

Original Article

Effect of Caudal Epidural Steroid Injection in Chronic Low Back Pain due to Prolapse Intervertebral Disc

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Abstract

Background: Low back pain (LBP) due to disc herniation is a frequent cause of back pain. It is a debilitating condition having enormous medical and socio-economic effects. Epidural injection of steroids has been used to treat LBP for many decades. Despite widespread use and numerous publications there is significant controversy with regards to the medical necessity and indications for epidural injections, hence we planned this study.

Materials and methods: This was a prospective follow-up study. Forty-one patients of confirmed diagnosis of prolapse intervertebral disc (PIVD) were included. Caudal epidural steroid injection (CESI) of 80 mg methylprednisolone acetate diluted in 20 ml of 0.9% saline was given. Outcome was assessed by Numeric Pain Rating Scale (NRS), Oswestry Disability Index (ODI), Straight Leg Raise (SLR) and Modified Schober Test (MST) at baseline, one, three, six and twelve weeks follow-up.

Results: Thirty-seven patients completed the study. Significant improvement in patient's status was observed after CESI, as measured with MST, SLR, NRS and ODI at one and three weeks post injection and the improvement were maintained till 12th week. Eighty-three per cent of patients were satisfied at the end of the study and side-effects reported were mild.

Conclusion: CESI is a simple, safe and cost effective intervention procedure for the treatment of chronic LBP due to PIVD. It provides rapid pain relief and improvement of physical function starting within a week of injection.

Key words: Epidural injection, herniated disc, low back pain, prolapsed disc.

Introduction:

Low back pain (LBP) or sciatica as a clinical phenomenon dates back to Domenico Cotugno's article *De Ischiade Nervosa Commentarius* in 1764¹. The importance of LBP is due to its high lifetime prevalence (80%) in the community and effect on individual in terms

of pain and disability². Thirteen per cent of population suffer with persistent back pain of high intensity, with either moderate or severe disability^{2,3}. Amongst various structure causing LBP, disc herniation accounts for 30% of the cases⁴. Back pain due to disc herniation may present as local pain or as radicular pain⁵.

Traditional conservative medical treatments for patients with low back pain include trials of oral medications, exercise therapies, manual therapies, and lifestyle modifications. Epidural steroid injections first advocated in 1952 by Robecchi and Capra⁶, have also become a widely utilized conservative therapeutic modality in the treatment of patients with LBP. The rationale behind injecting glucocorticoid into the epidural space is that it will combat the inflammatory response associated with disc herniation and will thus reduce pain. Reports of the effectiveness of epidural corticosteroids have varied from 18% to 90%². Thus, epidural steroid injections are not only the most commonly used intervention, but also the most contentious and misunderstood modality of treatment. There are various studies stating the effectiveness of caudal epidural steroid injection (CESI), however very

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few Indian studies document efficacy of CESI in chronic back pain due to PIVD.

The present study was planned to examine the effectiveness of CESI in patients with discogenic back pain due to disc herniation, which are non-responsive to other conservative modes of treatment.

Materials and Methods:

A prospective follow-up study of one year duration (May 2009 to April 2010) conducted in Department of Physical Medicine & Rehabilitation Safdarjang Hospital with the aim of assessing the efficacy of CESI in cases of prolapsed intervertebral disc (PIVD). Forty-one patients of PIVD satisfying the inclusion criteria were consecutively enrolled for the study.

Inclusion criteria: Age above 18 years of both genders, history of low back pain and lower extremity pain of at least six weeks duration not responding to conservative treatment. SLR <60 degree, diagnosis of PIVD confirmed by MRI.

Exclusion criteria: Unwilling to participate in the study, PIVD with neurological deficits, previous lumbar surgery, spinal stenosis, spinal structural abnormalities, any acute or chronic uncontrolled medical illness and psychiatric disorders which might interfere with assessment of the patient. Patients with history of possible adverse reaction to steroid were also excluded from the study.

All the patients were explained about the procedure. Informed written consent was taken from all patients. Examination of spine and neurological examination was done at baseline and subsequent follow-ups. X-ray of lumbosacral (LS) spine and magnetic resonance imaging (MRI) of LS spine, complete haemogram (haemoglobin, total leukocyte count, differential leucocyte count and erythrocyte sedimentation rate and blood sugar (fasting and postprandial) were done at baseline.

Intervention: The patient was made to lie in the left lateral position. A 20-gauge needle was passed through the sacral hiatus and needle placement was confirmed by "whoosh" test⁷. The epidural space was injected with 80 mg of methylprednisolone acetate diluted in 20 ml of 0.9% saline. Following the injection the patient remained on bedrest for a day in the hospital with regular monitoring of pulse and blood pressure.

Patients were evaluated at baseline, one, three, six and twelve weeks using Objective Parameters of Straight Leg Raise (SLR) and Modified Schober Test (MST) and subjective parameters of pain using Numeric Pain Rating Scale (NRS) and Disability using Oswestry Disability Index (ODI).

Straight Leg Raise: The SLR test causes gliding of lumbar nerve roots which get compressed by the herniated disc proximal to neural foramina leading to radiation of pain down the leg in nerve root distribution⁸. SLR less than 60 degree was taken as positive.

Modified Schobers Test: In MST distraction of skin marked over the lumbar spine is measured which corresponds to the flexion movement of the lumbar spine⁹. Normally there is more than 5cm of distraction.

Numeric Pain Rating Scale: It is an eleven-point numerical pain rating scale in which patients rate their pain ranging from zero (no pain) to ten (worst imaginable pain). A two-point change on the NRS in patients with LBP represents a clinically meaningful change¹⁰.

Oswestry Disability Index: The Oswestry Disability Index is the commonly recommended condition specific outcome measure for spinal disorders¹¹. It has ten sections namely pain intensity, personal care, lifting, walking, sitting, standing, sleep, social life, travelling and employment. Total scores can range from zero (highest level of function) to 50 (lowest level of function). For each section the total score ranged zero to five according to the deterioration of function. The total score is expressed in percentage.

Statistical analysis: Descriptive statistics including mean and standard deviation (SD) were found for each quantitative variable. For non-parametric data, mean changes at different follow-ups was analysed using Friedman test followed by Wilcoxin signed ranks test. The results were considered significant at five per cent level of significance ($p < 0.05$).

Results:

Forty-one (41) subjects were enrolled in the study but only 37 patients completed three months follow-up period. The age distribution of 37 patients (27 male and 10 females) ranged from 19 to 50 years; average being 33.11 ± 8.319 (Table 1). Duration of back pain ranged from three months to 36 months, average being 11.64 ± 13.74 (Table 2). Out of 37 subjects 18 patients (48.6%) had pain for less than six months duration. PIVD was present at both L4-L5 and L5-S1 levels in 18 (48.6%) followed by L4-L5 level in ten patients (27.02%) confirmed by MRI (Table 2).

Table 1: Demographic Profile

Gender	Age in years				Average
	10-20	21-30	31-40	41-50	
Male	3	8	11	5	27 (73%)
Female	0	4	4	2	10 (27%)

Table 2: Duration of Low Back Pain and Level of PIVD

Pain duration	Level of PIVD
<6 months = 48.6 %	L4-5 = 27.1%
6-12 months = 24.3%	L5-S1 = 24.3%
>12 months = 27.1%	L4-5 and L5-S1 = 48.16%

Mean NRS, SLR, MST and ODI score at baseline was 7.51 ± 1.12 , 40.53 ± 11.62 , 18.24 ± 0.94 and 50.43 ± 12.54 respectively (Table 3). There was improvement in all the assessment parameters post CESI (Table 4). A statistically significant improvement was observed at one week and three weeks post injection which was maintained till 12 weeks (Table 4). Though mild change was observed between third and sixth and sixth and twelfth weeks follow-up, but it was not significant. Maximal improvement was found after one week post injection in all the parameters.

Only three patients reported side-effects after receiving CESI. Two patients (5.4%) reported transient mild headache which improved the same day while one (2.7%) had transient increase in leg pain, improved within three days without any medication. Three subjects out of 37 patients who received CESI underwent surgery. Out of these, one patient did not show any improvement after surgery.

Discussion:

Pain due to a herniated nucleus pulposus is an important medical and socio-economic problem. Pain and reduced mobility severely compromise quality of life and are particularly disruptive to the working individual. The

aim of any therapy should be achievement of normal lifestyle as soon as possible.

The result of our study showed a significant improvement in patient's status after CESI which started within a week post injection and persisted till the end of the study. We observed significant improvement in mobility of spine one week post injection. Valat *et al*¹² and Apathy *et al*¹³ also observed significant improvement in lumbar flexion movement within one week post injection.

We observed significant reduction in pain score after CESI at one week and third week follow-up and no significant change in subsequent follow-ups, however the improvement in the pain score persisted till 12 weeks. Wilson-MacDonald *et al*¹⁴ also observed significant early reduction in pain in their study but found no long term effect. Similar results were obtained by Buchner *et al*¹⁵ with greatest relief in pain in the initial two weeks and no significant improvement at six weeks and six months follow-up.

A statistically significant improvement in Straight Leg Raise was observed in our study which persisted till 12 weeks. This is in accordance with the study done by Bush and Hillier¹⁶, who also observed statistically significant improvement in SLR at four weeks, they however observed improvement till 52 weeks follow-up. Buchner *et al*¹⁵ also observed significant improvement in SLR at two weeks and six weeks follow-up and no significant change at six months follow-up. In our study 83 % of the patients were SLR negative at the end of three months. Similarly Sayeh *et al*¹⁶ also observed negative SLR in 88% of patients six months post injection.

Table 3: Assessment at Baseline and Follow-ups

Parameters	Time				
	0 Weeks T0	1Weeks T1	3 Weeks T3	6 Weeks T6	12 Weeks T12
NRS	7.51 ± 01.12	3.59 ± 2.38	2.86 ± 2.47	3.22 ± 2.61	2.84 ± 2.41
SLR	40.53 ± 11.62	63.41 ± 13.30	67.45 ± 12.89	67.96 ± 13.42	69.35 ± 13.05
MST	18.24 ± 0.94	19.64 ± 1.28	20.14 ± 1.49	20.23 ± 1.45	20.28 ± 1.46
ODI	50.43 ± 12.54	36.32 ± 13.44	26.32 ± 13.39	25.95 ± 15.57	25.32 ± 14.92

Table 4: Change in NRS, SLR, MST and ODI between Various Follow-ups

Time interval (in weeks)	Mean change in NRS \pm SD	Mean change in SLR \pm SD	Mean change in MST \pm SD	Mean change in ODI \pm SD	P value
T0-T1	3.91 ± 2.37	22.87 ± 13.95	$1.39 \pm .97$	14.10 ± 11.21	S
T0-T12	4.67 ± 2.36	28.81 ± 16.75	2.04 ± 1.26	26.10 ± 17.04	S
T1-T3	0.72 ± 1.38	4.04 ± 6.92	$0.5 \pm .85$	10 ± 10.40	S
T3-T6	0.35 ± 1.47	0.51 ± 5.69	$0.09 \pm .28$	0.38 ± 18.18	NS
T6-T12	0.37 ± 1.31	1.38 ± 3.88	$0.05 \pm .19$	1.62 ± 5.88	NS

T0= Score at baseline, T1= Score at one week, T3= Score at 3 weeks, T6= Score at 6 weeks, T12= Score at 12 weeks, SD= Standard deviation, NS=Not significant, S=Significant

The improvement in the ODI in our study started at one week post injection and significant change was observed at three weeks follow-up. There was minimal change at six weeks and twelve weeks follow-up, however significant improvement in ODI was maintained till 12 weeks. Thus, improvement in ODI score within three weeks showed early improvement in physical function leading to early return to work and in other functional activities. Manchikanti *et al*³ also observed significant improvement in ODI score at three months and no further improvement at six months and one year follow-up. Sayeh *et al*¹⁷ also observed significant change in ODI at one month post injection with no significant change at one year follow-up.

In our study, 81% patients were satisfied with the treatment at three weeks and 83% at 12 weeks, whereas Bowman¹⁸ reported some improvement in 85% patients at one week and 43% had improvement lasting three months.

Three patients (8%) who received CESI underwent surgery after completion of study because of failure of relief and pain, which is less than that reported in the literature (10-15%)¹⁸. However our study was of short duration with a follow-up of three months and hence we cannot comment on whether CESI potentially avoids the need for a more invasive surgical procedure which is costly, involves a significant risk to the individual patient, and may not always be successful.

Our results were consistent with the previous studies, which have suggested that the benefits of CESI is for short term, regarding improvement in pain and functional status of the patient, however we could not comment on long term effect because of short duration of the study period. We also observed that CESI was well tolerated. Minor complications are reported in our study such as mild exacerbation of radicular pain during injection and transient headache but there was no major complication.

CESI is a simple, rapid and easily performed procedure that can offer significant and faster pain relief, reduction in disability and return to work. CESI may be considered as an alternative to operative procedure in patients not responding well to conservative treatment, avoiding high operative risk or when they refuse to be operated upon.

Conclusions:

It can be inferred from our study that CESI is a simple, safe and cost effective intervention procedure for the treatment of PIVD. It provides rapid pain relief and improvement of physical function starting within a week of injection and hence can be used in PIVD patients not responding to other conservative methods of treatment. Further studies

are required to assess the long term efficacy and safety of CESI.

Carry Home Message: CESI is effective in the management of not only acute PIVD but it can be used for management of chronic PIVD not responding to other conservative method of treatment

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