Systematic Review of Caudal Epidural Injections in the Management of Chronic Back Pain

GAURAV DIGHE, MD; JOSEPH H. FRIEDMAN, MD

ABSTRACT

Epidural steroids recently attracted world attention due to medication contamination resulting in many cases of fungal meningitis. What was rarely noted in these reports is that there is little data to support use of this treatment. This article reviews the literature on epidural steroids for various types of back pain and concludes that further testing should be performed to determine if and in what situations this intervention is useful before wide-spread use is resumed.

KEYWORDS: Epidural steroids, low back pain, radicular pain, spinal stenosis

INTRODUCTION

Chronic low back pain is a common complaint. Caudal epidural injections (CEI) for managing chronic low back pain conditions are frequently performed interventions in the western world but their efficacy is controversial.

Multiple systematic reviews and guidelines have been published. Primary data used for making these guidelines is sparse and of varying quality. There have been few randomized prospective controlled studies evaluating the efficacy of CEI and these studies are in disagreement regarding their efficacy for lower back pain conditions. Therefore, the most effective mode of administration, the most effective medication and the conditions likely to benefit from this therapy remain unclear.

This systematic study reviewed the evidence regarding the use of CEIs in chronic back pain conditions. We evaluated the clinical effectiveness of [A] CEIs of steroids without local anesthetics [LA]; [B] CEIs of steroids plus LA; [C] CEIs of LA alone; in chronic back pain secondary to disc herniation or radiculopathy, disco-genic pain with predominantly low back pain; spinal stenosis; and post-lumbar-surgery pain syndrome.

METHODS

Literature Search

A comprehensive literature search was conducted which included the search of databases including PubMed and EMBASE from 1985 through 2012, Clinical Trial Registry, systematic reviews, narrative reviews, and cross-references to the reviews published in English.

The search strategy emphasized chronic back pain with a focus on caudal epidural injections. Search terminology included lumbar intervertebral disc, disco-genic pain, spinal stenosis, post-lumbar-surgery syndrome, caudal epidural injections of local anaesthetic and steroids, chronic back pain, sciatica.

Selection Criteria

This review included only randomized controlled trials (RCTs) and prospective randomized studies. Retrospective studies were excluded.

Outcome Parameters

The primary outcome measure that we reviewed was pain relief, for short duration (< 6 weeks) or long duration (> 6 weeks). Secondary outcome measures reviewed included functional assessment, need for surgeries, psychological improvement, return to work, and change in opioid intake.

Outcome of the Studies

A study was judged to be positive if the CEI therapy was effective, either with a placebo control or active control in randomized trials. Most papers utilized relief from pain as a measure of effectiveness; one paper also used the number of subsequent surgeries as a measure. In a negative study, there was no difference between the study treatments or no improvement from baseline.

The data was reviewed separately for disc herniation or radiculopathy, disco-genic pain with predominantly low back pain, spinal stenosis, and post-lumbar-surgery pain syndrome.
**DISCUSSION**

*Effectiveness*

Of 11 randomized trials (Table 1–4), 8 were positive for short-term pain relief and 5 were positive for long-term relief. Regarding pain relief by etiology, of 6 trials evaluating predominantly disc herniation or radiculopathy, 4 were positive and 2 were negative for short-term relief. 6 out of 6 were negative for long-term relief. Two trials evaluated for disco-genic pain were positive for both short and long term. Two trials evaluating patients with lumbar spinal stenosis showed varied results as one was positive for both short and long term and the other was negative for both short and long term and the only trial evaluating patients with chronic back pain due to post-lumbar-surgery syndrome was positive for both short- and long-term effect.

*Level of Evidence*

The evidence for CEIs of steroid without LA is limited for short term and long term in managing all of the above conditions.

The evidence for CEIs of steroid plus LA in managing disc herniation or radiculopathy was moderate for short term and limited for long term. The evidence was moderate to strong in managing spinal stenosis, disco genic pain and post-lumbar-surgery syndrome.

The evidence of CEIs of LA alone is moderate to strong for both short term and long term in reducing pain secondary to spinal stenosis, disco-genic pain and post-lumbar-surgery syndrome.

**(A) CEIs of steroid or steroid plus LA vs. Placebo:**

Three studies were reviewed in this section to determine the efficacy of CEIs. A multicenter, blind, randomized controlled trial of 133 patients demonstrated that CEIs of either saline or steroids have no effect on pain from a unilateral radiculopathy. Patients treated with CEIs did not show any reduction in pain or disability when compared with the patients treated with sham injections. A study of 158 patients with sciatica due to a herniated nucleus pulposus were treated with CEIs of steroid. The differences in improvement between the experimental and control group were not significant. The study showed that CEIs of steroids have a limited short-term benefit over placebo. Arden et al. showed that CEIs of steroid plus LA have a very limited benefit over placebo for sciatica and the pain relief did not last beyond 6 weeks. The majority of patients in the study still had significant pain and disability at the end of the study. The conclusions of the above studies question the role of CEIs in the management of radiculopathy or sciatica.

**CEIs of steroid vs. lumbar decompression procedure (mild procedure)**

A double-blind, randomized, prospective study compared the CEIs of steroids with the lumbar decompression procedure (mild procedure). This procedure provided minimally invasive posterior lumbar decompression performed fluoroscopically through a small 6-gauge port on 38 patients with lumbar spinal stenosis. They failed to show any benefit of CEIs of steroid over the lumbar decompression procedure. In fact the operation produced better pain reduction and improved functional mobility.

**(B) CEIs of steroid plus LA vs. LA alone.**

Five studies were reviewed under this category. The results of CEIs of steroids in combination with LA are more promising, especially for short-term relief (< 6 weeks) than...
### Table 2. CEIs of steroid vs. lumbar decompression procedure (mild procedure)

<table>
<thead>
<tr>
<th>Study Design</th>
<th>Etiology</th>
<th>Participants</th>
<th>Intervention(s)</th>
<th>Outcome(s)</th>
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<th>Conclusion: Short term (&lt;6 weeks) pain relief</th>
<th>Conclusion: Long-term (&gt;6 weeks) pain relief</th>
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</tr>
</thead>
<tbody>
<tr>
<td>1. Brown 2012 Double-blind, randomized, Prospective</td>
<td>Lumbar spinal stenosis</td>
<td>38 patients with LSS were randomized into 2 treatment groups, 21 in “mild” and 17 in ESI.</td>
<td>Patients for CEIs received 80 mg of triamcinolone acetate (40 mg in diabetic patients) mixed with 6 mL of preservative-free saline. Patients for “mild” procedure underwent a minimally invasive posterior lumbar decompression performed fluoroscopically through a small 6-gauge port.</td>
<td>Assessments: 6 &amp; 12 weeks Outcome measures: Visual Analog Scale, Oswestry Disability Index, and Zurich Claudication Questionnaire (ZCQ) patient satisfaction</td>
<td>Lumbar decompression procedure (mild procedure) provided significantly better pain reduction and improved functional mobility vs. treatment with CEIs.</td>
<td>Negative</td>
<td>Negative</td>
<td>CEIs of steroid did not show any benefit over lumbar decompression procedure (mild procedure) in treating lumbar spinal stenosis.</td>
</tr>
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</table>

### Table 3. CEIs of steroid plus LA vs. LA alone

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<tr>
<th>Study Design</th>
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<th>Intervention(s)</th>
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<tbody>
<tr>
<td>1. Manchikanti 2012 Randomized, double-blind, active controlled trial</td>
<td>Lumbar spinal stenosis</td>
<td>120 patients with Lumbar central spinal stenosis</td>
<td>Group 1: lidocaine 0.5%, 6 ml. Group 2: 5 mL of lidocaine + 1 mL of betamethasone</td>
<td>Assessments: 3 mos., 6 mos., and 12 mos. Outcome measures: NRS, ODI, Employment status, and opioid intake</td>
<td>Pain relieved for a longer duration in both the groups (70% in Group 1 and 63% in Group)</td>
<td>Positive</td>
<td>Positive</td>
<td>CEIs of steroid plus LA were more effective than LA alone in reducing pain secondary to lumbar spinal stenosis.</td>
</tr>
<tr>
<td>2. Manchikanti 2011 Randomized, double-blind, active-controlled trial</td>
<td>Discogenic low back pain.</td>
<td>120 patients with chronic discogenic low back pain.</td>
<td>Group 1: lidocaine 0.5% 10 ml. Group 2: 9 mL of 0.5% lidocaine + 1 mL of Betamethasone or methylprednisolone</td>
<td>Outcome measures: NRS, ODI, Employment status and opioid intake</td>
<td>Significant pain relief and functional status improvement in 55% in Group 1 and 68% in Group 2</td>
<td>Positive</td>
<td>Positive</td>
<td>CEIs of steroid plus LA were more effective than LA alone in treating discogenic low back pain.</td>
</tr>
<tr>
<td>3. Manchikanti 2010 Randomized, double-blind, active-controlled trial</td>
<td>Discogenic low back pain</td>
<td>70 patients with discogenic low back pain</td>
<td>Group 1: lidocaine 0.5%, 6 ml. Group 2: 0.5% lidocaine, 5 ml, + betamethasone</td>
<td>Assessments: 3 mos., 6 mos., and 12 mos. Outcome measures: NRS, ODI, employment status and opioid intake</td>
<td>Pain relieved for a longer duration in both the groups (74% in Group 1 and 86% in Group 2)</td>
<td>Positive</td>
<td>Positive</td>
<td>CEIs of steroid plus LA were more effective than LA alone in treating discogenic low back pain.</td>
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<tr>
<td>4. Manchikant 1985 Randomized, Double-blind, active controlled trial</td>
<td>Post lumbar surgery syndrome</td>
<td>140 patients with a history of chronic function-limiting low back pain post-lumbar-surgery</td>
<td>Group 1: 10 ml of lidocaine 0.5%; Group 2: 5 ml of lidocaine + 6 mg of Betamethasone</td>
<td>Assessments: 3 mos., 6 mos., and 12 mos. Outcome measures: NRS, ODI, employment status and Opioid intake</td>
<td>Improvement in pain and disability reduction for a longer duration (53% in Group 1, and 59% in Group 2). No significant differences after 1 year.</td>
<td>Positive</td>
<td>Positive</td>
<td>CEIs of steroid plus LA were more effective than LA alone in treating low back pain secondary to post-lumbar-surgery.</td>
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<tr>
<td>5. Cukier 1985 Prospective, randomized, double-blind study</td>
<td>Radiculopathy</td>
<td>73 patients with lumbar nerve-root compression</td>
<td>Experimental group: 2 ml of sterile water containing 80 mg of methylprednisolone + 5 ml of 1% procaine Control Group: 2 ml of saline + 5 ml of 1% procaine.</td>
<td>Assessments: 24 hours, followed for 60 mos. Every 3 mos. Outcome measures: Subjective improvement</td>
<td>There were no significant differences between the patients in the experimental and control groups.</td>
<td>Negative</td>
<td>Negative</td>
<td>CEIs of steroid plus LA did not show any significant difference vs. LA in reducing pain secondary to radiculopathy.</td>
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steroids alone. A double-blind, active control trial evaluated 120 patients with lumbar central spinal stenosis,\textsuperscript{10} 70% of patients treated with CEIs of LA alone had better pain relief compared with 63% of patients treated with CEIs of LA plus steroid. The study failed to show any benefit of adding steroid to LA for CEIs in treating LSS. Two randomized, double-blind, active-controlled trials on the patients with disco-genic low back pain concluded that CEIs of steroid plus LA were more effective than LA alone in treating disco-genic low back pain.\textsuperscript{11,12} Another randomized, double-blind, active-controlled trial\textsuperscript{13} on 140 patients with a history of chronic function-limiting low back pain post-lumbar-surgery showed that CEIs of steroid plus LA were more effective than LA alone but there was no significant difference after one year. A prospective, randomized, double-blind study of 73 patients with lumbar nerve-root compression\textsuperscript{14} reported that CEIs of steroid plus LA did not show any significant difference vs. LA alone in reducing pain.

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<td>1. Ghahreman et al. 2010</td>
<td>Radiculopathy</td>
<td>150 patients with pain radiating into the lower limb.</td>
<td>Group 1: TF 0.75 mL of 0.5% bupivacaine + 1.75 mL triamcinolone.</td>
<td>Assessments: 1 mos., 3 mos., 6 mos., &amp; 12 mos.</td>
<td>54% with TF steroid plus LA; 7% with TF with LA; 19% of TF Saline. 21% of IM steroids &amp; 13% of IM saline achieved relief of pain.</td>
<td>Positive</td>
<td>Positive</td>
<td>CEIs were effective than IM injections in pain reduction secondary to radiculopathy.</td>
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<td>2. Wilson-MacDonald 2004</td>
<td>Disc prolapse or spinal stenosis</td>
<td>92 patients with disc prolapse or spinal stenosis</td>
<td>Epidural group: Bupivacaine 0.5% 8 ml + Methylprednisolone 2 ml Control group: IM injections of the same.</td>
<td>Assessments: Followed for 2 years Outcome measures: Oxford pain chart and the Oswestry disability index</td>
<td>There were no significant differences in the outcome measurements between the two groups and in the rate of operations.</td>
<td>Positive</td>
<td>Negative</td>
<td>CEIs did not show any benefit over IM injections in treating disc prolapse or spinal stenosis.</td>
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(C) CEIs of steroid plus LA vs. IM injections

Two studies compared the routes of administration of steroid or LA for chronic back pain. A prospective, randomized study compared transforaminal CEIs (TFCEIs) with intramuscular (IM) injections in treating radiculopathy and concluded that CEIs were equally effective as IM injections in short-term pain reduction. The other prospective, randomized, controlled trial compared the effect of CEIs of steroid plus LA with IM injections of LA on 92 patients with disc prolapse or spinal stenosis and reported that CEIs had no benefit over IM injections in pain relief. The data therefore does not support the use of CEI over IM injections of anesthetic for pain from spinal stenosis or disc prolapse.

There are no RCTs comparing CEIs of LA alone against placebo. Therefore, the efficacy of CEIs of LA alone needs to be ascertained from RCTs which include CEIs with LA alone as part of the control group. In these studies, no advantage was seen with addition of steroid to CEIs of LA\textsuperscript{10} and with CEIs of steroid plus LA vs. LA alone.\textsuperscript{14} Therefore, it would be unreasonable to expect long-term (>6 week) benefit from these injections due to their short half-lives of a few hours. There are no reported RCTs comparing CEIs of steroid plus LA vs. steroid alone.

**CONCLUSION**

This review is in agreement with others,\textsuperscript{1,17–20} that the evidence for CEIs ranges from nil to possible, based on the cause of chronic back pain conditions. There is no convincing evidence for the efficacy of CEI for long-term relief of back pain of any studied etiology.

**References**


