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Clinical outcome of caudal epidural steroid injection in lumbosacral radiculopathy

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Abstract

This is a prospective, non-randomized, single-blind study conducted in twenty-three patients of both sexes, with either L5 or S1 or both L5 and S1 radiculopathy, secondary to disc pathology at L4L5 and L5S1 suffering from chronic leg pain for three months or more. The objective of this study was to analyze the difference in the efficacy of administering caudal epidural corticosteroid in patients with single and double-level disc pathology, in terms of improvement of walking distance and relief of leg pain-decrease in Visual Analog Score (VAS). All the patients were evaluated clinically and radiologically, including magnetic resonance imaging of the spine. The patients were divided into two groups i.e., Group I – with single level pathology at either L4L5 or L5S1 and Group II – with double level pathology. Injection Dexamethasone 8mg mixed with injection Bupivacaine 0.5% and distilled water was injected by the caudal route to all patients under fluoroscopy. The pre-injection, 3 weeks, 3 months and 6 months post-injection Visual Analogue Score (VAS) and walking distance were analysed. There was a significant reduction of VAS & improvement of walking distance at 3 weeks, 3 months and 6 months post-Caudal Epidural Steroid Injection (CESI) in both the groups. There is no statistical correlation in both the groups in terms of clinical efficacy of the corticosteroid with respect to the number of levels of disc pathology. No major adverse event was reported in this series. Caudal Epidural Steroid Injection is a safe and reproducible modality for the treatment of lumbosacral radiculopathy. We would recommend CESI in L5 and S1 radiculopathy, secondary to disc pathology and may be repeated after 3 months.

Keywords: Caudal epidural steroid injection (CESI), visual analogue score (VAS), lumbar, radiculopathy, dexamethasone

Introduction

Chronic lumbosacral radiculopathy is a very disabling condition for most of the patients. It is defined as a clinical presentation of leg and back pain associated with diminished sensation, muscle power and/or reflexes transmitted via a particular nerve root(s) lasting for more than 12 weeks^[1]. The reported prevalence of lumbar radiculopathy is approximately 5.3% in men and 3.7% in women^[2, 3]. Lumbar radiculopathy secondary to disc prolapse resolves spontaneously in 23-48% of patients, but up to 30% might have aggravated manifestations after 1 year, 20% might be out of their professional work and 5-15% may require surgery^[4]. In young adults, the leg pain is commonly due to prolapsed intervertebral disc or disc degeneration. But in elderly patients, the back or leg pain or both, could be due to one or combinations of multiple factors such as disc prolapse, thickened flavum, facet joints hypertrophy, spinal instability, etc. The treatment modalities for lumbar radiculopathy are short-term NSAIDs, bed rest, strengthening of spinal muscles and specific etiopathology targeted physiotherapy. Additionally, change of posture, occupational rehabilitation, quitting smoking and reducing alcohol consumption play significant roles in alleviating the symptoms. Local steroid injection around the inflamed nerve root or the disc by various methods plays a vital role in reducing the pain and inflammation. Modes of epidural corticosteroid delivery to the target roots have been either trans laminar (Interlaminar), transforminal or caudal. (Table 1)

Table 1: Route, Advantages and Disadvantages of Epidural Steroid Injection

Routes	Trans-foraminal	Trans-laminar	Caudal
Safety factor	Safe	Safer	Safest
Amount of drug and volume	Least	More	Most
Procedure feasibility	Needs training/ Anaesthetist /Pain specialist	Trained orthopaedic/ Spine surgeon	Trained orthopaedic/ spine surgeon
Distance from nerve root	Closest	Closer	Farthest
Efficacy	Best	Better	Good
Complications	Most	More	Least

In this present study, we have tried to establish the degree of improvement in pain (decrease in VAS) and change in walking distance in patients with single-level pathology i.e., affecting one pair of nerve roots, and also with double-level pathology i.e., affecting two pairs of nerve roots, following CESI. This study also analyses the duration of pain relief following CESI in the different groups of patients and the statistical correlation between them, if any.

Methods

This is a prospective non-randomised single-blind study. Thirty-one patients underwent caudal epidural steroid injection (CESI) in our institution from July 2018 to June 2019. Twenty three patients, who had complete data and follow-up were considered as the sample size for our study.

The Inclusion criteria

A. Clinical criteria

1. Patients with leg pain
2. Patients with moderate back pain and leg pain
3. Neurological deficit – motor power (MRC) not less than Grade 4

B. Radiological(MRI) Criteria

1. Diffuse Disc bulge
2. Lateral recess stenosis

The Exclusion Criteria (Clinical and Radiological)

1. Patient is not willing for the procedure
2. Severe leg pain with large disc prolapse
3. Neurological deficit less than (MRC) grade 4
4. Poor skin conditions such as fungal or bacterial infections at sacral hiatus or nearby area
5. Patients with previous spine surgery
6. Patients with coagulation disorders
7. Patients with chronic co-morbidities (uncontrolled diabetes mellitus and hypertension, Coronary artery disease, chronic obstructive pulmonary disease, etc.)

All patients fulfilling the above-mentioned criteria were included for the study. A formal informed written consent was obtained from each patient, in which they were explained about the procedure, possible side effects, and the follow-up intervals. The procedure was done under fluoroscopy in an operation theatre adhering to strict aseptic protocols. The patients were made to lie in a prone position over one pillow under the chest and one under the pelvis. The sacral hiatus was located by the equilateral triangle method. The hiatus was then cleaned and draped.

Inj. Dexamethasone sodium phosphate 8mg [Dexona, 4 mg per ml, Zydus Fortiza, Zydus Healthcare Ltd., India], mixed with 5ml of distilled water and 1ml of Inj. Bupivacaine hydrochloride (0.5%) [Anawin, 5mg per ml, Neon Laboratories Ltd, India] was loaded in a syringe. 2ml of water-soluble, non-ionic contrast, Iohexol [Omnipaque, 350

mg/ml, GE Healthcare Inc, McKesson US] and 2 ml of Lignocaine hydrochloride (2%) [LOX 2%, Neon Laboratories Ltd, India] were taken in separate syringes. The drugs used in the procedure had added preservatives such as Methylparaben IP (0.15% w/v, and Propylparaben IP (0.02% w/v) in Dexona and Methylparaben IP (1mg/ml) in Anawin and LOX. The tip of the 22- Gauge spinal needle is slightly bent up to 1cm. After local infiltration at sacral hiatus; the needle was advanced at 45 degrees to the skin. After advancing the needle up to 3cm, it was turned 180 degrees so that the kyphosis of the sacrum fits the bent needle, easing the needle advancement. The needle was advanced up to the junction of S2 and S3 vertebrae (Fig 2a). 1ml of contrast was injected to exclude the intra-dural or intravascular placement of the needle. “Inverted Christmas Tree” (Fig 2b) appearance in fluoroscopy confirmed the proper needle placement in the epidural space. The diluted corticosteroid mixed with water and Bupivacaine was injected.

The patients were transferred to the post-op room for monitoring vitals and neurology for two hours. After two hours, the patient was discharged. Patients were given Tablet Paracetamol (650mg) [Calpol, Glaxo Smith Kline Pharmaceuticals Ltd], as and when necessary basis. The patients were reviewed at 3 weeks, 3 months and 6 months post CESI. On each visit, the VAS and walking distance were noted. The mean pre-injection VAS, post-injection VAS and the mean pre- & post-injection walking distances were tabulated.

The data were analyzed by a statistical software R Analytics ver 4.0. A comparison of the quantitative data between the study groups was done with the help of an unpaired *t*-test, and intergroup analysis was done with the help of paired *t*-test. The categorical data were analysed by using Chi-square tests and intergroup P values were obtained. $P < 0.05$ was considered statistically significant.

Results

The study population was divided into two groups:

Group I with single level pathology, i.e. L4L5 or L5S1 and **Group II** with double level pathology, i.e. L4L5 and L5S1 (Table 2). The pre-injection and post-CESI walking distance and VAS were analysed in both groups (Table 3). There were 23 patients - 13 males, 10 females (M: F:: 1.3:1). In group I, there were 9 males and 4 females in with average age of 34.61 years. In group II, there were 4 males and 6 females with an average age of 43.6 years. The average age of the entire study population was 38.52 years (21 years-55 years). Leg pain (23/23) was the predominant symptom, followed by back pain (18/23) (Table 2). All patients had chronic degenerative disc disease (DDD) and lateral recess stenosis of varying degrees. There were two cases of annular tear (2/23). None of them had modic changes. The average duration of back pain and leg pain in group II was almost twice the duration of group I. It may possibly be due to the double level of pathology and affecting 2 pairs of nerves in group II (Table 2).

Table 2: Comparison of Intergroup variables

	Group I	Group II
Avg Age (years)	34.61	43.6
Male: Female	9:4	2:3
Pathology level	L4L5- 3	L4L5 & L5S1 - 10
L5S1- 10		
Avg. Duration of Back Pain (months)	3.53	8.4
Avg. Duration of Leg Pain (months)	3.76	6.5

Table 3: Mean Walking distance & VAS - Pre & Post CESI and P value

Walking distance (Metres)	Group I (13)	Group II (10)	Entire Group (23)	P value (Intergroup)
Pre-Injection	213.84	259	233.47	0.68
Post-Injection				
3 weeks	742.30	845	786.95	0.40
3 months	1138.46	1230	1178.26	0.58
6 months	1100	1010	1060.86	0.63
Visual Analog Score (VAS)				
Pre-Injection	7.46	6.4	7	0.06
Post-Injection				
3 weeks	3	2.9	2.95	0.81
3 months	3.8	3.4	3.60	0.33
6 months	3.9	3.9	3.91	1

It is observed from the study that, there is a significant improvement in walking distance at three weeks, three months and six months following CESI in both the groups from the pre-injection walking distance. It is also noticed that there is a significant reduction of VAS from pre to post-injection periods in both the groups. But, there is less improvement in walking distance and a lower reduction in VAS from three months to six months post-CESI (Table 3). On analysing the intergroup correlation for the rate of improvement in walking distance and VAS with respect to levels of pathology affected, the P-value for all durations post-injection was higher than 0.05 and hence is not significant (Table 3).

Discussion

The first epidural corticosteroid administration for lumbar radiculopathy was by Lievre and associates in 1953 [5]. Various indications for CESI administration include patients with sciatica [6, 7, 8], low back pain [9, 10], low back pain and sciatica [11, 12] radicular pain and lumbosacral radiculopathy [10, 13, 14], discogenic pain [15, 16], post laminectomy syndrome and lumbar canal stenosis [17].

The probable causes of radicular pain are-

- Mechanical compression of the disc,
- Nerve root irritation by ruptured nucleus pulposus material without mechanical compression,
- Pro-inflammatory chemical agents causing ectopic neuron firing [18, 19, 20].

Corticosteroid injection reduces the inflammation of the nerve roots, decreases the stimulation of the dorsal horn neurons and suppresses the transmission from the nociceptive C fibres [21]. It also decreases cicatrisation of the lumbar nerve roots by inhibiting fibrin and collagen deposition.

Methylprednisolone Acetate (MPA) is the most commonly used steroid documented in several published reports. The other steroids used are Dexamethasone & Betamethasone. A study by Delaney and co-workers' [22] showed that, Triamcinolone acetate is an excellent anti-inflammatory drug which has a lower potential for sodium salt retention and

remains in suspension of the local anaesthetic for a long time. The hydrocortisones used in past, are no longer used now as they have a shorter duration of activity and possibly cause seizures. In our series of 23 cases, we have used Dexamethasone diluted with water and Bupivacaine.

Corticosteroids have been injected in forms of non-dilution or dilution with isotonic saline or local anaesthetic with conflicting results. The several theoretical advantages with local anaesthetic are:

- Immediate, dramatic pain relief gives psychological benefit to patients
- It breaks the "pain muscle spasm ischemic pain" cycle and improve muscle spasm.
- Associated reflex sympathetic dystrophies decrease
- Anaesthetises nerves supplying facet joint and overlying muscles
- Verifies the presence of corticosteroid in epidural space by presence of sensory epidural blockade.

We have diluted the steroid with water and Bupivacaine 0.5% in all cases. The duration of back pain and leg pain in group II was almost twice the duration of group I. It may possibly be due to the double level of pathology and affecting 2 pairs of nerves in group II. The pre-injection walking distance in both group I and II and the entire group was comparable. There had been a relevant increase in the walking distances at 3 weeks, 3 months and at 6 months post-CESI in all groups as compared to their pre-injection walking distances. However, there was no significant increment of walking distance from 3 months to 6 months post-injection in both the groups (Table 3). A decrease in post-injection VAS by two scales, or 50% pain relief within 3 weeks of epidural steroid, or 40% reduction of Oswestry Disability Index (ODI) is considered as significant according to Sudhir Singh *et al.* [23]. In our series, the VAS decreased by 3-4 scales in both the groups post CESI at 3 weeks, 3 months and at 6 months which is considered as significant (Table 3).

The increment in walking distances and decrease in VAS was statistically significant in group I and group II at 3 weeks, 3 months and at 6 months post-injection (Table 3). However, analysing the walking distances and VAS at all durations (pre-injection to post-injection) - there was no significant correlation between group I and Group II (Table 3). This implies that irrespective of the pathology levels [single or double], the clinical efficacy of the corticosteroid remains equal.

The walking distance increased at 3 weeks and remained the same at 3 months and at 6 months post-injection. This may suggest that the local steroid was very effective at 3 weeks up to 3 months and may be less effective after 6 months post-injection. Thus, it may be beneficial to repeat CESI after 3 months of the first CESI.

Two cases (L5S1) with annular tear did not show a significant reduction of VAS or increment of walking distance, requiring micro-discectomy at 6 months of post-CESI.

The various documented complications that have been encountered are dural puncture and vascular injection²⁴, post-puncture and transient non-positional headaches, unintentional subdural or subarachnoid injection, weight gain due to salt and water retention, exacerbation of CCF or hypertension, mild aggravation of radicular pain during injection, vasovagal reaction to the needle, insomnia, facial flushing, etc. Nanjayan *et al.* [25] reported arachnoiditis after CESI. In our series, we had none of the aforementioned complications.

The disadvantages of this study were the small size population and short follow-up period, and limited to lower lumbar and sacral radiculopathy. Larger amounts of corticosteroid diluted with more volume of water and local anaesthetics may be necessary to ascertain the efficacy of the treatment for higher levels of lumbar radiculopathy.



Fig 1a: Sagittal MRI- DDD & Disc Bulge L4L5

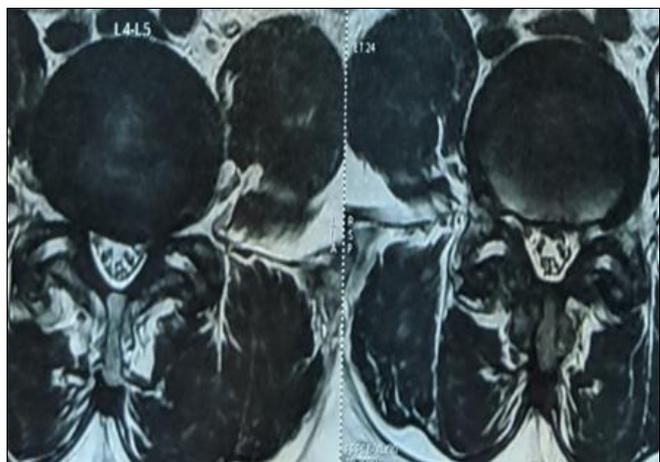


Fig 1b: Coronal MRI-L4L5 Disc prolapse with Lateral recess stenosis (L>R)

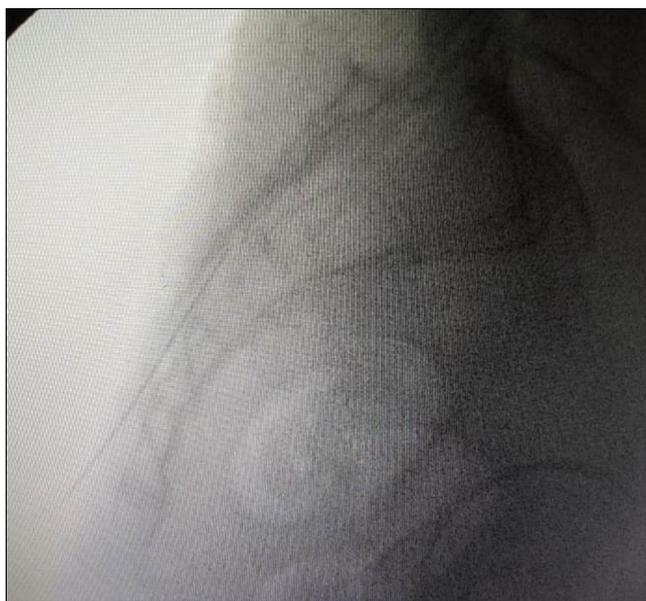


Fig 2a: C-arm image of the spinal needle at the junction of S2 & S3 vertebrae



Fig 2b: C-arm image of post-contrast “Inverted Christmas Tree” appearance



Fig 2c: C-arm image of contrast in the epidural canal

Conclusion

There was a significant reduction of VAS and an increase in walking distance at 3 weeks, 3 months and even at 6 months post-injection in single level or double level disc pathology. However, at 6 months post-CESI, the VAS and walking distance remained unchanged as compared to 3 months post-CESI. Hence, we would recommend repeating the injection after 3 months of the first caudal epidural steroid administration. There was no statistically significant difference in VAS or walking distance between single or double-level pathology post CESI. There have been no adverse reactions or complications by this procedure. A larger randomized study with longer periods of follow-up are however required to ascertain the efficacy of caudal epidural steroid injection in treatment of lumbosacral radiculopathy.

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