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Comparative study between caudal epidural steroid vs selective inter-laminar epidural steroid in chronic low back ache

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ABSTRACT

Background: One of the most common painful disorders is lower back pain with the lifetime prevalence of around 54% to 80%. Annual prevalence of chronic back pain is around 15% to 45% and 25% - 60% of patients have persisting low back pain with one year beyond initial episode. This condition often disrupts work, social activities, and daily living. Our study aimed to assess the outcomes of inter-laminar epidural steroid injection versus caudal epidural steroid injection in patients experiencing chronic lower back pain, focusing on pain relief and potential complications.

Methods: A total of 60 individuals with chronic low back pain were selected. Among these, 30 patients were randomly assigned to the first group, receiving caudal epidural steroid injection, and 30 patients to the second group, receiving inter-laminar epidural steroid injection under fluoroscopy control. Follow-up assessments for both groups were conducted at 1 hour post injection, 1 week, 4 weeks, 8 weeks and 12 weeks.

Results: Pain score was analysed with Visual Analog Scale score. Inter-laminar epidural steroid injection exhibited excellent results in early follow-ups with VAS score <3, transitioning to a moderate pain relief with VAS score of 4 at 8 weeks and VAS score of 5 by the 12-weeks post procedure. Conversely, caudal steroid injection provided moderate degree pain relief at early weeks and also at 12 weeks post procedure with average VAS score of 4to5.

Conclusion: Caudal epidural steroid injection proves to be cost-effective, easy to administer, and associated with fewer complications compared to interlaminar steroid injection. Both procedures are considered safe, well-tolerated outpatient interventions.

Keywords: Chronic low back ache, caudal epidural steroid injection, Inter-laminar epidural steroid injection, Methyl prednisolone, Lignocaine,

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INTRODUCTION

One of the most important causes of disability in the developed as well as the developing world is low backache affecting 65 to 80 percent of people worldwide causing significant restrictions in activities of daily life as well as livelihood. [1] There are multiple causes for low back pain like mechanical back pain, discogenic, facet joint arthropathy, sciatica and spinal stenosis. [2] Of all the causes, most common cause of lumbosacral radiculopathy in all age groups is intervertebral disc prolapse and 10 to 15 % of the patients end up eventually needing surgery due to persistent symptoms and accompanying neurological deficits. [3]

Majority of patients improve with conservative management like bedrest, spinal injections, lumbar brace and physiotherapy. Pharmacological methods like NSAIDs, muscle relaxants, pregabalin and/or gabapentin can be tried. Conventionally, selective epidural steroid injections and caudal epidural steroid injections are used in conjunction with medication and physiotherapy to supplement the benefits. Studies by various authors report that the success rates of epidural steroid injection (ESI) is not constant and have a variable range of 20% to 100% (average of 67%). [4] Usually, efficacy of ESIs on an average lasts about 3-4 months. So, the efficacy and long-term effectiveness of ESIs is still controversial. ESIs can be used for treatments of radiculopathy caused by disc prolapse, axial spinal pain and spinal cord stenosis. [5] ESIs benefit a patient by usually one of three reasons. 1. By the drug causing the space around the compressed nerve to expand, 2. Short term and immediate pain relief by the local anaesthetic. 3. Long-term anti-inflammatory effect by the steroid.

In most cases, surgery is considered to be the only treatment providing long term relief. Taking in account of the significant morbidity and mortality associated with surgery along with the cost of surgery, a series of new techniques have been considered as an alternative, like minimally invasive lumbar decompression and percutaneous adhesiolysis and non-surgical interventional techniques like epidural injections. [6, 7]

Administration of epidural injections in lumbar spine can be one of three ways- caudal epidural, lumbar inter-laminar and lumbar transforaminal. [8] These are administered in three separate regions of the spine with variable drug delivery with variable results. Interlaminar injection requires less volume than the caudal route as entry is directed closest to the site of the pathology. Since transforaminal is target specific, it requires a very small volume to reach the

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primary site of pathology specifically the dorsal root ganglion and anterolateral epidural space. Caudal entry is relatively easy and can be achieved without risk of dura puncture but requires the largest volume of around 15-40 ml of drug. The mechanism of action is not comprehended very well but it is theorized that the neural blockade alters the nociception pathway, of the afferent fibres reflex mechanisms, self-sustaining activity of neuron and the pattern of central neuronal activity. Combination of local anaesthetic and corticosteroids interrupt the pain spasm cycle and interrupt the nociceptor transmission as well as reduce inflammation. Atluri S. et al have performed a randomized controlled trial demonstrating that bilateral transforaminal epidural are superior to interlaminar epidural but transforaminal epidural have higher risks. [9]

The aim of this study was to assess the outcome and to compare both caudal and inter-laminar epidural steroid injection in chronic low back pain.

Hypothesis: The hypothesis was that inter-laminar lumbar epidural injections are superior to caudal epidural injections of steroids in pain relief and/ or radiculopathy in chronic lower back pain.

METHODOLOGY

In this study, a total of 60 patients after obtaining informed written consent were included in this study. Patients who had complaints of low back pain lasting more than 3 months with or without radiculopathy, who hadn't achieved relief with oral therapies like NSAIDs, pregabalin, gabapentin and supportive management like lumbar brace and physiotherapy with or without MRI done. Of the 60 patients, patients were assigned to two groups equally. First group of 30 patients received caudal epidural steroid injection and second group received inter-laminar epidural steroid under fluoroscopy control. The patients were followed up at 1 hour post procedure,1 week, 4 weeks, 8 weeks and 12 weeks. All the patients received supportive management of NSAIDs, lumbar brace and physiotherapy which was exactly the same for both the groups. Usually both of these procedures were performed as an outpatient procedure.

In group A (Caudal epidural steroid) - a total of 30 ml was injected with 2ml (80mg) methylprednisolone with 5ml of 2% lignocaine, added by 0.9% saline to make the rest of infiltrate.

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In group B (Inter-laminar steroid) - a total 10 ml was injected with 2ml (80mg) methylprednisolone with 5ml of 2% lignocaine and added with 0.9% Saline to make rest of the infiltrate.

Case selection:

Inclusion criteria: Patients with an age group of 25-65 years, either sex were selected with low back pain lasting more than 3 months.

Exclusion criteria: Patients of age less than 25 years and more than 65 years, cauda equina syndrome, patients with progressive or non-progressive neural deficits, patients with history of spinal corticosteroid injections within last one year, patients with structural spine deformities (scoliosis greater than 40°, spondylolisthesis etc.), previous low back surgery, pregnancy, diabetes mellitus, blood-coagulation disorder, allergy to local anaesthetics, allergy to radio opaque dye, local infection.

Materials:

- Injection methylprednisolone acetate 80mg
- Isotonic saline (0.9%)
- 2% lignocaine
- 20-gauge, Quincke spinal needle
- 18-gauge, Tuohy's epidural needle
- Iohexol – radio opaque dye
- Syringes: 5ml, 20 ml and 50 ml

Methods: This randomized, prospective comparative study was conducted at Srinivas Institute of Medical Sciences, Mangaluru, from October 2022 to November 2023. A tertiary referral health care centre, after taking consent from ethical committee.

Caudal epidural injection technique: under aseptic precautions, patient in prone position, parts painted and draped, the sacral cornu and sacral hiatus was palpated, and entry point of injection was marked under fluoroscopic control. After confirming the entry, at 45 degree, the needle was advanced into the hiatus towards the bone. Needle was gradually advanced horizontally in the midline confirming the placement in the canal with fluoroscopy. The advancement of the needle is stopped at the mid-point of the S3 and the drug is injected into the caudal space, after confirming the position. Larger volume of medication is used due

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to the large caudal space to ensure proper drug distribution. Due to higher percentage of complications with blind injection, current recommendations are to use fluoroscopic control, which were followed in our study to ensure accuracy and efficacy and avoid complications.

Inter-laminar epidural injection technique: Under fluoroscopic guidance, midline approach was used after placing the patient in lateral position. The needle was inserted till there was a loss of resistance. A lateral position was comfortable to patients with radiculopathy and opening up of the spinous process for better access. A direct midline approach between the spinous processes is also better as it targets the posterior epidural space. The needle is slowly advanced in 1 mm increments with "air release technique" using a low-resistance syringe. An injected puff of air at each position causes the plunger to retract, except when the epidural space has been encountered. Position of the needle was then confirmed under fluoroscopy and the drug injected.

Every patient was followed on 1st hour post procedure, 1 week, 4 weeks, 8 weeks and 12 weeks post procedure.

RESULTS:

A total 60 patients were enrolled for the study out of which 31 were males (51.66%) and 29 were females (48.33 %). Pain score was analysed with Visual Analog Scale score. Inter-laminar epidural steroid injection exhibited excellent results in early follow-ups with VAS score <3, transitioning to a moderate pain relief with VAS score of 4 at 8 weeks and VAS score of 5 by the 12-weeks post procedure. Conversely, caudal steroid injection provided moderate degree pain relief at early weeks and also at 12 weeks post procedure with average VAS score of 4to5.

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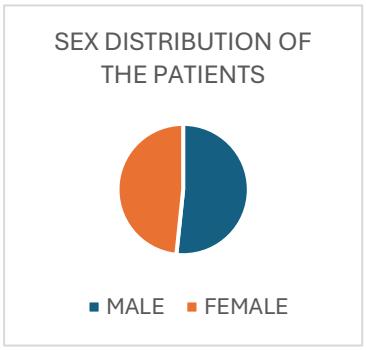

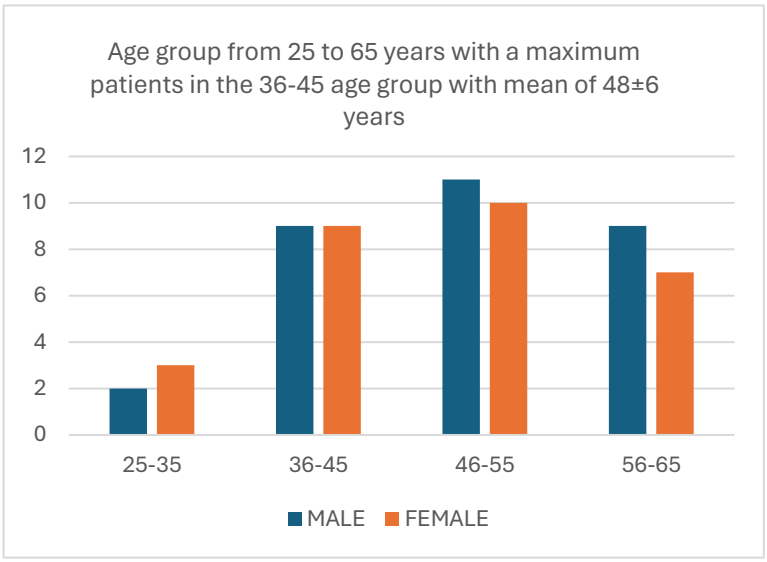

Outcome Measure - Mean (SE) VAS back pain			
Time	Respondents (N = 25)	Non-Respondents (N = 3)	P Value
Pre-injection	7.8 (0.3)	6.7 (1.1)	>0.05
1-hour post-injection	3.8(0.2)	3.6(1.2)	>0.05
1 weeks post-injection	3.6 (0.2)	3.5(1.2)	>0.05
4 weeks post-injection	4.2 (0.2)	4.1 (1)	>0.05
8 weeks post-injection	4.7(0.2)	3.8 (1.2)	>0.05
12weeks post-injection	4.7 (0.2)	5 (0.9)	>0.05

Table 1: Results of pain (VAS) in caudal epidural steroid injection group

Outcome Measure - Mean (SE) VAS back pain			
Time	Respondents (N = 29)	Non-Respondents (N = 1)	P Value

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Pre-injection	8.1 (0.2)	7.5 (0.7)	>0.05
1 hour post-injection	3.0(0.3)	3.0(0.2)	>0.05
1 week post-injection	2.8 (0.2)	2.9 (0.3)	>0.05
4 weeks post-injection	3.0(0.2)	3 (0)	>0.05
8 weeks post-injection	4.3(0.2)	4.3(0.4)	>0.05
12 weeks post-injection	5.0 (0.2)	4.8 (0)	>0.05

Table 2: Results of pain (VAS) in inter-laminar epidural steroid injection group

DISCUSSION:

Radcliff et al. found that L4/L5 involvement was prevalent in 90% of cases in their 2013 study. This suggests that, at times, the administered drug may not effectively target the pathology in caudal epidural injections.[6] Consequently, lumbar interlaminar epidural injection emerges as a more effective alternative, delivering the drug in close proximity to the pathology. Study done by Akram et al showed similar results of lumbar epidural of steroids injections being more effective then caudal epidural injection of steroids in treating spinal stenosis.[10] Several studies corroborate the efficacy of lumbar interlaminar epidural injection for managing lumbar spinal stenosis [11,12,13].

Contrary to these findings, Friedly et al.'s 2014 study contradicted the outcomes, particularly regarding lumbar epidurals' effectiveness in treating lumbar spinal stenosis with moderate to severe leg pain [14]. Anderson criticized Friedly et al.'s study design, outcome assessment methodology, literature review quality, variability in drug injection volumes during procedures, and their conclusion of inefficacy. Despite these criticisms, the results clearly indicated that both Transforaminal and Interlaminar approaches were effective, with the Inter-laminar approach demonstrating superior results [15, 16].

Radcliff et all in 2013 showed that after failure of conservative management, epidural steroid injection was the treatment of choice, despite there being conflicting randomized

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controlled trials regarding the efficacy and cost effectiveness. However their subgroup analysis of Spine Patient Outcomes Research Trial (SPORT) provided inaccurate conclusion because of inappropriate conclusion of literature and an improperly designed retrospective analysis and large difference in sample sizes. [6]

Similarly, Bresnahan et al. and Ammendolia et al. faced criticism for inadequate search criteria and inappropriate analysis, leading to conclusions lacking evidence [16, 17]. However, systematic reviews with proper methodologies have shown moderate efficacy in managing central spinal stenosis [19].

In a cohort study involving 44 patients experiencing low back and leg pain, no significant improvement was observed when compared to the administration of 40 mg of methylprednisolone. Notably, these procedures were not conducted under fluoroscopy. [20] Another study reported that 23 out of 34 patients (68%) demonstrated at least a temporary or partial response to initial unscreened caudal epidural injections. Among the eight patients who received two or three epidural injections, four experienced sustained relief from their leg pain [21].

In our study, the injection of 80 mg of methylprednisolone was performed under fluoroscopy, resulting in a significant improvement in pain for both groups.

The optimal method for administering epidural steroids remains a subject of debate. Among the various options, caudal epidural injections are considered the safest and simplest, carrying minimal risks of unintended dural puncture or other adverse effects. Studies have demonstrated their significant effectiveness compared to interlaminar epidural injections. [22, 23] Only 36% of interlaminar epidural injections displayed ventral contrast flow, and bilateral contrast flow was observed in just 16% of cases [24]. Three years later, the same group of practitioners, who previously reported on interlaminar injection patterns, found that fluoroscopically guided caudal epidural steroid injections (ESIs) may alleviate bilateral radicular pain and enhance standing and walking tolerance in individuals with degenerative lumbar spinal stenosis [25]. While it is acknowledged that caudal epidural injections without fluoroscopic guidance are prone to inaccuracies [26, 27], studies on patients with low back pain and/or sciatica treated with caudal epidural steroid injections have indicated satisfactory effectiveness [28]. In our current study, a subset of patients underwent treatment with caudal epidural steroid injections, along with post-injection radiographs to assess epidurograms.

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Based on the post-injection epidurograms and clinical outcomes, caudal epidural steroid injections were found to be precise and successful in all these patients.

Literature reports indicate that blind caudal injections without fluoroscopic control may lead to needle misplacement, such as the needle tip being positioned outside the epidural space, intravascular injection, or inaccurate targeting of the presumed level of the pathological process. [21] Hence, it is recommended that caudal steroid injections be carried out under fluoroscopic guidance to enhance safety, accuracy, and potential efficacy.

The consensus among most experts is that transforaminal epidural steroid injections (TFESI), which deliver the injectate directly to the ventral epidural space, are considered superior to caudal epidural steroid injections [23, 29]. Although there are limited comparative studies between selective epidural steroid injection and caudal epidural steroid injection, a retrospective study by Lee et al. involving 233 patients with radiculopathy from spinal stenosis or herniated discs revealed that satisfaction and pain scores were higher for selective epidural steroid injection recipients compared to those who underwent caudal epidural steroid injection for up to 2 months. Interestingly, varying injectate volumes did not impact the final outcome, regardless of the administration route [30].

In a randomized evaluator-blinded study focused on subjects with S1 radiculopathy secondary to L5-S1 herniated nucleus pulposus and treated with selective epidural steroid injection, interlaminar epidural steroid injections (ILESIs), or caudal epidural steroid injection, the transforaminal route demonstrated greater effectiveness in terms of pain relief and improved function at both 12 and 24 weeks. Additionally, patients in the selective epidural steroid injection group, where ventral epidural spread was more common, experienced better outcomes [31]. In our group's presented study, patients with stenosis who received selective epidural steroid injection exhibited significantly better outcomes than those in the caudal epidural steroid injection group at the 6-month and 1 year mark. This finding supports the notion that the proximity of the injection to the inflammation (selective epidural steroid injection) is more crucial.

One distinctive feature of caudal epidural steroid injection setting it apart from selective epidural steroid injection is that caudal epidural steroid injection attains its maximum effect at 2 weeks post-injection, while selective epidural steroid injection reaches a plateau at 6 weeks post-injection [31]. This explains why the notable difference observed in Visual Analog Scale

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(VAS) among patients in the selective epidural steroid injection group occurs between 2 weeks and 3 months, whereas such a difference is not evident for patients in the caudal epidural steroid injection group.

The duration of pain relief achieved through epidural steroid injections (ESI) varies and can extend up to a year [32, 33]. In our 1 year follow-up study, the improvement in symptomatology at 1 year remained statistically significant when compared to pre-injection data for both caudal epidural steroid injection and selective epidural steroid injection.

There is a potential risk of dural puncture associated with interlaminar epidural injections. Predisposing factors to dural puncture in caudal epidural steroid injections include, short stature (height less than 5 feet), a short sagittal dimension of the sacrum, blind injection without fluoroscopic guidance, an inexperienced operator, the needle tip being above the level of the anterior foramen of S1 in anteroposterior view and atypical anatomy within the sacral canal, such as the presence of a tethered cord.

Potential challenges in entering the caudal epidural space include, an acute angle of sacral dorsal convexity, difficulty in identifying anatomic landmarks, deformity of the sacral coccygeal area due to previous trauma or birth defects, sealed sacra with a rare hiatus, a relatively long coccyx with a "superior" location of the sacral hiatus and developmental fusion of the sacral canal.

CONCLUSION:

In the present investigation, the group subjected to interlaminar epidural steroid injection exhibited superior symptomatic improvement for short-term pain relief and moderate pain relief over the medium term when compared to the caudal steroid injection group, which consistently experienced moderate pain relief throughout the study period. The peak benefit typically extended up to 12 weeks, suggesting that this interventional pain relief method could potentially serve as an alternative to spinal surgery in cases of painful radiculopathy of the lower limbs, especially if the relief is substantial.

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Nevertheless, it is worth noting that caudal steroid injection proves to be cost-effective, easily administered, and associated with fewer complications compared to interlaminar steroid injection. Both procedures are deemed safe, well-tolerated outpatient interventions.

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