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COMPARISON OF THE EFFECTIVENESS BETWEEN FLUOROSCOPY GUIDED TRANSFORAMINAL EPIDURAL AND CAUDAL EPIDURAL DEXAMETHASONE INJECTION IN THE REDUCTION OF PAIN AND DISABILITY IN POST LAMINECTOMY SYNDROME: A RANDOMIZED CONTROLLED TRIAL

Medical Science

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ABSTRACT

Low back pain is a highly prevalent, worldwide problem and is a very frequent reason for medical consultations. Epidural fibrosis is a complication of laminectomy surgery done for low back pain. Use of epidural steroid injections has been shown to decrease the frequency and intensity of the pain in post laminectomy syndrome.

In this study, 24 patients from Manipur, who were diagnosed as post-laminectomy syndrome with epidural fibrosis on magnetic resonance imaging (MRI) were randomly assigned into 2 equal groups. Group A (caudal epidural) and group B (transforaminal epidural). Both groups were injected dexamethasone injection and outcomes measured by using Visual Analogue Scale (VAS) and Oswestry Disability Index (ODI) and compared base line with outcomes at 1, 4 and 8 weeks

In this study both fluoroscopy guided caudal epidural and transforaminal epidural dexamethasone injections are effective in reducing pain and functional disability in post laminectomy syndrome.

However, transforaminal epidural injection is better than caudal epidural. High concentration of steroid in the target site accounts for the result.

KEYWORDS

Low Back Pain, Post Laminectomy Syndrome, Caudal Epidural, Dexamethasone, Hiatus, Oswestery Disability Index

INTRODUCTION:

Low back pain is a worldwide problem and highly prevalent condition that can have a tremendous social, financial, and psychological impact on a patient's life. An estimated global incidence of low back pain is 9.4%, creating more disability than any other condition in the world.[1] Post-laminectomy syndrome (PLS), or "Failed Back Surgery Syndrome" (FBSS), is defined by the International Association for the Study of Pain (IASP) as back pain, with or without referred or radiating pain, that is located mainly in the lower limbs, is of unknown origin and persists or begins after surgical procedures are performed to treat lumbar disc herniations.[2]

The incidence of failed back syndrome have not declined, despite advances in surgical technology with an overall incidence of up to 10-40%. Factors contributing to development of PLS may occur in the preoperative, intraoperative, and postoperative periods.[3] Epidural fibrosis accounts 20% to 36% of all cases of PLS. However, conditions like epidural fibrosis, discogenic pain, disc herniation and spinal stenosis, are amongst many conditions which do not require repeat surgery and are managed by interventional techniques.[4,5] Epidural steroid injections and adhesiolysis are two of the most commonly utilized interventions for managing long term pain in PLS. The analgesic effects of corticosteroids most likely are related to the following mechanisms:

1) Inhibition of Phospholipases A2 (PLA2) and inflammation
2) Membrane stabilizing action resulting in inhibition of ectopic discharge
3) Inhibition of neural transmission in nociceptive C-fibers
4) Reduction of capillary permeability.[6]

But the use of epidural injection has been associated with many controversies and has faced criticism for its use in all the above indications majorly due to lack of clinical evidence.[7,8] Multiple studies have been criticized, most importantly for their design and their inability to confirm the location of the injection by not using fluoroscopy.[9] So we performed this randomized controlled trial to compare effectiveness between fluoroscopy guided lumber epidural and caudal epidural dexamethasone injection in 24 patients with post laminectomy syndrome.

MATERIALS AND METHODS:

A randomized control trial on 24 patients from Manipur, who were diagnosed as post-laminectomy syndrome with epidural fibrosis on magnetic resonance imaging (MRI) and admitted in the Physical Medicine and Rehabilitation ward, Regional Institute of Medical Sciences (RIMS), Imphal, India, was conducted from 1st August 2017 to 31st July 2019. Approval from the research ethics board, RIMS, Imphal was taken before the start of the study and written informed consent which described in detail all aspects of the study and withdrawal process were provided to all the subjects.

Patients with PLS with epidural fibrosis on MRI, pain severity with minimum score of 5 based on 10 point scale VAS (Visual Analogue Score), ODI (Oswestry Disability Index) score more than 40 percent,

willingness to comply with treatment and follow-up assessments were included in the study. However, patients with mental or physical condition that would invalidate evaluation results, cauda equina syndrome, pregnancy, systemic or local infection at site of injection, known allergy to corticosteroids, contrast dye or anesthetics, history of any malignancy, bleeding disorders, uncontrolled hypertension, uncontrolled diabetes mellitus, prior history of epidural steroid injection in the past 3 months and subjects who refuse to sign informed consent were excluded from the study.

Patients enrolled in the study were assigned into two groups (Group A and B) by block randomization method. Group A received fluoroscopic guided caudal epidural injection with dexamethasone phosphate 8mg while Group B received fluoroscopic guided transforaminal epidural injection with dexamethasone phosphate 8mg mixed with preservative free xylocaine.

For transforaminal epidural injection, fluoroscope was placed in the antero-posterior (AP) position, tilted it if necessary in a cephalad to caudal motion to "square up" the end plates of the vertebral bodies. The level of interest was visualized and the fluoroscope rotated obliquely towards the side of the pain. The fluoroscope was rotated enough so that the lateral border of the pedicle 1 to 2 mm being superimposed on the lateral edge of the vertebral body. The initial target was the 6 O' clock position of the pedicle. Under aseptic condition skin and subcutaneous tissues were anesthetized using 2% preservative free lignocaine. A 22-gauge 10 cm spinal needle was advanced towards the target point. The needle position is then checked initially in the AP position and subsequently in the lateral position to ensure that the tip of the needle is finally at optimum position. At this point in the AP view tip of the needle should lie just below the midpoint of the pedicle and should not cross the facet joint line. In the lateral view the needle tip should lie in the posterior superior quadrant of the neural foramen. One ml of radiopaque dye (Iohexol) was injected and confirmed appropriate position by fluoroscope. Once an epidurogram was obtained, 8 mg of Dexamethasone diluted with lignocaine was injected into the epidural space.[10] Transforaminal injection was given only for one nerve root which was responsible for maximum symptoms in patient.

For caudal epidural injection the patient was placed prone with a pillow placed beneath the head. The legs and heel are abducted for relaxation of gluteal opening and toes were internally roated. Sacral hiatus was identified and under aseptic conditions, local infiltration was done with 2% preservative-free lignocaine. A 22-gauge epidural needle was advanced at an angle of 45° to the skin until a 'give-way' sensation was felt and position of the needle was confirmed by lateral and AP fluoroscopic images. Then 5 ml of iohexol solution was injected through it to confirm the position. A properly placed needle was confirmed by classical appearance of 'inverted fern tree' or a 'filling defect' in AP view after dye injection. The needle was introduced up to S3 level for proper spread of the drug.[11]

Patients were advised bed rest for 2 hours. Follow up assessments were done at 1st, 4th and 12th weeks post treatment. No additional intervention was given to any patient and there were no specific additional interventions were continued during the entire study.

Images:

Figure 1: Position of patient and local skin infiltration with xylocaine

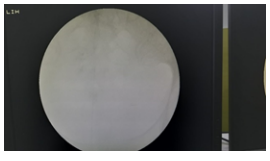

Figure 2: Classical 'inverted fern tree' appearane on lateral view

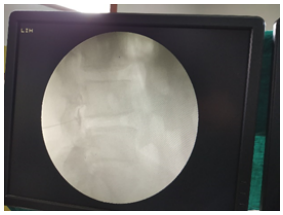

Figure 3: Transforaminal epidural space confermed on lateral view

Statistical analysis:

A sample size of 24 patients (12 in each group) was calculated using formulae;

$N= (z\alpha+z\beta)^2 (S_1^2+S_2^2)/ (m_1-m_2)^2$

Where, S= standard deviation, m= mean, zα= 1.96 at 95% CI, zß= 1.28 at 90% power and taking into consideration a drop-out rate of 10%.[12]

Data analysis were done using Statistical Package for Social Sciences (SPSS) version 21. Descriptive analysis including mean, percentage, and standard deviation were used. Independent t-test was used for significant test between group comparison of mean scores and Paired t-test was used for within group comparison over time. Value of $p < 0.05$ was considered to be statistically significant.

RESULTS:

Table 1. Baseline characteristics of the patients

Characteristics	Group A N(SD%)	Group B N(SD%)	P value
Mean age (yrs)	48.33 (9.90)	46.67 (4.89)	0.608
Gender Male Female	 4 (33.33) 8 (66.66)	 5 (41.6) 7 (58.3)	0.67
Side of affection Unilateral Bilateral	 8 (66.6) 4 (33.3)	 6 (49.9) 6 (50.1)	0.408
Duration (months)	9.17 (3.69)	9.50 (1.78)	0.781
BMI	25.01 (1.60)	23.77 (4.50)	0.376
VAS	8.0 (0.60)	7.33 (0.98)	0.54
ODI	81.23 (7.69)	78.94 (4.63)	0.62

There were no significant differences in the baseline characteristics of the two groups (table 1) and hence were comparable ($p>0.05$).

Table 2. Mean improvement in VAS and ODI in the follow up

Follow up eriod	VAS			ODI		
	Group A	Group B	P value	Group A	Group B	P value
1 Week	5.17 (1.11)	4.0 (1.04)	0.00	53.85 (12.0)	43.49 (8.0)	0.00
4 Week	3.50 (1.0)	2.67 (0.78)	0.00	35.08 (10.87)	30.50 (10.11)	0.00
8 Week	2.67 (0.78)	1.83 (0.72)	0.00	26.56 (6.86)	23.93 (11.50)	0.00

Mean age of the patients in the Group A (Caudal epidural injection) and Group B (Transforaminal epidural injection) were 48.33±9.90 and 46.67±4.89 years respectively.

Females constituted 62.5% (n=15) of the total patients. Radiating pain to both lower limb was found in 41.66% (n=10). The reduction of pain intensity was measured by VAS score showed significant reduction at the follow up periods in both the groups. Group B showed better improvement in pain from baseline to 8 weeks as shown by reduction in VAS score from 7.33±0.98 to 1.83±0.72. Reduction in Oswestry Disability Index (ODI) from 78.94±4.63 to 23.93±11.50 in Group B was significantly more than 81.23±7.69 to 26.56±6.86 in Group A ($p=0.000$).

DISCUSSION:

The incidence of postlaminectomy syndrome (PLS) is up to 40%, where patient presents with recurrent and persistent pain with or without radiculopathy in spite of successful disc related spine surgery. The possible pathological changes may include inflammation, edema, fibrosis, venous congestion, mechanical pressure on the posterior longitudinal ligament, reduced nutrient delivery to spinal nerve or nerve root, and central sensitization.[3] The treatments of PLS include

physical therapy, minor nerve blocks, transcutaneous electrical nerve stimulation, behavioral medicine, nonsteroidal anti-inflammatory medications, membrane stabilizers, antidepressants, spinal cord stimulation, and intrathecal morphine pump.[13]

Magnetic resonance scanning is needed to differentiate epidural fibrosis from residual disc herniation, foraminal stenosis or new lateral disc prolapse in patients with failed back surgery syndrome.[14] Fager and Freidberg concluded following analysis of FBSS about poor results with recurrence of pain in 55% of cases of re-surgery.[15] The patients developing extensive epidural fibrosis are likely to get recurrent radicular pain caused by peridural scar formation and abnormal dorsal root ganglion response. Use of epidural steroid injections has been shown to decrease the frequency and intensity of the pain.[16,17]

Considering the above evidences and availability at our setup we planned for transforaminal epidural steroid injections and caudal epidural steroid injection in our patient. In our study we found reduction in pain and improvement in functional score are significantly more in patients receiving transforaminal epidural injection at 1, 4 and 8 weeks follow ups (p value< 0.05, Independent t-test). This may be because of high concentration of steroid at target site as transforaminal injection route is lateral which allows high concentration of corticosteroid to be delivered precisely to the target site while caudal epidural injection route is dorsal, and the dorsal median epidural septum may confine the spread of dorsal epidural flow to the side ipsilateral to the injection. A retrospective study had shown that 50% of failed back surgery syndrome patients had more than 50% pain relief after transforaminal epidural injection.[18] Kim et al. demonstrated that 34% of post laminectomy syndrome patients had 50% pain relief as result of caudal epidural steroid injection.[19]

Our study has not long term followup results. However, epidural injection should not be the solo therapy for patients with PLS. Ultimate goal of epidural steroid injections is to provide pain relief so that psychology, physical therapy, and pharmacologic management can be maximized to lead behavioral changes.[7] However, there are no prospective comparisons between caudal and transforaminal injection techniques in post laminectomy syndrome patient population. Our study compared the efficacy of transforaminal and caudal epidural injections. However, our patient population is small. A future randomized, double-blinded, placebo-controlled, large patient population study is necessary.

There were no major complications following caudal and transforaminal epidural injection. One patient had mild paralumbar muscle spasm, another patient complaint of nausea and headache and were managed conservatively.

CONCLUSION:

Fluoroscopy guided caudal epidural and transforaminal epidural dexamethasone injections are effective in reducing pain and functional disability in post laminectomy syndrome. However, transforaminal epidural injection is better than caudal epidural.

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