week after each injection as well as at follow-up after 3, 12 and 24 months. Results revealed improvements at 3-, 12- and 24-month follow-up. The authors concluded that prolotherapy resulted in positive outcomes for a majority of the patients who attended the 3-month follow-up visit. This study provides Level IV evidence that, in patients with sacroiliac joint pain diagnosed using clinical criteria who undergo three prolotherapy injections, 76% of patients will receive improvements in pain and function at 12 months, though this declines to 1/3 of patients at 24 months.

Slipman et al<sup>3</sup> evaluated the effectiveness of

fluoroscopically-guided therapeutic SI joint injections for sacroiliac joint syndrome in a retrospective study. Patients with LBP who failed to improve after at least 4 weeks of physical therapy and who had a positive response to a fluoroscopically-guided diagnostic SI joint injection were included. Participants received up to four total therapeutic fluoroscopically-guided SI joint injections of 2.0 ml of betamethasone sodium phosphate and acetate suspension, 6 mg/ml and 0.5 ml 2% lidocaine hydrochloride. Pain (VAS), disability (Oswestry), work status and medication usage were recorded at baseline and an average of 94.4 weeks after the last injection. There were statistically significant

improvements in disability, pain and work status over time. The authors concluded that fluoroscopically-guided SI joint injections are clinically effective for the treatment of SI joint syndrome. This study provides Level IV evidence that patients with LBP and reduced function due to sacroiliac joint dysfunction having an 80% improvement from a diagnostic sacroiliac joint injection followed by an intra-articular steroid joint injection experienced a clinically and statistically significant reduction in pain and disability scores. The average number of injections was 2.1.



### Future Directions for Research

The work group does not have any recommendations for future research on this topic.

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**Interventional Question 6.** In patients with pelvic posterior girdle pain relieved temporarily by image guided SIJ injections or lateral branch blocks, does lateral branch neurotomy decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate?

*Work Group Narrative: There are other studies in the literature that show clinical benefits from cooled lateral branch radiofrequency neurotomies for the treatment of sacroiliac joint pain that were not included in our systematic review. These studies were omitted from our review because they either did not fulfill our initial definition or inclusion criteria, or were published after our literature search closed.*

**Cooled radiofrequency ablation of the sacral lateral branch nerves and dorsal ramus of L5 may be considered in patients with sacroiliac joint pain diagnosed with dual diagnostic blocks.**

**Grade of Recommendation: C**

Kapural et al<sup>1</sup> retrospectively reviewed the effect of cooled radiofrequency denervation on pain, function and global patient satisfaction. Patients with chron-

ic LBP (n=27) who had >50% pain relief after 2 diagnostic sacroiliac joint (SI) joint blocks and underwent cooled radiofrequency were included in this case se-

**172** Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

ries. Pain relief (VAS), function (pain disability index) and global patient satisfaction were analyzed. Three to 4 months after the procedure, function and pain scores significantly improved functional capacity and patient satisfaction. This study provides Level IV evidence that, in patients who experience a 50% reduction in LBP with dual diagnostic intra-articular injections, cooled radiofrequency ablation of the lateral branch nerves and L5 dorsal ramus reduces pain by approximately 50% in half the patients.

Karaman et al<sup>2</sup> evaluated the safety and efficacy of cooled radiofrequency for sacral lateral-branch denervation. Patients with chronic sacroiliac pain who reported at least 75% pain relief from two diagnostic joint blockages were included in this observational

study. Participants (n=15) received fluoroscopically-guided cooled radiofrequency denervation on the dorsal ramus and the S1-3 lateral branches. Pain (VAS) and physical function (Oswestry Disability Index) were recorded after one, 3 and 6 months. Eighty percent of the participants reported at least 50% reduction in pain scores at 6 months. The authors concluded that cooled radiofrequency for sacroiliac denervation was effective and safe in the short to intermediate term. This study provides Level IV evidence that, in patients who reported a 75% reduction in pain with dual diagnostic intra-articular SI joint injections, cooled radiofrequency neurotomy of the lateral branch nerves and L5 dorsal ramus produced a least a 50% improvement in pain in roughly 80% of patients.



### Future Directions for Research

1. The work group recommends future research on comparative studies between lateral branch blocks and intraarticular sacroiliac joint injections for the diagnosis of sacroiliac joint pain versus pain from the posterior sacroiliac complex.
2. The work group recommends randomized controlled trials of radiofrequency denervation of the lateral branch nerves following lateral branch blocks.
3. The work group recommends randomized controlled trials comparing the various nerve ablation techniques of the lateral branch nerves for SI joint pain.

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**Interventional Question 7.** In patients with low back pain, does spinal cord stimulation decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate?

**There is insufficient evidence to make a recommendation for or against the use of spinal cord stimulation as a treatment for low back pain.**

**Grade of Recommendation: I**

Vallejo et al<sup>1</sup> investigated the effectiveness of spinal cord stimulation for relieving discogenic pain in a prospective observational study. Patients with intrac-table discogenic LBP were enrolled. A control group was formed of patients with insurance denial, medical reasons, or failed trial (n=4) while the remaining participants underwent spinal cord stimulation implan-tation (n=9). Pain (Numerical Rating Scale), disability (Oswestry Disability Index) and opioid use were re-corded at intervals for twelve months. At 12 months, there was no change in pain in the control group, but significant improvements were observed in the spi-nal cord stimulation group. Disability decreased, but there were no differences in average disability be-

tween groups at 12 months. There was a 69% reduc-tion in opioid consumption in the spinal cord stimu-lation group and 54% increase in opioid consumption in the control group. The authors concluded that spi-nal cord stimulation may effectively improve pain and disability and reduce opioid usage in patients with discogenic pain. In critique of the methodology, the work group downgraded this potential Level II article to Level III due to the small sample size. This study provides Level III evidence that, in patients with dis-cogenic LBP diagnosed with provocative discography, spinal cord stimulation produces clinically and statis-tically significant improvements in pain and function.



#### Future Directions for Research

The work group recommends randomized controlled trials utilizing spinal cord stimulation in patients with LBP.

#### Reference

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**Interventional Question 8.** In patients with low back pain, does continuous delivery of intrathecal opioids decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate and are there risks associated with its use?

**A systematic review of the literature yielded no studies to adequately address this question.**



#### Future Directions for Research

The work group does not have any recommendations for future research on this topic.



**Interventional Question 9.** In patients with low back pain, is provocative lumbar discography more accurate than other diagnostic modalities in identifying the disc as a source of pain?

**There is high-level evidence that provocative discography without manometric measurements correlates with pain reproduction in the presence of moderate to severe disc degeneration on MRI/CT discography.**

**Grade of Recommendation: A**

Chen et al<sup>1</sup> retrospectively investigated the relationship between magnetic resonance (MR) findings and pain response during discography. Patients with LBP for at least a year who underwent MRI and provocation discography were included (n=93). The MR images were interpreted by two experienced radiologists and included the grading of disc degeneration (DD) per Pearce grade I-V, the presence of high-intensity zone (HIZ) and the presence of endplate abnormalities (Modic changes). Discography was reviewed by 2 experienced radiologists who classified disc morphology as Type I cotton ball; Type II, lobular; Type III, irregular; Type IV, fissured; or Type V, ruptured. Concordant pain (numeric rating scale) reported by the patient during discography was considered positive. There were statistically significant correlations between concordant pain and Type IV-V discs on discography, Grade IV-V DD on MR imaging, presence of HIZ and endplate abnormalities. The authors

concluded that DD grades on MR imaging were associated with discographic grades. This study provides Level I evidence that provocative discography without manometric pressure measurements correlates with grade IV-V DD, the presence of HIZ and endplate abnormalities on MRI.

Weishaupt et al<sup>2</sup> aimed to determine the effectiveness of MR imaging abnormalities in predicting symptomatic disc derangement by investigating the relationship with discography as the standard. Fifty patients with chronic LBP underwent MR imaging followed by lumbar discography with pain provocation test. MR images were evaluated for DD, high-signal-intensity zone and endplate abnormalities. Standard discography was conducted and pain provocation was rated as concordant, noncordant or painless. The abnormalities on MR images were compared with disc morphology characteristics and pain response on discogra-



phy. When comparing abnormalities and considering only moderate and severe type I and type II endplate abnormalities, all injected discs caused concordant pain with provocation (sensitivity, 38%; specificity, 100%; PPV, 100%). The authors concluded that DD and presence of HIZ may not correlate to painful DD, but moderate and severe endplate type I and type II abnormalities on MR imaging may predict painful disc derangement in patients with LBP. This study provides Level I evidence that provocative discography without manometry correlates with pain in the presence of moderate to severe endplate abnormalities on MRI. It did not correlate with HIZ and DD.

Vanharanta et al<sup>3</sup> investigated the relationship between radiographic findings on CT and pain provocation discography. Patients with LBP (n=91) underwent discography and CT/discography. Disc deterioration on discogram was classified as normal, slight, moderate or severe. Pain on provocation discography was classified as no pain, dissimilar, similar or exact reproduction of clinical pain. The authors concluded that as disc deterioration increased, discography was more likely to be painful and that CT/Discography is a reasonable tool to demonstrate why injection into a disc is provoking a patient's clinical pain. This study provides Level I evidence that provocative discography without manometry correlates with pain in the presence of DD on CT scan post discography. The absence of pain on provocative discography without manometry correlates with a normal disc on CT scan post discography.

Collins et al<sup>4</sup> compared magnetic resonance imaging (MRI) findings and lumbar provocative discography in order to more precisely define the role in each pain diagnosis due to degenerative disc disease. Patients being considered for surgical treatment due to

spinal pain for more than 4 months that was not relieved with conservative therapy were enrolled. After patients were examined by MRI, they underwent discography and reported pain provoked. Seventy-three levels were studied by discography in 29 subjects; 13 of which reproduced the patient's symptoms. The discography findings correlated with MRI in 65 (89.5%) subjects. The authors concluded that, of the patients who underwent surgery, an annular bulge was present in the majority. There were no specific features found on the MR images to differentiate symptomatic from asymptomatic damaged discs. This study provides Level III evidence that provocative discography without manometric pressure measurements correlated with DD on MRI scan 90% of the time. Seventy-five percent of patients who had a positive discography did well with surgical fusion.

Lim et al<sup>5</sup> investigated the relationship between magnetic resonance (MR) and CT discography findings with pain response on provocative discography. Patients with discogenic back pain (n=47) were enrolled in the study and underwent MR imaging followed by CT discography. MR images were evaluated for DD, endplate abnormalities, facet joint osteoarthritis and high intensity zone. Pain during discography was recorded as concordant or discordant. In a total of 97 discs analyzed, there was a significant correlation between concordant pain and grade 4 or 5 DD, high intensity zone, combination of the above two findings, fissured and ruptured disc at discogram and contrast beyond inner annulus on CT discogram. The authors concluded that these findings are typical with concordant pain at discography. This study provides Level III evidence that provocative discography without manometry correlates with concordant pain in the presence of grade 4-5 DD on MRI. The presence of annular tearing on discography and postdiscography CT scan also correlates with painful disc.

**There is high-level evidence that provocative discography without manometric pressure measurements correlates with the presence of endplate abnormalities on MRI imaging.**

**Grade of Recommendation: A**

Chen et al<sup>1</sup> retrospectively investigated the relationship between magnetic resonance (MR) findings and pain response during discography. Patients with LBP for at least a year who underwent MRI and provocation discography were included (n=93). The MR images were interpreted by two experienced radiologists

and included the grading of DD (Pearce grade I-V), the presence of high-intensity zone (HIZ) and the presence of endplate abnormalities (Modic changes). Discography was reviewed by two experienced radiologists who classified disc morphology as Type I cotton ball; Type II, lobular; Type III, irregular; Type IV, fis-

**176** Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

sured; or Type V, ruptured. Concordant pain (numeric rating scale) reported by the patient during discography was considered positive. There were statistically significant correlations between concordant pain and Type IV–V discs on discography, Grade IV–V DD on MR imaging, presence of HIZ and endplate abnormalities. The authors concluded that DD grades on MR imaging were associated with discographic grades. This study provides Level I evidence that provocative discography without manometric pressure measurements correlates with grade IV–V DD, the presence of HIZ and endplate abnormalities on MRI.

Weishaupt et al<sup>2</sup> aimed to determine the effectiveness of MR imaging abnormalities in predicting symptomatic disc derangement by investigating the relationship with discography as the standard. Fifty patients with chronic LBP underwent MR imaging followed by lumbar discography with pain provocation test. MR

images were evaluated for DD, high-signal-intensity zone and endplate abnormalities. Standard discography was conducted and pain provocation was rated as concordant, nonconcordant or painless. The abnormalities on MR images were compared with disc morphologic characteristics and pain response on discography. When comparing abnormalities and considering only moderate and severe type I and type II endplate abnormalities, all injected discs caused concordant pain with provocation (sensitivity, 38%; specificity, 100%; PPV, 100%). The authors concluded that DD and presence of HIZ may not correlate to painful DD, but moderate and severe endplate type I and type II abnormalities on MR imaging may predict painful disc derangement in patients with LBP. This study provides Level I evidence that provocative discography without manometry correlates with pain in the presence of moderate to severe endplate abnormalities on MRI. It did not correlate with HIZ and DD.

**Bony vibration provocation may be considered to correlate with the presence of pain in patients who have pain on provocation discography without manometric pressure measurements. There is no correlation with the segmental level of pain.**

**Grade of Recommendation: C**

Yrjama and Vanharanta<sup>6</sup> aimed to find a noninvasive tool for examining the intradiscal source of pain in patients with low back disorders. Patients with LBP underwent an evaluation using an electrical tool to produce bony vibration to the lumbar spinal processes. Participants indicated when pain was induced when the vibrator, a standard electric toothbrush shaft with a blunt head instead of a brush, compressed the lumbar spinal processes. Immediately following the evaluation, participants underwent discography evaluation under fluoroscopy with local anesthesia. Results of pain provocation were compared between methods. The sensitivity and specificity of the vibration test was 0.71 and 0.63, respectively. The authors concluded that this non-invasive bony-vibration stimulation test is easy, quick, inexpensive and reliable for examining intradiscal pain. In critique of the methodology, the work group noted that the bony vibration provocation test was not used to identify a segmental level of pain. For that reason, along with nonconsecutive patients and small sample size, the work group downgraded the level of evidence for this potential Level III study. This study provides Level IV evidence that bony vibration provocation test may correlate with the presence of pain on provocative discography without manometry, although does not identify the

segmental level of pain.

With the same purpose of identifying a non-invasive method for spine diagnostics, Yrjama et al<sup>7</sup> aimed to compare findings on ultrasound, bony vibration stimulation and discography. Patients with LBP were enrolled in the study (n=38). Participants were evaluated with ultrasound (discs were classified as Grade 0, 1, 2, or 3 based on annular ruptures), bony vibration stimulation (induced pain was recorded after compression with a commercial electric toothbrush) and discography (induced pain was recorded after standard fluoroscopically-guided injections). The sensitivity and specificity of the vibration provocation test in cases of intradiscal ultrasound findings was 0.90 and 0.75, respectively; however, the sensitivity and specificity was only 0.50 and 0.50 in ultrasound findings of total annular ruptures. The authors concluded that a combination of ultrasound and the bony vibration test are useful screening tests when evaluating LBP. In critique of the methodology, the work group downgraded the level of evidence for this potential Level III study as the quality of evoked pain was not defined, there was no correlation between the segment of pain and discography findings, a poor reference standard was used and due to nonconsecutive patients and small

sample size. This study provides Level IV evidence that ultrasound and vibration screening may possibly indicate that the spine is the source non-specific LBP.

Yrjama et al<sup>8</sup> later compared magnetic resonance imaging (MRI) and bony vibration test with discographic pain provocation findings in patients with LBP. Participants (n=33) underwent evaluation by MRI, bony vibration test and fluoroscopically-guided discography. The sensitivity and specificity of the bony vibration test was 0.88 and 0.50, respectively. The authors concluded that the addition of bony vibration stimulation

to MRI evaluation can provide more information on the origin of LBP compared to MRI alone. In critique of the methodology, the work group downgraded the level of evidence for this potential Level III study due to lack of a definition for evoked pain, poor reference standard, nonconsecutive patients and a small sample size. This study provides Level IV evidence that bony vibration provocation test may correlate with the presence of pain on provocative discography without manometry, although does not identify the segmental level of pain.

### There is insufficient evidence to make a recommendation for or against the use of axial loaded magnetic resonance imaging (MRI) for the diagnosis of low back pain.

#### Grade of Recommendation: I

Hanna and Tommy<sup>9</sup> investigated the relationship between high-intensity zones (HIZ) and pressure-controlled discography and aimed to determine if detection of HIZ was affected by axial load. Patients with chronic LBP were enrolled (n=41) and underwent pressure-controlled discography, CT, magnetic resonance imaging (MRI) and axial loaded MRI. Presence of HIZ was compared between MRI methods and provoked pain was recorded as none, unfamiliar, similar, or exact, on discography. There were no signifi-

cant correlations between HIZ and the pain response at discography. The sensitivity, specificity, positive predictive value and negative predictive value of HIZ in detecting discs with “exact pain” on discography was 0.49, 0.69, 0.39 and 0.76, respectively. The authors concluded that HIZ was not influenced by axial load. This study provides Level I evidence that pressure-controlled provocative discography does not correlate with the presence of abnormal findings on axial loaded MRI.

### There is conflicting evidence that pressure controlled provocative discography correlates with nuclear T2 signal intensity on magnetic resonance imaging (MRI) in patients with low back pain.

#### Grade of Recommendation: I

O'Neill et al<sup>10</sup> aimed to determine the accuracy of magnetic resonance imaging (MRI) for the diagnosis of discogenic pain in an observational report of patients with chronic LBP. Participants (n=143) underwent MRI which were evaluated for high intensity zone (HIZ), nuclear signal, disc height, disc contour and bony marrow intensity change. Participants were then evaluated using fluoroscopically-guided discography using a syringe with an integrated pressure transducer; pain provocation was classified as positive or negative at each disc. Moderate loss of nuclear signal combined with disc bulge has a sensitivity

of 79.8% and specificity of 79.3% for the diagnosis of discogenic pain. The authors concluded that MRI parameters are correlated with each other and with discography findings. This study provides Level I evidence that pressure-controlled provocative discography correlates with pain in the loss of nuclear T2 signal intensity on MRI.

Scuderi et al<sup>11</sup> prospectively studied patients with symptomatic lumbar degenerative disc disease to investigate the relationship between magnetic resonance imaging (MRI) grade, biochemical inflamma-

**178** Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

tory markers and concordant pain on discography. Participants (n=48) underwent MRI, discography and biochemical analysis for inflammatory markers. Pfirrmann grading of MRI, concordant pain (VAS) on discography and levels of biochemical inflammatory markers were compared. The authors concluded that

there are only weak correlations between demographic, discogram and radiographic variables. This study provides Level I evidence that pressure-controlled provocative discography does not correlate with Pfirrmann scores on MRI.

### There is conflicting evidence that provocative discography without manometric pressure measurements correlates with the presence of a high-intensity zone (HIZ) on MRI imaging.

#### Grade of Recommendation: I

Chen et al<sup>1</sup> retrospectively investigated the relationship between magnetic resonance (MR) findings and pain response during discography. Patients with LBP for at least a year who underwent MRI and provocation discography were included (n=93). The MR images were interpreted by 2 experienced radiologists and included the grading of DD (Pearce grade I-V), the presence of high-intensity zone (HIZ) and the presence of endplate abnormalities (Modic changes). Discography was reviewed by 2 experienced radiologists who classified disc morphology as Type I cotton ball; Type II, lobular; Type III, irregular; Type IV, fissured; or Type V, ruptured. Concordant pain (numeric rating scale) reported by the patient during discography was considered positive. There were statistically significant correlations between concordant pain and Type IV-V discs on discography, Grade IV-V DD on MR imaging, presence of HIZ and endplate abnormalities. The authors concluded that DD grades on MR imaging were associated with discographic grades. This study provides Level I evidence that provocative discography without manometric pressure measurements correlates with grade IV-V DD, the presence of HIZ and endplate abnormalities on MRI.

Weishaupt et al<sup>2</sup> aimed to determine the effectiveness of MR imaging abnormalities in predicting symptomatic disc derangement by investigating the relationship with discography as the standard. Fifty patients with chronic LBP underwent MR imaging followed by lumbar discography with pain provocation test. MR images were evaluated for DD, high-signal-intensity zone and endplate abnormalities. Standard discography was conducted and pain provocation was rated as concordant, nonconcordant or painless. The abnormalities on MR images were compared with disc morphologic characteristics and pain response

on discography. When comparing abnormalities and considering only moderate and severe type I and type II endplate abnormalities, all injected discs caused concordant pain with provocation (sensitivity, 38%; specificity, 100%; PPV, 100%). The authors concluded that DD and presence of HIZ may not correlate to painful DD, but moderate and severe endplate type I and type II abnormalities on MR imaging may predict painful disc derangement in patients with LBP. This study provides Level I evidence that provocative discography without manometry correlates with pain in the presence of moderate to severe endplate abnormalities on MRI. It did not correlate with HIZ and DD.

Saifuddin et al<sup>12</sup> retrospectively studied the relationship between magnetic resonance imaging (MRI) and discography findings to determine the sensitivity of MRI in detecting painful annular tears manifested by the high-intensity zone (HIZ). Patients with LBP underwent MRI followed by discography (n=58). MR images were evaluated for annular tears based on presence of HIZ. Presence and site of disrupted annulus and concordant pain reproduction on discography were classified as a positive MRI. A HIZ observed on MRI with normal discography was classified as a false-positive. Of the 152 discs examined by discography, 27 HIZ were identified on MRI; 24 were associated with pain reproduction on discography. The authors concluded that the high-intensity zone is a marker of a painful posterior annular tear, but its usefulness is limited by low sensitivity. This study provides Level I evidence that provocative discography without manometry correlates with pain in the presence of an HIZ on MRI. Provocative discography without manometry also identified painful discs without an HIZ.



### Future Directions for Research

The work group does not have any recommendations for future research on this topic.

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**Interventional Question 10.** In patients with low back pain, is anesthetic lumbar discography more accurate than other diagnostic modalities in identifying the disc as a source of pain?

**There is insufficient evidence to make a recommendation for or against the use of anesthetic discography.**

**Grade of Recommendation: I**

Alamin et al<sup>1</sup> prospectively compared the findings from standard pressure-controlled provocative discography and functional anesthetic discogram in patients with chronic LBP. Patients with chronic LBP in consideration for surgery (n=52) underwent magnetic resonance imaging (MRI) followed by standard pressure-controlled provocative discography. Pain (VAS) and concordancy were reported. If the disc was assessed as positive (greater than 5/10 on VAS and "similar" or "exact" pain reproduction), functional anesthetic discogram was performed. The functional

anesthetic discogram evaluation involved two separate fluoroscopically-guided injections of 4% lidocaine and placebo (normal saline) into one or more discs of the lumbar spine while the patient was in a position or activity that typically caused pain. Pain scores were compared at baseline and after each injection. Forty-six percent of the patients had discordant results of the pressure-controlled provocative discography and functional anesthetic discogram. The authors concluded that the findings from the functional anesthetic discogram differed from those of

standard pressure-controlled provocative discography in 46% of the cases reported. This study provides Level III evidence that there is a poor correlation between the findings on provocation discography with manometry and functional anesthetic discography.

Putzier et al<sup>2</sup> compared the results of provocative discography, discoblock (disc analgesia) and magnetic resonance (MR) imaging findings. Patients with LBP for at least 6 months who had MR imaging with degenerative disc disease Pfirrmann grade III or IV, with or without Modic changes and with or without high intensity zones (HIZ) were included (n=26). Participants underwent MR discogram without an MRI-pressure measurement syringe and reported pain (Numerical Rating Scale, Dallas Discogram Scale) immediately after injection. If there was no concordant pain (pain endpoint) or fast/markedly manually-registered elastic resistance (pressure endpoint) after 2.0 ml contrast was applied, patients were categorized as the contrast agent leak out through the annulus was registered in discogram (anatomic endpoint) or not (volume endpoint). Concordant pain was evoked in 35% of the idiopathic degenerated discs and discoblock was positive in 64%. Discoblock correlated with concordant pain and Modic changes/discography endpoint. The authors concluded that discoblock correlates with concordant pain on provocative discography as well as presence of Modic changes and can be added to surgery decision-making in patients with idiopathic degenerated discs. This study provides Level III evidence that single injection anesthetic discography correlates with a concordant response on provocative discography without manometry.

Derby et al<sup>3</sup> compared data from a multicenter prospective review against published results of pain relief following injection of local anesthetic into lumbar discs that caused concordant pain during provocation testing. Patients who underwent stand-alone analgesic discography (n=33), routine provocative discography followed by injection of local anesthetic (n=120), or provocation discography followed by injection of local anesthetic through a catheter (n=28) were included in the prospective data

review from 3 separate facilities. Two cohorts were drawn from a previously published study of patients who underwent conventional, pressure-controlled provocation discography without anesthetic (n=23) or provocative discography using an equal combination of local anesthetic and contrast (n=47) were also included. Subjective pain relief was compared for each protocol. None of the patients who received pressure-controlled provocation discography without anesthetic had pain relief. Less than 10% of the patients who underwent provocative discography using an equal combination of local anesthetic and contrast had pain relief. The authors concluded that the stand-alone analgesic discography, provocative discography followed by injection of local anesthetic and provocative discography with injection of local anesthetic through a catheter have similar results in confirming painful annular tears by concordant pain provocation and 80% or greater pain relief after injection of local anesthetic to the lumbar disc. This study provides Level IV evidence that local anesthetic plus contrast produces similar results to contrast alone in the performance of pressure-controlled provocative discography. The addition of local anesthetic reduces postdiscogram pain.

Ohtori et al<sup>4</sup> conducted a randomized controlled study to compare discography and discoblock for the diagnosis of discogenic LBP. Patients with LBP and evidence of DD on MRI were randomized to be evaluated by discography or discoblock. Surgery was performed if the procedure response was positive (n=15 in each group). Pain (VAS, Japanese Orthopedic Association Score) and disability (Oswestry Disability Index) were recorded before and 3 years after surgery. The patients who were evaluated with discoblock had significantly greater improvements in outcomes compared to those evaluated with discography. The authors concluded that discoblock with bupivacaine into the painful disc was useful for the diagnosis of discogenic LBP compared with discography. This study provides Level IV evidence that pain and functional outcomes after surgical fusion are improved more in patients who had a single positive anesthetic discogram compared to provocation discography without manometry.



### Future Directions for Research

The work group does not have any recommendations for future research on this topic.

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**Interventional Question 11.** In patients with low back pain, does intradiscal injection decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate?

**Intradiscal steroids are suggested to provide short-term improvements in pain and function in patients with Modic changes.**

**Grade of Recommendation: B**

Cao et al<sup>1</sup> conducted a double-blind, randomized, controlled, prospective clinical study to evaluate the effectiveness of intradiscal injection regimens for the treatment of LBP. Patients with degenerative chronic discogenic LBP and endplate Modic changes on magnetic resonance imaging (MRI) who received discography but did not accept surgical operation were categorized into Group A (Modic change Type I and Type I-predominated mixed Type I/II) or Group B (Modic change Type II and Type II-predominated mixed Type I/II). Each group was randomized into one of 3 subgroups: (A1/B1) intradiscal injection of normal saline, (A2/B2) intradiscal injection of diprosan, or (A3/B3) intradiscal injection of diprosan mixed with songmeile (cervus and cucumis polypeptide). Pain (VAS) and disability (Oswestry Disability Index) were recorded 3 and 6 months after the procedure. There were no significant differences in outcomes between Group A and Group B. There were no significant changes in pain or disability in subgroups 1 after 3 or 6 months. Subgroups 2 and 3 had significant improvements in pain and disability at both follow-up points, with no significant differences between groups. The authors concluded that intradiscal injection of corti-

costeroid could be a short-term efficient alternative for discogenic LBP in patients with endplate Modic changes on MRI unwilling to accept surgery. This study provides Level I evidence that intradiscal steroid injections can provide pain relief in patients with single level Modic changes and positive provocative discography with contrast contained within the disc space for up to 6 months.

Fayad et al<sup>2</sup> investigated the relationship between the severity of Modic changes on magnetic resonance imaging (MRI) and clinical response to intradiscal corticosteroid injections in patients with chronic LBP. Patients with chronic LBP with inflammatory Modic changes on MRI who had no response to conservative treatment for 3 months were included. Patients were classified as Modic type I with pure edema endplate changes (n=37), Modic I-2 with mixture of Modic type I and type II changes but predominantly edema changes (n=25) and Modic II-1 with predominantly fatty changes (n=12). All participants received a lumbar intradiscal injection of corticosteroids and reported pain intensity (VAS) before and one, three and six months after injection. Modic I and Modic I-2 groups

had significantly greater reductions in pain scores after one month compared to the Modic II-1 group. The authors concluded that intradiscal injection of corticosteroids can provide short-term treatment for patients with chronic LBP and predominantly inflam-

matory endplate changes. This study provides Level III evidence that intradiscal steroid injections provide short-term pain relief in patients with Modic changes.

### **There is insufficient evidence that intradiscal steroids provide improvements in pain or function in patients with discogenic low back pain.**

#### **Grade of Recommendation: I**

Khot et al<sup>3</sup> conducted a randomized trial of patients with chronic discogenic LBP to determine the effect of intradiscal steroid injections in clinical outcomes after one year. Patients with concordant pain on discography were randomized to receive an injection into the disc space of normal saline (n=60) or methylprednisolone (n=60). Patients reported pain (VAS) and disability (Oswestry Disability Index) for 12 months post-injection (46 of 60 in the steroid group and 52 of 60 in the saline group). There were no significant differences in percent change in disability or change in pain score between the groups. The authors concluded that intradiscal steroid injections do not improve clinical outcomes in patients with discogenic back pain. The work group downgraded this potential Level I study due to low follow-up. This study provides Level II evidence that intradiscal steroids provide no benefit over intradiscal saline in patients with discogenic LBP.

Yavuz et al<sup>4</sup> investigated the effectiveness of intradiscal steroid injections in patients with chronic LBP. Patients with chronic LBP due to degenerative disc disease (n=18) underwent provocative discography to identify the discogenic pain level followed by injection of 1 cc betamethasone. Patients reported pain (VAS) and disability related to LBP (Quebec Back Pain Disability Scale scores) before as well as 2 weeks and 3 months after injection. There was a significant reduction in pain intensity and significant improvement in disability at 2 weeks and 3 months compared to baseline. The authors concluded that intradiscal steroid injection may provide short- and mid-term effectiveness in reducing pain intensity and improving LBP-related disability. This study provides Level IV evidence that intradiscal steroids result in improved pain and function in patients with chronic LBP and MRI findings of dark disc, an HIZ or annular tearing on discography.

### **There is insufficient evidence to make a recommendation for or against the use of intradiscal bone marrow concentrate in patients with discogenic low back pain.**

#### **Grade of Recommendation: I**

Pettine et al<sup>5</sup> evaluated the safety and feasibility of intradiscal bone marrow concentrate injections for the treatment of discogenic LBP. Candidates for surgery (failed conservative treatment) with discogenic LBP for at least 6 months and evidence of degenerative disc pathology on magnetic resonance imaging (MRI) with modified Pfirrmann grade of IV-VII were included (n=26). Participants received a fluoroscopically-guided injection of intradiscal bone marrow concentrate into the nucleus pulposus of the symptomatic disc(s). Patients were clinically evaluated and reported disability (Oswestry Disability Index) and pain (VAS) prior to injection and 3, 6, 12

and 24 months after treatment. Twenty-four patients avoided surgery for 12 months; 21 avoided surgery throughout the 24-month follow-up period. Pain and disability improved in the patients who avoided surgery. The authors concluded that autologous bone marrow concentrate is a safe and feasible non-surgical treatment option for discogenic pain through two years. This study provides Level IV evidence that intradiscal injection of autologous bone marrow concentrate may provide reductions in back pain and disability at 2 years in patients with discogenic back pain.



**There is insufficient evidence to make a recommendation for or against the use of intradiscal platelet rich plasma in patients with discogenic low back pain.**

**Grade of Recommendation: I**

In a double-blind, randomized controlled study, Tuakli-Wosornu et al<sup>6</sup> evaluated the effect of a single injection of autologous platelet-rich plasma (PRP) on pain and function. Patients with chronic lumbar discogenic pain for at least 6 months who were unresponsive to conservative treatment were randomized to receive intradiscal PRP (n=36) or contrast (n=22) after provocative discography. Pain (Numeric Rating Scale, NRS) and physical function

(Functional Rating Index, FRI) were recorded after one, 4 and 8 weeks, 6 months and one year. The authors concluded that patients who received PRP had significant improvements in FRI and NRS Best Pain at 8 weeks compared to control; the FRI improvements remained significant at one year. This study provides Level II evidence that intradiscal platelet-rich plasma may provide improvements in pain and function as compared with intradiscal contrast.

**There is insufficient evidence to make a recommendation for or against the use of intradiscal Methylene Blue in patients with discogenic low back pain.**

**Grade of Recommendation: I**

Peng et al<sup>7</sup> conducted a randomized placebo-controlled trial to evaluate the effectiveness of intradiscal methylene blue for the treatment of chronic discogenic LBP. Patients with discogenic LBP longer than 6 months who underwent discography were randomized to receive injection of intradiscal methylene blue (n=36) or placebo (n=36). Pain (Numerical Rating Scale) and functional recovery (Oswestry Disability Index) were recorded 6, 12 and 24 months after randomization. The participants who received methylene blue had significantly greater

improvements in pain and disability at 24-month follow-up compared to the placebo group. There were no adverse effects or complications in the methylene blue group. The authors concluded that methylene blue injections into painful discs is a safe, effective and minimally-invasive method for the treatment of intractable and incapacitating discogenic LBP. This study provides Level I evidence that Intradiscal Methylene Blue provides improvements in pain and function when compared with intradiscal normal saline in patients with chronic discogenic LBP.



### Future Directions for Research

The work group recommends:

- High-level randomized controlled trials using platelet rich plasma and stem cells in patients with disc degeneration
- Another RCT of intradiscal steroids in patients with Modic changes
- High-level randomized controlled trials Methylene Blue in patients with disc degeneration

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**Interventional Question 12.** In patients with low back pain, does intradiscal electrothermal therapy or biacuplasty decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate?

**Intradiscal electrothermal annuloplasty is suggested to provide improvements in pain and function at up to two years. This treatment is limited in its effectiveness with roughly 40-50% of patients receiving a 50% reduction in pain.**

**Grade of Recommendation: B**

Pauza et al<sup>1</sup> conducted a randomized controlled trial to investigate the effectiveness of intradiscal electrothermal therapy (IDET) for the treatment of discogenic LBP. Patients with discogenic LBP greater than 6 months were randomized after provocation discography to receive IDET (n=37) or sham treatment of introducing a needle onto the disc in the same environment as the real procedure (n=27). IDET was performed using a standard protocol, in which a flexible electrode was navigated into the posterior annulus of the painful disc and heated to 90°C. After heating and removing the electrode, 1 cc of bupivacaine 0.75% mixed with antibiotic was injected into the disc. Pain and disability (VAS, Oswestry Disability Scale and Short Form-36) were recorded before treatment and six months after treatment. Eighty-five percent and 89% of participants were included in follow-up analysis in the IDET group and sham group, respectively. Both groups experienced improvements, but the treatment group had significantly greater improvements compared to the sham group. The authors concluded that the efficacy of IDET cannot be completely attributed to a placebo effect. This study provides Level I evidence that IDET provides significant improvements in pain and function as compared with sham at 6 months. Forty percent of treatment patients received at least a 50% reduction in pain.

Bogduk et al<sup>2</sup> prospectively evaluated the efficacy of intradiscal electrothermal annuloplasty (IDETA) for the treatment of LBP. Patients with LBP related to inter-

nal disc disruption who underwent discography and met inclusion criteria were allocated to a treatment group to receive IDETA (n=36) or comparison group if their insurer did not approve IDETA (n=17). The treatment group underwent IDETA following standard procedure in which an electrode was placed within one to 3 electrode diameters from the outer surface of the annulus fibrosus and heater to 80-90°C. Cefalozin was prophylactically administered intravenously before the procedure and intradiscally after the procedure. The comparison group completed a 36-month physical therapy program. Pain (VAS), return to work and opioid consumption were assessed at baseline, 3 months, 12 months and 2 years after treatment. The comparison group did not experience significant improvement in their pain at any follow-up point. The treatment group experienced significant improvements in median pain scores which was sustained at all follow-up points. The authors concluded that IDETA results in long-term results, 54% of patients can reduce their pain by half and one in five patients can expect to achieve complete relief of pain. This study provides Level II evidence that, in patients who had IDETA, pain and functional outcomes remained improved at 2 years.

In a randomized, double-blind, placebo-controlled trial, Freeman et al<sup>3</sup> evaluated the safety and efficacy of intradiscal electrothermal therapy (IDET) for the treatment of chronic discogenic LBP. Patients with chronic discogenic LBP with evidence of one- or

2-level symptomatic DD with posterior or posterolateral annular tears per provocative discography with CT were included. Participants were randomized to a treatment group to receive IDET (n=38) or placebo group to receive sham treatment (n=19). After the IDET catheter was positioned to cover at least 75% of the annular tear, the treatment group received electrothermal energy while the placebo group did not. Low Back Outcome Scores, Oswestry Disability Index, Short Form-36, Zung Depression Index and Modified

Somatic Perceptions Questionnaire were measured before treatment and after 6 months. There were no significant improvements in either group. The authors concluded that IDET provides no significant benefit over placebo but the procedure itself appeared safe. The work group downgraded this potential Level II study due to the small sample size that does not meet the power statement. This study provides Level III evidence that IDET provides no improvements in pain and function as compared with sham.

## **Biacuplasty is an option to produce clinically and statistically significant improvements in pain at 6 months in patients with discogenic low back pain.**

### **Grade of Recommendation: C**

Desai et al<sup>4</sup> aimed to investigate the effectiveness of intradiscal biacuplasty compared to conventional medical management for the treatment of lumbar discogenic pain in a multicenter randomized controlled trial. Patients who underwent provocation discography and diagnosed with lumbar discogenic pain were randomized to receive intradiscal biacuplasty plus conventional medical management (n=29) or individualized conventional medical management including physical therapy, pharmacological management, interventional procedures and lifestyle changes (n=34). Pain (VAS), disability (Oswestry Disability Index), physical functioning (Short Form-36), depression (Beck Depression Inventory), Patient Global Impression of Change, EQ-5D and back pain-related medication usage were assessed at baseline and after 6 months. Patients were classified as responders if they experienced a 2-point or 30% decrease in VAS scores. The intradiscal biacuplasty group experienced significantly greater pain reduction compared to conventional medical management alone. Differences in other outcomes favored intradiscal biacuplasty. The authors concluded that intradiscal biacuplasty is more effective for discogenic pain treatment than conventional medical management alone. This study provides Level I evidence that biacuplasty provides statistically significant improvements in pain, but no statistically significant improvement in function as compared with conservative management at 6 months.

Kapural et al<sup>5</sup> investigated the effectiveness of intradiscal biacuplasty, a bipolar cooled radiofrequency system, for the treatment of degenerative disc disease. Patients with chronic LBP for more than 6 months

and concordant pain on provocative discography underwent intradiscal biacuplasty (n=15). Biacuplasty was performed under fluoroscopy using 2 radiofrequency probes. Pain disability (Oswestry and Short Form-36) and pain (VAS) were assessed at baseline and after one, 3 and 6 months. There were no complications related to the procedure. Pain and disability improved at one month and remained improved after 6 months. The authors concluded that intradiscal biacuplasty improves pain measures in patients with discogenic pain. This study provides Level IV evidence that biacuplasty produces clinically and statistically significant improvements in pain in patients with discogenic LBP.

Fukui and Rohof<sup>6</sup> aimed to study the effect of biannular pulsed radiofrequency disc method in patients with discogenic LBP. Patients with chronic discogenic LBP that did not respond to conservative nonoperative care (n=15) underwent the pulsed radiofrequency technique involving 2 electrodes placed bilaterally in the annulus in the disc to apply a radiofrequency current for 12 minutes. Pain intensity (Numeric Rating Scale) and disability (Roland-Morris Disability Questionnaire) were measured at baseline and after one week and one, 3 and 6 months after treatment. Pain and disability improved significantly at the 6-month follow-up compared to baseline. The authors concluded that the biannular pulsed radiofrequency technique using Diskit needles is a safe and minimally invasive treatment option for patients with chronic discogenic LBP. This study provides Level IV evidence that biacuplasty produces clinically and statistically significant improvements in pain and function in patients with discogenic LBP.

In a prospective observational study, Karaman et al<sup>7</sup> evaluated the efficacy and safety of TransDiscal Biacuplasty. Patients with chronic discogenic LBP for at least 6 months, DD or internal disc disruption and positive discography who did not respond to conservative treatment were included. Participants (n=15) underwent the procedure in which 2 radiofrequency probes were passed through introducers and fitted into the disc with the probe tip in the posterior annulus. TransDiscal Biacuplasty was applied for 15 minutes with the software set at a temperature of 45°C and Ramp Rate of 2.0°C/min. Patients were recommended to wear lumbar braces for 6–8 weeks after the intervention. Physical function (Oswestry Disability

Index), pain (VAS) and patient satisfaction were recorded at baseline and one, 3 and 6 months after treatment. At 6-month follow-up, 57.1% of patients had at least 50% reduction in pain at 6-month follow-up and 78.6% reported reduction of at least 2 points in VAS. A total of 78.6% reported 10-point improvement in physical function. There were no reported complications related to treatment. The authors concluded that TransDiscal Biacuplasty is effective and safe. This study provides Level IV evidence that biacuplasty produces clinically and statistically significant improvements in pain and function in patients with discogenic LBP.

**There is insufficient evidence to make a recommendation for or against the use of percutaneous intradiscal radiofrequency thermocoagulation.**

**Grade of Recommendation: I**

Kvarstein et al<sup>8</sup> conducted a randomized double-blind controlled trial to evaluate the long-term safety and efficacy of percutaneous intradiscal radiofrequency thermocoagulation with the discTRODE probe. Patients with chronic LBP, evidence of moderate structural DD on MRI and concordant pain on pressure-controlled provocation discography were randomized to receive intra-annular percutaneous intradiscal radiofrequency thermocoagulation (n=10) or sham (n=10). Pain intensity (Numeric Rating Scale), Oswestry Disability Index and SF-36 were recorded

at baseline and after 6 and 12 months. There were no significant differences between groups at either follow-up point. The authors concluded that there is no evidence of percutaneous intradiscal radiofrequency thermocoagulation. The work group downgraded this potential Level I study due to the small sample size; the study was discontinued due to no beneficial effects shown. This study provides Level II evidence that percutaneous intradiscal radiofrequency thermocoagulation provides no improvements in pain and function as compared with sham.



### Future Directions for Research

The work group recommends a randomized controlled trial for biacuplasty.

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**Interventional Question 13.** In patients with low back pain, do trigger point injections decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate?

**There is insufficient evidence to make a recommendation for or against the use of trigger point injections in the treatment of low back pain. The type of injectate does not influence outcomes.**

**Grade of Recommendation: I**

In a randomized, double-blind study, Garvey et al<sup>1</sup> investigated the efficacy of trigger-point injection therapy for the treatment of LBP. Patients who failed four weeks of conservative treatment were included in this study LBP (n=63). Patients were randomized to receive an injection of lidocaine (n=13), lidocaine combined with a steroid (n=14), a single dry-needle stick (n=20), or vapocoolant spray with acupressure (n=16). Patients rated their level of pain on a scale of 1 to 10, with 10 being the worst pain experienced, 2 weeks after injection. Patients reported improvement in pain in the lidocaine injection group (40%), lidocaine plus steroid group (45%), acupuncture group (61%) and vapocoolant and acupressure (66%). The authors concluded that trigger-point therapy is a useful adjunct in treatment of low-back strain, but the injected substance is not the critical factor. The work group downgraded this potential Level I study due to the short follow-up. This article provides Level II evidence that trigger point therapies reduce pain in 40-60% of patients at 2 weeks. The type of medication used for injection does not affect the outcome.

De Andrés et al<sup>2</sup> conducted a double-blind randomized controlled trial to evaluate the efficacy of type-A botulinum toxin for LBP relief. Patients with LBP due to myofascial pain syndrome were enrolled (n=27). Each patient received a fluoroscopically-guided injection of type-A botulinum toxin to a randomly-selected side of the back and a control drug (NaCl 0.8% or bupivacaine 0.25%) injected to the opposite side. Patients completed questionnaires at baseline and after 15, 30 and 90 days to record pain (VAS), disability (Oswestry Disability Index) and other lifestyle and psychological characteristics. There were no significant changes in pain, daily life activities, or psychologic status between injections. The authors concluded that type-A botulinum toxin can provide post-intervention pain relief, but only with small differences compared to control treatments. The work group downgraded this potential Level I study due to the small sample size. This article provides Level II evidence that trigger point injections with either botulinum toxin A or bupivacaine or normal saline provide similar results; none provide clinically meaningful improvements in pain or function.



### Future Directions for Research

The work group does not have any recommendations for future research on this topic.

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**Surgical Question 1.** In patients with low back pain, does surgical treatment vs. medical/interventional treatment alone decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate?

**A systematic review of the literature yielded no studies to adequately address this question.**

*Work Group Narrative: Several frequently-referenced studies evaluating surgical treatment compared to medical/interventional treatment were excluded because they did not meet inclusion criteria. Patient populations with prior surgical treatment or pain below the knee without subgroup analysis were primary factors for eliminating these studies.*



### Future Directions for Research

The work group recommends undertaking additional randomized controlled trials comparing surgical treatment to medical/interventional treatment in patients with low back pain (LBP) **only** without history of prior lumbar surgery.



**Surgical Question 2.** In patients with low back pain, are there predictive factors which determine the benefit of initial treatment with surgical intervention versus initial medical/interventional treatment?

**A systematic review of the literature yielded no studies to adequately address this question.**



### Future Directions for Research

The work group recommends undertaking large database observational studies, such as multi-center registry studies, examining the clinical characteristics associated with clinical predictors for treatment options in patients with LBP only.



**Surgical Question 3.** In patients undergoing fusion surgery for low back pain, which fusion technique results in the best outcomes for the following: decreased duration of pain, decreased intensity of pain, increased functional outcomes of treatment and improved return-to-work rate?

- Posterolateral fusion without internal fixation versus
- Posterolateral transverse fusion with internal fixation versus
- Stand-alone (anterior) interbody fusion versus
- Transforaminal lumbar interbody fusion (TLIF) or posterior lumbar interbody fusion (PLIF) versus
- Circumferential fusion (anterior interbody, lateral techniques)

**There is insufficient evidence to make a recommendation for or against a particular fusion technique for the treatment of low back pain.**

**Grade of Recommendation: I**

Madan et al<sup>1</sup> described a comparative study of 74 LBP patients who received either instrumented circumferential fusion through a posterior approach (PLIF and posterolateral fusion, n=35) or instrumented anterior lumbar interbody fusion (ALIF) using the Hartshill horseshoe cage (n=39). Although the article states that study data was collected prospectively, it is unclear whether the study was carried out in this manner. Therefore, the work group evaluated this study as a retrospective analysis. Outcomes were assessed using the Oswestry Disability Index (ODI), quality of life questionnaire (subjective), pain drawing, visual analog scale (VAS), disability benefit, compensation status and psychological profile using the Modified Somatic Perception Questionnaire (MSPQ) and the Zung Depression Scale (ZDS). At follow-up, 74% of patients in the circumferential fusion group and 72% in ALIF group reported a satisfactory outcome ( $p < 0.05$ ) and 80% of patients in both groups reported satisfactory outcomes according to ODI criteria. Return to work, compensation and disability rates were also similar between groups. Authors reported 4 complications in the circumferential fusion group, including 3 infections and 1 patient with persistent iliac crest donor site pain for 4 months. Rates of complications in the ALIF group were similar with infections in 2 patients and severe sciatica due to impingement from the screw necessitating another operation in 1 patient. The authors concluded that ALIF with the Hartshill horseshoe cage and circumferential fusion using instrumented PLIF are both acceptable in the treatment of discogenic back pain. This study provides Level III therapeutic evidence that there were no differences in

outcomes between circumferential fusion and ALIF using Hartshill fixation at 2 years follow-up.

Vamvanij et al<sup>2</sup> performed a retrospective analysis of various fusion techniques in 56 patients with chronic LBP. Patients received either posterolateral fusion (PLF) with iliac crest autograft and translamina facet screw augmentation (Group 1, n=16), anterior retroperitoneal interbody fusion (ALIF) with allograft (Group 2, n=11), PLF with iliac crest autograft supplemented with pedicle screw rod fixation (Group 3, n=13), or ALIF with threaded fusion cages and posterior facet fusion with iliac crest autograft (Group 4, n=16) and followed for a mean of 4.2 years. Pain intensity, medication required, activity tolerance and work status were evaluated on a 4-point scale (excellent, good, fair, poor). The Dallas Pain Questionnaire (DPQ) was used to evaluate the degree of pain intensity on daily activities. At follow-up, solid fusion was achieved in 50% of patients in Group 1, 60% in Group 2, 69% in Group 3 and 88% in Group 4. In Groups 1-4, a satisfactory result was achieved in 38%, 36%, 46% and 63%, respectively. Group 4 had significantly lower DPQ scores compared to Groups 1 and 2 ( $p < 0.05$ ) at follow-up. Thirty-one percent of patients in Groups 1 and 2 returned to work and 38% in Groups 3 and 4 returned to work by follow-up. There were no differences in compensation status and disability periods between patients who were able and those unable to go back to work in any group. Complications rates were not discussed. The authors concluded that ALIF using cages with posterior facet fusion offered the highest fusion rate, pain relief and clinical success.



In critique, this study had limited statistical analysis and subgroup populations were small. Due to these limitations, the work group downgraded the study from Level III to Level IV. This study provides Level IV therapeutic evidence that circumferential fusion is

correlated with better outcomes compared to both instrumented PLF and ALIF with allograft, but similar in outcomes to PLF with autograft supplemented by pedicle screw rod fixation.



### Future Directions for Research

The work group recommends the undertaking of:

1. Large database observational studies, such as multi-center registry studies, examining various fusion techniques in patients with LBP only.
2. Randomized controlled trials examining various fusion techniques in patients with LBP only.
3. Economic studies evaluating the cost-effectiveness of various fusion techniques in patients with LBP only. Given the dearth of literature supporting superiority of fusion technique in LBP patients, economic analysis studies are needed to further investigate the costs associated with various techniques.

## References

1. Madan SS, Boeree NR. Comparison of instrumented anterior interbody fusion with instrumented circumferential lumbar fusion. *Eur Spine J*. Dec 2003;12(6):567-575.
2. Vamvanij V, Fredrickson BE, Thorpe JM, Stadnick ME, Yuan HA. Surgical treatment of internal disc disruption: an outcome study of four fusion techniques. *J Spinal Disord*. Oct 1998;11(5):375-382.



**Surgical Question 4.** In patients undergoing fusion surgery for low back pain, are clinical outcomes, including duration of pain, intensity of pain, functional outcomes and return-to-work status, different for multilevel fusions versus single-level fusions?

**A systematic review of the literature yielded no studies to adequately address this question.**



### Future Directions for Research

The work group recommends the undertaking of:

1. Large database observational studies, such as multicenter registry studies, examining various fusion techniques, including single and multi-level fusions, in patients with LBP only.
2. Randomized controlled trials examining various fusion techniques, including single and multi-level fusion, in patients with LBP only.



**Surgical Question 5.** In patients with low back pain, does intradiscal electrothermal therapy or biacuplasty decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate?

**There is insufficient evidence to make a recommendation regarding whether radiographic evidence of fusion correlates with better clinical outcomes in patients with low back pain.**

**Grade of Recommendation: I**

Vamvanij et al<sup>1</sup> performed a retrospective analysis of various fusion techniques in 56 patients with chronic LBP. Patients received either posterolateral fusion (PLF) with iliac crest autograft and translaminar facet screw augmentation (Group 1, n=16), anterior retroperitoneal interbody fusion (ALIF) with allograft (Group 2, n=11), PLF with iliac crest autograft (Group 3, n=13), or ALIF with threaded fusion cages and posterior facet fusion with iliac crest autograft (Group 4, n=16) and followed for a mean 4.2 years. Pain intensity, medication required, activity tolerance and work status were evaluated on a 4-point scale (excellent, good, fair, poor). The Dallas Pain Questionnaire (DPQ) was used to evaluate the degree of pain intensity on daily activities. At follow-up, solid fusion was achieved in 50% of patients in Group 1, 60% in Group 2, 69% in Group 3 and 88% in Group 4. Fifty percent of patients who achieved solid fusion had satisfactory results compared to only 28% of patients with pseudarthrosis ( $p < 0.05$ ). Return to work was also significantly higher in patients with successful fusion com-

pared to those without, 43% versus 17% ( $p < 0.05$ ). In Groups 1-4, a satisfactory result was achieved in 38%, 36%, 46% and 63%, respectively. Group 4 had significantly lower DPQ scores compared to Groups 1 and 2 ( $p < 0.05$ ) at follow-up. Thirty-one percent of patients in Groups 1 and 2 returned to work and 38% in Groups 3 and 4 returned to work at follow-up. There were no differences in compensation status and disability periods between patients who were able and those unable to go back to work in any group. Complications rates were not discussed. The authors concluded that ALIF using cages with posterior facet fusion offered the highest fusion rate, pain relief and clinical success. In critique, this study had limited statistical analysis and subgroup populations were small. Due to these weaknesses, the work group downgraded the study from Level III to Level IV. This study provides Level IV therapeutic evidence that there is a correlation between solid fusion and functional outcomes.



### Future Directions for Research

The work group recommends the undertaking of:

1. Large database observational studies, such as multi-center registry studies, examining the correlation between radiographic evidence and functional and clinical outcomes in patients with LBP only.
2. Randomized controlled trials examining the correlation between radiographic evidence and functional and clinical outcomes in patients with LBP only.

### Reference

1. Vamvanij V, Fredrickson BE, Thorpe JM, Stadnick ME, Yuan HA. Surgical treatment of internal disc disruption: an outcome study of four fusion techniques. *J Spinal Disord.* Oct 1998;11(5):375-382.



**Surgical Question 6.** In patients undergoing fusion surgery for low back pain, does the use of bone growth stimulators (versus fusion alone) decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate?

A systematic review of the literature yielded no studies to adequately address this question.



#### Future Directions for Research

The work group recommends the undertaking of:

1. Large database observational studies, such as multi-center registry studies examining the use of bone growth stimulators with fusion in patients with LBP only.
2. Randomized controlled trials examining the use of bone growth stimulators with fusion in patients with LBP only.



**Surgical Question 7.** In patients undergoing fusion surgery for low back pain, does the use of BMP (versus fusion alone) decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate?

A systematic review of the literature yielded no studies to adequately address this question.



#### Future Directions for Research

The work group recommends the undertaking of:

1. Large database observational studies, such as multicenter registry studies examining the use of BMP with fusion in patients with LBP only.
2. Randomized controlled trials examining the use of BMP with fusion in patients with LBP only.



**Surgical Question 8.** In patients undergoing fusion surgery for low back pain, does the use of minimally invasive techniques decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work-rate compared to open fusion techniques?

**A systematic review of the literature yielded no studies to adequately address this question.**



#### Future Directions for Research

The work group recommends the undertaking of:

1. Large database observational studies, such as multi-center registry studies examining the use of various minimally invasive fusion techniques in patients with LBP only.
2. Randomized controlled trials examining the use of various minimally invasive fusion techniques in patients with LBP only.



**Surgical Question 9.** Inpatients undergoing surgery for low back pain, do motion preserving systems (disc prosthesis and dynamic stabilization systems treatment) decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate compared to fusion surgery?

**A systematic review of the literature yielded no studies to adequately address this question.**

*Work Group Narrative: Several frequently referenced studies comparing motion preserving systems to fusion surgery were excluded because they did not meet inclusion criteria. Patient populations with prior surgical treatment or pain below the knee without subgroup analysis were primary factors for eliminating these studies.*



#### Future Directions for Research

The work group does not have any recommendations for future research on this topic.



**Surgical Question 10.** In patients undergoing surgery for low back pain, do motion preserving systems (disc prosthesis and dynamic stabilization systems) result in lower incidence of symptomatic adjacent segment disease?

**A systematic review of the literature yielded no studies to adequately address this question.**



#### Future Directions for Research

The work group recommends the undertaking of randomized controlled trials evaluating the efficacy of motion preserving systems for the prevention of symptomatic adjacent segment disease in patients with LBP only.



**Surgical Question 11.** In patients with low back pain, does fusion treatment decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate compared to treatment with:

- a. Discectomy
- b. Discectomy plus rhizotomy
- c. Decompression alone

**A systematic review of the literature yielded no studies to adequately address this question.**



#### Future Directions for Research

The work group recommends the undertaking of:

1. Large database observational studies, such as multi-center registry studies, examining discectomy with additional pain management techniques in patients with LBP only.
2. Randomized controlled trials examining discectomy with additional pain management techniques in patients with LBP only.



**Surgical Question 12.** In patients with low back pain due to sacroiliac joint dysfunction, does sacroiliac joint fusion compared with medical/interventional treatment decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate?

**A systematic review of the literature yielded no studies to adequately address this question.**

*Work Group Narrative: The majority of literature evaluating sacroiliac joint dysfunction includes patients with prior lumbar surgery (which is a frequently recognized predisposing factor for the development of sacroiliac dysfunction) and/or lower limb pain (which is a common clinical finding in patients with sacroiliac dysfunction). This review examined only evidence in the subset of patients without prior lumbar surgery and without pain below the knee. Additional literature comparing surgical treatment to medical/interventional treatment including patients with prior lumbar surgery or pain below the knee were not included in our systematic review. Therefore, a definitive statement favoring sacroiliac fusion over medical/interventional treatment in patients suffering with LBP from an SI source cannot be made.*



#### Future Directions for Research

The work group recommends additional randomized controlled trials (non-industry funded) to confirm the superiority of surgical treatment for SJD in patients failing medical/interventional treatment.

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## Introduction

The cost of low back pain (LBP) in our society has reached staggering proportions. Some studies estimate that LBP costs as much as all cancer care in the United States.<sup>1</sup> Overall cost of LBP might be as much as 100 billion dollars per year including indirect costs such as lost productivity.<sup>2</sup> There is enormous practice variation as it relates to the management of LBP. Utilization of advanced imaging differs widely and utilization of interventional treatments and surgery are also sources of variation.<sup>3-5</sup> Cost-effectiveness and cost-utility research permits valid comparison of different approaches to managing LBP. The purpose of this section of the guideline is to summarize the evidence on cost-utility analysis as it relates to the management of LBP.

A cost-utility analysis is a specific type of cost-effectiveness evaluation that compares 2 or more alternative treatment strategies in terms of both cost and outcome. Outcomes are measured in terms of quality-adjusted life years (QALYs) gained using a preference-based health-related quality of life (HR-QOL) outcome tool, such as the EQ-5D (EuroQol Group).<sup>6-7</sup> An alternative, the SF-6D, which consists of 11 items from the short form 36 item Health Survey (SF-36)<sup>8</sup>, is also used in some studies.<sup>9</sup> Preference-based HR-QOL is reported as a number from 0 (death) to 1 (perfect health). QALYs gained are determined by multiplying the number of years in a given health state

by the preference-based HR-QOL score. For example, a single year spent in perfect health would be 1 QALY.<sup>10</sup>

In order to compare the cost-utility of two interventions, A and B, it is important to calculate the incremental cost-utility ratio:  $\text{Cost of B} - \text{Cost of A} / (\text{QALYs gained from B} - \text{QALYs gained from A})$ .<sup>10</sup> In general, a treatment is considered to be cost-effective in our society when a treatment costs less than \$100,000/QALY gained.<sup>11</sup>

Calculating costs is often challenging. Costs are not the same as charges. Direct costs are health costs that involve physician time/expertise, facility cost and material costs (eg, implant costs). Indirect costs refer to loss of productivity or costs associated with a patient's inability to function (need for home health aide or nurse).<sup>10</sup> In general, a comprehensive economic analysis should include both direct (inpatient and outpatient) health costs along with indirect costs, which can sometimes be much greater over time than direct costs alone.

In this section of the guideline, we have included only papers that provided valid cost-utility analyses. In some of the sections, there were no papers that satisfied the criteria of a true cost-utility analysis and therefore no recommendation could be issued. It is important to note that cost-utility is largely dependent upon the country and health system in which the research was performed.

**198** Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

## References:

1. Martin BI, Deyo RA, Mirza SK, et al. Expenditures and health status among adults with back and neck problems. *JAMA*. 2008;299(6):656-664.
2. Katz JN. Lumbar disc disorders and low-back pain: socioeconomic factors and consequences. *J Bone Joint Surg Am*. 2006;88 Suppl 2:21-24.
3. Cherkin DC, Deyo RA, Loeser JD, Bush T, Waddell G. An international comparison of back surgery rates. *Spine*. 1994;19(11):1201-1206.
4. Volinn E, Mayer J, Diehr P, Van Koeveering D, Connell FA, Loeser JD. Small area analysis of surgery for low-back pain. *Spine*. 1992;17(5):575-581.
5. Chou R, Qaseem A, Snow V, et al. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. *Ann Intern Med*. 2007;147(7):478-491.
6. Rabin R, de Charro F. EQ-5D: a measure of health status from the EuroQol Group. *Ann Med*. 2001;33(5):337-343.
7. Suhonen R, Virtanen H, Heikkinen K, et al. Health-related quality of life of day-case surgery patients: a pre/posttest survey using the EuroQoL-5D. *Qual Life Res*. 2008;17(1):169-177.
8. Brazier J, Usherwood T, Harper R, Thomas K. Deriving a preference-based single index from the UK SF-36 Health Survey. *J Clin Epidemiol*. 1998;51(11):1115-1128.
9. Brazier J, Roberts J, Deverill M. The estimation of a preference-based measure of health from the SF-36. *J Health Econ*. 2002;21(2):271-292.
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11. Braithwaite RS, Meltzer DO, King JT, Jr., Leslie D, Roberts MS. What does the value of modern medicine say about the \$50,000 per quality-adjusted life-year decision rule? *Med Care*. 2008;46(4):349-356.



**Cost-Utility Question 1.** Who is the most cost-effective spinal care provider for evaluating patients with low back pain:

- a. Chiropractor versus
- b. Physical Therapist versus
- c. Primary Care Provider (including nonphysician providers) versus
- d. Neurologist versus
- e. Psychiatrist versus
- f. Spine Surgeon versus
- g. Anesthesiologists/Pain Medicine Physician versus
- h. Radiologist

**A systematic review of the literature yielded no studies to adequately address this question.**

*Work Group Narrative: Differential utilization of advanced imaging among providers would be expected to influence cost of evaluating patients with LBP, but a thorough review of the literature did not identify any true cost-utility studies that permitted any recommendation to be made regarding the effect of provider on the cost-utility. One study<sup>1</sup> found that the cost of evaluating LBP was higher for orthopedic spine surgeons compared with general practitioners; however, there were no outcomes assessed and therefore no conclusion could be made regarding cost-effectiveness or cost-utility.*





### Future Directions for Research

Future studies would need to compare different providers by collecting all health resource cost data including indirect costs (eg, loss of work productivity) as well as measurement of health utility using a validated health preference quality of life tool such as the EQ-5D in order to generate true cost-utility comparisons.

### References

1. Shekelle PG, Markovich M, Louie R. Comparing the costs between provider types of episodes of back pain care. *Spine*. 1995;20(2):221-227.



**Cost-Utility Question 2.** What is the cost-utility of diagnostic imaging studies/workup in the evaluation of low back pain (acute, subacute and chronic), in terms of influencing/altering treatment or in terms of leading to pain reduction and functional improvement?

- a. X-rays (lumbar standing, lumbar flexion-extension, entire spine)
- b. CT scan / CT myelogram
- c. MRI (conventional or dynamic/upright/weight bearing)

**There is insufficient evidence to make a recommendation for or against the cost-effectiveness of the use of routine ordering of lumbar spine radiographs for low back pain lasting greater than 6 weeks in the absence of red flags.**

**Grade of Recommendation: I**

Kendrick et al<sup>1</sup> and Miller et al<sup>2</sup> reported on a multicenter randomized controlled trial in the United Kingdom with a patient preference arm to test the hypotheses that lumbar spine radiography in primary care patients with LBP is not associated with improved outcomes, is not associated with changes in patient management and is not cost-effective compared with usual care. Patients with LBP  $\geq 6$  months were randomized to receive general care from their general practitioner (n=211) or a lumbar spine radiograph with explanation from their general practitioner (n=210). Participants completed questionnaires and interviews at baseline, 3 and 9 months, which included the Roland Morris Disability Questionnaire (RMDQ) score, a VAS for pain, EuroQol-5 (EQ-5D) and use of health services. An intention-to-treat analysis and economic evaluation with a societal perspective were completed. Additionally, 55 participants entered a patient preference arm of the study and were given the option to choose to have an x-ray (58%). Kendrick et al<sup>1</sup> concluded that, in the studied population, lumbar spine radiography is not associated with improved

functioning, severity of pain or overall health status and is associated with an increased in workload for the general practitioner. In critique of the methodology, the work group downgraded this potential Level I article due to the heterogeneous patient population. This study provides Level II evidence that cost per quality-adjusted life-year (QALY) gained is redundant and no significant difference between the EQ-5D scores for the groups was found. Additional QALYs cannot be gained at any cost using lumbar spine radiography. Lumbar spine radiographs for the evaluation of LBP lasting  $>6$  weeks in the absence of red flags is not cost-effective. Miller et al<sup>2</sup> concluded that lumbar spine radiography is associated with increased patient satisfaction, but not improvement in clinical outcomes. The work group downgraded this potential Level I study due to the heterogeneous patient population. This study provides Level II evidence that radiography is likely to be cost-effective only when satisfaction is valued relatively highly. Strategies to enhance satisfaction for patients with LBP without using lumbar radiography should be pursued.

*Work Group Narrative: A thorough review of the literature failed to yield any true cost-utility studies that permit any recommendations to be made regarding treatment effect cost-utility of the use of MRI, CT scan, or CT-myelogram; and the same review yielded limited evidence regarding the use of plain radiographs. Additional literature that evaluated diagnostic imaging studies in the evaluation of low back pain that did not meet this guideline's inclusion criteria were not included in our systematic review. Therefore, a definitive statement of the cost-utility of diagnostic imaging studies/workup for all patients with LBP cannot be made.*



### Future Directions for Research

Intuitively, it would not be expected that diagnostic imaging would provide a positive cost-utility in terms of influencing physical treatment, pain reduction, or functional improvement in patients with LBP. The work group recommends prospective studies evaluating implementation of patient education programs regarding the utility of imaging in order to align patient expectations with imaging utility, improve patient satisfaction and reduce cost.

### References

1. Kendrick D, Fielding K, Bentley E, Miller P, Kerslake R, Pringle M. The role of radiography in primary care patients with low back pain of at least 6 weeks duration: a randomised (unblinded) controlled trial. *Health Technol Assess.* 2001;5(30):1-69.
2. Miller P, Kendrick D, Bentley E, Fielding K. Cost-effectiveness of lumbar spine radiography in primary care patients with low back pain. *Spine.* 2002;27(20):2291-2297.



**Cost-Utility Question 3.** Does the use of ordering physician-owned diagnostic and treatment facilities affect the cost of low back pain related healthcare services?

**A systematic review of the literature yielded no studies to adequately address this question.**

*Work Group Narrative: Although a systematic review of the literature revealed no publications directly answering the question of whether physician ownership alters the cost-utility of diagnostic or treatment services for patients with LBP, some publications have suggested a possible connection. Although methodological deficiencies in these publications (including the absence of rigorous cost-utility analyses) excludes them from forming an evidence base for recommendations in this guideline, they serve as a foundation for future research in this area.*



### Future Directions for Research

It is thought that financial incentives may, in some cases, influence clinical decision-making. Physician ownership of diagnostic or treatment facilities could theoretically increase rates of referral and utilization of those facilities by the owning physicians or colleagues. In the case of patients with LBP, early or frequent ordering of diagnostic imaging or of therapeutic interventions when not clearly indicated could produce higher overall costs in the care of these patients. The work group recommends prospective comparative studies to understand how physician owned treatment facilities might influence the cost-utility of the care of patients with LBP.

Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

## Cost-Utility of Medical/Interventional Treatments Questions



**Cost-Utility Question 4.** Are epidural steroid injections (including interlaminar, transforaminal and caudal injections and selective nerve root blocks) more cost-effective in the management of patients with low back pain than other medical/interventional treatments?

**A systematic review of the literature yielded no studies to adequately address this question.**



#### Future Directions for Research

The work group recommends that future studies assessing epidural steroid injections for LBP should consider including cost-utility analysis.



**Cost-Utility Question 5.** Is spinal cord stimulation more cost-effective in the management of patients with low back pain than other medical/interventional treatments?

**A systematic review of the literature yielded no studies to adequately address this question.**



#### Future Directions for Research

The work group recommends that future studies assessing spinal cord stimulation for LBP should consider including cost-utility analysis.



**Cost-Utility Question 6.** Is physical therapy in the management of patients with low back pain more cost-effective than other medical/interventional treatments?

**There is insufficient evidence to make a recommendation for or against the cost-utility of physical therapy in the management of low back pain versus other medical/interventional treatments.**

#### Grade of Recommendation: I

The UK BEAM Trial Team<sup>1</sup> conducted a cost-utility analysis with a pragmatic randomized trial to assess the cost-effectiveness of adding spinal manipulation, exercise classes or combined treatment to usual care for patients with LBP. In this multicenter study in the

United Kingdom, 1,287 participants were randomized into 4 groups: the “best care” group (n=326) to receive active

**202** Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

e management and *The Back Book*, the exercise program group (n=297) with up to 9 community classes over 12 weeks in addition to “best care,” the spinal manipulation group (n=342) with 8 sessions over 12 weeks in addition to “best care,” or the combined group (n=322) which included 6 weeks of manipulation and 6 weeks of exercise in addition to “best care.” Participants completed questionnaires which included the EQ-5D at baseline, 3 months and 12 months.

Health care costs, quality adjusted life years (QALYs) and cost per QALY were assessed over 12 months. All three treatments improved the average QALY compared to usual care alone. The authors concluded that spinal manipulation is a cost-effective addition to “best care” for back pain in general practice and may have a better value for money alone compared to manipulation with exercise. This study provides Level II evidence that exercise therapy alone may not be cost-effective when compared to other therapies for LBP.



### Future Directions for Research

The work group recommends that future studies assessing physical therapy in the management of LBP versus other medical/interventional treatments should consider including cost-utility analysis.

## Reference

1. UK BEAM Trial Team. United Kingdom back pain exercise and manipulation (UK Beam) randomised trial: cost effectiveness of physical treatments for back pain in primary care. *BMJ*. 2004 Dec 11; 329(7479): 1381. Epub 2004 Nov 19.



**Cost-Utility Question 7.** Is pharmacological management (over-the-counter + prescription medications) for patients with low back pain more or less cost-effective than interventional treatments including physical therapy and injection therapies?

**A systematic review of the literature yielded no studies to adequately address this question.**



### Future Directions for Research

The work group recommends that future studies assessing pharmacological treatment alone for LBP should consider including cost-utility analysis.



**Cost-Utility Question 8.** Is spinal manipulative therapy in the management of patients with low back pain more cost-effective than other medical/interventional treatments?

**There is insufficient evidence to make a recommendation for or against the cost-utility of spinal manipulative therapy for the treatment of low back pain.**

**Grade of Recommendation: I**

The UK BEAM Trial Team<sup>1</sup> conducted a cost-utility analysis with a pragmatic randomized trial to assess the cost-effectiveness of adding spinal manipulation, exercise classes, or combined treatment to usual care for patients with LBP. In this multicenter study in the United Kingdom, 1287 participants were randomized into four groups: the “best care” group (n=326) to receive active management and *The Back Book*, the exercise program group (n=297) with up to 9 community classes over 12 weeks in addition to “best care,” the spinal manipulation group (n=342) with 8 sessions over 12 weeks in addition to “best care,” or the combined group (n=322) which included 6 weeks of manipulation and 6 weeks of exercise in addition

to “best care.” Participants completed questionnaires which included the EQ-5D at baseline, 3 months and 12 months. Healthcare costs, quality adjusted life years (QALYs) and cost per QALY were assessed over 12 months. All three treatments improved the average QALY compared to usual care alone. The authors concluded that spinal manipulation is a cost-effective addition to “best care” for back pain in general practice and may have a better value for money alone compared to manipulation with exercise. This study provides Level II evidence that spinal manipulation is a cost-effective treatment for LBP compared with other medical interventional therapies.



#### Future Directions for Research

The work group recommends that future studies assessing spinal manipulative therapy for LBP should consider including cost-utility analysis.

#### Reference

1. UK BEAM Trial Team. United Kingdom back pain exercise and manipulation (UK Beam) randomised trial: cost effectiveness of physical treatments for back pain in primary care. *BMJ*. 2004 Dec 11; 329(7479): 1381. Epub 2004 Nov 19.



**Cost-Utility Question 9.** Is acupuncture-based therapy in the management of patients with low back pain more cost-effective than other medical/interventional treatments?

**Acupuncture-based therapy in the management of patients with low back pain is suggested to be cost-effective when compared with other medical/interventional treatments.**

**Grade of Recommendation: B**

Witt et al<sup>1</sup> conducted a randomized controlled trial with a nonrandomized observational cohort in order to evaluate the cost-effectiveness of acupuncture in addition to routine care compared to routine care alone for patients with chronic LBP  $\geq 6$  months in Germany. Participants who agreed to take part in the RCT were randomized into an immediate acupuncture group (n=1,309 included in analysis) or a delayed acupuncture group to receive acupuncture 3 months later (n=1,183 included in analysis). If patients did not consent to randomization, they received immediate acupuncture and were included in the nonrandomized acupuncture group (n=3,846 included in analysis). Trained physicians administered a maximum of 15 needle acupuncture sessions to each participant. All participants completed a questionnaire at baseline and after 3 months. Fifty randomly selected participants also completed the questionnaire after 6 months. The participants in the acupuncture group experienced better improvements in function. No life-threatening side effects were reported. A cost analysis evaluation using a societal perspective (n=2,388) found that the probability that acupuncture was cost-effective was close to 100%. The authors concluded that acupuncture added to routine care was associated with clinical outcome improvements and was relatively cost-effective. This paper provides Level II evidence that acupuncture plus usual care is cost-effective compared to usual care.

Ratcliffe et al<sup>2</sup> conducted a randomized controlled trial and cost-effectiveness analysis to evaluate the cost-effectiveness of acupuncture in 241 patients with non-specific LBP in England. Participants were randomized at a ratio of 2:1 into an acupuncture group (n=160) or usual care only group (n=81). Bodily pain was reported on the SF-36 at baseline, 3, 12 and 24

months. Health care utilization details were collected from provider notes, admission documentation and patient questionnaires. Cost-effectiveness analysis was completed on participants who completed the questionnaire at all four time points. During the 2-year analysis, total cost was higher for the acupuncture group compared to the usual care group, but the incremental cost-effectiveness ratio was positive for the acupuncture group. The authors concluded that a short course of acupuncture offers a modest health benefit for a minor cost compared to usual care for the treatment of LBP. In critique of the methodology, the work group downgraded this potential Level II study due to the limited sensitivity analyses performed. This study provides Level III evidence that acupuncture is cost-effective when compared to usual care.

In a randomized controlled trial in the United Kingdom, Thomas et al<sup>3</sup> tested the hypothesis that patients with nonspecific LBP would gain more long-term pain relief for equal or less cost with acupuncture added to conventional primary care, compared to conventional care only. Participants were randomized into an acupuncture group (n=159) or usual care group (n=80) and completed the bodily pain dimension of the SF-36 at baseline, 3, 12 and 24 months. Cost-effectiveness was measured using the SF-6D (derived from SF-36), EuroQoL 5 Dimensions (EQ-5D) and quality-adjusted life-years (QALYs). Four patients reported minor side effects such as pain at the site of needling. At 24 months, the acupuncture service was found to be cost-effective. The authors concluded that acupuncture in a general practice environment was associated with improvement in clinical outcomes and was cost-effective over a 2-year period. The work group downgraded this potential Level II study due to the limited sensitivity analyses performed. Therefore, this study provides Level III evidence that acupuncture is cost-effective when compared to usual care.



### Future Directions for Research

The work group recommends a systematic review of existing well-designed cost-utility studies evaluating acupuncture versus usual care.

### References

1. Witt CM, Jena S, Selim D, et al. Pragmatic randomized trial evaluating the clinical and economic effectiveness of acupuncture for chronic low back pain. *Am J Epidemiol.* 2006;164(5):487-496.
2. Ratcliffe J, Thomas KJ, MacPherson H, Brazier J. A randomised controlled trial of acupuncture care for persistent low back pain: Cost effectiveness analysis. *BMJ.* 2006;333(7569):626-628.
3. Thomas KJ, MacPherson H, Ratcliffe J, et al. Longer term clinical and economic benefits of offering acupuncture care to patients with chronic low back pain. *Health Technol Assess.* 2005;9(32):68.



**Cost-Utility Question 10.** Are over-the-counter medications only without other medical interventions more cost-effective in the management of patients with low back pain than other medical/interventional treatments?

**A systematic review of the literature yielded no studies to adequately address this question.**



### Future Directions for Research

The work group recommends that future studies assessing over-the-counter medications only for LBP should consider including cost-utility analysis.



**Cost-Utility Question 11.** Is cognitive or psychological-based therapy in the management of patients with low back pain more cost-effective than other medical/interventional treatments?

**There is conflicting evidence regarding the cost-utility of cognitive or psychological-based therapy in the management of low back pain.**

**Grade of Recommendation: I**

Jellema et<sup>1</sup> al assessed the cost-effectiveness of a psychological-based program compared to usual care for the treatment of LBP in the Netherlands. A total of 314 participants from 41 general practices were enrolled in this cluster-randomized controlled trial with an economic evaluation. The participants in the intervention group (n=143) participated in a 20-minute discussion regarding psychosocial prognostic factors related to LBP. The participants

in the control group (n=171) received usual care. Outcomes such as functional disability (Roland-Morris disability questionnaire), perceived recovery (Likert scale) and health-related quality of life (EuroQol) were collected at baseline and after 12 months. Using cost diaries and follow-up information from general practitioners, an economic evaluation from a societal perspective was conducted. There were no statistically significant differences in clinical outcomes between

**206** Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

groups. The complete case analysis and sensitivity analyses resulted in inconsistent results regarding cost-effectiveness of the intervention. The authors concluded that Dutch general practitioners should not replace usual care with this new intervention at this time. In critique of the methodology, the work group downgraded this potential Level II study due to missing data and uncertainty of applying the results to environments outside of the Netherlands. This study provides Level III evidence that a very specific minimal intervention strategy exploring psychological factors was not cost-effective compared to usual care, which was not protocolized.

Lamb et al<sup>2,3</sup> conducted a multicenter randomized controlled trial and cost-effectiveness analysis from 7 English regions to assess the clinical and cost-effectiveness of a group cognitive behavioral intervention program added to best practice for the treatment of LBP. A total of 701 patients with LBP for at least 6 weeks were randomized into a control group (n=233) to receive usual care advice (which included *The Back Book*) or an intervention group (n=468) to receive usual care advice plus cognitive behavioral intervention. This intervention included an individual assessment along with 6 1.5-hour group sessions over a 2-day course. Questionnaires were completed at 3, 6 and 12 months. At 12 months, an intention-to-treat analysis included 199 (85%) participants in the control group and 399 (85%) participants in the intervention group. The intervention group had significantly greater improvement in RMDQ scores and modified Von Korff disability scores. The additional quality-adjusted life-year (QALY) gained from the intervention was 0.099 with an incremental cost per QALY of £1786 and a >90% probability of cost-effectiveness. The authors concluded that the intervention resulted in long-term (one-year) effectiveness and cost-effectiveness in treating subacute and chronic LBP at a low cost to the health-care provider. This study provides Level III evidence that addition of cognitive behavioral approach may be cost-effective for patients with LBP.

These results were supported by a cost-utility study by Norton et al<sup>4</sup> that aimed to evaluate the cost-utility of CBT for the treatment of LBP in the United States. Commercial health plan members with LBP for at

least 6 weeks who independently sought care from a general practitioner received standard education and were subsequently randomized to a control group or treatment group as part of the Back Skills Training Trial (BSTT). The control group consisted of a comprehensive strategy of multiple approaches to LBP. The treatment group received an individual assessment and up to 6 group CBT sessions. All participants completed questionnaires that included the EuroQol 5-dimension (EQ-5D) after one year used to estimate quality-adjusted life-year (QALY). A Markov decision tree model was used to estimate cost-effectiveness of the CBT intervention at one and 10 years, using costs from the US commercial payer perspective. The 10-year cost-effectiveness was estimated using the probability of distribution into 3 possible health states (improved, not improved and dead). After the first year, the incremental cost-utility of CBT was \$7,197 per QALY and \$5,855 per QALY after 10 years. The authors concluded that CBT is a cost-effective approach for treatment of chronic LBP. Although this study was not used to develop the final recommendation for this question, it provides supplemental evidence by approaching the question from the perspective of the US payers with findings similar to those of Lamb et al.<sup>2,3</sup>

Whitehurst et al<sup>5</sup> compared the cost-utility and cost-effectiveness of a brief pain management program (BPM) and physical therapy (PT) for the treatment of LBP in the United Kingdom. All participants received one 40-minute session plus up to 6 additional 20-minute sessions of the assigned treatment from a physiotherapist. Patients randomized to receive the BPM (n=201) received a management plan that addressed known psychosocial risk factors for LBP and included general exercises that were not back-specific (no physical therapy). Participants randomized into the PT group (n= 201) received the same amount and time of sessions from a physiotherapist that focused on manual physiotherapy and back-specific exercises. There were no significant differences in outcomes or health care costs between groups. The incremental cost-per quality-adjusted life-year (QALY) was £2,362. The authors concluded that PT is a cost-effective treatment for LBP and suggested that BPM could be a possible additional care approach. This study provides Level III evidence that a psychological based program administered by physical therapists is slightly less cost-effective compared to usual care.





### Future Directions for Research

The work group recommends that future studies assessing the cost-utility of cognitive or psychological therapies should clearly define the interventions in order to compare them to other medical/interventional treatments.

### References

1. Jellema P, van der Roer N, van der Windt DA, et al. Low back pain in general practice: Cost-effectiveness of a minimal psychosocial intervention versus usual care. *Eur Spine J.* 2007;16(11):1812-1821.
2. Lamb SE, Lall R, Hansen Z, et al. A multicentred randomised controlled trial of a primary care-based cognitive behavioural programme for low back pain. The back skills training (BeST) trial. *Health Technol Assess.* 2010;14(41):1-281.
3. Lamb SE, Hansen Z, Lall R, et al. Group cognitive behavioural treatment for low-back pain in primary care: a randomised controlled trial and cost-effectiveness analysis. *Lancet.* 2010;375(9718):916-923.
4. Norton G, McDonough CM, Cabral H, Shwartz M, Burgess JF. Cost-utility of cognitive behavioral therapy for low back pain from the commercial payer perspective. *Spine.* 2015;40(10):726-733.
5. Whitehurst DG, Lewis M, Yao GL, et al. A brief pain management program compared with physical therapy for low back pain: Results from an economic analysis alongside a randomized clinical trial. *Arthritis Rheum.* 2007;57(3):466-473.



**Cost-Utility Question 12.** In patients with low back pain, is a symptom guided treatment approach using directional preference/centralization matched exercise more cost-effective than usual care (home care vs medication vs nonspecific physical therapy exercise vs nonspecific physical therapy modalities) long-term at 12 months, 36 months?

**There is insufficient evidence to make a recommendation for or against the cost-utility of directional preference based therapy versus alternatives.**

**Grade of Recommendation: I**

Apeldoorn et al<sup>1</sup> compared the cost-effectiveness of usual care physical therapy versus a modified version of Delitto's classification-based approach for the treatment of LBP in the Netherlands. Patients randomized to the control group (n=82) received usual physical therapy such as resistive strengthening, stretching and postural exercises. Patients randomized into the intervention group (n=74) were classified to receive direction-specific exercises, spinal manipulation, or stabilization exercises based on a standard treatment protocol. Global perceived effect (7-point Likert scale), pain intensity (11-point numerical rating scale), functional

status (10-item ODI) and health-related quality of life (EuroQol) were recorded at baseline and after one year. Quality-adjusted life-years (QALYs) were calculated and costs were collected from a societal perspective. The participants in the intervention group had significantly greater global perceived effect, but there were no differences between groups in any of the other outcome measures. There was no significant difference in cost between groups. The authors concluded that the intervention was not cost-effective compared to physical therapy. This study provides Level III evidence that a specific directional preference treatment approach was not cost-effective when compared to the usual approach.



### Future Directions for Research

The work group recommends that any research regarding the therapeutic benefit of directional preference should consider the inclusion of cost-utility analysis.

### Reference

1. Apeldoorn AT, Bosmans JE, Ostelo RW, de Vet HC, van Tulder MW. Cost-effectiveness of a classification-based system for subacute and chronic low back pain. *Eur Spine J.* 2012;21(7):1290-1300

## Cost-Utility of Medical/Interventional Treatment versus Surgical Treatment Questions



**Cost-Utility Question 13.** Is the surgical management (including fusion and lumbar disc replacement and spinal cord stimulators) of patients with low back pain more cost-effective than medical/interventional treatments?

**There is insufficient evidence to make a recommendation for or against the cost-utility of surgical therapies versus medical/interventional therapies for low back pain.**

**Grade of Recommendation: I**

Johnsen et al<sup>1</sup> assessed the cost-effectiveness of total disc replacement (TDR) compared to multidisciplinary rehabilitation (MDR) in a randomized clinical trial of patients with chronic LBP >1 year in Norway. Patients randomized to the TDR group (n=86) received a disc prosthesis using fluoroscopic guidance. Patients randomized to the MDR group (n=87) participated in an interdisciplinary outpatient program that included exercise and cognitive intervention. Outcomes recorded included EuroQoL 5D (EQ-5D), Short Form 6D (SF-6D) and costs at 6 weeks and 3, 6, 12 and 24 months. Cost analyses were conducted using a societal perspective. The authors concluded that TDR was cost-effective when using EQ-5D, but not with SF-6D. This study provides Level III evidence that total disc replacement versus multidisciplinary rehabilitation results in conflicting evidence regarding the cost-utility of total disc replacement based on the specific tool used to assess QALYs. The intention to treat versus per protocol analysis also provided conflicting results.

Rivero-Arias et al<sup>2</sup> conducted an economic evaluation of a randomized controlled trial by Fairbank et al<sup>3</sup> to compare the cost-effectiveness of surgical spine stabilization with a rehabilitation program in patients with chronic LBP in the United Kingdom. Participants were randomized to receive spinal stabilization surgery (n=176) or an intensive rehabilitation program (n=173). The rehabilitation program included exercise and education-based on principles of cognitive behavior therapy for a total of 75 hours. All participants completed the EuroQoL 5D (EQ-5D), which was used to estimate quality-adjusted life-years (QALYs). Results revealed that spinal stabilization surgery had higher associated mean total cost per patient compared to the rehabilitation group, with no significant difference between groups in mean QALYs gained. The authors concluded that surgical stabilization of the spine may not be a cost-effective use of scarce health care resources, but that this could change. The work group determined that this study provides Level III evidence that surgical stabilization is not cost-effective when compared to an intensive rehabilitation program.



#### Future Directions for Research

The work group recommends that future studies assessing the effectiveness of surgery should consider including cost-utility analysis.

#### References

1. Johnsen LG, Hellum C, Storheim K, et al. Cost-effectiveness of total disc replacement versus multidisciplinary rehabilitation in patients with chronic low back pain: A Norwegian multicenter RCT. *Spine*. 2014;39(1):23-32.
2. Rivero-Arias O, Campbell H, Gray A, Fairbank J, Frost H, Wilson-MacDonald J. Surgical stabilisation of the spine compared with a programme of intensive rehabilitation for the management of patients with chronic low back pain: Cost utility analysis based on a randomised controlled trial. *BMJ*. 2005;330(7502):1239-1243.
3. Fairbank J, Frost H, Wilson-MacDonald J, Yu LM, Barker K, Collins R. Spine Stabilisation Trial Group. *BMJ*. 2005 May 28;330(7502): 1233. Epub 2005. Erratum in: *BMJ* (2005 Jun 25;330(7506): 1485.



**Cost-Utility Question 14.** Is cognitive or psychological-based therapy in the management of patients with low back pain more cost-effective than surgical therapies?

**There is insufficient evidence to make a recommendation for or against the cost-utility of cognitive or psychological-based therapies vs surgical therapies in the treatment of low back pain.**

**Grade of Recommendation: I**

For the purposes of evaluating studies for this question, the work group included studies with treatments that incorporated the principles of cognitive- or psychological-based therapy.

Rivero-Arias et al<sup>1</sup> conducted an economic evaluation of a randomized controlled trial by Fairbank et al<sup>2</sup> to compare the cost-effectiveness of surgical spine stabilization with a rehabilitation program in patients with chronic LBP in the United Kingdom. Participants were randomized to receive spinal stabilization surgery (n=176) or an intensive rehabilitation program (n=173). The rehabilitation program included exercise and education based on principles

of cognitive behavior therapy for a total of 75 hours. All participants completed the EuroQoL 5D (EQ-5D), which was used to estimate quality adjusted life years (QALYs). Results revealed that spinal stabilization surgery had higher associated mean total cost per patient compared to the rehabilitation group, with no significant difference between groups in mean QALYs gained. The authors concluded that surgical stabilization of the spine may not be a cost-effective use of scarce healthcare resources, but that this could change. The work group determined that this study provides Level III evidence that cognitive-based or psychological-based rehab programs may be a cost-effective option compared with surgical therapies.



#### Future Directions for Research

The work group recommends that future studies assessing the effectiveness of cognitive or psychological-based therapies for LBP should consider including cost-utility analysis.

#### References

1. Rivero-Arias O, Campbell H, Gray A, Fairbank J, Frost H, Wilson-MacDonald J. Surgical stabilisation of the spine compared with a programme of intensive rehabilitation for the management of patients with chronic low back pain: Cost utility analysis based on a randomised controlled trial. *BMJ*. 2005;330(7502):1239-1243.
2. Fairbank J, Frost H, Wilson-MacDonald J, Yu LM, Barker K, Collins R. Spine Stabilisation Trial Group. *BMJ*. 2005 May 28;330(7502): 1233. Epub 2005. Eratum in: *BMJ* (2005 Jun 25;330(7506): 1485.

## Cost-Utility of Surgical Treatment Questions



**Cost-Utility Question 15.** Are minimally invasive surgical procedures more cost-effective in the management of patients with low back pain than conventional open surgical procedures?

**A systematic review of the literature yielded no studies to adequately address this question.**



#### Future Directions for Research

The work group recommends future studies assessing the effectiveness of minimally invasive versus open surgery for LBP should consider including cost-utility analysis.



**Cost-Utility Question 16.** Is instrumented lumbar fusion more cost-effective compared to non-instrumented fusion for the treatment of patients with low back pain?

**A systematic review of the literature yielded no studies to adequately address this question.**



#### Future Directions for Research

The work group recommends that future studies comparing instrumented versus noninstrumented fusion for LBP should consider including cost-utility analysis.

## Appendix A: Levels of Evidence for Primary Research Question

### Levels of Evidence For Primary Research Question<sup>1</sup>

As Adopted by the North American Spine Society January 2005

	Types of Studies			
	Therapeutic Studies Investigating the results of treatment	Prognostic Studies Investigating the effect of a patient characteristic on the outcome of disease	Diagnostic Studies Investigating a diagnostic test	Economic and Decision Analyses Developing an economic or decision model
Level I	<ul style="list-style-type: none"> <li>High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals</li> <li>Systematic review<sup>2</sup> of Level I RCTs (and study results were homogenous<sup>3</sup>)</li> </ul>	<ul style="list-style-type: none"> <li>High quality prospective study<sup>4</sup> (all patients were enrolled at the same point in their disease with <math>\geq</math> 80% follow-up of enrolled patients)</li> <li>Systematic review<sup>2</sup> of Level I studies</li> </ul>	<ul style="list-style-type: none"> <li>Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard)</li> <li>Systematic review<sup>2</sup> of Level I studies</li> </ul>	<ul style="list-style-type: none"> <li>Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses</li> <li>Systematic review<sup>2</sup> of Level I studies</li> </ul>
Level II	<ul style="list-style-type: none"> <li>Lesser quality RCT (eg, &lt; 80% follow-up, no blinding, or improper randomization)</li> <li>Prospective<sup>4</sup> comparative study<sup>5</sup></li> <li>Systematic review<sup>2</sup> of Level II studies or Level I studies with inconsistent results</li> </ul>	<ul style="list-style-type: none"> <li>Retrospective<sup>6</sup> study</li> <li>Untreated controls from an RCT</li> <li>Lesser quality prospective study (eg, patients enrolled at different points in their disease or &lt;80% follow-up)</li> <li>Systematic review<sup>2</sup> of Level II studies</li> </ul>	<ul style="list-style-type: none"> <li>Development of diagnostic criteria on consecutive patients (with universally applied reference "gold" standard)</li> <li>Systematic review<sup>2</sup> of Level II studies</li> </ul>	<ul style="list-style-type: none"> <li>Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses</li> <li>Systematic review<sup>2</sup> of Level II studies</li> </ul>
Level III	<ul style="list-style-type: none"> <li>Case-control study<sup>7</sup></li> <li>Retrospective<sup>6</sup> comparative study<sup>5</sup></li> <li>Systematic review<sup>2</sup> of Level III studies</li> </ul>	Case-control study <sup>7</sup>	<ul style="list-style-type: none"> <li>Study of non-consecutive patients; without consistently applied reference "gold" standard</li> <li>Systematic review<sup>2</sup> of Level III studies</li> </ul>	<ul style="list-style-type: none"> <li>Analyses based on limited alternatives and costs; and poor estimates</li> <li>Systematic review<sup>2</sup> of Level III studies</li> </ul>
Level IV	Case series <sup>8</sup>	Case series <sup>8</sup>	<ul style="list-style-type: none"> <li>Case-control study<sup>7</sup></li> <li>Poor reference standard</li> </ul>	Analyses with no sensitivity analyses
Level V	Expert opinion	Expert opinion	Expert opinion	Expert opinion

1. A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.
2. A combination of results from two or more prior studies.
3. Studies provided consistent results.
4. Study was started before the first patient enrolled.
5. Patients treated one way (eg, cemented hip arthroplasty) compared with a group of patients treated in another way (eg, uncemented hip arthroplasty) at the same institution.
6. The study was started after the first patient enrolled.
7. Patients identified for the study based on their outcome, called "cases"; eg, failed total arthroplasty, are compared to those who did not have outcome, called "controls"; eg, successful total hip arthroplasty.
8. Patients treated one way with no comparison group of patients treated in another way.

Recommendations were developed based on a specific definition, inclusion/exclusion criteria, and the resulting literature which excluded conditions such as presence of a neurological deficit or leg pain experienced below the knee, among others. Given the **exclusion criteria**, these guideline recommendations address a subset of low back pain care as opposed to low back pain in its entirety. This clinical guideline is not intended to be a fixed treatment protocol; it is anticipated that there will be patients who require more or less treatment than what is outlined. This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

## Appendix B: Grades of Recommendations for Summaries or Reviews of Studies

### Grades of Recommendation for Summaries or Reviews of Studies As Adopted by the North American Spine Society January 2005

- A: Good evidence (Level I studies with consistent findings) for or against recommending intervention.
- B: Fair evidence (Level II or III studies with consistent findings) for or against recommending intervention.
- C: Poor quality evidence (Level IV or V studies) for or against recommending intervention.
- I: There is insufficient or conflicting evidence not allowing a recommendation for or against intervention.

## Appendix C: Linking Levels of Evidence to Grades of Recommendation

Grade of Recommendation	Standard Language	Levels of Evidence	
A	Recommended	Two or more consistent Level I studies	
B	Suggested	One Level I study with additional supporting Level II or III studies	Two ore more consistent level II or III studies
C	May be considered; is an option	One Level I, II, III or IV study with supporting Level IV studies	Two or more consistent Level IV studies
I	Insufficient evidence to make recommendation for or against	A single level I, II, III or IV study without other supporting evidence	More than one study with inconsistent findings*

\* Note that in the presence of multiple consistent studies and a single outlying, inconsistent study, the Grade of Recommendation will be based on the level of the consistent studies.

## Appendix D: Protocol for NASS Literature Searches

One of the most crucial elements of evidence analysis, to support the development of recommendations for appropriate clinical care or use of new technologies, is the comprehensive literature search. Thorough assessment of the literature is the basis for the review of existing evidence, which will be instrumental to these activities.

### Background

Since the quality of a literature search directly affects the quality of recommendations made NASS adheres to a protocol to ensure that all NASS searches are conducted consistently to yield the most comprehensive results

### Protocol for NASS Literature Searches

When it is determined that a literature search is needed, NASS research staff will work with the requesting parties and our contracted medical librarian to run a comprehensive search employing at a minimum the following search techniques:

1. A preliminary search of the evidence will be conducted using the following clearly defined search parameters (as determined by the content experts). In addition to the project goal and clinical question(s) of interest, the following parameters are to be provided to research staff to facilitate this systematic literature search:
  - Time frames for search
  - Foreign and/or English language
  - Order of results (chronological, by journal, etc.)
  - Key search terms and connectors, with or without MeSH terms to be employed
  - Age range
  - Must answer the following questions:
    - Should duplicates be eliminated between searches?
    - Should searches be separated by term or as one large package?
    - Should human studies, animal studies or cadaver studies be included?

This preliminary search should encompass a search of the Cochrane database when access is available.

2. Search results with abstracts will be compiled by the medical librarian in both Endnote software and a PubMed account, whenever possible. The

medical librarian typically responds to requests and completes the searches within 2–5 business days. Results will be forwarded to the Research staff, who will share it with the appropriate NASS staff member or requesting party(ies). (Research staff has access to Endnote software and will maintain a database of search results for future use/documentation.)

3. NASS staff shares the search results with an appropriate content expert (NASS Committee member or other) to assess relevance of articles and identify appropriate articles to review and on which to run a “related articles” search.
4. Based on the content expert’s review, NASS Research staff will then coordinate with the medical librarian to conduct the second level searching to identify relevant “related articles.”
5. The medical librarian will forward results to Research staff to again share with appropriate NASS staff member.
6. NASS staff shares related articles search results with an appropriate content expert (NASS Committee member or other) to assess relevance of this second set of articles and identify appropriate articles to review and on which to run a second “related articles” search.
7. NASS Research staff will work with the medical librarian to obtain the 2nd related articles search results and any necessary full-text articles for review.
8. NASS members reviewing full-text articles should also review the references at the end of each article to identify additional articles which should be reviewed, but may have been missed in the search.

### Protocol for Expedited Searches

Numbers 1, 2 and 3 should minimally be followed for any necessary expedited search. Following #3, depending on the time frame allowed, deeper searching may be conducted as described by the full protocol or request of full-text articles may occur. If full-text articles are requested, #8 should also be included. Use of the expedited protocol or any deviation from the full protocol should be documented with explanation.

Following these protocols will help ensure that NASS recommendations are (1) based on a thorough review of relevant literature; (2) are truly based on a uniform, comprehensive search strategy; and (3) represent the current best research evidence available. Research staff will maintain a search history in Endnote, for future use or reference.



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