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Comparison of Trans-Foraminal Epidural Triamcinolone with or Without Local Anesthetic in Lumbar DISC Herniation for Pain Relief

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Abstract

Low back pain is a leading cause of disability and the commonest cause is intervertebral disc degeneration. We decide to compare the efficacy and safety of transforaminal epidural triamcinolone with or without local anaesthetic in the patients of Lumbar Disc Herniation for pain relief. Patients of low back pain with unilateral radiating pain not benefited by 6 weeks of conservative analgesia, having lumbar disc prolapse on X-ray and one-two level compression on MRI were included in the study. They divided into 2 groups; Group I receive fluoroscopic guided triamcinolone with bupivacaine, while Group II received Triamcinolone with normal saline. The patients were observed for improvement in VAS, ODI and at 3 weeks, 6 weeks and 9 weeks and analgesic intake after 9 weeks. The results showed improvement in VAS and ODI in both the groups but improvement was more in group I ($p<0.05$). Analgesic intake was also decrease in both the groups but more in Group I. We conclude fluoroscopic guided transforaminally injected triamcinolone is effective modality of treatment in lumbar disc degeneration patients. Its efficacy is improved by adding local anaesthetic with steroid.

Keywords: Transforaminal; Epidural Steroid; Visual Analogue Score; Oswestry Disability Index.

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Introduction

Chronic low back pain (LBP) is defined as pain persisting >12 weeks or longer, even after an initial injury or underlying cause of acute low back pain has been treated [4]. Twenty percent people affected by acute low back pain develop chronic low back pain with persistent symptoms at one year [25].

LBP is a leading cause of disability, having life time incidence of 80% in USA [18]. Prevalence is thought to be high in developing country like INDIA as people are living in more difficult environment and working under more compromised condition in terms of heavy exertion, repetitive bending, twisting or heavy lifting [21].

LBP can be caused by inter-vertebral disc degeneration, sprains and strains, lumbar disc herniation, degenerative arthritis, failed back surgery syndrome (FBSS), spinal stenosis, congenital defects like scoliosis & spina bifida. Among these, lumbar disc herniation is the most frequent cause of LBP. LBP can be treated conservatively or with intervention (epidural steroid or surgical). Conservative treatment like bed rest resolve pain by self healing but may have significant recurrence, different analgesics may

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relieve pain but have its own side effects and not able to cure the etiology. If the patients do not respond to such treatments within 4 to 6 weeks, they may be benefitted from an epidural steroid injection [32]. Surgical intervention is costly and has high failure rate in the form of FBSS [30]. Excision of the bulging or protruding disc that had not ruptured through the annulus resulted in complete relief in 63%, and removal of normal or minimally bulging disc resulted in complete relief in 38%, which is near the level for the placebo response[9].

Epidural steroid injection (ESI) has been used for the treatment of low back pain andd leg pain for more than 50 years [21]. Epidural injection were first given in 1901 with cocaine for low back pain while the first use of epidural steroid was reported in 1952 using hydrocortisone through sacral route[27]. Recent research reports that lumbar epidural steroid injections are successful in 80%patients with persistent sciatica from lumbar disc herniation [29], Steroid injections not only reduces inflammatory mediators (e.g. neural peptides, phospholipase A, histamine, and kinin) but also block nerve conduction via nociceptive C fibers, thus suppressing the direct pain pathway and further relieving the symptoms [23]. It also decreased sensitivity of nerve roots to irritants [23,1].

Even in experienced hands, the epidural steroid without the use of fluoroscopy or contrast media may be misplaced from the intended target in 30% of cases [36,31]. There are 3 approaches for ESI

1. Transforaminal

2. Translaminar

3. Caudal. Fluoroscopic guided transforaminal ESI is more accurate, specific nerve root can be blocked and safe because low volume is required which in turn reduces systemic side effects. The agents commonly used for ESI are:

1. Triamcinolone

2. Hydrocortisone

3. Betamethasone acetate and

4. Methylprednisolone [23,24]. Amongst these, Triamcinolone is most commonly used agent being most potent and having higher anti-inflammatory action as compared to hydrocortisone and methylprednisolone. Present study was conducted to determine the efficacy of fluoroscopic guided transforaminal epidural injection using triamcinolone with or without bupivacaine in patients of chronic LBP with or without radiculopathy.

Materials and Methods

After approval from the Institutional Review Board [(IRB No.594/2016) & (CTRI registration no. CTRI/2017/06/008933)] and informed written consent from all the patients, this prospective, randomized, double blind controlled study was carried out in the Department of Anaesthesiology, Govt. Medical College and Sir. T. Hospital, Bhavnagar, Gujarat. The patients who were referred to pain clinic having history of chronic low back pain and treated by IITV guided transforaminal lumbar epidural steroid injection were enrolled in this study. After thorough preanaesthetic check up, patients were included and excluded according to following criteria.

Inclusion Criteria

- Age 20-70 years.
- Sex: Either gender
- Patients with history of low back pain with unilateral radiating pain at least below the knee joint and not relieved with 6 weeks of conservative analgesia.
- Lumbar disc prolapse visible on plain radiograph & 1- 2 level compression visible on MRI.

Exclusion Criteria

- Patient refusing to give consent.
- Antenatal female.
- The patients who had previous surgery at the lumbar spine
- Previous history of epidural steroid injections.
- Allergies to contrast media and/or local anaesthetic.
- Gross neurological deficits.
- Cauda equina syndrome
- Inflammatory joint diseases
- Pars defects.

The patients were randomized using computer generated random number sequence method into 2 groups:

Group I: Patients received IITV guided TFESI using triamcinolone 40 mg + 2ml 0.125% Bupivacaine

Group II: Patients received IITV guided TFESI using triamcinolone 40 mg + 2ml Normal saline

- The vital parameters heart rate (HR), non invasive blood pressure (NIBP) and peripheral

oxygen saturation (SpO_2) were recorded in the pain clinic.

- Haemogram, RFT and RBS were done before procedure.
- Clinical examination was performed by Straight Leg Rise (SLR) Test, deep tendon reflex and motor and sensory deficit if any.
- Written informed consent was taken in local language.
- The patients were shifted to pre-procedure room, 22G intravenous catheter was inserted on non dominant hand, SpO_2 was recorded using pulse oxymeter.
- Patient was shifted to procedure room and prone position was given. The pillow was put under the abdomen to correct lumber lordosis.
- C-arm fluoroscope was positioned to locate T_{12}-L_1 interspinous space and then identified the level of spine and foramen of target level.
- The "Scotty dog" appearance was obtained in oblique view (as shown in Fig. 1) After local infiltration with 2% Lidocaine, a 23G spinal needle was advanced. By maintaining tunnel view using subsequent IITV images, the lateral view was obtained to confirm the needle position in posterior and superior transforaminal space. The non ionic contrast media 0.5-1 ml (Diatrizote Meglumine) was injected to confirm the neural spread in AP view. After confirming the neural spread, Triamcinolone (40mg) was injected slowly with or without local anesthetic according to assigned group. Patient was shifted to the recovery room and observed for one hour and discharged, if no complications.

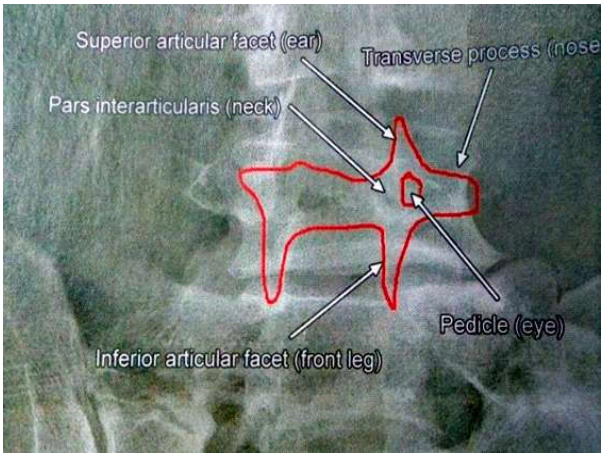

Fig. 1: Scotty Dog apperance

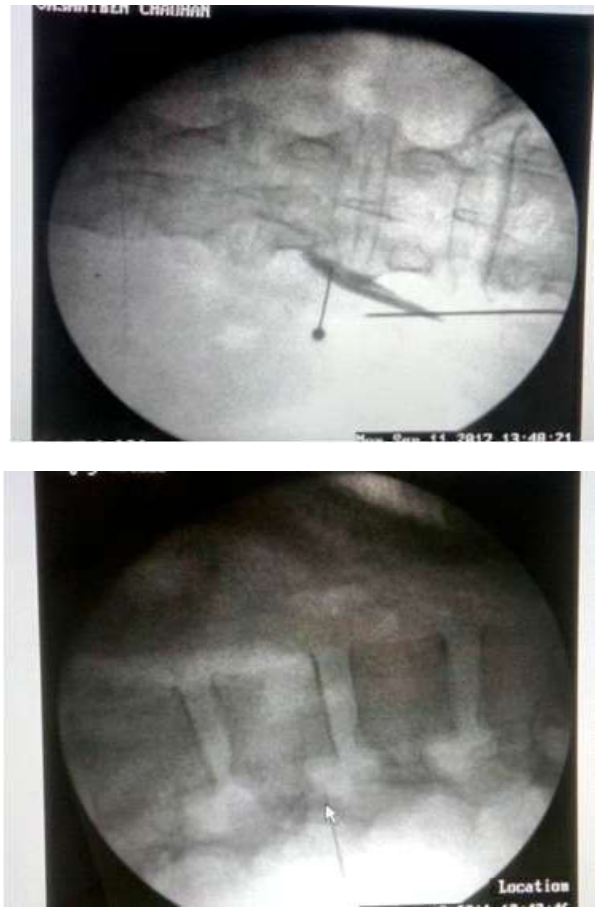

Fig. 2: AP and lateral view of lumbar vertebra

Antero posterior and Lateral view of Lumbar vertebra is shown in fig. 2.

- At the interval of 3, 6, 9 weeks, short term outcome will be assessed using

1. Subjective assessment of pain using VAS.
2. Functional assessment using ODI. (Table 1)
3. Frequency and total dose of NSAIDS intake was compared with preoperative usage at the end of 9 weeks.
4. Successful outcome of the treatment with the help of VAS, ODI and presence of pain (Table 2).

Visual Analogue Score[35]

VAS score is a psychometric response scale which is subjective. When responding to VAS system respondent specify their level of agreement to a statement by indicating a position along a continuous line between to end position.

Visual Analogue Score as given in Fig 3.

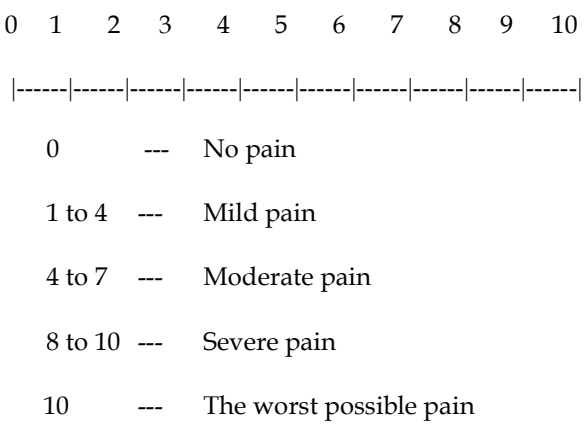

Fig. 3: Visual Analogue score

Oswestry Disability Index: [12]

- It is important tool that evaluate patient's permanent functional disability and gold standard method for pain assessment.
- It includes ten sections. Each section is having 6 points which are scored from 0-5 according to intensity.

Sections are:

1. Pain intensity	2. Personal care
3. Weight Lifting	4. Walking
5. Sitting	6. Standing
7. Sleeping	8. Sex-life (if applicable)
9. Social Life	10. Travelling

The questionnaire has been designed to give us information to know how back or leg pain is affecting ability to manage everyday life.

Calculation of ODI

- Summation of all section score divided by possible maximum score,

And % of score will be calculated.

Example: 16 (total score)/50 (Total possible score) X 100 = 32%

Interpretation of score as shown in Table 1

Table 1: Interpretation Of ODI Score

	Interpretation of ODI score	
1	0-20%	Minimal Disability
2	21-40%	Moderate Disability
3	41-60%	Severe Disability
4	61-80%	Crippled
5	81-100%	Bed ridden

Successful outcome of treatment as shown in Table 2

Table 2: Outcome of treatment

Grade	Improvement in VAS	Improvement in ODI	Pain relief
Excellent	>50%	>30%	100% pain relief
Good	>50%	>30%	>50% pain relief
Fair	<50%	<30%	< 50% pain relief
Poor	No improvement	No improvement	No improvement

Excellent - Good - > Successful treatment
Fair - Poor - > Unsuccessful treatment

Statistical Analysis

The data obtained in the study for various parameters are presented in the tabulated form using statistical software (graph pad prism statistical software). Mean and standard deviation will be calculated for all the quantitative variables. Intra group comparison will be made using the Turkey Kramer test and inter group comparison among the different groups will be done using repeated measures ANOVA. Inter group comparison of qualitative data will be done by chi square test. p value <0.05 w considered statistically significant.

Sample size calculation assuming a error being 0.05 and ß error being 0.2with a power of study 80% showed that 30 patient will be required per study group to compare the effect of trans foraminal injection triamcinolone with Bupivacaine and Injection triamcinolone with Normal Saline.

Observation and Results

Demograpic Data

As shown in Table 3, patient characteristics in terms of age, gender, weight and height were comparable among the two groups (p>0.05).

VAS Score

As shown in Table 4 and 5 the comparison of VAS intra group with pre injection (Baseline) is <0.05. The difference is significant in both the groups

As shown in figure 4 Intergroup Comparison of VAS between pre injection and post injection is not significant. While between 3weeks, 6weeks and 9weeks is significant.

ODI Score

As shown in Table 6 and 7 the comparison of ODI score intra group with pre injection is <0.05, The difference is significant in both the groups .

Table 3: Demograpic Data

Patient Characteristics	Group I (Bupivacaine) (n=30) (Mean ± SD)	Group II (NS) (n=30) (Mean ± SD)	P value
Age (Years)	43.266± 14.47	46.6±14.419	0.375
Sex (M/F)	16/14	11/19	0.72
Weight (Kg)	57.33±7.725	58.7±7.134	0.729
Height (cm)	157.5±3.560	158±4.012	0.189

As P value is more than 0.5 demographic comparison is not significant

Table 4: Intragroup comparision of VAS score in Group I:

Pre injetion Mean±SD Baseline	Post injection Mean± SD	P value	After 3 weeks Mean± SD	P value	After 6 weeks Mean± SD	P value	After 9weeks Mean± SD	P value
7.766±0.9353	6.4666± 1.332	<0.001	5.133± 1.196	<0.001	3.50± 1.042	<0.001	2.233± 1.006	<0.001

As the comparison of VAS intra group with pre injection (Baseline) is <0.05. The difference is significant.

Table 5: Intragroup comparison of VAS score in Group II

Pre injetion Mean±SD Baseline	Post injection Mean± SD	P value	After 3 weeks Mean± SD	P value	After 6 weeks Mean± SD	P value	After 9weeks Mean± SD	P value
7.633± 0.808	6.533± 0.8604	<0.0001	5.70± 0.5960	<0.0001	4.566± 1.006	<0.0001	3.70± 1.022	<0.0001

As the comparison of VAS intra group with pre injection (Baseline) is <0.05. The difference is significant.

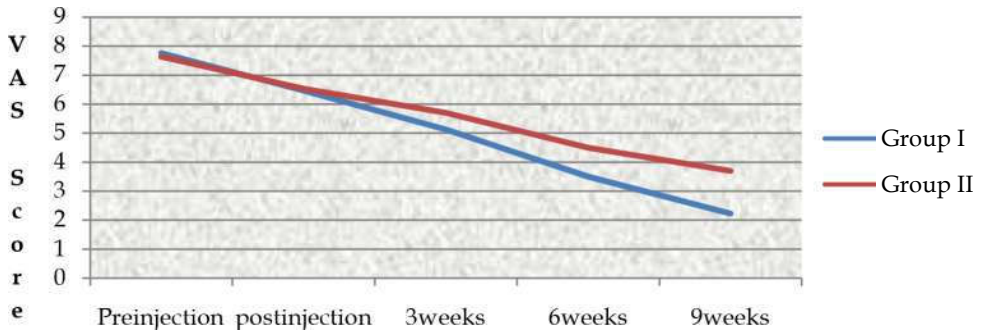

Fig. 4: Intergroup Comparision of VAS Score

VAS score was comparable at pre injection, post injection interval in both the groups while at 3weeks, 6weeks and 9weeks statistically significant decrease in VAS score in Gr.I compared to Gr.II.

Table 6: Intragroup comparision of ODI score in Group I

Pre injetion Mean±SD Baseline	After 3 weeks Mean±SD	P value	After 6 weeks Mean±SD	P value	After 9weeks Mean±SD	P value
3.7± 0.6513	2.8± 0.4842	<0.05	2.0± 0.6433	<0.05	1.4± 0.4983	<0.05

As the comparison of ODI score intra group with pre injection is <0.05, The difference is significant.

Table 7: Intragroup comparision of ODI score Group II

Pre injetion Mean±SD Baseline	After 3 weeks Mean± SD	P value	After 6 weeks Mean± SD	P value	After 9weeks Mean± SD	P value
3.66 ± 0.6609	3.133± 0.6814	<0.05	2.633± 0.7649	<0.05	2.3± 0.7944	<0.05

As the comparison of ODI score intra group with pre injection is <0.05, The difference is significant.

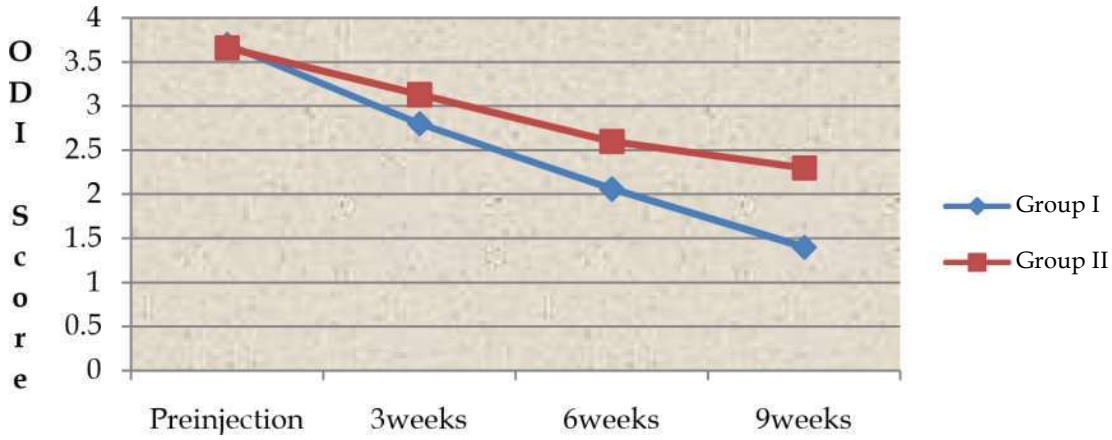

Fig. 5: Inter group Comparison ODI Score

ODI decreased more in Gr. I compared to Gr. II at 3weeks, 6weeks and 9weeks interval. (p <0.05)

Table 8: Analgesia intake comparison of both group

	Group I (n=30)	Group II (n=30)
Pre-injection	30(100%)	30(100%)
After 9 weeks	4(13.33%)	8(26.66%)

Analgesic intake at 9 weeks interval was 13.33% in Gr. I and 26.66% in Gr.II

Table 9: Successful Outcome of the treatment

	Number of Patients			
	Excellent	Good	Fair	Poor
Group I- Bupivacaine	3(10%)	22(73.33%)	5(16.66%)	0
Group II-NS	0	15(50%)	14(46.66)	1(3.33%)

Outcome of Gr. I is more successful as compare to Gr. II

As shown in Figure 5 Comparison of intergroup ODI, pre injection is not significant, while at 3 weeks, 6 weeks and 9 weeks is significant as p value is <0.05.

Analgesic intake as shown in Table 8, Analgesic intake at 9 weeks interval was 13.33% in Gr. I and 26.66% in Gr. II As shown in Table 9, Outcome of group 1 is more successful as compare to group 2.

Discussion

Back pain, the ancient curse, is now an international health issue of major significance. Impairments of the back and spine are ranked as the most frequent cause of limitations of activity in people younger than 45 years by the National Centre for health statistics. Hult [6] estimated that up to 80% of people are affected by these symptoms at sometime in their lives. Andersson [3] noted the lifetime incidence of low back pain to be 61% in 40-47 years old man and 66% in woman.

Degenerative lumbar spondolythiasis (DLS) is found to be a common cause of low back pain, radiculopathy and neurogenic claudication in adults. The superior vertebra slides forward on an inferior resulting in narrow central canal and lateral recesses which lead to wide range of clinical presentation.

Multiple factors also contribute to the development of the back pain. Frymoyer et al. [13]noted that risk factors associated with severe lower back pain include jobs requiring heavy repetitive lifting, the use of jackhammers and machine tools and the operations of motor vehicles. They noted that patients with severe pain were more likely to be cigarette smokers and had greater tobacco consumption. They also reported that patients with backache had more episodes of anxiety and depression and had more stressful occupations.

The definitive treatment of DLS is disc removal but surgical management was not universally successful. A study [33] shows that the primary benefit of surgery was early in the first year, but with time statistical significance of the improvement was lost. The incidence of persistent back pain after surgery was found to inversely proportional to the degree of herniation [32]. Non progressive neurological deficits can be treated non-operatively with expected improvement clinically. The judicious use of epidural steroids also is supported.

Epidural steroid injections have been used since decades in the management of low back pain. It is minimally invasive and effective treatment modality in many orthopaedic centres. While doing literature search, more than 40 (approximately 4000 patients), mostly uncontrolled studies have been published on the efficacy of lumbar and caudal epidural corticosteroid injections. According to Bogduk [5], only 4 studies are not in favour of the use of lumbosacral epidural corticosteroids in the management of radicular pain in the lumbosacral spine. Landa et al.[20] defined two major types of lumbar epidural injections, the translaminar epidural steroid injection (TLESI) and transforaminal epidural steroid injection (TFESI). Few studies [20,28] reported that TFESI was superior to the TLESI for treating lumbar disc herniation. The former (TFESI) typically focus on single nerve root pathology while the later (TLESI) best address diffuse symptoms. The transforaminal approach allows access to the ventral epidural space, where the disc lies, and thus, is thought to be most effective for a mono-radiculopathy due to disc herniation. As proven by several studies transforaminally injected corticosteroids provide pain relief by inhibiting nerve root oedema with improved microcirculation and reduced ischemia, inhibition of prostaglandin synthesis, and also the anti-inflammatory action of direct inhibition of C-fibre neuronal membrane excitation [17].

Accidental intravascular injections also can occur, as the absence of blood return with needle aspiration before injection is not a reliable indicator of this complication.

Additional benefits can be achieved by adding local anaesthetic Bupivacaine which provides additive anti-inflammatory effect with triamcinolone and immediate pain relief [6]. Particles of triamcinolone vary greatly in size and are densely packed. When diluted with Bupivacaine triamcinolone may coalesce into large (>100 microgram) aggregates causing clouding of the solution. Manchikanti et al. [22] had done a two year follow up of patients who had given fluoroscopic guided epidural injections with or without steroids and concluded that both the types of injection were effective for a selected group of patients having chronic function limiting low back and lower extremity pain secondary to lumbar spinal stenosis.

The present study shows lower VAS in group I compared to group II at post injection, 3 weeks, 6 weeks and 9 weeks interval ($p<0.05$), however while doing intra group comparison there is significant lowering of VAS on subsequent visits in both the groups ($p<0.05$). The results of improvement in VAS of this study is supported by Dr. Ahadian et al.[2] who documented safety and efficacy of transforaminal steroid in different doses, and found significant improvement in VAS by the end of 12th week however they used dexamethasone. In present study there is also significant improvement in VAS on subsequent visits which is correlated by a study done by Dr Jamadar et al. [11] on "Efficacy of Epidural Steroid Injections in Management of Chronic Low Back Pain", he found significant improvement in VAS score in subsequent visits of next 6 months. But he used methylprednisolone instead of triamcinolone.

ODI is considered as the gold standard for measuring degree of disability and estimating quality of life in a person with low back pain. The result of this study shows improvement in functional ability in terms of lowered ODI in group I compared to group II at 3 weeks, 6 weeks and 9 weeks interval ($p<0.05$) in both the groups, however while doing intra group comparison there is significant improvement in functional ability in terms of lowering of ODI on subsequent visits ($p<0.05$). The result of this study can be correlated with the study of Koes et al. [19] who reviewed 12 randomised controlled trials to assess the efficacy of epidural steroid injections for low-back pain and found effective in six studies, other six are not better or worse than the reference treatment. Dr. Jamadar [11] as mention earlier also found similar results in ODI as VAS.

We also compared frequency of analgesic intake in both the groups. It is observed that there is significant decrease intake of analgesics in group I compared to group II at 9 weeks . This may be due to Local anaesthetic has immediate pain relief and anti inflammatory action. While doing intra group comparison there is decrease in analgesic intake in both the group compared to pre injection requirement.

The improved VAS, lower ODI and lesser requirement in analgesic intake in group I compared to group II may be due to addition of local anaesthetic solution to steroid in group I. Local anesthetics are useful adjuvant with triamcinolone as it provides immediate pain relief and has additive anti-inflammatory effect with triamcinolone. It is also supported by a study done by Reiw et al. [26] who compared transforaminally injected Bupivacaine with betamethasone with Bupivacaine alone and found that local anaesthetic with steroid is more effective however he had given only local anaesthetic in other group.

Varied range of complication may be encountered during the course of epidural injection. The most adverse immediate reaction during an epidural injection is vasovagal reaction. Accidental intravascular injection is also a common complication of epidural injection having rate of 11.2% [34]. The paraplegia can be considered as most fearsome complication which occurs via the artery of Adamkiewicz which travels with the nerve root through the neural foramen and supplies the anterior spinal artery [10,16] Houten et al. [16]reported on three cases of paraplegia after lumbosacral nerve block believed to be the result of inadvertent intraarterial injection and an unusually low origin of the artery of Adamkiewicz. Another common adverse reaction is infection which was reported by Goodmen et al.[15], and cited the frequency of infections from epidural / transforaminal steroid injections as varying from 1% to 2% with more severe infections being noted in approximately 0.1% of patients. One more complication, dural puncture has been estimated to occur in 0.5%-5% of patients having lumbar epidural steroid injections. The anaesthesiology literature reported a 7.5% to 75% incidence of post dural puncture headaches, with the highest estimates associated with the use of 16 and 18 gauge needles [7]. Few serious complications have been reported as individual case reports who receive epidural corticosteroid injection; they are epidural abscess, hematoma [14], duro cutaneous fistula and cushing syndrome. All the above complications might be more common if the epidural injection was given by conventional techniques, but in this study we had given fluoroscopy guided transforaminal epidural steroid, so we might not encountered any of mentioned complications. It indicates safer approach of epidural steroid injection. There were no any neurological deficits were observed in our study.

In this study, long term follow up in the form of surgical intervention and chronic usage of analgesics was not evaluated due to limited time period. We have also not assessed long term improvement in pain relief in the form of VAS and functional disability in the form of ODI.

Epidural steroid injection is found to be one of the effective non-operative modality for the patients of lumbar disc prolapse having low back pain with lower limb radiating pain. We recommend use of TFESI with Bupivacaine (success rate of 83.33%) before surgical intervention.

Conclusion

This randomized clinical trial comparing the efficacy of fluoroscopic guided transforaminal triamcinolone with or without local anaesthetic in the chronic low back pain patients concludes tha–

1. Transforaminally given epidural corticosteroid-triamcinolone with or without bupivacaine is effective in the treatment of chronic low back pain as it reduces VAS and improves the ODI on subsequent visits compared with pre injection values.

2. The study shows that triamcinolone with bupivacaine is more effective in the pain relief and improving functional ability as compared to triamcinolone with normal saline.
3. The frequency of analgesic intake is decrease in both the groups but more in Group I.
4. TFESI can be considered as successful treatment modality in chronic LBP in patients of lumbar disc herniation as it improves VAS > 50% and functional disability in the form of ODI > 30%.

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