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Evaluation of Functional Outcome of Caudal Epidural Steroid Injection in Patients of Chronic Low Back Ache with Radiculopathy

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ABSTRACT
lower back pain is one of the most common painful disorders with the lifetime prevalence of around 54-80%. 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. Majority of patients improve with rest, pharmacotherapy and physical therapy. Spinal injections are also used in conjunction with medication and physiotherapy to supplement the benefits in patients with radiculopathy. Commonly used spinal injections are transforaminal epidural steroid injection, caudal epidural steroid injection and inter laminar epidural steroid injection. Our study aimed to assess the functional outcome of caudal epidural steroid injection in patients of lower back pain with radiculopathy, focusing on pain relief and potential complications. A total of 30 individuals of low back pain with radiculopathy were selected and administered with caudal epidural steroid injection under fluoroscopy control. Follow-up assessment was conducted at 1 hour post injection, 1 week, 4 weeks, 8 weeks and 12 weeks. Pain score was analysed with Visual Analog Scale score. Caudal 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. No potential complications were noted with the procedure. Caudal epidural steroid injection proves to be the effective modality of pain relief in patients of low back ache with radiculopathy. It is safe, easy to administer, well-tolerated, outpatient intervention and associated with fewer complications.

INTRODUCTION

One of the most important causes of disability in the developed as well as the developing world is low back ache affecting 65-80 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, disco genic, 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 10-15% 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 rest, pharmacotherapy and physical therapy. Pharmacological drugs like NSAIDs, muscle relaxants, pregabalin, gabapentin and/or nortryptalline is used in the treatment. Spinal injections also have shown promising results with regard to improvement in pain scores and early rehabilitation of the patient. Commonly used spinal injections are epidural steroid injections (ESI) like transforaminal epidural steroid injection, caudal epidural steroid injection and inter laminar epidural steroid injection. Studies by various authors report that the success rates of epidural steroid injection (ESI) is not constant and have a variable range of 20-100% (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 per cutaneous 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 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 15-40ml 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 functional outcome of caudal epidural steroid injection in patients of low back ache with radiculopathy, focusing on pain relief and potential complications.

MATERIALS AND METHODS

After obtaining informed and written consent, a total of 30 patients were included in this study. Patients who had complaints of low back pain lasting more than 3 months with 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. All patients received caudal epidural steroid injection as an outpatient procedure. The patients were followed up at 1 hour post procedure, 1 week, 4 weeks, 8 weeks and 12 weeks post procedure. All the patients received supportive management of NSAIDs, lumbar brace and physiotherapy. Injection composition: 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.

Case Selection:

Inclusion Criteria: Patients with an age group of 18-60 years, either sex were selected with low back pain lasting more than 3 months with radiculopathy.

Exclusion Criteria: Patients of age less than 18 years and more than 60 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.
- Iohexol-radio opaque dye .
- Syringes: 5ml, 20 ml and 50ml.

Methods: After obtaining clearance from the ethical committee, this prospective observational study was

conducted at a tertiary referral health care centre in Karnataka, India, from October 2022 to November 2023.

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 Quincke's 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. 0.5ml iohexol dye is injected into the caudal space. Dye spread is confirmed with fluoroscopy. After confirming the position, 30ml of injection mixture is administered. Large volume of medication is used due 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. Every patient was followed on 1st hour post procedure, 1 week, 4 weeks, 8 weeks and 12 weeks post procedure.

RESULTS AND DISCUSSIONS

A total 30 patients were enrolled for the study out of which 16 were males (53.33%) and 14 were females (46.66 %). Pain score was analysed with Visual Analog Scale score. Caudal epidural steroid injection exhibited excellent results in early follow-ups with VAS score <3, transitioning to a moderate pain relief with VAS score of 4.3 at 8 weeks and VAS score of 5 by the 12-weeks post procedure.

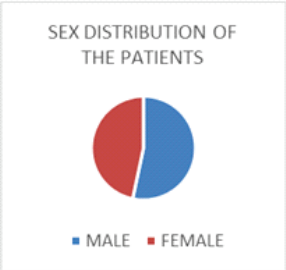

Fig. 1: Demographics

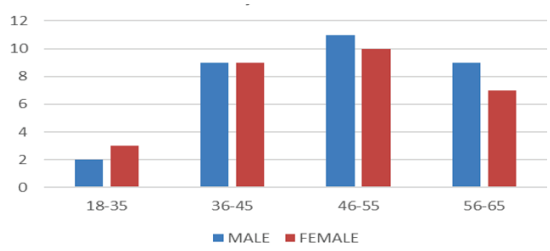

Fig. 2: Age Group from 60-80 Years with a Maximum Patient in the 46-55 Age Group Mean of 48±6 Years

Table 1: Results of Pain (VAS) Score with Caudal Epidural Steroid Injection

Outcome Measure - Mean (SE) VAS Back Pain	
Time	(N=30)
Pre-injection	8.1 (0.2)
1 hour post-injection	3.0(0.3)
1 week post-injection	2.8 (0.2)
4 weeks post-injection	3.0(0.2)
8 weeks post-injection	4.3(0.2)
12 weeks post-injection	5.0 (0.2)

Redcliff *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[11-13] (Table 1). 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]. Redcliff *et all*. in 2013 showed that after failure of conservative management, epidural steroid injection was the treatment of choice, despite there being conflicting randomized 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 40mg 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[1]. In our study, the injection of 80mg of methylprednisolone was performed under fluoroscopy, resulting in a significant improvement in pain. 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[21,22]. Only 36% of interlaminar epidural injections displayed ventral contrast flow and bilateral contrast flow was observed in just 16% of cases[23]. 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 reticular pain and enhance standing and walking tolerance in individuals with degenerative lumbar spinal stenosis[24]. While it is acknowledged that caudal epidural injections without fluoroscopic guidance are prone to inaccuracies[25,26], studies on patients with low back pain and/or sciatica treated with caudal epidural steroid injections have indicated satisfactory effectiveness[27]. In our current study, patients underwent treatment with caudal epidural steroid injection along with post-injection radiographs to assess epidurograms. Based on the post-injection epidurograms and clinical outcomes, caudal epidural steroid injections were found to be precise and successful in all the 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, intra vascular injection, or inaccurate targeting of the presumed level of the pathological process[1]. 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[22,28]. 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[29]. 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[30]. 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[30]. The duration of pain relief achieved through epidural steroid injections (ESI) varies and can extend up to a year[28,31]. In our study, at 12 weeks follow up, there was good pain relief. 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 our study, the caudal epidural injection exhibited superior symptomatic improvement for short-term pain relief and moderate pain relief over the medium and long term. 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. Nevertheless, it is worth noting that caudal steroid injection proves to be cost-effective, easily administered and associated with fewer complications.

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