

Efficacy of Single Injection of Caudal Epidural Steroid in Chronic Lumbago-Sciatica Syndrome – A Retrospective Study from an Institute of National Importance (Bhopal)

Sandeep Kumar Gupta¹, Rachit Gulati², Reni Benny³, Shashank Yeshwant Kothari⁴

^{1, 2, 3, 4} Department of Physical Medicine and Rehabilitation, AIIMS Bhopal, Madhya Pradesh, India.

ABSTRACT

BACKGROUND

Epidural steroid injections (ESIs) have been widely used for over 50 years in the treatment of back pain with or without radiculopathy. In this study, we intended to evaluate the effect of single caudal epidural steroid injection (CESI) in patients suffering from chronic lumbago-sciatica syndrome, resistant to conservative medical therapy.

METHODS

This was a retrospective study. CESI was performed on thirty-four patients suffering from chronic lumbago-sciatica syndrome, from April 2019 to March 2020. Single injection of caudal epidural steroid (40 mg Triamcinolone Acetonide) diluted with 10 ml. of sterile water was given guided by anatomic landmark, confirmed by "Whoosh" test and radiologically with dye. Patients were followed for 12 weeks using Numeric Rating Scale (NRS) for pain, Oswestry disability index (ODI) and North American spine society patient satisfaction index (NASS). Values were recorded before the injection and after the injection at 1 week, 3 week, 6 week and 12 week during follow-up.

RESULTS

Significant improvement in patient's status was observed after CESI, as measured with NRS, ODI and NASS at one, three, six and twelve weeks as compared to pre injection (zero week) but no significant difference was observed at successive follow ups at first to third and third to six weeks. There was significant reversal of NRS and ODI Score from 6 week to 12 week follow-up. Sixty seven percent of patients were satisfied at the end of the follow-up and mild side-effects were reported in a few patients.

CONCLUSIONS

CESI is a safe, simple and cost-effective intervention procedure for the treatment of chronic lumbago-sciatica syndrome. It provides rapid pain relief and physical function improvement of the patient starting within a week.

KEYWORDS

Injections, Epidural, Sciatica, Low Back Pain

Corresponding Author:

*Dr. Shashank Yeshwant Kothari,
J-106, Maple Tree, New Jail Road,
Bhopal - 462038, Madhya Pradesh, India.
E-mail: kothari_sy@yahoo.com*

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BACKGROUND

Chronic low back pain could be a multifactorial disorder with many possible aetiologies. It may occur due to irritation/compression from inter-vertebral discs, facet joints, ligaments, fascia, muscles, and nerve roots as tissues capable of transmitting pain in the low back.¹ The lifetime prevalence of chronic low back pain has been reported as high as 80 % with an annual prevalence ranging from 15 % to 45 %.^{1,2} Thirteen percent of the population suffers with persistent back pain of high intensity, with either moderate or severe disability.² Lumbago-sciatica syndrome is low back pain with lower extremity pain secondary to disc disruption, disc herniation, and nerve root compression in lumbar spine.² Mixter and Ayers in 1935 demonstrated that radicular pain can occur without disc herniation.³ Subsequently, numerous investigators have described pain syndromes emanating from the lumbar intervertebral disc without mechanically compressing neural structures.⁴ Thus, in addition to the mechanical component, inflammation of the compressed nerve root is an important factor in the patho-physiology of radicular and discogenic pain.⁴ Traditional conservative medical treatments for patients with chronic low back pain include trials of oral medication, exercise therapies, manual therapies, electrotherapies and lifestyle modifications.

The caudal epidural steroid injection approach was first described in 1901 by a French radiologist who injected diluted solutions of cocaine through the sacral hiatus to treat intractable low back pain or sciatica.⁵ Capio in 1957 investigated the therapeutic benefit of injecting corticosteroid into the epidural space via the caudal approach.⁶ In addition, lumbar epidural steroid injections have become a widely utilized conservative therapeutic modality in the treatment of patients with chronic low back pain after it was first advocated in 1952 by Robecchi and Capra.⁷ There have been many studies on epidural steroids but conclusive efficacy has not been demonstrated. The effectiveness of epidural corticosteroids has been reported to be varying from 18 % to 90 %.^{2,4} Level - I evidence exists for short- and long-term relief with CESI in managing chronic low back and lower extremity pain secondary to lumbar disc herniation and/or radiculitis and discogenic pain without disc herniation or radiculitis.⁸ Routinely we use caudal epidural steroid injection in our institute to manage chronic cases after exhausting conservative methods taking care of clear criterion of selection. Consecutively treated 34 patients were reviewed considering earlier prospective studies.

The purpose of the study was retrospective evaluation of effect of single injection of caudal epidural steroid on pain disability and satisfaction in chronic lumbago-sciatica syndrome cases resistant to conservative medical therapy.

METHODS

Retrospective analysis was conducted at tertiary care centre in India on patients treated with CESI for chronic lumbago-sciatica syndrome from April 2019 to March 2020. CESI was

performed as a routine therapeutic procedure in our institute in patients who found refractory to other conservative methods. The routine of our follow up was at one, three, six and twelve weeks for neurological status, Numeric Rating Scale (NRS), Oswestry disability index and North American Spine Society Patient's Satisfaction Index which was compared with pre-treatment levels. The previous studies^{1,2} observed that lifetime prevalence of low back pain was 80 %. Taking this value as reference, the minimum required sample size with 20 % of relative precision and 5 % level of significance measured to 25 patients. Our sample size of 34 patients with requisite follow-up was fully used to reduce margin of error.

Ethical approval was taken for retrospective analysis and for publication of the hospital data after relevant statistical analysis (IHECAIIMS Bhopal – LOP / 2020 / IM0319 dated 12 / 11 / 2020).

Individuals of both genders, above 18 years of age with chronic lumbago sciatica syndrome confirmed by MRI, of at least 6 weeks duration, not responding to conservative therapy were included for analysis. Exclusion criteria were - 1 - Unwillingness to participate in study, 2 - Previous lumbar surgery, 3 - Spinal structural abnormalities, 4 - Acute or chronic uncontrolled medical illness, 5 - Psychiatric disorders, 6 - Pregnant women, 7 - History of potential adverse reaction to steroids, 8 - Localized skin disease or pathology, 9 - Neurovascular deficiency in lower limbs.

As routine pre-procedure formalities in our institute all the patients were explained about the procedure and a detailed written consent was taken. Examination of spine and neurological examination including Magnetic Resonance Imaging (MRI) of lumbo-sacral spine, blood sugar (fasting and postprandial) was done before the procedure.

Procedure

Patient lying in prone position with pillow under abdomen, a 22 G needle 38 mm length was inserted through sacral hiatus into caudal epidural space. The injection needle was inserted 0.5 cm distal to rostral tip of the sacral hiatus which can be easily located and palpated. The needle was pointed anteriorly and 70° rostral. After piercing the ligament covering sacral hiatus, the needle touches bony anterior wall of the sacral spinal canal. The needle was then retracted 2 mm and pushed rostrally at an angle of 30 - 40° for about 1 cm. Ten ml air was injected in epidural space which gives minimal resistance as confirmation of being in epidural space. "Whoosh test" was performed with 5 ml of air.⁹ Thus, 10 to 15 ml of epidural space was created with air dissection.

Radiological confirmation was obtained with injection of 2 ml radio-opaque dye diluted in 5 ml water for injection and visualized under C-arm image intensifier (Figure-1). Finally, triamcinolone acetate 40 mg diluted in 10 ml of sterile water was injected. Post procedure vitals were recorded. Patient was kept on bed rest for a day in the hospital with regular monitoring of blood pressure and pulse. Patients were re-assessed after one, three, six and twelve weeks of injection as a routine follow-up in our hospital. Improvement in pain on Numeric Rating Scale (NRS), functional improvement in disability on Oswestry disability index and

satisfaction assessed on North American spine society patients satisfaction index (NASS).

Numeric Pain Rating Scale (NRS)

An eleven-point numerical pain rating scale in which patients rate their pain ranging from zero (no pain) to ten (worst imaginable pain) was used for assessing pain intensity. A two-point change on the NRS in patients with low back pain (LBP) was taken as a clinically meaningful change.¹⁰

Oswestry Disability Index (ODI)

Oswestry disability index is a condition specific outcome measure for spinal disorders.¹¹ It comprises of ten sections namely pain intensity, personal care, sitting, lifting, walking, 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 ranges from zero to five according to deterioration of function. The total score is expressed in percentage. The ODI scores patient's functional status.

North American Spine Society Patients Satisfaction Index (NASS)

This is a four-point scale (1 - 4) about patient satisfaction after injection with choices as follows "(1) The treatment met my expectations, (2) I did not improve as much as I had hoped, but I would undergo the same treatment for the same outcome. (3) I did not improve as much as I had hoped, and I would not undergo the same treatment for the same outcome, and (4) I am the same or worse than before treatment."¹² Satisfaction Score 1 and 2 were considered as showing successful outcome.¹³

Statistical Analysis

The presentation of the categorical variables was done in the form of number and percentage (%). On the other hand, the presentation of the continuous variables was done as mean \pm SD and median values. The data normality was checked by using Kolmogorov-Smirnov test. The quantitative variables were analysed using Wilcoxin signed ranks Test (across follow up). The qualitative variables were analysed using Fisher's exact test. Analysis was done with the use of Statistical package for social sciences (SPSS) software version 21.0. Significance of results was rated at P value of less than 0.05.

RESULTS

Thirty-four (34) subjects who completed twelve weeks follow-up period were analysed in the study. The age distribution of thirty-four patients (23 male and 11 females), 49.5 ± 13.2 years (ranged from 30 to 80 years) as shown in Table 1. Duration of back pain ranged from two months to 60 months, average being 2.37 ± 1.69 years (Table 2). Out

of 34 subjects, 12 patients (35.30 %) had pain for less than one year duration.

Mean NRS and ODI scores at baseline (T0) were 6.47 ± 1.28 and 50.71 ± 14.62 respectively and maximal improvement was found at one week in pain (NRS) and functional disability (ODI) post CESI (Table 3). A statistically significant improvement was observed at one week and subsequent follow-up of up to 12 weeks post injection as compared to baseline (Table 4). There was non-significant regression from one to three weeks (T1 - T3) and three to six weeks (T3 - T6) but significant regression from six to twelve weeks (T6 - T12) follow up.

Thirty one out of 34 patients (91.18 %) have satisfaction score 1 at first week post procedure while 9 patients (26.47 %) regressed to level 1 at twelve weeks after improvement in the interregnum (Table 5).

Gender	Age in Years			Average
	30 - 50	50 - 70	> 70	
Male	12	8	3	23 (67.75 %)
Female	6	5	0	11 (32.25 %)

Table 1. Demographic Profile

Duration of Symptoms (in Years)		
< 1 year	1-2 year	> 2 year
12	8	14

Table 2. Duration of Symptoms

Parameters	0 Week (T0)	1 Week (T1)	3 Week (T3)	6 Week (T6)	12 Week (T12)
NRS	6.47 ± 1.28	1.62 ± 0.82	2.62 ± 1.72	1.79 ± 1.37	2.03 ± 1.53
ODI	50.71 ± 14.62	14.09 ± 6.76	18.44 ± 14.65	14.56 ± 11.27	15.91 ± 13.15

Table 3. Numeric Rating Scale and Oswestry Disability Index Scores

T0 = Score at baseline, T1 = Score at one week, T3 = Score at 3 weeks, T6 = Score at 6 weeks, T12 = Score at 12 weeks

Time Interval (in Weeks)	Change in NRS Mean \pm SD	Change in ODI Mean \pm SD	P Value
T0 - T1	4.85 ± 1.3	36.62 ± 13.64	S
T0 - T3	4.68 ± 1.43	36.15 ± 15.02	S
T0 - T6	4.44 ± 1.48	34.79 ± 15.84	S
T0 - T12	3.85 ± 1.74	32.26 ± 18.23	S

Table 4. Change in NRS and ODI at Follow-Ups

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, S=Significant

North American Spine Society Patients' Satisfaction Index	At 1 Week (N = 34)	At 3 Weeks (N = 34)	At 6 Weeks (N = 34)	At 12 Weeks (N = 34)
1	31 (91.18 %)	26 (76.47 %)	21 (61.76 %)	9 (26.47 %)
2	3 (8.82 %)	7 (20.59 %)	9 (26.47 %)	14 (41.18 %)
3	0 (0 %)	1 (2.94 %)	4 (11.76 %)	10 (29.41 %)
4	0 (0 %)	0 (0 %)	0 (0 %)	1 (2.94 %)

Table 5. North American Spine Society Patients Satisfaction Index (NASS) Score

DISCUSSION

Chronic lumbago sciatica syndrome is an important medical and socio-economic problem. Pain and reduced mobility severely compromise quality of life and are disruptive to active life of a working individual. The aim of any therapy should be achievement of normal lifestyle as soon as possible.

Our patients started improving after CESI within a week which persisted till the end of the observed period. We found significant reduction in pain score after CESI at one week, three, six- and twelve-week follow-up. The improvement in the pain score persisted till 12 weeks. Wilson–MacDonald et al.¹⁴ also observed significant and 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 of pain in the initial two weeks and but the improvement did not persist till six weeks and six months follow-up. Chaudhary et al.¹⁶ found significant pain relief in first three weeks, which was maintained till 12 weeks but no significant change occurred from 3 to 6 and 6 - 12-week period.

The improvement in the ODI in our study started at one-week post injection and significant change was observed at twelve weeks follow-up in comparison to baseline. There was minimal change at three, six- and twelve-weeks follow-up. Patients returned to work and other functional activities early because of improvement in physical disability within one week. Manchikanti et al.² also observed significant improvement in ODI score at three months but 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, 100 % patients were satisfied (satisfaction score 1 and 2) with the treatment at one week, 88 % at 6 weeks and 67.6 % at 12 weeks where as Bowman¹⁸ reported some improvement in 85 % patients at one week while 43 % had improvement lasting for three months. The present study was of short duration with a follow-up of three months only. Hence, we cannot comment on whether CESI potentially avoids the need for surgical procedures which are costly, involves significant risk to the individual patient, and may not always be successful. Many of the earlier authors found that benefits of CESI last for short term, regarding improvement in functional status and pain of the patient.^{14, 19-21}

CONCLUSIONS

For the treatment of chronic lumbago-sciatica syndrome, CESI is a safe, simple and cost-effective procedure in patients not responding to other conservative treatments. It provides rapid pain relief and improvement of function starting within a week. It may delay more invasive surgical procedures. Further studies on large sample are required to assess the long-term efficacy and safety of CESI.

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