ORIGINAL RESEARCH

Therapeutic efficacy of epidural bupivacaine with or without corticosteroid in intervertebral disc prolapse: A randomised controlled study

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ABSTRACT
The role of local anaesthetics or saline in epidural injections is emerging. There have been contradicting opinions regarding whether steroids produce superior clinical effects compared with local anaesthetics or saline. A meta-analysis stated that epidural injections with only local anaesthetics obtained comparable clinical benefits to those with mixture of local anaesthetics and steroids. Some studies have reported that local anaesthetics and steroids are equally effective in pain control and functional improvements in patients with low back pain or stenosis, and that it is not necessary to use epidural injections of steroids in such cases. MeanODIat12thweekwas16.34±12.304ingroupSBwhichwas significantly lower compared to group Bwhich was 29.22±12.189. Mean VAS score at 12thweek was 1.98±1.525 which was significantly lower compared to group B in which it was 3.46±1.614. Mean VAS score at 12thweek was 1.98±1.525 which was significantly lower compared to group B in which it was 3.46±1.614. There was significant difference in repeated need for analgesics between the groups with higher need in B(bupivacaine only) group.
In conclusion, the present study found that interlaminar epidural steroid injections are efficient in decreasing VAS and ODI scores at 3 month follow-upinpatientswithchroniclowbackpainwithradicularpainwhowere diagnosed with intervertebral disc.
Key words: Corticosteroids; Lumbar disc herniation; epidural steroid injection; interlaminar; multiple level radiculopathy; local anesthetic; steroid.

Introduction

Epidural injection administration routes include transforaminal, interlaminar, and caudal approaches. Among the three approaches available to access the lumbar epidural space, the transforaminal approach requires the smallest volume to reach the primary site of pathology, and the interlaminar approach is the most commonly used.[1]

Local anesthetics have been utilized in performing epidural injections since 1901 until epidural steroids were advocated in 1956. In addition to the initial invention of epidural local anesthetic and their reported effectiveness, multiple studies have been published since then with extensive use of local anesthetics and local anesthetic and steroids since the introduction of epidural steroids.[2]

The role of local anesthetics or saline in epidural injections is emerging. These agents play a role in diluting corticosteroids to increase injection volumes, based on the hypothesis that increased volume might facilitate rupture of possible adherence between the spinal root and nearby structures or wash out inflammatory mediators around nervous tissues. [3] Furthermore, clinical advantage of local anesthetics had been explained by the various mechanisms including the suppression of ectopic discharges from inflamed nerves, change of nociceptive circuit, the lysing of iatrogenic and inflammatory adhesions, or anti-inflammatory effects. There have been contradicting opinions regarding whether steroids produces superior clinical effects compared with local anesthetics or saline. A meta-analysis stated that epidural injections with only local anesthetics

obtained comparable clinical benefits to those with mixture of local anesthetics and steroids.[4] Some studies have reported that local anesthetics and steroids are equally effective in pain control and functional improvements in patients with low back pain or stenosis, and that it is not necessary to use epidural injections of steroids in such cases.

Methodology

This study is a Randomized controlled trial done to compare the outcome in for low backache due to disc prolapse.

Adult patients of either sex with intervertebral disc prolapse with or without neurological deficits visiting or admitted in hospitals were taken into the study.

Patients with cauda equina syndrome were excluded from study. A total of 82 patients were included in the study. Patients with signs and symptoms ofdisc prolapse, and who come under the inclusion criteria and give informed written consent will be selected. After the clinical assessment, investigations of the patients will be done, which includes routine CBC, ESR, CRP, X rays of Lumbar spine both in AP and Lateral views, flexed and extension views, MRI (Fig). X rays were done to rule out other causes of back pain like tumours, instability, spondylolisthesis, infections, osteoporosis, thoracolumbar fractures. MRI is done to assess nerve root compression, level and stage of disc prolapse. Following MRI disc prolapse will be confirmed.

Inclusion Criteria

1. An adult of age group between 18 to 60 yrs, of either sex.
2. X- Ray of lumbosacral spine – AP and LATERAL, flexion and extension (to diagnose instability)
3. Evidence of lumbar disc herniation or nerve root compression or both on MRI.
4. History of lower back pain radiating to unilateral or bilateral lower limbs with mild motor or sensory deficits for at least 6 weeks.
5. Patient willing to give informed consent.

Exclusion Criteria

1. Patients with significant coagulopathies and use of anticoagulants.
2. Patient with history of allergy to steroids and local anaesthetic agents.
3. Previous lumbar spine surgeries or epidural steroid injections.
4. Multileveldegenerativespinedisease,unstablespine ,vertebralcompression fractures, spondylolisthesis, cauda equina syndrome and arachnoiditis.
5. Patient diagnosed to have active cancer, history of substance abuse, current psychiatric co-morbidity, pregnancy, diabetes mellitus and congestive cardiac failure.
6. Signs of lumbar disc degeneration without lumbar disc herniation.

Patients were randomized using computer generated randomization software into 2 groups depending on the treatment modality they receive

Group1:

Consistsofpatientswhoreceivedepiduralinterlaminarsteroidwith bupivacaine injection

Group 2: Consists of patients who received epidural interlaminar bupivacaine only

Patients were explained about the procedure and informed and written consent were obtained.

Results:

Table 1: Comparison of ODI score between the treatment groups

ODI	Treatment	Mean	SD	P Value
ODI Base	SB	46.83	4.753	0.758
	B	46.44	6.550	
ODI 1	SB	44.20	6.047	0.593
	B	44.93	6.310	
ODI 6	SB	23.22	10.039	0.000*
	B	33.51	8.715	
ODI 12	SB	16.34	12.304	0.000*
	B	29.22	12.189	

Mean ODI score was 46.83±4.753 in group SB and was 46.44±6.550 in group B without any significant difference. Mean ODI at 1st week was 44.20±6.047 in group

SB which was almost similar to group B in which it was 44.93±6.310. Mean ODI score at 6th week was 23.22±10.039 in group SB which was significantly lower comparedtogroupBwhichwas33.51±8.715.MeanODIat 12thweekwas 16.34+12.304 in group SB which was significantly lower compared to group B which was 29.22±12.189

Table 2: Comparison of vas score between the treatment groups

VAS	Treatment	Mean	SD	P Value
VAS 0	SB	5.78	0.652	0.881
	B	5.80	0.813	
VAS 1	SB	5.44	0.838	0.639
	B	5.54	1.027	
VAS 6	SB	2.68	1.507	0.000*
	B	3.95	1.244	
VAS 12	SB	1.98	1.525	0.000*
	B	3.46	1.614	

Mean VAS score at baseline was 5.78±0.652 in group SB which was almost similar to group B in which it was 5.80±0.813. Mean VAS score at 1st week was 5.44±0.838 which was similar to group B in which it was 5.54±1.027. Mean VAS score at 6th week was 2.68±1.507 which was significantly lower compared to Group B in which it was3.95±1.244.MeanVASscoreat12thweekwas1.98±1.525whichwas significantly lower compared to group B in which it was 3.46±1.614.

Table 3: Comparison of JOA score between the treatment groups.

JOA	Treatment	Mean	SD	P Value
JOA 0	SB	17.51	1.075	0.6522
	B	17.09	1.913	
JOA1	SB	18.15	1.276	0.008*
	B	17.21	2.424	
JOA6	SB	23.10	2.478	0.000*
	B	20.44	2.618	
JOA12	SB	23.90	3.254	0.001*
	B	21.44	3.248	

Mean JOA score at baseline was 17.51±1.075 in group SB which was similar to group B in which it was 17.09±1.913. Mean JOA score at 1stweek was 18.15±1.276 in group SB which wassignificantly higher compared to groupB in which it was 17.21+2.424. Mean JOA score at 6th week was 23.10±2.478 in group SB which was significantly higher compared to group B in which it was 20.44±2.618. Mean JOA at 12th week was 23.90±3.254 in group SB which was significantly higher compared to group B in which it was 21.44±3.248.

Table4:Comparisonofreducedneedforrepeatedanalgesics between the groups

Reduced need for RA		Treatment		P value
		B	SB	
Yes	Count	14	28	0.004*
	%	34.1	68.3	
No	Count	27	13	
	%	65.9	31.7	

27(65.9%) in group B were in need of repeated analgesics and 13(31.7%)in group SB were in need of repeated analgesics. There was significant difference in repeated need for analgesics between the groups with higher need in B(bupivacaine only) group.

Table5:Comparisonofcomplicationsbetweenthe treatment groups

Complications(safety)		Treatment		P value
		B	SB	
Nil	Count	41	41	NA
	%	100.0	100.0	

All the subjects in both the groups had no complications.

Discussion

Inthepresentstudy,MeanODIscorewas46.83±4.753ingroupSBandwas 46.44+6.550 in group B without any significant difference. Mean ODI at 1st week was 44.20+6.047 in group SB which was almost similar to group B in which it was 44.93+6.310. Mean ODI score at 6th week was 23.22±10.039 in group SB which wassignificantly lower compared to group B in which it was 33.51±8.715. Mean ODI at 12thweek(3 months) was 16.34+12.304 in group SB which was significantly lowercompared to group B in which it

was 29.22±12.189. In a study by Manchikanti *et al*.[13] mean ODI score at baseline in group B and SB was 31.0 ± 6.3 and 30.5 ± 8.4 respectively which was almost similar, mean ODI score at 3 months was 15.3 ± 5.3 in group B and was 15.2 ± 6.2 (77%) in group SB which was almost similar, ODI score at 6 months 14.8 ± 6.4 in group SB, at 12 months mean ODI score was 15.0 ± 6.4 in Group B which was significantly higher compared to Group SB 14.4 ± 6.4.

In a study by Leslie Ng *et al*. 98mean change in ODI score was 12.9±3 in group Bwhich was higher compared to group SB in which it was 7.8 ±2.8 and at 12 weeksmean ODI change was 12.3±3.2 in group B which was higher compared to group SBin which it was 10.8±3.4.

In a study done by Ökmen K *et al* [2016], Between the groups, a statistically significant difference was seen in the ODI scores measured at one, three, six, and 12 months between the groups (p<0.05). The mean baseline ODI was 37.7 ± 4.5 in group S(steroid + bupivacaine) and 37.8 ± 6.1 in group L(Bupivacaine only). The mean ODI at 3 months(12 weeks) was 15.7 ± 8.9in group S(steroid + bupivacaine) and29.4 ± 6.6 in group L(Bupivacaine only) which was similar to this study. TheODI scoreswere higher in Group L, compared to Group S at all time points.[5]

In a study by Carette *et al*.[6] at three weeks, the Oswestry score had improved by a mean of -8.0 in the methylprednisolone group and -5.5 in the placebo group which was not significant, after three months, there were no significant differences between the groups and at 12 months, the cumulative probability of back surgery between the groups was not significant.

In the present study, Mean VAS score at baseline was 5.78±0.652 in group SB which was almost similar to group B in which it was 5.80±0.813. Mean VAS score at 1stweek was 5.44±0.838 which was similar to group B in which it was 5.54±1.027. Mean VAS score at 6thweek was 2.68±1.507 in group SB which was significantly lower compared to Group B in which it was 3.95±1.244. Mean VAS score at 12thweek was 1.98±1.525 in group SB which was significantly lower compared to groupB in which it was 3.46±1.614.

In a study by Manchikanti *et al*.mean VAS score was 8.0 ± 0.7 in group B and was8.0 ± 1.0 in group SB which was similar to this study, mean VAS score at 3 months(12 weeks) was 3.7± 1.3 in group B and 3.7± 1.5 in group SB.[7]

In a study by Leslie Ng *et al*. mean VAS score (for back pain) at 6 weeks in group B was 6.3± 4.6 and was 9.9 ±5 0.61 in group SB and at 12 weeks mean VAS score was 8.0+5.5 in group B and was 4.8±5.4 in SB group.[8] It was observed that pain scorewas less for bupivacaine and steroids group at 12 weeks compared to bupivacaine only group which was similar to this study. In a study done by Ökmen K *et al* [2016], the mean VAS score at 12 weeks was found to be 4.4 ± 1.3 and 2.4 ± 1.4 in group B and SB respectively.[5]

In a study by Valat *et al*.[9] there was no significant difference in VAS scores between the groups.

In a study by Koc *et al*. [10] which conducted the effectiveness of steroids in lumbar spinal stenosis it was revealed that VAS scores significantly improved at every follow-up visit. A few studies comparing the effects of steroid and local anesthetics, have found that steroids do not provide additional benefit which was contrary to this study. Despite equivocal evidence about their efficacy, epidural steroid injections are currently being suggested as a reasonable treatment option in LSS patients.

In the present study,27(65.9%) in group B were in need of repeated analgesics and 13(31.7%)in group were in need of repeated analgesics. There was significant difference in repeated need for analgesics between the groups with higher need in B(bupivacaine only) group. All the subjects in both the groups had no complication. In a study by Manchikanti *et al*[13], significant reduction in analgesic use was observed in both B and SB groups.

Conclusion

From our study we found that patients treated with epidural steroids for a lumbar disc herniation will improve. As per literature, 80% may improve with epidural steroids. The exact percentage may vary.The less success rate for patients with symptom duration exceeding 12 months advocates for early initiation of injection treatment.Even though Steroid effect detoriates over a time period in majority of patients due to progression of disease process, but significant number of patients have good response which lasts upto 3 months. Pain relief effect of steroid starts very early and lasts longer than disability improvement.

In conclusion, the present study found that interlaminar epidural steroid injections are efficient in decreasing VAS and ODI scores at 3 month follow-up in patients with chronic low back pain with radicular pain who were diagnosed with intervertebral disc prolapse.

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