EPIDURAL CORTICOSTEROID INJECTIONS FOR LOW BACK PAIN

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Introduction:

Low back pain affects up to 84% of adults at some point in their life, with about 85% of those affected having non-specific back pain, or no specific cause for their pain (Chou, 2017). There are many surgical and non-surgical treatments for back pain, with the balance of potential benefits and harms being considered in choosing the appropriate course of treatment as well as the diagnosis and cause of the back pain.

Due to the risks of Surgical intervention, it is considered an option for most patients only once a reasonable trial of non-surgical options has occurred. Many patients are not eligible for surgery due to the nature of their disease process or else some other medical comorbidity that increases their potential for harm. For these reason, non-surgical treatments of back pain are exceedingly important to explore and evaluate, in order to best understand and treat those who suffer back pain. Physical therapy, epidural injections, and pharmacologics are the main categories of non-surgical interventions, each having specific harms and benefits.

This project explores epidural corticosteroid injections, which is a non-surgical, intervention that has been utilized frequently for the treatment of low back pain, but has been a contentious issue in the research world. The FDA has not approved them due to their lack of supporting data for their efficacy, and due to the associated risks involved. Epidural injections that have been tried including steroids, Botox or TNF-Alpha inhibitor, but this project will explore corticosteroid injections only. Epidural glucocorticoid injections have been used for patients with radiculopathy, spinal stenosis (narrowing of the intraspinal canal commonly caused by degenerative arthritis in those over 60) and non-specific low back pain. (Chou, 2017). Despite their widespread use, there is not a well-established position on their use, nor specific population demographics for whom they are most effective. This report will attempt to summarize some of the current research positions on the use of corticosteroid epidural injections.

The research is mixed on the efficacy of epidural steroid injections on pain relief and functioning. Uptodate summarizes it as “the efficacy is unclear due to inconsistent results as well as heterogeneous populations and interventions in randomized trials “(Chou, 2017).

A Cochrane Review in 2008 looked at many types of injection therapy for subacute and chronic low-back pain and found that there was insufficient evidence to support the use of injection therapy in subacute and chronic low back pain. However, in looking at this review, there were only 2 studies included that were specifically looking at epidural corticosteroid injections compared to placebo injections for low back pain, as relevant to the topic of this study.
One of the studies was rated as high quality evidence and the other was of low quality, according to Cochrane and both studies did not show a significant result for pain relief

or work disability in favor of the corticosteroid group. Patient satisfaction and back-specific disability were not measured (Staal, 2008).

There was one literature review by Epstein done in 2013, that came to an overall conclusion that the risks outweigh the benefits of the injections, but found studies on both the positive and negative sides of the issue. The review found one article that found transforaminal epidural injections decreased pain in the visual analogue scale by 26.6% at 12 weeks but did not have an improvement in functioning on the Oswestry Low Back Disability Index (ODI). This study had no adverse events (Ahadian, *et al*., 2011). Another two-year study found Significant pain relief and functional status improvement in groups that received local anesthetic only and those that received anesthetic and steroids, with 51% improvement in the anesthetic only group and 57% in the steroid and anesthetic group after two years. Significant pain relief and functional status improvement were seen in 38% of anesthetic group and 44% in steroid group, suggesting in favor of the corticosteroid group overall (Manchikanti et. Al, 2012).

Benny et al reviewed the literature to see if lumbosacral transforaminal steroid injections (TFESI) were effective, and they concluded that Eight of 10 randomized control studies, and 9 prospective trials utilizing computed tomography (CT) or fluoroscopic-guided injections documented “positive outcomes in both the short-term and long-term results” (Epstein 2013, Benny et. Al 2011).

Roberts et. Al also did a multi-data base review and found Trasnforaminal epidural steroid injections were better than placebo, interlaminar and caudal injections in acute radiculopathy. It was not better than placebo for subacute/chronic radiculopathy however (Epstein, 2013; Roberts et. Al, 2009).

Epstein also found several studies that did not show improvement from the injected steroids, including Arden et. Al and Valat et. Al, however these were single studies only.

A recent systematic review of the literature revealed that injected epidural steroid injections provide short-term but not long-term, as denied as 12 weeks, relief of leg pain and improvement in function in patients with benign lumbosacral radicular syndrome. It also found that injected local anesthetic had the same effect as steroids with the local anesthetic. They did not find any patient characteristics that correlated to the short-term relief they received. They concluded by saying that they do not recommend off-label steroid injections for the use of treating low back pain (shamliyan et. Al, 2014).

The evidence available seems not strongly in favor of either side. According to Uptodate, the best evidence available for benefit “comes from trials for patients with radiculopathy due to a herniated disc, and demonstrates short-term but no long-term benefit (Chou, 2017).

Besides efficacy, one must also consider the risks of the procedure and the related available research. There are risks associated with epidural steroid injections that have

been well documented in scientific literature, including, most notably, an outbreak of infections in 2012 of due to Aspergillosis contaminated methylprednisolone acetate (MPA) solution from a single compounding pharmacy resulting in meningitis, stroke, paralysis, and at least 25 deaths (Epstein, 2013). There were 337 patients sickened, and 14,000 exposed to contaminated steroids in total due to this outbreak. Of course, contaminated steroids are a rare event, but nevertheless, risk of infection for an epidural steroid injection is estimated to be 1-2%, with more serious infection occurring in 0.1% of patients (Goodman, 2008).

The literature review done by Epstein 2013 looked at several studies that researched adverse effects of epidural steroid injections, besides the ones looking at efficacy, as mentioned above. Some of the risks found in these studies were rare but devastating complications, including nerve damage, paralysis, and strokes. Other risks include accidental Dural puncture, which occur at an estimated rate of about 0.4-6% in a study done on epidural injections on women prior to giving birth (Berger 1998). In general, cervical spinal injections have a far greater risk for adverse events than Lumbar region injections. The FDA has not approved their use “noting the potential for rare but serious adverse effects (loss of vision, stroke, paralysis, and death) and that effectiveness has not been established” (Chou, 2017).

In summary, the research is generally not strongly against or in favor of corticosteroid injections for back and research must continue to identify particular groups which may receive significant benefit or be experience particular risks.

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Methods:

This study looked at a small population of patients who have received epidural steroid injections in the past and what their experience was with the procedure and the effects it had on overall pain and functioning in order to gauge if this procedure is beneficial to the patients receiving it, and to gain some insights into which types of patients might benefit from them.

In this study, Dr Don. Klassen, a family physician with anaesthesia training, performed lumbar spinal corticosteroid injections at the L3/4 or L4/5 level using the translaminar approach. There was no imaging used, but instead relied on the Loss of resistance technique to know when the needle was in the intralaminar epidural Space. This was performed on 34 Patients with diagnosis including degenerative disc disease, herniated disc, foraminal stenosis, spinal stenosis, Spondylolisthesis, disc enlargement, joint space narrowing, and vertebral disc disease. These diseases were grouped into just two groups called Degenerative disc disease (DDD) and disc protrusion (DP).

Patients were selected from Dr. Klassen’s spinal injection clinic list and included all the patients from February through to June 15th of 2017 who had received at least one spinal injection within this time. This number was 34 in total. Next a chart review was

done to collect the demographic information from these patients, as well to look at any imaging that had been done to determine the clinical diagnosis and cause of the back pain.

Finally, a phone survey was developed and administered to patients at home by telephone. The survey included the following questions found in Figure 1 and was in part inspired by the Oswestry low back pain disability index questionnaire.

The back pain patients were called at their primary phone numbers and were called multiple times if they did not respond the first time. After at least three attempts on three separate days the patients were considered “non-respondents” and were excluded from the survey results. There were no patients who refused to participate once they were reached, however there were some answers given as “N/A” if the patient was not able to answer a particular question, in these cases that question’s data was left out of the total data summary.

Due to the nature of the data collection, this study would be considered a retroactive, non-controlled study and as such, the results cannot be considered to prove any causation in any way. The results of this study are strictly qualitative, and to reflect on the experiences of a small cohort of patients both individually and collectively for the purposes of observation only.

The survey results of the patients that were reached were compiled in a table and the respondents were divided into two categories based on their MRI findings and clinical diagnosis. The categories were degenerative disc disease” and “disc protrusion”. Degenerative disc disease included aetiologies such as spondylolisthesis, joint space narrowing, anteriorlisthesis and disc desiccation as recorded in the MRI reports or chart notes. Disc protrusion included illnesses such as “disc enlargement”, “protrusion” or “herniation”. The following results in **Table 1** are compiled to compare these two groups in order to look for differences between them and look for trends in their pain relief experience within these groups. They were not specifically divided into those with or without spinal stenosis, there were some in each group with and without spinal stenosis as diagnosed by MRI.

Figure 1: The Survey administered by telephone for patients to evaluate back pain relief following epidural steroid injections.

Hi, My name is Lindsay and I am a medical student calling from the Winkler clinic, and I'm doing a short satisfaction survey for patients who've received spinal steroids by Dr. Don Klassen for back pain. The purpose of the survey is to better understand the effectiveness of steroid injections in treating back pain. Do you have about 10 minutes to answer some questions about your previous steroid injection from Dr. Klassen for your back pain?

If not, Is there a better time to call?

1. How many spinal steroid injections have you had in total? 2
   (if more than 1) the questions I ask today will refer to your most recent spinal injection, ok?

2. What other treatments for your pain were you trying before the injection(s)?

3. Thinking back to before your most recent back injection with steroids, what was your average level of pain: **Prior** to your injection On a scale of 1-10 ? with 10 being the worst pain possible and 1 being the least?

   1 2 3 4 5 6 7 8 9 10

4. **And now thinking about After** your most recent spinal injection, what was your average level of pain? On a scale of 1-10?

   1 2 3 4 5 6 7 8 9 10

5. Where was your pain before the injections: did you experience:

Upper back pain?
Lower back pain?
Buttock pain? Right, Left or both sides?
Leg pain? Right, Left or both?
How far down did the pain go into your legs?

6. In what regions, if any, did you experience relief after your injection? Back/leg/buttocks

7. How long did the relief last? in Days or weeks? Ongoing?

8. Thinking back to immediately before your most recent spinal injection – how was your walking? Please choose one of the following 5 options I will read:

- ☐ Option 1: Pain did not prevent me walking any distance
- ☐ Option 2: Pain prevented me from walking more than 1 mile
- ☐ Option 3: Pain prevented me from walking more than ½ mile
- ☐ Option 4: Pain prevented me from walking more than 100 m
- ☐ Option 5: I could only walk using a stick or crutches I was in bed most of the time

9. **after** your most recent spinal injection – how is your walking now? Using the same options from above?

Option: ___

10. **Thinking back to immediately before your most recent spinal injection – how was your sleep? Please choose one of the following options that I will read:**

- ☐ Option 1: My sleep was never disturbed by pain
- ☐ Option 2: My sleep was occasionally disturbed by pain
- ☐ Option 3: Because of pain I had less than 6 hours sleep
- ☐ Option 4: Because of pain I had less than 3 hours sleep
- ☐ Option 5: Pain prevented me from sleeping at all

11. Now, after your most recent spinal injection: using the same options previously mentioned, which option describes your sleep now?

Option

12. **Thinking back to before your most recent spinal injection – how did back pain affect your Personal care (washing, dressing etc) – Please choose one of the following options that I will read:**

- ☐ Option 1: I could look after myself normally without causing extra pain
- ☐ Option 2: I could look after myself normally but it caused extra pain and took extra time
- ☐ Option 3: I needed some help but managed most of my personal care
- ☐ Option 4: I needed help every day in most aspects of self-care
- ☐ Option 5: I did not get dressed, I washed with difficulty and stayed in bed

13. **After your most recent spinal injection – how does back pain affect your Personal care now? (washing, dressing etc) – using the same options as above?**

Option: __

Finally, I will ask you a couple of questions regarding the procedure itself:

14. After the back injection did you experience any complications: please answer yes or no as I read each option -

- ☐ Increased pain
- ☐ Infection
- ☐ Headache
- ☐ vision changes
- ☐ tingling in your arms or legs;
- ☐ sudden weakness or numbness
- ☐ dizziness
- ☐ other:

15. On a scale of 1-10 how satisfied are you with the overall effect the epidural steroid injection had on the level of your pain and functioning, with 10 being the most satisfied and 1 being the least

    1 2 3 4 5 6 7 8 9 10

thank you, that concludes the survey for today. If you have any concerns or questions you can contact the winkler CW Wiebe clinic at 204-325-4312 and leave a message for Dr. Don Klassen

Thank you very much for your participation in this survey

Note that the results do not discuss the question related to the “methods tried before injection” since this question was not answered completely or accurately by the patients and did not offer any useful comparison.

Pain level was asked on a 10-point verbal Likert scale, similar to a visual analog scale, with 1 being the least and 10 being the worst pain imaginable. The post-injection pain level was also assessed on this scale. The average decrease in pain level was calculated as the difference between the average prior pain level and the average post-injection pain level as told by the patient. The overall satisfaction of the procedure was also rated on a scale of 1 to 10 with 5 being neutral, 1 being completely dissatisfied and 10 being completely satisfied.

The location of pain was assessed based on the answers given and sorted into two categories: those with lower back pain and leg pain in the first category and the second one including those with only lower back pain. Leg pain included those with pain in any area below the back such as hip, buttock, thigh, knee, foot on at least one side.
The location of pain relief was assessed by asking the patient where they experienced relief. It was simplified from the original data collected and divided into 4 categories: firstly, those with any amount of leg and back relief both occurring according to the patient, second, any amount of back relief only and thirdly, any amount of leg relief only. The fourth category is those who did not have any pain relief, or could not articulate any specific location of their relief upon prompting. For this study, patients having a decrease in pain level of 3 points or more are considered to have a “significant pain relief”.

For the functioning categories, the respondents were graded on 5 levels of functioning in the categories of walking, sleeping and self-care. The exact criteria for each level in the scheme can be viewed above in Figure 1., though to summarize, option 1 represented the highest level of functioning, and 5 represented the lowest level of functioning. For examples, in the walking category, option 1 represented patients who could walk any distance they wanted without being stopped by pain, option 3 meant their pain prevented them from walking ½ a mile, and 5 meant the patient had severely decreased mobility limited by pain to requiring a walker and confining them to a bed most of the time. In the sleeping category, option 1 meant their sleep was never disrupted by pain, option 3 meant pain prevented them from getting more than 6 hours of sleep and 5 meant they were prevented from sleeping at all. See Figure 1 for more details on the sleep related question. For self-care: option 1 was fully independence and maintained speed in bathing, dressing and option 3 meant they needed some assistance, and option 5 meant they were not able to dress at all and bathed with full assistance. See Figure 1 for more details on the self-care related option.

Results and discussion:

The total number of respondents was 24 patients out of the total 34 patients called. Of these respondents, they were divided into two categories based on their MRI findings and clinical diagnosis into “degenerative disc disease” (DDD) and “disc protrusion” (DP) as described above. There were 14 respondents in the DDD group and 10 in the DP group. The results were compiled to compare the two groups in each category and are available below in Table 1.

Demographics of the patients in the full list were:
Average age: 61 years, Range: 24-88
Sex: 19 F, 15 M = 34 total
Diagnosis: Degenerative disc disease (18) or disc protrusion (13)
1 had both DDD and DP and 1 had an unknown diagnosis from the chart reviewed.
Average age: DDD = 65.55, average age disc protrusion – 56 years old

For the DDD group, the average level of lower back pain prior to the injection was 8.2/10. And for the DP group that value was 7.7/10. The average post injection pain level for the DDD group was 4.1 and for the DP group was 4.6, creating a decrease in pain level of 4.2 (or 42%) for the DDD group and 3.1 (31%) for the DP group. These values in of themselves may or may not be significant, but it is reassuring to see that many patients reported a decrease in pain level post injection. One an individual level, there were 10 patients (71%) in the DDD group and 6 patients (60%) in the DP group that had a decrease in pain level of 3 points or more, defined here as “significant pain relief”.

The location of pain prior to and post injection were assessed, as seen in the table below, most patients had both lower back and some leg pain as well. In the DDD group, half (7/14) of the respondents had leg and back pain relief, compared to just 3/10 in the DP having both back and leg relief. However, in the DDD group, there were a significant number (5/14) with no relief or no specific location relieved of pain, compared to just 1/10 in the DP group.

A note about the 5 patients with no location identified with pain relief: One of these patients reported a decrease in pain level without specifying where the pain was relieved, which explains the discordance of numbers, since 9 patients total had pain relieved in a specific area, but 10 patients had a decrease level of pain by 3 points in the DDD group.

Table 1: Survey Results from Patients Who had an Epidural Steroid Injections for Back Pain

Patient Demographic	**Degenerative Disc Disease Group**	**Disc Protrusion Group**	**Total # of patients**
Total number of patients	21	13	34
Total respondents	14	10	24
Total with confirmed spinal stenosis via MRI	9/14	6/10	15 (/24)
Average prior pain level (out of 10)	8.2	7.7	-
Average post injection pain level (out of 10)	4.1	4.6	-
Average decrease in pain level (out of 10)	4.2	3.1	-
Number of patients that had a decrease in pain ≥ 3 points	10	6	16 (/24)
Number of patients with decrease in pain of 0 or 1 point	3	1	4 (/24)
Patient Satisfaction overall towards the procedure (out of 10)	5.7	6.7	-
Number of patients satisfied (with scores 6 or higher)	9	8	17 (/24)
Location of pain:			
Number of patients with Prior lower back and leg pain -	13	10	23
Number of patients with prior lower back pain only	1	0	1
Number of patients who had Leg and back relief	7	3	10
Number of patients who had Back only relief	1	1	2
Number of patients who had Leg only relief	1	5	6
Not available /no location had relieved pain	5	1	6
Functioning scores:			
Walking score pre (points scale 1-5 – 1 is best)	3.7	2.8	-
Walking score post	2.8	2	-
Difference in walking scores (in points)	0.86	0.8	-
Sleeping score pre-injection (points scale 1-5 – 1 is best)	2.4	3.0	-
Sleeping score post injection	2.1	1.9	-
Sleeping score -change/difference (in points)	0.21	1.1	-
Personal care score pre (points scale 1-5 – 1 is best)	2	1.7	-
Personal care score post	1.36	1.2	-
Personal care score change	0.64	0.5	-
Adverse events: - Severe - Minor - None	 1 8 5	 0 5 5	 Severe: 1 Minor: 13 None: 10
Length of relief range (in weeks)	0 -20	0 -9	-
Length of relief average (in weeks)	4.9	2.8	-
Length of relief median (in weeks)	3.5	2.5	-
Number of respondents with at least 3 weeks relief	8	5	13 (/24)
Number of respondents with < 1 week relief	4	1	5 (/24)
Total number of respondents with 1 injection to date	3	5	8 (/24)
Total number of respondents with 2 injections to date	4	3	7 (/24)
Total number of respondents with 3 or more injections	7	2	9 (/24)

As for the level of patient satisfaction, again, the comparison between the groups cannot be deemed significant on its own, but it was reassuring to see many people were very satisfied with the results of the injection on their level of pain and functioning. There were 9/14 (64%) of patients in the DDD group satisfied (with score 6 and above) and 8/10 (80%) in the DP group satisfied with the effect the injection had on pain and functioning. Anecdotally there were many comments such as “It improves all my pain levels all around, I would like to make another appointment” and “not everything was relieved, but I had to use way less pain meds”,
And "improved ability to do stretches and exercises" are just some of the positive remarks.
However, there were also some negative remarks, “it made the pain worse,” and “I had a severe reaction”, and “I had no relief” or “the relief came much later and I couldn’t tell if it was helping”.

In terms of functioning, the DDD group had a similar improvement in walking compared to the DP group with 0.86 improvement and 0.8 improvement respectively. For sleeping, as well the improvement was greater in the DP group with an increase of 1.1 compared to just 0.21 in the DDD group. And for personal care, the groups were again similar with 0.65 point improvement and 0.5 improvement with the DDD and DP groups respectively.

In terms of adverse effects, there were more reported in the DDD group, and included one patient with severe symptoms including vision changes, sudden weakness and numbness and dizziness after the steroid injection. The other 8 in the DDD group who had minor symptoms included headache, temporary increased pain, insomnia, diarrhea, localized lump, breathing changes, facial sweating and abdominal pain/gas. It is unclear from interviewing the patients if these symptoms can actually be attributed to the spinal injection as the causative factor, but these were the symptoms self-reported by the patients. 5/14 patients reported no adverse symptoms at all.

In the DP group, there were no severe adverse effects and 5 patients had minor effects such as dizziness, increased pain temporarily, leg cramping, and headache. There were 5 respondents in the DP group that had no adverse effects at all.

The range of relief length was from 0 to 20 weeks in the DDD and from 0 to 9 weeks in the DP group, with an average relief length of 4.9 weeks in the DDD group and 2.8 weeks in the DP group. When looking at the median values however, these values are much closer together, at 3.5 weeks and 2.5 weeks for DDD and DP respectively, indicating that there were more patients in the DDD group with much longer relief times that skewed the mean to be higher.

And finally, the number of injections was evaluated to see how many patients were returning for this treatment, and how many were trying it for the first time, which could influence the results and satisfaction overall. In the DDD group, 7 respondents had received 3 or more injections, and 4 of them had 2 or more. Only 3 from the DDD group had received their very first injection. Contrast this to the DP group where 5 had

received their first injection and only 2 people had received more than 3 injections, and only 3 people had received 2 injections previously. One might expect that the patients who had returned for multiple injections would be more satisfied and have greater reduction in pain and greater increase in functioning overall due to selection bias, which might explain some of the values seen in the DDD above which seem to exceed the DP, but due to study design limitations, this cannot be confirmed as a randomized controlled trial would be required to test this potential source of selection bias.

There were 3 respondents in the DDD group and 1 in the DP group that had 1 point decrease in pain or none at all. There were also 4 patients in the DDD group and 1 in the DP group that had < 1 week relief.

One limitation is that this study did not look at length of time these patients had pain, it was difficult to get this information from the charts and it was not included in the survey due to wanting to keep the format concise.

One further point to consider is that in all the randomized control trials and previous research done, the concept of “mental suffering” or “mental relief” was never discussed but seems to be a substantial part of the experience of suffering for those living with back pain. Even though this study cannot show causation, and even if the research community is divided on the issue of efficacy of these injections, there is no doubt that many people received relief from suffering from their back pain following their spinal injection. There is a strong possibility that part of this relief was a placebo. However, assuming that the steroid and anesthetic combination were at least in part effective in reducing the inflammatory pain process, for many patients, even a short period of decreased pain was a significant relief for them, both in the physical and mental experience of pain. The stories shared during the phone survey cannot all be quantified or measured, but there were a lot of people expressing satisfaction and emotional/mental benefits from the pain that go beyond just the quantity of time they had relief or the amount it was relieved. For people living with chronic pain, even a short glimpse of relief can be of exponential value.

Conclusion and Recommendations:

Given the limitations of the study design and methods, no definitive causational evidence can be drawn from the data collected, however we can conclude that many patients were quite satisfied with the procedure itself and found personally that they had significant pain relief and functional benefit in many cases. 9/14 patients in the DDD group and 9/10 patients in the DP group had some level of relief in at least one specific location of their low back and leg pain after the injection. And 10/14 patients and 6/10 patients in the DDD and DP groups respectively, had a decrease in pain level of 3 points or more, which is defined in this study as significant pain relief. Without a placebo control, these results cannot be considered to show causation between the spinal steroid injections and the pain relief and functional improvement.

There were some patients that did not seem to benefit in either decrease in pain for any significant length of time, from this injection treatment, and some who had adverse effects, including one patient with severe adverse effects.

All evidence considered, it seems there is a correlation between the DDD group and having longer and more substantial pain relief, but with little difference in overall functioning. Given the limitations of the methods use. From the individual stories heard throughout the interviews, it seems clear that a substantial number of people received a great benefit from their experience with the epidural spinal injections and were quite satisfied with the results. It is the recommendation of this study that further research be continued, and that each patient considering the injections weighs the risks and potential benefits in regard to emotional and physical suffering with their health care providers before considering epidural steroid injections.

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