

Original research article

Prospective observational study to evaluate the role of caudal epidural steroid injections in the management of chronic-LBP**Dr. Rohit Amar¹, Dr. G.N.Khare², Dr. Rupesh Jung Belbase³, Dr. Yogesh Kumar⁴****¹Junior Resident, Department of Orthopaedics, Institute of Medical Sciences, Banaras Hindu University, Varanasi, Uttar Pradesh, India****²Professor, Department of Orthopaedics, Institute of Medical Sciences, Banaras Hindu University, Varanasi, Uttar Pradesh, India****³Junior Resident, Department of Orthopaedics, Institute of Medical Sciences, Banaras Hindu University, Varanasi, Uttar Pradesh, India****⁴Junior Resident, Department of Orthopaedics, Institute of Medical Sciences, Banaras Hindu University, Varanasi, Uttar Pradesh, India****Corresponding Author: Dr. Rohit Amar****Abstract**

Aim: to find the role of caudal epidural steroid injections in the management of chronic low backache.

Material and methods: This prospective observational study was carried out in the Department of Orthopaedics, Institute of Medical Sciences, Banaras Hindu University, Varanasi, Uttar Pradesh, India from March 2016 to October 2017. 60 Patients more than 20 years and less than 65 years with chronic function-limiting LBP of at least 6 months duration not responding to oral medications, short wave diathermy and physiotherapy, were included in the study. History regarding demographic status, duration of LBP, and medications used, was recorded. The severity of backache was assessed by using pain rating scores using the numeric rating scale (NRS), Prolo and Macnab criteria. Similarly, work status and functional status was assessed by Oswestry disability index 2.0 (ODI). The patients were routinely followed up in the orthopedics outpatient clinic, 6 weeks and 12 weeks. The initial (15-30 min) pain response was prospectively collected using a visual analogue scale.

Results: 60 patients with LBP between ages 20-65 years were studied. Average of patients were 50.84 ± 7.7 , out of these 32 (53.33%) were males and 28 (46.67%) females. 33(55%) patients belonged to poor families, 20 (33.33%) to average, while 7(11.67%) to rich families. The mean follow-up period was 3 months. Only 2 patients suffered from paraesthesia for 5-6 hours post injection, in the rest of the patients no complication was seen. Post-epidural back pain relieved were 50-70% in 20 (33.33%), 70-80%, 19 (31.67%), 80-90% 13 (21.67%), and 90-100% 8(13.33%). After 3 months (medium-term effect), pain relief of more than 50% persisted in 44- 48 (73.33-80%) patients. Final over view of outcome of ESIs in LBP. Functional assessment results assessed by the ODI showed significant improvement in the functional status from baseline to 3 months. Reduction of ODI scores of at least 40% was seen in 96.67% of patients at 6 weeks, and then 12 weeks (3 months).

Conclusion: ESIs are very effective and significantly reduce pain in patients with chronic function-limiting LBP.

Keywords: Low back pain, Epidural steroid injections

Introduction

Chronic low back pain, which has negative effects on life and which causes labor force loss, is an important community health problem. According to the data, 10% of all low back pains continue for 4 - 6 weeks, and are then called chronic low back pain. The treatment of chronic axial and/or radicular low back pain, which is the most frequently encountered complaint in general neurosurgery practice, includes a wide range of options. Lumbar epidural steroid applications and surgical methods can be used when the conservative methods are inadequate.¹ LBP is second only to the common cold as a cause of lost work time; it is the fifth most frequent cause for hospitalization and the third most common reason to undergo a surgical procedure. LBP is defined as chronic after 3 months because most normal connective tissues heal within 6-12 weeks unless pathoanatomic instability persists. A slowed rate of tissue repair in the relatively avascular intervertebral disc may impair the resolution of chronic LBP. Traumatic or degenerative conditions of the spine are the most common causes of chronic LBP. A number of anatomic structures of the lumbar spine have been considered as the origin of LBP.²⁻⁶ Many studies have shown significant improvement with epidural injections with or without steroids in patients with chronic LBP. Among the multiple interventions used in managing chronic spinal pain; lumbar epidural injections have been used extensively to treat lumbar radicular pain. Epidural steroid injections (ESIs) are a common treatment option for many forms of LBP and leg pain. They have been used for low back problems since 1952 and are still an integral part of the non-surgical management of sciatica and LBP. The goal of the injection is pain relief; at times the injection alone is sufficient to provide relief, but commonly ESIs is used in combination with a comprehensive rehabilitation program to provide additional benefit.⁷⁻⁸ However, there is a paucity of studies exploring the prediction of the therapeutic efficacy of an epidural injections are administered by accessing the lumbar epidural space by multiple routes including transforaminal, caudal, and interlaminar. Substantial differences have been described among these 3 approaches, with the transforaminal approach having the advantage of being target-specific and using the smallest volume, fulfilling the aim of reaching the primary site of pathology, namely the ventral lateral epidural space.⁹⁻¹¹ In our set up, ESIs are routinely used to support non-operative treatment for chronic LBP and our anecdotal perception is that a considerable proportion of patients report substantial pain relief after this procedure and save health care costs.

The aim of this study was to evaluate the functional outcomes in cases of chronic low back ache of more than three months managed by caudal epidural steroid injections at Department of Orthopaedics, Institute of Medical Sciences, Banaras Hindu University, Varanasi, Uttar Pardesh, India.

Material and methods

This prospective observational study was carried out in the Department of Orthopaedics, Institute of Medical Sciences, Banaras Hindu University, Varanasi, Uttar Pardesh, India from March 2016 to October 2017, after taking the approval of the protocol review committee and institutional ethics committee.

Methodology

60 Patients more than 20 years and less than 65 years with chronic function- limiting LBP of at least 6 months duration not responding to oral medications, short wave diathermy and physiotherapy, were included in the study. Patient's with evidence of disc herniation and those who had under gone and failed to show positive response to facet joint nerve blocks were excluded. Patients with LBP due to fractured vertebrae, pressure on nerve roots in spinal canal or uncontrolled psychiatric disorders, were also excluded from the study. All

patients included were examined and investigated after taking detailed history. History regarding demographic status, duration of LBP, and medications used, was recorded. The severity of backache was assessed by using pain rating scores using the numeric rating scale (NRS), Prolo and Macnab criteria. Similarly, work status and functional status was assessed by Oswestry disability index 2.0 (ODI). Pre-informed and written consent was obtained from all the patients included in this study.

All injections were performed in orthopedic operation theatre. The epidural is done as an outpatient procedure. The patient may be given a light sedative although most patients do not need any sedation and are able to drive themselves home. A local anesthetic is used to numb the skin. The epidural space is located under image intensifier and the needle is positioned appropriately. The patient's blood pressure, pulse, oxygen saturation and respiration are monitored. The steroid is injected into the epidural space under c-arm image intensifier using radio- opaque dye. After appropriate disinfection, the skin over the spine was anesthetized with 2-3 ml of xylocaine 2%. Subsequently, a mixture of 9.0 ml of local anesthetic (bupivacaine 0.5%) and 1 ml of methyl prednisolone-80 mg (depomedrol) was injected through sacral hiatus by using 20 gauge spinal needles. The position of needle was checked by injecting 2.0 ml of air and auscultation with a stethoscope before injecting medicines in the epiduralspace. The patient is monitored for 60 minutes and then discharged.

The patients were routinely followed up in the orthopedics outpatient clinic, 6 weeks and 12 weeks. The initial (15-30 min) pain response was prospectively collected using a visual analogue scale. For immediate- term response analysis, we asked patients to score the degree of pain reduction in relation to the pain level before the caudal epidural block. Besides patient age, sex, and marital status, the following general health indicators were asked: general life satisfaction, general health, and whether the patient smokes. In addition, patients were asked about other clinical variables including the first episode and the number of episodes of LBP, maximum pain level, influence of different provocation movements, and pain alleviation by motion. The following outcome variables were considered: pain reduction 15-30min after injection (immediate effect); pain reduction for more than 1 week (6 week usually short-term effect); and pain reduction for more than 3months (medium-term effect). Responders were defined as those who reported a reduction in pain of more than 50%.

Results

60 patients with LBP between ages 20-65 years were studied. Average of patients were 50.84 ± 7.7 , out of these 32 (53.33%) were males and 28 (46.67%) females. 33(55%) patients belonged to poor families, 20 (33.33%) to average, while 7(11.67%) to rich families. The mean follow-up period was 3 months. Only 2 patient suffered from paraesthesia for 5-6 hours post injection, in the rest of the patients no complication was seen.

Post-epidural back pain relieved were 50-70% in 20 (33.33%), 70-80%, 19 (31.67%), 80-90% 13 (21.67%), and 90-100% 8(13.33%) showed in Table 1.

After 3 months (medium- term effect), pain relief of more than 50% persisted in 44- 48 (73.33-80%) patients. Final over view of outcome of ESIsin LBP is given in Table 2.

Functional assessment results assessed by the ODI showed significant improvement in the functional status from baseline to 3 months. Reduction of ODI scores of at least 40% was seen in 96.67% of patients at 6 weeks, and then 12 weeks (3 months) as shown in Table 3, fig- 1.

Table 1: Back pain relieved post-epidural

Post-epidural	Frequency	%
50-70%	20	33.33
70-80%	19	31.67

80-90%	13	21.67
90-100%	8	13.33

Table 2: Pain relief outcome of ESIs in LBP

Time of review	Back pain relieved	
	Frequency	%
One week	48	80
6 weeks	46	76.67
12 weeks (3 months)	44	73.33

Table 3: Reduction of ODI scores.

Time of review	Reduction of ODI Scores	
	Frequency	%
6 weeks	58	96.67
12 weeks (3 months)	58	96.67

**Fig. 1:** Showing needle insertion for caudal ESI**Discussion**

Results of this study of 60 patients demonstrated significant pain relief over 12 weeks period. Similarly, ODI used for functional assessment showed significant improvement with at least 40% reduction in 96.67% patients. Strict criteria were incorporated into the study and the patients only judged not to have facet joint pain were included in the study, thus avoiding the criticism of including the patients with facet joint pain in the study contributing to the negative results. With regards to medical necessity and indications of lumbar epidural injections either by interlaminar approach or caudal approach, significant controversy exists. Multiple guidelines and systematic reviews have identified indications for ESIs in positive reports to treat radicular pain from herniated lumbar intervertebral discs. Two prospective evaluations have shown positive results in patients without disc herniation or radiculitis, in chronic function-limiting LBP.^{12,13} In the present study it is illustrated that pain relief can be achieved with judicious use and appropriate evaluation in patients without facet joint pain. These results are similar to the patients receiving caudal epidural injections either with or without steroids with disc herniation and radiculitis.¹⁴

Despite increasing utilization of lumbar transforaminal epidural injections, significant debate continues regarding their effectiveness. Buenaventura et al in a systematic review of therapeutic lumbar transforaminal epidural steroid injections, evaluated 4 randomized trials

based on cochrane musculoskeletal review group criteria, with criteria of short-term relief as <6 months and long-term relief as >6 months.¹⁵ They showed level II-I evidence for short-term relief and level II-2 for long-term relief in managing chronic low back and lower extremity pain. Chou and Huffma concluded that 3 higher qualities, placebo-controlled trials evaluating the transforaminal approach reported mixed results, and concluded that for LBP with sciatica, evidence for the efficacy of epidural steroid injection by the transforaminal approach was mixed, with 2 of 3 higher quality trials showing no benefit compared to controlled injections.¹⁶⁻²¹

In a critical evaluation of American pain society (APS) guidelines, Manchikanti et al concluded that the evidence appears to be fair, based on grading of good, fair, and poor in managing lumbar nerve root pain with transforaminal epidural injections.²² Favorable evidence has also been described in other manuscripts.^{23,24} Buenaventura et al also showed limited evidence for transforaminal epidural injections for lumbar radiculating pain in post-surgery syndrome.²⁵ There were no studies evaluating transforaminal epidural injections in spinal stenosis meeting the inclusion criteria.²⁵ Depalma et al showed that there was moderate evidence in support of selective nerve root blocks in treating painful radicular syndromes.²³

European guidelines for the management of chronic nonspecific LBP also provided a favorable level of evidence for transforaminal epidural steroid injections, while providing negative evidence for other modalities.²⁴ They showed positive outcomes in both short-term and long-term results, concluding that there was strong evidence for transforaminal injections in the treatment of lumbosacral radicular pain for both short-term and long-term relief. In another evidence-based radiology review, the authors concluded that there was moderate to strong evidence supporting the use of transforaminal therapeutic epidural injections for lumbar nerve-root compression.²⁶ In a systematic review, Roberts et al concluded that there was fair evidence supporting transforaminal epidural injections as superior to placebo for treating radicular symptoms, whereas there was good evidence that they should be used as a surgery-sparing intervention, and that they were superior to interlaminar ESIs and caudal ESIs for radicular pain.²⁷ Rho and Tang, in an evaluation of the efficacy of lumbar epidural steroid injections, concluded that there was strong evidence to support the use of lumbar transforaminal ESIs in patients with acute to sub acute unilateral radicular pain caused by a herniated nucleus pulposus or spinal stenosis.²⁸ They also concluded that a lumbar transforaminal epidural steroid injection is an effective surgery-sparing procedure that should be a part of conservative care in the management of LBP and radiculopathy. Overall, the evidence in this report demonstrates caudal epidural injections in patients negative for lumbar facet joint pain confirmed by controlled, comparative local anesthetic block with a criteria of 80% pain relief, which is not sustainable after prior painful movements for appropriate duration of action of local anesthetic, without disc herniation or radiculitis, may be treated with caudal epidural injection with steroids, providing approximately 12 weeks of relief with each procedure.

Conclusion

ESIs are very effective and significantly reduce pain in patients with chronic function-limiting LBP.

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