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# Do Epidural Injections With Local Anesthetic With Steroids Have Superiority Over Injections with Local Anesthetic Alone When Treating Chronic Back Pain Due To an Intervertebral Disc Herniation in Men and Women Over 18 Years Old?

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**Do epidural injections with local anesthetic with steroids have superiority over injections with local anesthetic alone when treating chronic back pain due to an intervertebral disc herniation in men and women over 18 years old?**

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies  
Philadelphia College of Osteopathic Medicine  
Philadelphia, Pennsylvania

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## ABSTRACT

**OBJECTIVE:** The objective of this selective EBM review is to determine whether or not, “Do epidural injections with local anesthetic with steroids have superiority over injections with local anesthetic alone when treating chronic back pain due to an intervertebral disc herniation in men and women over 18 years old?”

**STUDY DESIGN:** Review of three, double blind, randomized controlled trials (RCTs) published between 2011-2014, all in English language. The articles compared epidural injections containing local anesthetic with steroids to epidural injections containing local anesthetics alone.

**DATA SOURCES:** Three Randomized controlled trials found using PubMed. All articles were published in peer-reviewed journals and selected based on the correlation to topic choice, publication date <15 years old, RCT’s, and dealt with POEMs.

**OUTCOMES MEASURED:** The outcomes were measured using questionnaires such as the Numeric Rating Scale (NRS) 0(none)-10 (severe) pain scale and Oswestry Disability Index (ODI) 0(minimal)-50(severe) scale to assess functional status. Significant improvement ( $\geq 50\%$ ) pain relief associated with  $\geq 50\%$  improvement in functional status measured by and Neck Disability Index. 3,6,12 month post treatment assessments were also completed for pain and opioid use, classified via dosage frequency and schedule of the drug.

**RESULTS:** All three studies revealed both treatments (steroids vs anesthetic alone) are effective for pain improvement, but steroids have no superiority. One of the Manchikanti et al. studies showed a negative result of the steroid group. Significant improvement from baseline in 80% of local anesthetic group and 73% of local anesthetic plus steroid group via ODI and NRS, p-value = 0.357, ABI of -0.07%, NNT of -14.<sup>1</sup> The other two Manchikanti et al. studies displayed a greater improvement from baseline in the local anesthetic plus steroid group vs local anesthetic group alone, but no significance when compared.

**CONCLUSION:** The three RCT’s showed significant improvement from baseline, but treatment effects between steroid group and exclusively anesthetic group was not statistically different. In conclusion, steroid injections improve pain and function in those with chronic back pain due to an intervertebral disc herniation, but did not statistically show more improvement over the control.

**KEY WORDS:** “epidural steroid injections” “herniated discs” “chronic back pain

## INTRODUCTION

Back pain is a common ailment that impacts one's life tremendously. Not only is back pain the most common contributor to living with a disability, unfortunately the prevalence is only increasing, already at an overwhelming 15-20% in the United States.<sup>1</sup> Intervertebral disc herniation's make up a bulk of those statistics and occurs when the nucleus pulposus, contained within each vertebral disc, is forced through a weakened area in the annulus fibrosus, fibrous exterior of the disc, due to increased stress placed on the vertebrae.<sup>5</sup> While excess force via increase weight or physically demanding occupations exerted on the vertebral column is likely to cause a disc to herniate, individuals can inherit a predisposition.<sup>6</sup> The highest prevalence is among those aged 30-50 years with males at a higher risk.<sup>7</sup> 95% of disc herniations that occur in those under the age of 55, frequently occur in the lumbar spine, commonly levels L4/5 and L5/S1. Individuals greater than 55 years old generally herniate spinal discs above those levels.<sup>7</sup> Herniated discs can cause excruciating pain and may lead to irritation of the nerves and possibly permanent nerve damage if not treated.

Back pain is often times not severe, but it is an expensive condition to treat. Back pain is the most expensive ailment in a workplace to acquire, reaching up to \$8,000 per claim and \$38 to \$50 billion annually.<sup>4</sup> Low back pain, specifically, is the fifth most common reason for health care visits and still individuals are not seeking care because of the expense.<sup>4</sup> There were no reports found on the exact expenses of intervertebral disc herniations specifically, but with such a high prevalence in the population, it is a condition that needs to be focused on.

It is well known that herniated discs are caused by excess force directed through the spinal column causing it to lose its integrity. What is unknown is the development of the pain and how frequently one feels pain. This is questioned because some individuals with herniated discs do not experience back and/or neck pain.

Intervertebral disc herniations are diagnosed through medical history, physical examination, and imaging techniques via Magnetic Resonance Imaging (MRI) most commonly. Bed rest up to 48 hours is suggested for acute exacerbations of pain.<sup>9</sup> Besides that, first line treatment for herniated disc includes limiting stress and weight load on the back, medications such as NSAIDs and other analgesics, as well as physical therapy.<sup>9</sup> For severe pain, opioids, nerve pain medications (gabapentin, pregabalin, duloxetine, tramadol, amitriptyline), muscle relaxers, and cortisone injections are available as other options. When all of the above treatments have failed, surgery is the last resort. Microdiscectomy is the standard method of treatment with low complication rates and high satisfactory results.<sup>9</sup> Pharmacologically, treatment options stated above have only a short-term efficacy in pain management of herniated discs. There is also an increased addiction potential when starting controlled substances to control severe pain. It is known that surgery is a good option for patients with chronic back pain, but corticosteroid injections are another great choice for that population as well. The method of treatment proposed is comparing the administration of epidural injections containing local anesthetic combined with steroids and local anesthetics alone to examine if there was significant pain relief from the baseline measurement on the NRS scale.

## OBJECTIVE

The objective of this systematic review is to determine whether or not, “Do epidural injections with local anesthetic with steroids have superiority over injections with local anesthetic alone when treating chronic back pain due to an intervertebral disc herniation in men and women over 18 years old?”

## METHODS

The three studies used in this review consisted of randomized controlled trials (RCTs) comparing epidural injections containing local anesthetic with steroids to epidural injections containing local anesthetics alone. Inclusion criteria was restricted to men & women at least 18 years old with cervical disc, L4-5 and L5-S1 disc herniations, greater than 18 years old, and back pain at least 6 months with pain intensity limiting function.<sup>1,2,3</sup> The intervention of concentration included epidural injections containing local anesthetic with steroids, which was given to the experimental group.<sup>1,2,3</sup> This was compared to giving the studied population epidural injections containing local anesthetic only, which included the control group.<sup>1,2,3</sup> Outcomes were measured via significant improvement of pain relief ( $\geq 50\%$ ) based on Numeric Rating Scale (NRS) and function measured by the Oswestry Disability Scale (ODS).

The study conducted by Manchikanti L. analyzing transformational epidural injections in chronic lumbar disc herniation, was a randomized, double-blind, active-control trial.<sup>1</sup> Participants were at least 18 years old with chronic low back pain and lower extremity pain for at least 6 months, with pain limiting function and NRS score of 5/10.<sup>1</sup> There was 120 participants involved and equally split into two groups. Group I, control group, was treated with 1.5 mL of lidocaine 1% (local anesthetic) followed by 0.5 mL of

sodium chloride. Group II, experimental group, was injected with 1.5 mL lidocaine 1% (local anesthetic), followed by 0.5 mL of betamethasone (corticosteroid).<sup>1</sup> Only disc herniations occurring at L4-5 and L5-S1 were studied. Procedures for both groups were performed at L4, L5, and S1 with the patient prone, using a 22-gauge needle. Individuals only received one injection of specified solution and their pain and function were assessed 3,4,12,18, and 24 months after initial injection.

The study conducted by Manchikanti L exploring the management of chronic pain of cervical disc herniation and radiculitis with epidural injections was a randomized, double-blind, active-control trial.<sup>2</sup> The participants were over 18 years old with at least a 6 month history of chronic, debilitating neck and upper extremity pain.<sup>2</sup> There were 120 individuals included in the evaluation and split equally into 2 groups. Group I, control group, received 5 mL of lidocaine 0.5% (local anesthetic). Group II, experimental group, was treated with 4 mL lidocaine 0.5% (local anesthetic), mixed with 1 mL of betamethasone (corticosteroid).<sup>2</sup> Procedure was done with patients prone with injections placed between C7 and T1.<sup>2</sup> Injection was performed (gauge of needle not specified) only once with an assessment occurring 3, 6, and 12 months after initial dose.

The study conducted by Manchikanti L examining caudal epidural injections in the treatment of lumbar disc herniation and radiculitis was a randomized, double-blind, active-control trial.<sup>3</sup> There was 120 participants at least 18 years old with disc herniations causing chronic, function-limiting low back or lower extremity pain for at least 6 months.<sup>2</sup> Individuals were equally separated into two groups of 60. Group I, control group, received 10 mL of lidocaine 0.5% (local anesthetic). Group II, experimental group, was treated with 9 mL lidocaine 0.5% (local anesthetic), mixed with 1 mL of

betamethasone (corticosteroid).<sup>3</sup> Procedures were performed by the same physician, with patients in prone position, and injection placed in epidural space of lumbar levels.

Injection was given once (gauge of needle not specified) with an evaluation occurring 3, 6, and 12 months post-treatment via Numeric Rating Scale (NRS), Oswestry Disability Index 2.0 (ODI), and opioid intake.

Keywords used for the search in the databases included “epidural steroid injections,” “herniated discs,” and “chronic back pain.” Articles were written in English and published in peer-reviewed journals between the years of 2011-2014. The articles were researched through Philadelphia College of Osteopathic Medicine’s library database via PubMed. These chosen articles were selected based on the correlation to the topic choice, publication date no more than 15 years old, RCT’s, and dealt with POEMs. Summary of statistics reported according to the p-value, relative benefit increase (RBI), absolute benefit increase (ABI), and numbers needed to treat (NNT).

**Table 1 - Demographics and characteristics of included studies.**

Study	Type	# Pts	Age (yrs)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Manchik anti, 2014 (1)	RCT	120	18+ y/o	At least 18 y/o with L4-S1 disc herniation & chronic low back and low extremity pain >6 mths with pain intensity limiting function & NRS score >5.	History of previous lumbar surgery; radiculitis secondary to spinal stenosis, radiculitis without disc herniation; and patients with b/l radiculitis, Pts with uncontrolled medical illnesses, extremely high dose opioid users, pregnant or lactating.	17	Epidural injection of 1.5 mL of 1% lidocaine followed by 0.5 mL of betamethasone VS. Epidural injection of 1.5 mL of 1% lidocaine followed by 0.5 mL of sodium chloride solution
Manchik anti, 2012 (2)	RCT	120	18+ y/o	At least 18 y/o, cervical disc herniation & history of chronic, function-limiting neck & upper extremity pain >6 months.	History of previous lumbar surgery; radiculitis secondary to spinal stenosis, radiculitis without disc herniation; and patients with b/l radiculitis, Pts with uncontrolled medical illnesses, extremely high dose opioid users, pregnant or lactating.	5	Cervical interlaminar epidural injections with 0.5% lidocaine, 4 mL, mixed with 1 mL of non-particulate betamethasone VS. Cervical interlaminar epidural injections with 0.5% lidocaine, 5 mL
Manchik anti, 2011 (3)	RCT	120	18+ y/o	At least 18 y/o with disc herniation & history of chronic function-limiting low back and lower extremity pain >6 months.	History of previous lumbar surgery; radiculitis secondary to spinal stenosis, radiculitis without disc herniation; and pts with b/l radiculitis, Pts with uncontrolled medical illnesses, extremely high dose opioid users, pregnant or lactating.	3	Caudal epidural injections w/ 0.5% lidocaine 9 mL and 1 mL steroid VS. Caudal epidural injections with 0.5% lidocaine, 10 mL

OUTCOMES MEASURED

All studies measured the outcomes using Numeric Rating Scale (NRS) to measure pain, Oswestry Disability Index (ODI) to assess functional status, and 3,6,12 month post-treatment assessment for pain and opioid use – classified via dosage frequency and schedule of the drug. Lastly, significant improvement was evaluated through pain relief associated with at least 50% improvement in functional status.<sup>1,2,3</sup>

## RESULTS

This review assessed three randomized control trials, involving men and women over the age of 18 with chronic back due to an intervertebral herniated disc. The studies examined how an injection with steroid and anesthetic together would improve severity of back pain compared to an injection with anesthetic alone.<sup>1,2,3</sup>

The first Manchikanti L. study, analyzing injections in chronic lumbar disc herniation, assessed 182 patients and randomized 120 into the evaluation.<sup>1</sup> The 36 patients not meeting inclusion criteria, specified above, and 26 patients refusing to participate were excluded from the study.<sup>1</sup> The control group's, Group I, injection with local anesthetic alone was compared to the experimental group's, Group II, injection with local anesthetic and steroid.<sup>1</sup> There were differences in the two groups such as more women than men in Group I, along with weight and BMI also greater in Group I.<sup>1</sup> Weight for Group I was measured at 210.1 and Group II at 167 pounds.<sup>1</sup> The patients BMI was calculated to be 34.5 in Group I compared to Group II, which was at 26.8.<sup>1</sup> At the one year follow up, 83% (50/60) from group I 85% (51/60) were available.<sup>1</sup> At the two year follow up, 73% (44/60) of patients from Group I and 75% (45/60) of patients from Group II were available, 100% (60 patients) was included in the analysis.<sup>1</sup> Overall there was 601 injections given and out of those, the adverse events recorded included 28 (4.6%) intravascular infiltrations, 9 (1.5%) nerve root irritations, and 0 post subarachnoid puncture headaches documented.<sup>1</sup> There was an average of  $4.0 \pm 1.1$  injections for one year and the average relief per procedure was  $11.7 \pm 7.7$  weeks in Group I. Group II had an average of  $3.9 \pm 1.1$  injections for one year and average relief per procedure was  $11.5 \pm 7.6$  weeks in Group I.<sup>1</sup> The numbers needed to treat (NNT) was calculated to -14,

representing that for every 14 subjects treated with steroids, 1 fewer will have at least 50% improvement in pain and function when compared to the control group.<sup>1</sup>

**Table 2: Manchikanti L. Efficacy of Steroid Injections for Chronic Back Pain Due to Intervertebral Herniated Discs**

	Quantity of patients with chronic back pain on placebo (CER)	Quantity of patients with chronic back pain on steroids (EER)	Relative Risk Increase (RBI) $\frac{EER-CER}{CER}$	Absolute Benefit Increase (ABI) EER-CER	Numbers Needed to Treat (NNT) 1/ABI
Manchikanti L. et al <sup>1</sup>	0.80	0.73	-0.09	-0.07	-14

The second Manchikanti L study, reviewing the management of chronic pain from cervical disc herniation and radiculitis, assessed 166 eligible patients overall and randomized 120.<sup>2</sup> A total of 46 patients were excluded from the study, 30 individuals did not meet inclusion criteria, specified above, and 16 individuals refused to participate.<sup>2</sup> The 120 participants were divided equally into two groups, the control group, Group I, received local anesthetic alone and the experimental group, Group II, received local anesthetic plus betamethasone.<sup>2</sup> The only difference between the two groups documented was Group I having a significantly higher mean weight at 208.9 lbs compared to Group II measured at 168.1 lbs.<sup>2</sup> At the 12 month follow up, 98% (59/60) from Group I and 93% (56/60) were available.<sup>2</sup> Even though every participant was not available for the specified follow up, 100% of the patients were included in the analysis from both groups. The 24 month follow up was not assessed or recorded.<sup>2</sup> Overall, a total of 418 injections were performed and the adverse events that occurred included 1 subarachnoid puncture, 3 intravascular penetrations, and 1 report of soreness lasting for a week.<sup>2</sup> The total injections per year was  $3.6 \pm 1.2$  and total relief of  $41.4 \pm 12.7$  weeks in Group I. Group II had a total of  $3.4 \pm 1.3$  injections and total pain relief of  $36.3 \pm 14.6$ .<sup>2</sup> The numbers needed to treat (NNT) was calculated to 20, representing that for every 20 subjects

treated with steroids, 1 more will have at least 50% improvement in pain and function when compared to the control group.<sup>2</sup>

**Table 3: Manchikanti L. Efficacy of Steroid Injections for Chronic Back Pain Due to Intervertebral Herniated Discs**

	Quantity of patients with chronic back pain on placebo (CER)	Quantity of patients with chronic back pain on steroids (EER)	Relative Risk Increase (RBI) $\frac{EER-CER}{CER}$	Absolute Benefit Increase (ABI) EER-CER	Numbers Needed to Treat (NNT) 1/ABI
Manchikanti L. et al <sup>2</sup>	0.77	0.82	0.07	0.05	20

The third study conducted by Manchikanti L, examining caudal epidural injections in the treatment of lumbar disc herniation, reviewed 178 patients and randomized 120 of them.<sup>3</sup> This entails 58 participants were excluded, 46 not meeting criteria, specified above, and 12 refusing to partake in the study.<sup>3</sup> The 120 participants were separated equally into two groups, the control group, Group I, received local anesthetic alone and experimental group, Group II, received local anesthetic with a steroid.<sup>3</sup> The major differences published in the literature, but not noted as significant, was a higher mean weight in Group I of  $208.3 \pm 53.9$  pounds compared to Group II with a mean weight of  $177.5 \pm 46.8$  pounds.<sup>3</sup> At the 12 month follow up, 78% (47/60) from Group I and 83% (50/60) were available.<sup>3</sup> The 24 month follow up was not assessed or recorded. No adverse events were reported from any of the participants over the year.<sup>3</sup> The total injections per year was  $4.3 \pm 1.0$  and average relief of  $9.5 \pm 2.4$  weeks per procedure in Group I. Group II had a total of  $3.8 \pm 1.0$  injections per year and average pain relief per procedure of  $12.0 \pm 5.2$  weeks. The total relief per year, in weeks, was higher in Group II with  $42.7 \pm 11.0$  weeks and Group I with  $40.7 \pm 11.0$  weeks. The numbers needed to treat (NNT) was computed to 15, meaning that for every 15 subjects treated with steroids, 1

more will have at least 50% improvement in pain and function when compared to the control group.<sup>3</sup>

**Table 4: Manchikanti L. Efficacy of Steroid Injections for Chronic Back Pain Due to Intervertebral Herniated Discs**

	Quantity of patients with chronic back pain on placebo (CER)	Quantity of patients with chronic back pain on steroids (EER)	Relative Risk Increase (RBI) $\frac{EER-CER}{CER}$	Absolute Benefit Increase (ABI) EER-CER	Numbers Needed to Treat (NNT) 1/ABI
Manchikanti L. et al <sup>3</sup>	0.70	0.77	0.10	0.07	15

DISCUSSION

The studies displayed a significant improvement when compared to baseline pain and function. When the two groups were compared to one another, the results were not statistically significant. Manchikanti L. first and third studies found results that supported significant overall improvement in the experimental group with steroids.<sup>1,3</sup> The second Manchikanti L article displayed greater total relief in those who received local anesthetic alone.<sup>2</sup> All three articles were in correspondence with one another when the time it took to experience relief was conveyed. All reviews marked significant differences ( $\geq 50\%$ ) from baseline values after three months of treatment for both groups.<sup>1,2,3</sup> Along side of pain and function, opioid intake was analyzed during baseline and compared with post treatment opioid dependency for chronic pain. All studies had a decrease in opioid use with both treatment modalities from the baseline, but when compared to each other, there was no clinical significance.<sup>1,2,3</sup> Significant differences were noted after three months of epidural injections.<sup>1,2,3</sup>

Intervertebral disc injections improve pain and function in a patient with chronic pain, but the type of injection may be more costly than another. Lumbar tranforaminal epidural injections are roughly 30-40% more expensive than caudal epidural injections,

creating more turmoil for the patient.<sup>1</sup> A major limitation all three studies illustrated in the literature was lack of placebo group.<sup>1,2,3</sup> The first article referenced by Manchikanti L. states that a drawback in this review was more patients in Group I had a higher BMI compared to Group II.<sup>1</sup> The second and third article from Manchikanti L, expressed the main limitations present were only having a one year analysis, instead of waiting two years and assess them.<sup>1,2</sup> The third Manchikanti L article also experiences limitations such as differences in weight and BMI between the experimental and control groups.<sup>3</sup>

### CONCLUSIONS

After reviewing the three randomized, double-blind, active controlled trials, it can be concluded that epidural injections with local anesthetic and steroids are effective in the treatment of chronic back pain due to an intervertebral disc herniation in men and women over 18 years old. When both treatments were compared to one another, there was no statistical difference, but there was significant improvement in pain and function from the baseline. Overall, injections with local anesthetic and steroids improve pain, functional status, and over 35 weeks of total relief in a year time frame.<sup>1,2,3</sup> With this, it is not appropriate to confirm injections with local anesthetic combined with steroids to have superiority over injections with local anesthetic alone due to lack of statistical difference in the studies. Future study is warranted to evaluate injections with local anesthetic and steroids for longer periods of time, limiting the differences with group weight, and increasing the placebo size. Epidural injections with steroids have been a popular treatment option for those with a history of chronic back pain due to intervertebral disc herniations, but emerging evidence shows local anesthetics alone are just as effective.

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