4th Year SSC Project – 2022/23

Part 1:

Electronic modernisation of spinal injection forms

Part 2:

A comparison of patient outcomes following the use of different doses of steroid in lumbar nerve root block/transforaminal epidural injections for the management of radicular leg pain

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Ethical Approval Not Required

Part 1: Electronic modernisation of spinal injection forms

Abstract

Epidural steroid injections are commonly performed for the management of back and radicular pain. Sufficient recording of the procedure is important, both for patient notes and for use in future research.

Paper forms were previously used in Cardiff and Vale UHB, however digitalised post-procedure forms have been developed and implemented for a six-month trial period for use in the procedure room following injection. Following this trial period, the forms have been analysed and the data collected, to streamline the forms and make them more user-friendly for future use in the spinal injection service.

Introduction

Lower back and radicular pain are increasingly common patient presentations, often caused by disc herniation or spinal stenosis. When conservative measures fail to provide pain relief, epidural steroid injections are effective in reducing inflammation around impinged nerve roots and reducing irritation (1).

At Cardiff and Vale UHB, the spinal injection service administers around 1000 injections annually, most commonly nerve root blocks, transforaminal epidural injections and facet injections. Increasing patient demand necessitates the need for an updated, electronic method of recording procedures.

The implementation and improvement of digital post-procedure forms has many benefits, primarily the efficient collection of data for future studies. It also allows for easier and more efficient data input for the clinician. It presents a greener solution by reducing paper usage and contributing to environmental sustainability. It also increases data accuracy, improves integration with other systems such as Welsh Clinical Portal, and can improve data security and privacy.

A service improvement project was conducted a year ago, during which new electronic forms were created. These forms were implemented six months ago and have been used for 118 spinal injection procedures.

Aims and Objectives

The aim of this project was to review the existing digital forms and implement necessary changes, ensuring that all relevant variables are included. The project also aims to make the forms as user-friendly as possible to encourage full completion by the clinician.

In order to ensure consistency in patient notes and to foster a more unified system, it would be advantageous for there to be a standardised form that is used throughout the service. Therefore, creating a more manageable form should encourage more clinicians within the service to use it.

No ethical approval was required for this project.

Methodology

Electronic spinal injection forms were created a year ago during a previous project. This was completed using Adobe Acrobat Pro, which digitalised a basic template by adding tick boxes, text boxes and drop-down menus that can easily be filled in by the clinician. Separate forms were created for NHS and private use due to differing requirements. Following successful creation of the forms, they were implemented into the service for a six-month trial period.

Once the forms were completed in the procedure room, the data was uploaded to a locked database enabling efficient data collection. The radiology department uploaded the forms to RADIS, and a secretary to Welsh Clinical Portal. During the trial period, a database of 118 spinal procedures was collected which included a variety of different factors, including type of injection, steroid dose and pain provocation during injection. There was a 100% data completion rate.

Following the trial period, the digital forms were reviewed. Some changes were made in order to make the forms more comprehensive, such as adding the name of the procedure at the header of the page, and the patient's diagnosis to the private forms. Space for recording radiation dose, number of needles and exposure time was added to the private forms as a dropdown function, to match the NHS forms. Finally, to make the form simpler to read, several aspects were rearranged.

The form was also made more user-friendly by cutting down on some elements. The data was evaluated, and variables that changed on less than 5% of occasions were removed. This included factors such as satisfactory imaging, negative needle aspiration and flow of injection. The comments box was then expanded, with prompts for including such variables. This made the form look less busy and more likely to be completed correctly.

The improved forms can now be implemented back into the service, with plans to reaudit usage in future.

Specific results

The electronic forms produced a locked database of 118 injections. Subsequent injections on the same patient were removed from the dataset, creating a cohort of 107 patients. 42 injections were conducted under the NHS, and 65 were done privately. There were 50 males

and 57 females. Ages ranged from 20-88, with a mean of 60.78. There were 79 nerve root blocks, 12 facet injections, 2 caudal epidurals and 14 nerve root blocks with facet injections.

PROMs data was downloaded from the British Spine Registry (BSR) and added to the database – this had only been filled in by 66 of the patients (61.68%). From this smaller dataset, VAS scores could be analysed. The average VAS score for back pain before injection was 6.08, this decreased to 5.04 at 6 weeks post-injection. The average VAS score for radicular leg pain before injection was 5.82, decreasing to 4.26 at 6 weeks post-injection.

Data regarding radiation dose and time was also available. Doses ranged from 0.156 to 940.76 $Gycm^2$. The average radiation dose in private patients was 1.32$Gycm^2$, increasing to 149.56 $Gycm^2$ in NHS patients (however it is important to note outliers with high radiation doses).
Radiation time also varied significantly, from 3 seconds to 148 seconds. The average for NHS patients was 35.66 seconds, whilst the average for private patients was 9.11 seconds.

The disparity in radiation exposure between NHS and private practice is due to several factors. More specialised equipment is available in private practice, facilitating lower radiation time and dosage. Furthermore, the injection is likely to be done by a lower grade doctor when conducted in the NHS, and it was interesting to note that patients are exposed to 50.85 seconds less radiation on average when the procedure is conducted by a consultant rather than a registrar.

Discussion

Overall, the six-month trial period of the new digitalised forms has been successful. It has allowed for the creation of a strong data set for evaluation, created a greener solution for recording procedures and has reduced the time taken for the clinician to fill out post-procedure paperwork.

The forms have also received a positive response from radiologists involved in the injection procedures, particularly due to a reduction in paperwork.

The instant collection of full data sets makes for easier future research opportunities, without the need to manually filter through paper forms. Following injection, patients are encouraged to complete their PROMs through the BSR, and this data can easily be collated with the existing database to conduct future retrospective studies and allow various factors to be compared with patient outcomes. As only 66 of the 107 patients filled in their PROMs on the BSR, more should be encouraged to this to create more robust datasets. This could be done by increasing patient education of the importance of PROMs.

The more user-friendly interface of the forms should also encourage more consultants within the service to implement it, ensuring continuity and a more cohesive system. It may also reduce errors that can occur with manual data entry such as illegible handwriting.

The new inclusion of radiation dose and screening time on the forms will allow for future studies assessing the impact of radiation and improving patient safety.

Conclusion

The trial period for the electronic forms has shown that they can be time-saving, beneficial for the environment and efficient in creating data for future research. The implementation of more user-friendly changes should increase uptake and make the forms more robust for future use.

Part 2:
A comparison of patient outcomes following the use of different doses of steroid in lumbar nerve root block/transforaminal epidural injections for the management of radicular leg pain

Abstract

Aim

To evaluate whether the dose of steroid used in a lumbar nerve root block/transforaminal epidural spinal injection impacts the efficacy of the injection, measured through patient reported outcome measures (PROMs). We compared steroid doses of 40mg depo-medrone, 3.3mg dexamethasone and 6.6mg dexamethasone.

Study Design

A retrospective review.

Methods

Notes were collated from patients who had received a spinal injection between 2012 and 2023. Private patient and NHS databases were used to identify patients, creating a cohort of 1997 injections.
Inclusion criteria: those who had a primary lumbar nerve root block/transforaminal spinal epidural injection alone, receiving 40mg depo-medrone, 3.3mg dexamethasone or 6.6mg dexamethasone.
Exclusion criteria: other spinal injections (eg. facet injections, caudal epidurals), data sets for subsequent injections, those who had simultaneous facet injections, those who had previous spinal surgery, entries with a lack of data.
PROMS data was added from the British Spine Registry and using data collected from the surgeon. In total, a data set of 383 patients was created and statistically analysed.

Results

Of the 383 patients, 64 (16.71%) received 3.3mg dexamethasone, 102 (26.63%) received 6.6mg dexamethasone, and 217 (56.66%) received 40mg depo-medrone. Ages ranged from 18 to 92, with an average of 55.01 (95% CI = 1.57). There were 212 males and 171 females. Diagnoses consisted of disc prolapse, foraminal stenosis, lateral recess stenosis or a combination.
Injection outcome was classified as ‘worked’, ‘worked; wore off’ and ‘didn’t work’. There was a significant difference between the depo-medrone dose and the dexamethasone doses in the number of injections that worked, with the dexamethasone injections being more likely to be successful ($p<0.001$).
Those who were injected with dexamethasone were also less likely to require subsequent injections when compared to those who received depo-medrone ($p<0.001$).

There was no significant difference in the number of patients requiring subsequent spinal surgery (p=0.341). There was also no significant difference in injection outcomes when comparing 3.3mg/6.6mg dexamethasone doses alone (p=0.642).

Conclusion

There was a significant difference between depo-medrone and dexamethasone when correlated with injection outcome. Therefore, we would recommend that dexamethasone is used as the steroid agent of choice in NRBs/TfESIs for the management of radicular pain. The dose of dexamethasone (3.3mg vs 6.6mg) made no difference to injection outcome, suggesting that they are equally as effective for use.

Introduction

In the UK, lower back pain is a prevalent condition affecting up to 19% of adults on a single day (2). Approximately 31 million working days were lost in the UK in 2019 as a result of musculoskeletal illnesses, particularly back and radicular pain, according to estimates from the Office for National Statistics (ONS).

Epidural steroid injections are commonly performed for lower back and radicular pain and has been shown to provide short-term symptom relief (3). Nerve root blocks (NRB) and transforaminal epidural spinal injections (TfESI) are often delivered once other conservative measures have failed, and as a last method before referral to surgery. The two most common pathologies causing radicular pain are disc herniation and lateral recess stenosis (4) - the injection of steroid around the impinged nerve root acts to reduce inflammation and alleviate pain (5).

Prior to 2018, 40mg depo-medrone was used in the spinal injections at Cardiff and Vale UHB. Depo-medrone is a particulate steroid, and there is evidence to suggest that soluble steroids should be used in spinal injections (6). Therefore, the steroid agent was changed to dexamethasone, a soluble steroid. A dose of 6.6mg dexamethasone became commonplace.

At the start of the COVID-19 pandemic, the use of steroids was largely discouraged due to fears of immune suppression leading to increased viral propagation (7). This led to a smaller dexamethasone dose of 3.3mg being used. However, once these fears had been debunked, the higher dose of 6.6mg was reintroduced. This produced a good data set of both dexamethasone doses that could be plotted against patient-reported outcome measures, along with a previous cohort who received 40mg depo-medrone.

Aims and Objectives

To evaluate whether the dose of steroid used in a lumbar NRB/ TfESI impacts the efficacy of the injection.

In this single-surgeon, retrospective cohort, different doses of steroid were compared and assessed against patient-reported outcome measures (PROMs). We evaluated doses of 3.3mg and 6.6mg dexamethasone, and 40mg depo-medrone.

No ethical approval was required for this project.

Methodology

Notes were collated from patients who had received spinal injections by the same spinal consultant. These were found on NHS and private patient databases. The dates of these injections ranged from October 2012 to March 2023, creating a total database of 1997 injections.
Inclusion criteria: those who had a primary lumbar NRB/TfESI alone, receiving 40mg depo-medrone, 3.3mg dexamethasone or 6.6mg dexamethasone.
Exclusion criteria: other spinal injections (eg. facet injections, caudal epidurals), data sets for subsequent injections, those who had simultaneous facet injections, those who had previous spinal surgery, entries with no follow-up information.
In total, a locked database of 383 injection data sets was created using Microsoft Excel.

The injection data sets were then correlated with PROMs. Data was securely downloaded from the British Spine Registry (BSR) and added to the database. PROMs data collected by the surgeon was also added. The minimum follow-up period was 6 weeks.

An injection was deemed to have 'worked' if there was a successful reduction in back or limb pain, without recurrence of the pain within the follow-up period. If the injection was initially successful but the patient's pain recurred, it was classified as 'worked; wore off,' and if the patient received no reduction in their pain, the injection was deemed unsuccessful. Data was also collected regarding whether the patient had further spinal injections and whether they were listed for subsequent surgery.
A final combined database of 383 injections and PROMs was then statistically analysed using IBM SPSS 27.

Results

A total of 383 patients from various cohorts were used in the study. All patients received a NRB or TfESI between the L2 and S1 nerve roots. Injections were conducted between October 2012 and March 2023, in both the NHS and private practice. 64 patients (16.71%) received 3.3mg dexamethasone, 102 patients (26.63%) received 6.6mg dexamethasone, and 217 patients (56.66%) received 40mg depo-medrone. Ages ranged from 18 to 92, with an average of 55.01 (95% CI = 1.57). There were 212 males and 171 females. The patients'

diagnoses were sorted into disc prolapse, lateral recess stenosis, foraminal stenosis or a combination, with the majority had a diagnosis of disc prolapse.

Diagnosis	Number of patients
Disc prolapse	162
Lateral recess stenosis	112
Foraminal stenosis	40
Disc prolapse + lateral recess stenosis	20
Disc prolapse + foraminal stenosis	7
Disc prolapse + lateral recess stenosis + foraminal stenosis	1
Lateral recess stenosis + foraminal stenosis	12
Spondylolisthesis – disc prolapse	2
Spondylolisthesis – lateral recess stenosis	21 (3 also had facet cysts)
Spondylolisthesis – foraminal stenosis	5
Spondylolisthesis – lateral recess stenosis + foraminal stenosis	1

Figure 1: A table listing diagnoses of the patients and their frequencies.

Within the 3.3mg dexamethasone group, 3 injections did not work, 29 injections worked and wore off, and 32 injections worked for the duration of the follow-up period. In the 6.6mg group, 3 injections failed to work, with 53 wearing off and 46 working completely. In contrast, a much higher proportion of the 40mg depo-medrone group had injections that did not work, with 62 injections (28.57%). 98 injections wore off and 57 worked.
There was a significant difference between the three groups ($p<0.001$). When comparing the dexamethasone doses alone, there was no significant difference ($p=0.642$).

Steroid	Didn't work	Worked, wore off	Worked	Total
3.3mg dex	3 (4.69%)	29 (45.31%)	32 (50.00%)	64
6.6mg dex	3 (2.94%)	53 (51.96%)	46 (45.10%)	102
40mg depo	62 (28.57%)	98 (45.16%)	57 (26.27%)	217
Total	68	180	135	383

Figure 2: A table comparing the dose of steroid injected with injection outcome.

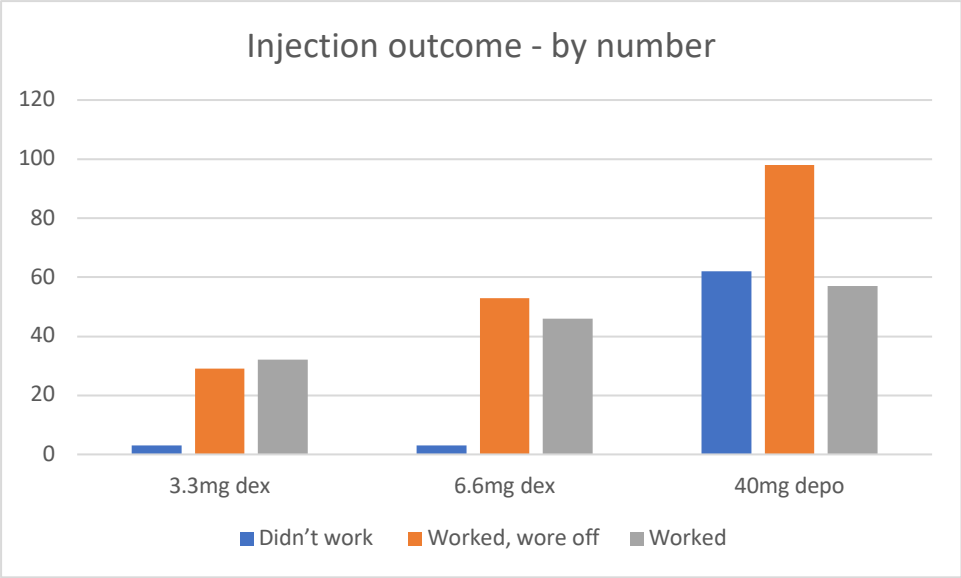

Figure 3: A bar chart comparing the dose of steroid injected with injection outcome, by number of injections.

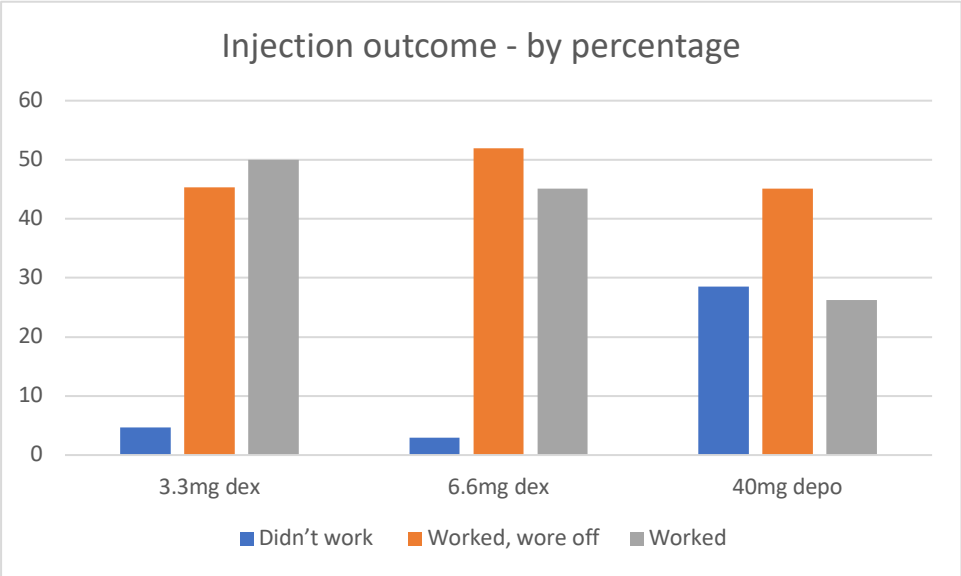

Figure 4: A bar chart comparing the dose of steroid injected with injection outcome, by percentage.

Additionally, data was collected regarding whether patients went on to have further spinal surgery after their injection. In the 3.3mg DXM group, 20 patients (31.25%) were listed for subsequent surgery, whilst 44 (68.75%) were not. In the 6.6mg DXM group, a smaller proportion had subsequent surgery, with 22 patients (21.57%). Similarly, in the 40mg depo-medrone group, 60 patients (27.65%) had further surgery. There was no significant difference between the groups (p=0.341).

Steroid	No surgery	Subsequent surgery	Total
3.3mg dex	44 (68.75%)	20 (31.25%)	64
6.6mg dex	80 (78.43%)	22 (21.57%)	102
40mg depo	157 (72.35%)	60 (27.65%)	217
Total	281	102	383

Figure 5: A table comparing the dose of steroid injected, and whether patients underwent subsequent surgery.

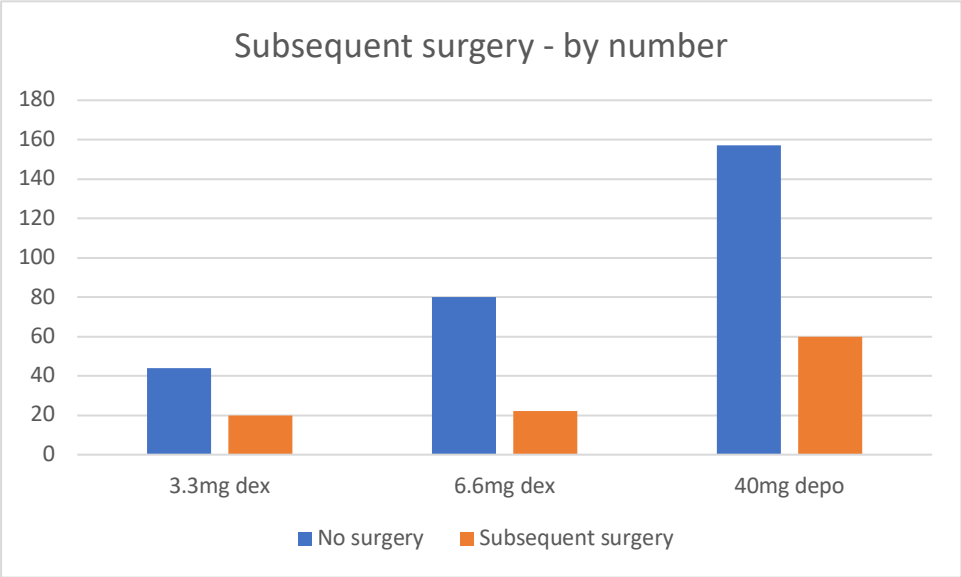

Figure 6: A bar chart comparing the dose of steroid injected with subsequent spinal surgery, by number of injections.

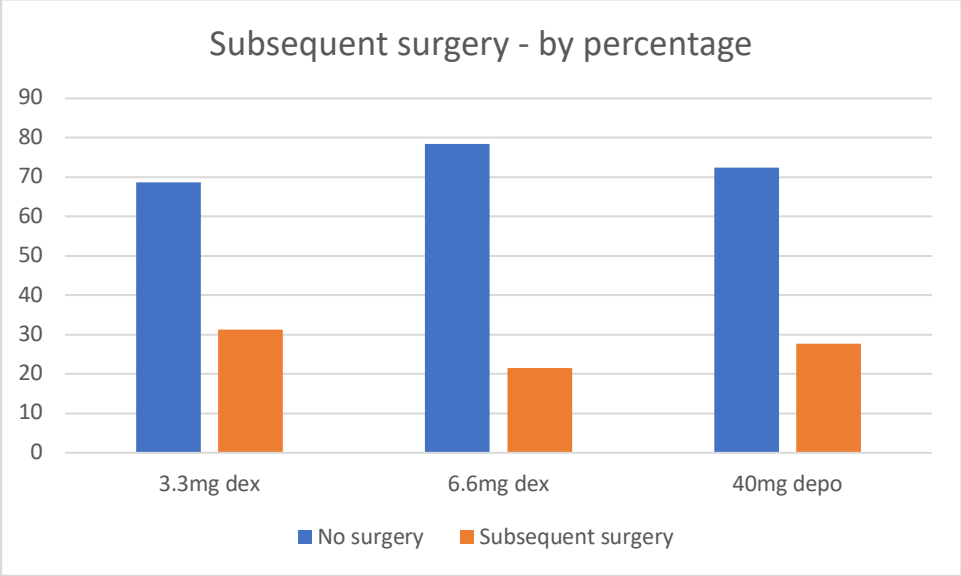

Figure 7: A bar chart comparing the dose of steroid injected with subsequent spinal surgery, by percentage.

Finally, data on whether patients had a repeat injection following their initial procedure was gathered. There were much lower incidences of repeat injection in the DXM groups, with just 21 patients in the 3.3mg group (32.87%) and 20 patients in the 6.6mg group (19.61%) undergoing a further injection procedure. In the 40mg depo-medrone group, 149 patients underwent a further injection (68.66%). When comparing the DXM dose groups alone, there was no significant difference between groups ($p=0.055$). However, when comparing the three groups together, there was a significant difference ($p<0.001$).

Steroid	No repeat	Repeat injection	Total
3.3mg dex	43 (67.19%)	21 (32.81%)	64
6.6mg dex	82 (80.39%)	20 (19.61%)	102
40mg depo	68 (31.34%)	149 (68.66%)	217
Total	193	190	383

Figure 8: A table comparing the dose of steroid injected, and whether patients underwent a subsequent spinal injection.

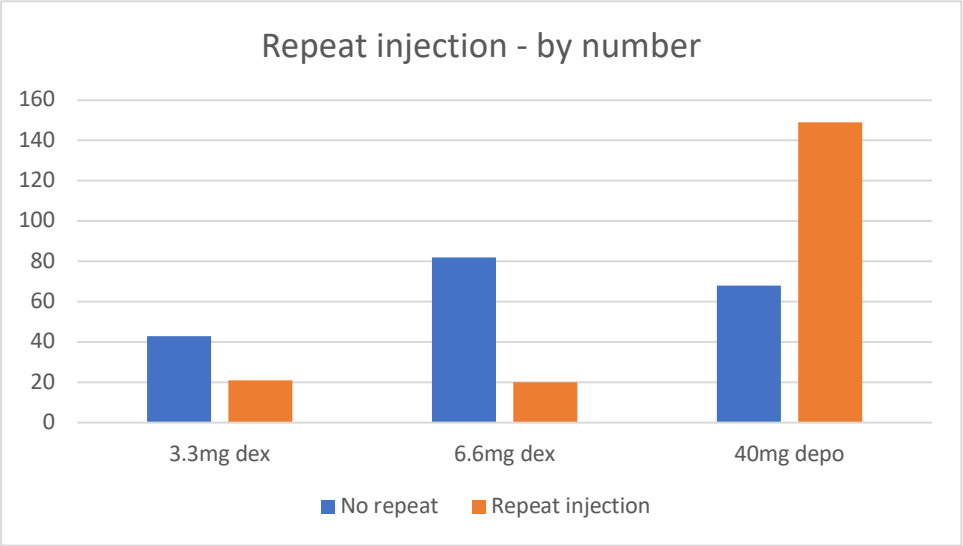

Figure 9: A bar chart comparing the dose of steroid injected with subsequent spinal injections, by number of patients.

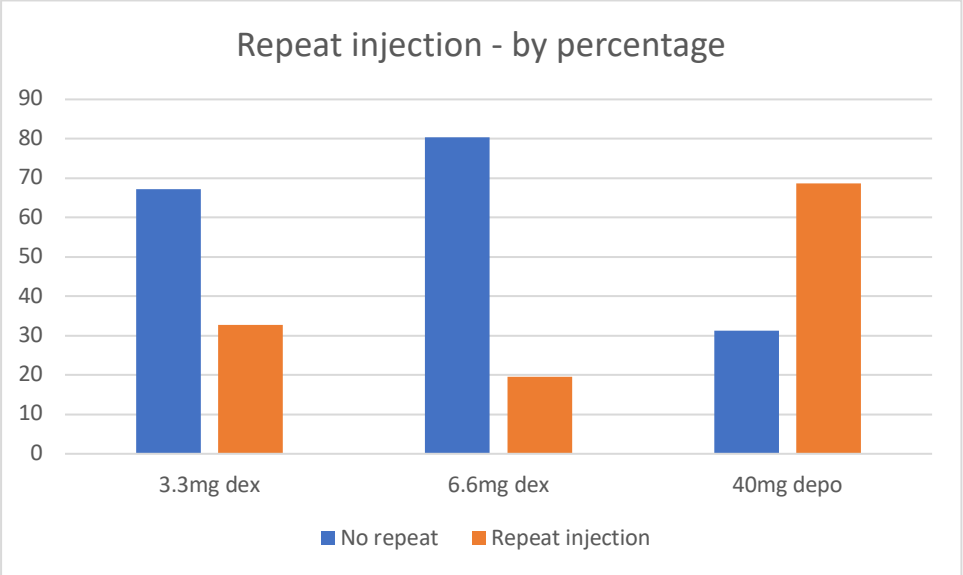

Figure 10: A bar chart comparing the dose of steroid injected with subsequent spinal injections, by percentage of patients.

Discussion

There is a variety of literature comparing post-injection outcomes following the use of different agents (6, 8, 9). In particular, a previous study has shown no difference in injection efficacy between different doses of dexamethasone (10), whilst another study showed no difference between injecting steroid and injecting local anaesthetic alone (11). Our study aims to add to this growing body of research.

The data showed that there was a significant difference between the three steroid doses and injection outcome. When a patient is injected with dexamethasone, the injection is more likely to completely work, or work in the short-term, whereas the depo-medrone dose was more likely to be unsuccessful. There was no significant difference in injection outcome between the two dexamethasone doses.

The results also show a significant difference between depo-medrone and dexamethasone for the number of patients requiring subsequent injections. This suggests that those who had a depo-medrone injection are more likely to require a repeat injection. Again, when comparing the dexamethasone doses alone, there was no significant difference.

When comparing the number of patients needing subsequent surgery, there was no significant difference between any of the doses. This means that none of the three doses of steroid increased the chances of requiring subsequent spinal surgery.

Some aspects of the literature state that spinal injections (particularly NRBs) rarely offer long-term pain relief, with the risks outweighing the benefits (12). Some documented risks of lumber epidural spinal injections include infection, paralysis, fluid leakage or death (13). In our study, 152 patients (36.36%) experienced a relief of pain for more than six weeks, without pain recurrence or complication, suggesting that spinal injections do provide a good chance of benefit.

A limitation in our study is that follow-up periods differed between patients, so a patient with a shorter follow-up period may not yet report a recurrence of their pain. Our data also assumes that patients did not go elsewhere to receive repeat injections or spinal surgery. Another limitation is the subjective nature of PROMs – it may be an inaccurate measure of injection efficacy due to external factors, for example, patients experiencing pain differently or patients reporting better outcome measures to please the spinal consultant.

Conclusion

From our results, there is evidence to support that dexamethasone is a more effective steroid than depo-medrone when used in NRBs or TfESIs for the management of radicular pain. There was a statistically significant higher chance of the injection working, either in the long or short term.
The results also suggested that using depo-medrone increased the chance of requiring a subsequent spinal injection. However, there was no difference between depo-medrone and dexamethasone in the number of patients requiring surgery.

Therefore, we would recommend that dexamethasone is used over depo-medrone in NRBs or TfESIs to provide the highest chance of pain relief for the patient.

With regards to the dose of dexamethasone, our results suggest that there was no difference between the two doses for injection outcome, or the need for subsequent surgery or repeat injections. Therefore, it may be concluded that using a greater dose of DXM, which could affect the long-term safety and tolerability of the injections, does not improve patient outcomes.

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