Correlation of functional results of caudal epidural steroid injections with duration of symptoms in PIVD

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Received: 12 February 2018
Revised: 23 March 2018
Accepted: 26 March 2018

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ABSTRACT

Background: Low backache and sciatica is a common complaint signifying some underlying pathology; it may be a soft tissue strain or disc protrusion, or conditions such as neoplasm or ankylosing spondylitis besides others. We aim to assess the functional outcome of epidural steroid injection in patients with low backache and sciatica as well as the effect of pre operative duration of symptoms in Indian population presenting to our centre, on the post procedure outcome, if any.

Methods: 50 patients were evaluated with complaints of low backache and radiculopathy. They were subjected to following questionnaires including the ODI and VAS, and the scores were evaluated before and after the intervention, and at every follow up.

Results: Patients commonly affected were from 4th and 5th decade. The commonest intervertebral disc involved was L4-5 (44%) followed by L5-S1 (30%). Significant Functional status improvement according to ODI scoring was observed in all follow up visits. Similarly significant reduction in pain intensity according to VAS scoring was observed in all follow up visits. On comparing the improvement in functional status (ODI) and pain (VAS) between the 3 groups, it is seen that patients in group A had the highest rate of improvement, while patients in group C had the least improvement.

Conclusions: Caudal epidural injections are safe, effective and less expensive modality of treatment without any significant complications. The lesser the duration of symptoms i.e. earlier the patient presents, better are the results with caudal epidural injection.

Keywords: Low backache, Sciatica, Radiculopathy, Epidural steroid injection

INTRODUCTION

Low backache has haunted human race since time immemorial. Its history can be traced down to the evolution of the bipedal gait. Low backache and sciatica is a common complaint signifying some underlying pathology; it may be a soft tissue strain or disc protrusion, or conditions such as neoplasm or ankylosing spondylitis besides others. Its incidence in the United States is 80%.

The data of our country is not available but the incidence is high because of difficult working condition and harsh living environment. Apart from suffering a heavy drain on man power, it has a huge economic cost too. The variable character of low backache, its multiplicity of causes and difficulties in its treatment render this affliction one of the most perplexing and frequent problems that confront the orthopedic surgeon. The treatments used for this problem may be conservative or surgical. Epidural steroid injection (ESI) is a nonsurgical treatment for managing low back and radicular pain caused by herniated lumbar disc. The low back pain of mechanical origin, accompanied by
signs and symptoms of nerve-root irritation, responds to epidural steroid injections with gratifying results. It relieves pain, improves function, and reduces the need for surgical intervention. It has been shown to provide analgesia for variable periods.\textsuperscript{5,6}

Since the patients with low backache present with variable duration of symptoms ranging from few days to few years, it has often been wondered, whether those presenting earlier have any advantage than those presenting late. The purpose of this study was to assess the functional outcome of epidural steroid injection in patients with low backache and sciatica as well as the effect of pre-operative duration of symptoms in Indian population presenting to our center, on the post procedure outcome, if any.

**METHODS**

This is a prospective study, conducted in teaching tertiary care institution at Udaipur (Rajasthan), from 2015 to 2017. During this period 50 patients were evaluated with complaints of low back pain and sciatica. Inclusion criteria included patients having low back pain not responding to conservative treatment for at least 6 weeks (i.e. NSAID, antidepressant, oral steroids, transcutaneous electrical nerve stimulation TENS, traction and ultrasound), MRI proven lumbar disc prolapse, age over 18 years and consent for procedure. Exclusion criteria included failed back syndrome, stenosis of spinal canal, spinal metastasis, associated with other pathological conditions of the spine apart from PIVD, motor deficit, diabetes and bleeding disorder.

This study was approved by the hospital research committee. Informed consent was obtained from each patient. All the patients underwent a thorough clinical evaluation in way of a history of the illness, including the details of pain, duration of the symptoms, as well as the nature of the conservative treatment they had received in the past. This was followed by a complete physical examination including neurological assessment of the lower limb as per a Performa prepared for the study. They were subjected to following questionnaires including the Oswestry Disability Index Score (ODI) and the Visual Analogue Scale (VAS); the scores were evaluated before and after the intervention, and at every follow up.\textsuperscript{7,8}

The investigations done formed a part of the routine assessment protocols at the center. All the cases were not made to undergo any investigation or procedure apart from the routine protocol followed at this center. The investigations that were done for every patient included an X-ray Lumbo-Sacral Spine – AP / LAT, MRI Lumbosacral Spine, Routine Hemogram, BT-CT, blood sugar level.

The selection of the cases was done by assessment (clinically, radiological and laboratory investigations) in the department of orthopedics and were tabulated by the principal author at a later date. Following which all the cases were allocated into the three cohort groups on the basis of their duration of symptoms (namely ‘Group A’ i.e. symptoms 1-6 months, ‘Group B’ i.e symptoms 7-12 months, ‘Group C’ i.e. symptoms >12 months). For every subsequent patient entering the study, the group was assigned as per duration of symptoms. Once the patient agreed to participate in the study, he was included in the group assigned to him by the duration of symptoms and then was treated by the allocated protocol.

The ESI was given by a trained surgeon in operation theatre. During the procedure, peripheral venous access was secured in all the patients. Patients were connected to the patient monitor for monitoring ECG, heart rate, non-invasive blood pressure (NIBP), and pulse oximetry. All the patients were put in prone position on two bolsters. Cleaning and draping of the part was done under aseptic precaution. The sacral hiatus was located by surface anatomy. Using strict aseptic technique, 2% lidocaine was infiltrated to the skin and subcutaneous tissue for surface anesthesia. An 18 gauge caudal epidural needle was inserted into the epidural space through sacral hiatus route with the bevel upward and stylet in position. The epidural space was identified by loss of resistance to air technique.

Injection methylprednisolone 2 ml (80 mg Depo-Medrol\textsuperscript{®} by pfizer) and 6 ml of 2% lignocaine was diluted in 10 ml of normal saline and injected into the caudal epidural space. After the procedure, patients were advised to lie supine for 6 hours. During this period they were observed for any possible complications. The patients were first reviewed after post procedure day, and then further follow up was carried out at 3 weeks, 3 months and 6 months after the caudal epidural steroid injection. During follow up, the Oswestry disability index (ODI) and visual analog score (VAS) were used to evaluate the response of treatment. The ODI was employed to quantitate the level of functional disability. It consist of ten questions, each with six alternative scores 0–5. A change of more than 10 points was considered a significant clinical improvement. VAS score was used for assessment of current back and lower-extremity pain, ranging from 0 (no pain) to 10 (worst pain possible).

Patients with low back pain and sciatica not responding to ESI were considered for surgery and were recorded as failure in study. All patients were advised to take mild analgesics during the first 10 post-injection days. No special exercise program or other physical therapy was employed after the injections.

The data analysis was done by using student’s t- test, and was applied to compare changes in functional status and pain intensity. P value of <0.05 was considered as significant.
RESULTS

50 patients were analyzed, among them 20 patients were from group A (1-6 months), 17 patients were from group B (7-12 months) and 13 patients were from group C (>12 months). Out of these patients, 26 (52%) were male and 24 (48%) female. Patients commonly affected were from 4th and 5th decade. The commonest intervertebral disc involved was L4-5 (44%) followed by L5-S1 (30%) in single level PIVD.

Significant functional status improvement according to ODI scoring was observed in all follow up visits, which was shown in Table 1. Similarly significant reduction in pain intensity according VAS scoring was observed in all follow up visits, as shown in Table 2. On comparing the improvement in functional status (ODI) between the 3 groups, it is seen that patients in group A had the highest rate of improvement, as shown in Table 3; while patients in group C had the least improvement. Similar was the findings with regard to VAS in terms of pain score, as shown in Table 4.

Table 1: Distribution of ODI scores.

<table>
<thead>
<tr>
<th>ODI Score</th>
<th>Mean ±SD</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ODI pre</td>
<td>24.44 ±5.90</td>
<td></td>
</tr>
<tr>
<td>ODI post</td>
<td>12.72 ±5.51</td>
<td>&lt;0.001 (HS)</td>
</tr>
<tr>
<td>ODI 3 weeks (n=46)</td>
<td>6.46 ±5.80</td>
<td>&lt;0.001 (HS)</td>
</tr>
<tr>
<td>ODI 3 month (n=41)</td>
<td>4.20 ±3.18</td>
<td>&lt;0.001 (HS)</td>
</tr>
<tr>
<td>ODI 6 month (n=41)</td>
<td>5.27 ±3.65</td>
<td>&lt;0.001 (HS)</td>
</tr>
</tbody>
</table>

Table 2: Distribution of VAS scores.

<table>
<thead>
<tr>
<th>VAS Score</th>
<th>Mean ±SD</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAS pre</td>
<td>7.58 ±1.70</td>
<td></td>
</tr>
<tr>
<td>VAS post</td>
<td>3.86 ±1.73</td>
<td>&lt;0.001 (HS)</td>
</tr>
<tr>
<td>VAS 3 weeks (n=46)</td>
<td>1.63 ±2.05</td>
<td>&lt;0.001 (HS)</td>
</tr>
<tr>
<td>VAS 3 month (n=41)</td>
<td>0.22 ±0.47</td>
<td>&lt;0.001 (HS)</td>
</tr>
<tr>
<td>VAS 6 month (n=41)</td>
<td>0.63 ±0.97</td>
<td>&lt;0.001 (HS)</td>
</tr>
</tbody>
</table>

Table 3: Comparison of improvement rate of ODI with duration of symptoms.

<table>
<thead>
<tr>
<th>Improvement rate</th>
<th>1-6 Months</th>
<th>7-12 Months</th>
<th>&gt;12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>%</td>
<td>No.</td>
</tr>
<tr>
<td>Failure</td>
<td>1</td>
<td>5.00%</td>
<td>1</td>
</tr>
<tr>
<td>&lt;50%</td>
<td>0</td>
<td>0.00%</td>
<td>0</td>
</tr>
<tr>
<td>50-75%</td>
<td>3</td>
<td>15.00%</td>
<td>7</td>
</tr>
<tr>
<td>&gt;75%</td>
<td>16</td>
<td>80.00%</td>
<td>9</td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td></td>
<td>17</td>
</tr>
</tbody>
</table>

Table 4: Comparison of improvement rate of VAS with duration of symptoms.

<table>
<thead>
<tr>
<th>Improvement rate</th>
<th>1-6 Months</th>
<th>7-12 Months</th>
<th>&gt;12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>%</td>
<td>No.</td>
</tr>
<tr>
<td>Failure</td>
<td>1</td>
<td>5.00%</td>
<td>1</td>
</tr>
<tr>
<td>&lt;50%</td>
<td>0</td>
<td>0.00%</td>
<td>0</td>
</tr>
<tr>
<td>50-75%</td>
<td>0</td>
<td>0.00%</td>
<td>1</td>
</tr>
<tr>
<td>&gt;75%</td>
<td>19</td>
<td>95.00%</td>
<td>15</td>
</tr>
<tr>
<td>Total</td>
<td>20.00</td>
<td>17.00</td>
<td>13.00</td>
</tr>
</tbody>
</table>

9 patients (18%) showed no improvement of functional status and pain, even after caudal ESI. Out of these 9 patients, 1 patient was from group A, 1 patient was from group B and 7 patients were from group C. These patients underwent surgery. Hence improvement in symptoms was recorded in 82% of the patients at final follow up. No complication was observed except local pain over injection site.

DISCUSSION

Epidural steroid injections have been used for long, time for the treatment of low back pain. It has been shown to
be effective as well as a less invasive therapeutic procedure in many orthopedic centers. Many studies in literature also have shown the effectiveness of ESI in LBP. A study by Bogduk et al recommended result in favor of the use of ESI in lumbo sacral pain.9 Similarly a study by Koes et al. demonstrated the efficacy of epidural steroid injections for management of low-back pain and found it to be effective.10 Hellmwell et al also demonstrated that LBP significantly improved following ESI.11 Singh al also demonstrated that ESI significantly improved the LBP.12

In several previous studies patients were followed up after ESI for periods ranging from few weeks to few year, and showed to be beneficial.13-16 However in our study we followed the patients only for a period of six months.

In our study Oswestry disability index (ODI) was used in patients for the assessment of functional status of low back pain. The ODI was decreased by more than 30% by first follow-up and by more than 70% by the end of six month following epidural steroid injection. Similarly VAS score was decreased by 30% in the first follow-up and by 70% at the end of six months. This result indicates that both the functional status and pain intensity was improved significantly in all follow up visits.

The origin of pain is due to prolapsed disc by mechanical or chemical stimulation which starts a sequence of events responsible for back pain and radiculopathy. Mechanical pain caused by compression, traction, spasm and chemical pain results from intraneural inflammation characterized by fibrosis, edema, and demyelination. As a result physiological changes lead to an alteration of normal nerve functioning which including sensory deficit and muscle weakness. The nerve roots, close to proximity of prolapsed disc may become sensitized by the release of arachidonic acid metabolites and cause low back and radicular pain.17,18

In our study we used methylprednisolone for the management of low back pain.19 Our study showed significant relief in the signs and symptoms of prolapsed disc as well as improvement in the pain intensity and functional status of the patients.

In our study we found 9 patients who did not improve with ESI and underwent discectomy. Considering those as failures, the success rate of this study was 82%. Cicala et al reported the success rates ranging from 63% to 80%. Roy et al, their overall success at 24 hours was 79%, at 1 month 60%, at 6 months 58.5% and at 1 year 59%.20 There are several factors for varied results like patient selection, technique of injection, dosage of steroid and follow up. In our study, majority of the patients who were a failure with this technique, had long duration of symptoms. This result was similar to study of Buttermann et al, in which patients didn’t respond to steroid injection and had to undergo surgery for improvement in signs and symptoms.22

ESI is a relatively safe procedure as post procedure complications in most series were less than 5%. Further, the administration of epidural steroids through sacral hiatus is safer than its lumbar interspace administration since the risk of intradural injection inadvertently, is less. In our study patients only reported local pain over the injection site, which subsided without any further treatment and no other complications were reported. However there are reports of headache, sweating, nausea, hypotension, epidural hematoma, epidural abscess, Cushing syndrome, bacterial meningitis and post-dural puncture in some studies.11

Thus this finding shows that epidural steroid injections are simple, safe, and minimally invasive and it improves the functional status and decreases the severity of pain. It also shows that results are better if the patient presents earlier with shorter duration of symptoms. However, a limitation of the study may be its short follow up. Hence these findings need to be further investigated with long term studies.

CONCLUSION

Hence it is pertinent to conclude that caudal epidural injections are safe, effective and less expensive modality of treatment without any significant complications. The lesser the duration of symptoms i.e. earlier the patient presents, better are the results with caudal epidural injection.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the institutional ethics committee

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6. Glenn R. Buttermann. Treatment of lumbar disc herniation: epidural steroid injection Compared with