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Comparative Study to Assess the Efficacy of Epidural Steroid Injection by Interlaminar and Trans-Foraminal Approach for Low Back Ache with Unilateral Lumbar Radicular Pain

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Abstract

Background: Interlaminar and trans-foraminal epidural steroid injections are commonly performed interventions in managing low backache with lumbosacral radicular pain. However, controversy exists to the superiority of one over the other. *Material and Methods:* Sixty six patients with low back ache with unilateral single level lumbar radiculopathy were randomly allocated to group IL (interlaminar approach)and group TF (trans-foraminal approach).In group IL needle was placed in epidural space by loss of resistance technique and in group TF, needle was placed in epidural space under C-arm guidance. In both the groups, Omnipaque® (Iohexol) radio contrast dye was used for confirmation of correct placement of respective needles. A solution of 1 ml (40 mg) triamcinolone with 3 ml of normal saline was injected into the epidural space. The primary outcome measure was pain relief at the end of 2nd and 3rd week. Secondary outcome measures werestraight leg raising test (SLRT),reduction inanalgesic use, reversal of paraesthesia and subjectiveimprovement in walking tolerance. *Results:* In Group IL, NRS score decreased from preprocedural score of 7.77±1.2 to 4.73±1.1 and 4.27±1.5 at the end of 2nd and 3rd week post procedure respectively. Where as in Group TF, NRS score decreased from preprocedural score of 7.8±1.3 to 2.77±1.7 and 2.63±1.7 at the end of 2nd and 3rd week respectively. This difference in NRS score was statistically significant both at the end of 2nd week and 3rd week with Group TF having better pain relief. There was no statistically significant difference among the 2 groups with respect to improvement of SLRT and walking tolerance, reduction in analgesic use and reversal of paraesthesia at the end of 3rd week. *Conclusion:* Epidural steroid injection by trans-foraminal approach provides better subjective pain relief than interlaminar approach in the short term.

Keywords: Epidural; Interlaminar; Trans-Foraminal; Triamcinolone; Chronic Low Back Ache; Lumbar Radicular Pain.

Introduction

Low back ache and lumbar radiculopathy are common problems that affect most individuals at some time during their lives. Intervertebral disk herniation(IVDH) and degenerative lumbar spinal stenosis are the two most common causes of lumbar radiculopathy [1].

Epidural injection of steroids is one of the most commonly used interventions in managing chronic low back pain [1].[1] Steroids presumably exert their effects by limiting inflammatory response, inhibiting leukocyte aggregation, preventing degranulation of inflammatory mediators, stabilizing lysosomal and other membranes, and reducing the synthesis and release of proinflammatory mediators [2].

Lumbar epidural space is accessible by interlaminar (IL), caudal, and trans-foraminal (TF) approaches [3]. While significant differences have been described between these 3 approaches, interlaminar approach is considered to deliver the medication closely to the assumed site of pathology. Caudal epidural is considered as the safest and easiest with minimal risk of inadvertent dural puncture, and preferred modality in post-surgery syndrome, even though requiring

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relatively high volumes.Trans-foraminal approach is considered the target specific modality requiring the smallest volume to reach the primary site of pathology [5]. The potential advantages of trans-foraminal over interlaminar and caudal include targeted delivery of a steroid to the site of pathology, presumably onto an inflamed nerve root. Nowadays, increasing emphasis is placed on fluoroscopically guided, target specific injections to improve the treatment outcomes.

The present study was aimed at comparing the efficacy of interlaminar and trans-foraminal route of epidural steroid injection (ESI) for chronic low backache with unilateral lumbar radicular pain.

Materials and Methods

After obtaining institutional ethical committee approval, this prospective, randomised controlled study was conducted at our institution from January 2014 to July 2015.

Patients of either sex, aged between 18-60 years, belonging to American Society of Anesthesiologists (ASA) physical status I and II, having low back ache with single level IVDH with unilateral lumbar radicular pain of more than three months' duration were included in the study.

Patients who refused to undergo the procedure, patients with significant coagulopathies and on anticoagulants, previous history of allergy to contrast media, steroids and local anaesthetic agents, patients who had undergone spine surgeries or previously received ESI, patients with multi-level degenerative spine disease, unstable spine, spondylolisthesis and vertebral fracture were excluded from the study.

All the patients with low back ache were thoroughly examined at our departmental pain clinic. They underwent routine investigations and magnetic resonance imaging(MRI) of the lumbar spine. Among them sixty-six patients who satisfied the above-mentioned criteria were selected and equally allocated to one of the two groups (Group IL – Interlaminar approach and Group TF- Trans-foraminal approach). Randomization was done by sealed envelope technique. Patients were explained about the procedure being performed and written consent was obtained. Procedures were performed in an operation theatre(OT) equipped with a portable x ray image intensifier system (C-arm) and C-arm compatible OT table.

ESI was performed as out-patient procedure. Patients with standard nil per oral status were taken to the operation theatre, intravenous line was secured, and pulse oximeter, non-invasive blood pressure, electrocardiogram monitors were connected.

In Group IL, the procedure was performed in the lateral knee chest position. After preparation of the back,18 G Touhy epidural needle was advanced into the epidural space by loss of resistance (LOR) technique. Fluoroscopic lateral view of lumbar spine was obtained and Omnipaque® (Iohexol,300 mg of iodine per ml) was then injected into the epidural space after negative aspiration for blood and cerebro-spinal fluid(CSF), and correct placement of the needle in the epidural space was confirmed by appropriate flow of radiocontrast dye in the epidural space in fluoroscopic imaging (Figure 1) A solution of 1 ml (40 mg) of triamcinolone mixed with 3 ml of normal saline was injected into the epidural space.

In Group TF, with the patient lying in the prone position, lower back was prepared. The procedure was done under fluoroscopic guidance. After obtaining antero-posterior view of lumbar spine, C-arm was tilted 10-20º in oblique plane on the side of pathology so that the typical scotty dog picture can be visualised. A skin mark is placed directly over this point at the desired foraminal level. After infiltration of skin and subcutaneous tissues with 1% lignocaine, a 9 cm, 23G Quincke spinal needle was advanced toward 6 o'clock position of the pedicle until change in resistance was felt. At this point in the AP view the tip of needle should lie just below midpoint of pedicle. Then, lateral view was taken to ensure needle tip placement within the epidural space. Omnipaque® was injected after negative aspiration forblood and CSF. Fluoroscopic antero-posterior image was obtained and correct placement of the needle in the epidural space was confirmed by appropriate dye flow pattern (Figure 2). A solution of 1 ml (40 mg) triamcinolone with 3 ml of normal saline was injected into the epidural space.

Patients were monitored for 15 mins following the procedure. Pre ESI and post ESI, evaluation of patients was done by an investigator who was not involved in the administration of the ESI and blinded to the approach used for ESI. Data were collected after 15 mins, at the end of 2nd and 3rd week after ESI.

Primary outcome measure was pain relief at the end of 2nd and 3rd week after the epidural steroid injection using Numerical Rating Scale (NRS).NRS involves asking the patient to rate his or her pain from 0 to 10 (11point scale) with the understanding that 0 is equal to no pain and 10 is equal to worst possible pain [7].

Secondary outcomes measures were pain relief at 15minutes after the epidural steroid injection, straight leg raising test (SLRT) at 15 min, end of 2nd and 3rd week, reduction in analgesic use and reversal of paraesthesia and subjective improvement in walking tolerance (which is defined as the distance patient could walk without pain)at the end of 2nd and 3rd week after the epidural steroid injection.

Sample size was calculated based on previous studies [8,9,10] and assuming a 20% improvement in pain scores in TF group as compared to IL group at the end of 2ndand 3rd week, with an alpha value of 0.05 and power of 0.8, sample size was calculated to be 30 in each group. Assuming 10% drop out rate, the final sample size was set at 66 patients.

The collected data were entered into an excel sheet. After appropriate data cleaning, the data sheet was transferred and analysed using SPSS for Windows: IBM Corp, version 20, Armonk, NY, USA. Descriptive statistics were used to describe the study variables of the subjects. To compare the categorical qualitative data variables among the two study groups, Chi-square test and Fisher exact test were used and to compare the continuous quantitative data variables 't' test and Mann Whitney Test were used. The 'P' values were corrected by the Bonferroni method and a 'P' value less than 0.05 was regarded as statistically significant.

Results

Three patients in each group did not come for follow ups. Thirty patients in each group successfully completed the study. Two groups were comparable with respect to demographic data (Table 1).

Laterality of lumbar radicular pain were similar between 2 groups.19(63.3%) patients in group IL and 20(66.6%) patients in group TF had radicular pain on left side (Table 1).

Among the patients included in the study, 41 patients (68.3%) had IVDH at the level of L4-L5. 20 patients in group IL and 21 patients in group TF had IVDH at L4-L5 levels (Table 1).

At 15 mins after ESI, NRS pain score reduced from preprocedural score of 7.77±1.2 to 6.93±1 and 7.8±1.3 to 6.7±0.8 in IL and TF groups respectively. The difference was not statistically significant (Table 2).

In Group IL, NRS pain score decreased from preprocedural score of 7.77±1.2 to 4.73±1.1 and 4.27±1.5 at the end of 2nd and 3rd week respectively. In Group TF, NRS pain score decreased from preprocedural score of 7.8±1.3 to 2.77±1.7 and 2.63±1.7 at the end of 2nd and 3rd week respectively. This difference in NRS pain score was statistically significant both at the end of 2nd week and 3rd week with a P value of 0.001 with Group TF having better pain relief (Table 2).

SLRT measured in degrees' pre-procedure, at 15 minutes, at the end of 2nd and 3rd week after ESI were 68.67±14.5, 70±12.5, 80±8.9 ,80±8.9 and 63.33±14.5, 67±11.5, 79.67±8.9 and 80.83±8.8 respectively in group IL and group TF respectively. Improvement in SLRT was of similar magnitude in both the groups (Table 3).

Table 1: Patient characteristics

Parameters	Group IL (N=30) Number (%)	Group TF (N=30) Number (%)
Age(Years)		
20-30	8(26.7)	6(20)
21-30	9(30.0)	14(46.7)
31-40	7(23.3)	5(16.7)
41-50	6(20.0)	5(16.7)
Sex		
Male	28(93.3)	27(90.0)
Female	2(6.7)	3(10.0)
ASA physical status		
ASA I	28(93.3)	27(90.0)
ASA II	2(6.7)	3(10.0)
Laterality of radicular pain		
Left side	19(63.3)	20(66.7)
Right side	11(36.7)	10(33.3)
Level of IVDH		
L3-4	0(0.0)	2(6.7)
L4-5	20(66.7)	21(70.0)
L5-S1	10(33.3)	7(23.3)

Table 2: Comparison of numerical rating scale (NRS) in two groups

Intervals	IL group (n=30) Mean±SD	TF group (n=30) Mean ±SD	P value
Preprocedural	7.77±1.2	7.8±1.3	0.919
At 15 min	6.93±1.1	6.7±0.8	0.354
End of 2nd week	4.73±1.1	2.77±1.7	0.001
End of 3rd week	4.27±1.5	2.63±1.7	0.001

Table 3: Comparison of improvement in Straight leg raising test in two groups

Intervals	IL group (n=30) Mean ±SD	TF group (n=30) Mean ±SD	P value
Preprocedural	68.67±14.5	63.33±14.5	0.159
At 15min	70 ±12.5	67±11.5	0.338
End of 2nd week	80±8.9	79.67±8.9	0.885
End of 3rd week	80±8.9	80.83±8.8	0.717

Table 4: Secondary outcome measures

Parameters	Response	Group IL (N=30) Number (%)	Group TF (N=30) Number (%)	P value
Reduction in analgesic use	Yes	10(33.3)	7(23.3)	0.39
	No	20(66.7)	23(76.7)	
Reversal of paraesthesia	Yes	10(33.3)	11(36.7)	0.758
	No	4(13.3)	6(20.0)	
	None	16(53.3)	13(43.3)	
Improvement in walking tolerance	Yes	20(66.67)	24(80.0)	0.243
	No	10(33.33)	6(20.0)	

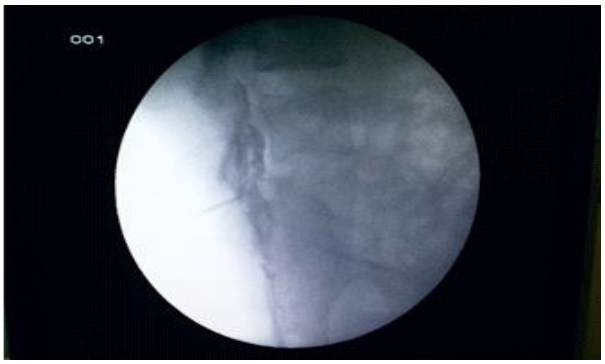

Fig. 1: Pattern of spread of radio contrast dye in interlaminar ESI

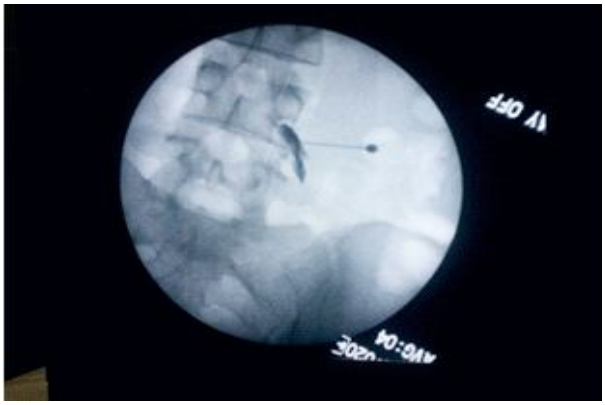

Fig. 2: Pattern of spread of radio contrast dye in trans-foraminal ESI

Use of analgesics was reduced in majority of the patients in both the groups. 20 (66.7%) patients in group IL and 23 (76.7%) patients in group TF found reduction in use of analgesics following the ESI (Table 4).

Paraesthesia disappeared in 10 (33.3%) patients in group IL and 11 (36.7%) patients in group TF at the end of 3rd week following ESI (Table 4).

There was no statistically significant difference among the 2 groups with respect to improvement in walking tolerance, reduction in use of analgesics and reversal of paraesthesia at the end of 3rd week (Table 4).

One patient in the IL group had a vasovagal reaction, 10 mins following the procedure which was successfully managed with inj. atropine 0.6mg and intravenous fluids. We did not encounter any other complication during the study.

Discussion

In our study, the primary outcome measure was to compare the pain relief between the two groups at the end of 2nd and 3rd week by using NRS. In Group IL,

NRS pain score decreased from pre ESI score of 7.77±1.2 to 4.73±1.1 and 4.27±1.5 at the end of 2nd and 3rd week respectively. In Group TF, NRS pain score decreased from pre ESI score of 7.8±1.3 to 2.77±1.7 and 2.63±1.7 at the end of 2nd and 3rd week respectively. This difference in NRS Pain score was statistically significant both at the end of 2nd week and 3rd week (P = 0.001) with Group TF having better pain relief (Table 2).

Secondary outcomes such as SLRT, reduction in use of analgesics, reversal of paraesthesia and walking tolerance improved from the preprocedural values at the end of 2nd and 3rd week following ESI in both the approaches. Though better improvement was seen in group TF, the difference in the improvement was statistically not significant (Table 3,4)

Visual Analogue Scale(VAS) has more practical difficulties than the VRS or the NRS, though all three pain-rating scales are valid, reliable and appropriate for use in clinical practice [11]. For simplicity, patients prefer the VRS, but it lacks sensitivity and the data it produces can be misunderstood. For general purposes the Numerical Rating Scale has good sensitivity and generates data that can be statistically analysed for audit purposes [10,11]. Hence, we used NRS to measure the intensity of pain in our study.

Gharibo GC et al [8] conducted a study to evaluate short-term benefit of IL versus TF ESI for the treatment of subacute lumbar radicular pain in patients with low back pain and unilateral radicular symptoms. Post-injection follow-up Numeric Rating Scale (NRS) was more greatly reduced in the TF group than IL group (1.7±1.4 vs 3.9±3.1). These findings are comparable with the results obtained in our study.

Rados I et al [9] in a randomized, prospective study compared the efficacy of two different routes in administering ESI (IL vs TF) in 64 patients with unilateral radicular pain. They concluded that using either route of epidural injections to deliver steroids for unilateral chronic radiculopathy secondary to herniated intervertebral disc provided significant improvements in patient's function and pain relief. However, they could not find a statistically significant difference between two groups either in functional improvement or in reduction in pain up to 24 weeks of follow ups.

This difference in the result, compared to our study can be explained by the fact that they used only half dose of the steroid and local anaesthetic (40 mg methylprednisolone and 3 ml of 0.5% lignocaine) in TF group as compared to IL group (80 mg methylprednisolone and 8 ml of 0.5% lignocaine). In our study, both groups received 40 mg triamcinolone made up to 4ml with normal saline in both the groups.

In our study, immediately (15 mins) after ESI pain reduced from a preprocedural NRS of 7.77 to 6.93 in Group IL and from 7.8 to 6.7 in Group TF. The difference among the 2 groups was not significant (P = 0.354).

Schaufele MK et al [10] in a retrospective study of 20 patients who received either ILESI or TFESI for the treatment of symptomatic lumbar IVDHs found thatILESI group felt significantly better pain relief immediately after the procedure. But overall, TFESI resulted in better short-term pain improvement and fewer long-term surgical interventions than interlaminar epidural steroid injection. The difference in the results between their study and our study can be explained by the fact that in their study, they used a mixture of steroid and local anaesthetics, in contrast we used only steroid injection.

In our study, most patients showed an improvement in SLRT of about 20^0 in both the groups by the end of 3rd week. The improvement in SLRT was almost equal in the 2 groups and hence, the difference in the improvement of SLRT between the 2 groups was not statistically significant. There are no studies available in literature so far, comparing the 2 routes with respect to SLRT.

As far as other short term benefits were considered, walking tolerance improved in 80% of patients in IL group as compared to 66.67% of patients in TF group. 33.3% of patients reported reduction in analgesic use in Group IL as compared to 23.3% in Group TF. 10 patients out of 14 (71.4%) in Group IL and 11 patients out of 17 (64.7%) in Group TF had reversal of paraesthesia. These differences between the 2 groups, with respect to the above parameters were not statistically significant.

Gharibo CG et al [8] in a prospective study to evaluate short-term benefit of IL versus TF ESI for the treatment of subacute lumbar radicular pain in 42 patients with low back pain and unilateral radicular symptoms, found similar magnitude of improvement in walking tolerance and reduction in use of analgesics among the 2 groups. These findings are similar to results seen in our study.

We agree with others that the more targeted delivery of the injectate along the inflamed spinal nerve is the most likely explanation for these better outcomes seen with TFESI [10,13].

The incidence of complications described in the literature with these epidural techniques is low. [13] The complications that can occur with epidural steroid injection are infection, hematoma formation,

vasovagal reaction, air embolism, dural puncture, anterior spinal artery syndrome, disc injury, trauma to spinal nerve or dorsal root ganglion and hypersensitivity reaction to the drug [14]. In our study, one patient in Group IL had vasovagal reaction 10 minutes following the procedure which was managed successfully. Though we used particulate steroid we did not come across any complication.

There are some limitations of the study undertaken. Long term outcome was not studied due to the shorter duration chosen for the study. Multiple level IVDH cases were not included in the study. Hence the results of this study may not be applicable to the patients with multiple level disc disease.

Further studies can be carried out to evaluate the long-term outcome of ILESI and TFESI, and efficacy of these approaches when IVDHs present at multiple levels. Studies using non-particulate steroids can be carried out to make epidural steroid injection safer and to evaluate the efficacy of non-particulate steroids as compared to particulate steroids.

Conclusion

Epidural steroid injection by trans-foraminal approach provides better subjective pain relief than interlaminar approach in short term. However, no significant difference is seen between two approaches with regard to improvement in SLRT, walking tolerance, reduction in analgesic use and reversal of paraesthesia in short term.

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