

## Original Research Article

# A PROSPECTIVE STUDY ON ROLE OF EPIDURAL STEROID INJECTION IN CHRONIC LOW BACK PAIN

P.Surrender Reddy<sup>1</sup>, Minumula Sreekanth<sup>2</sup>, Yamala Shwetha Madhuri<sup>3</sup>, Kodam Rammohan<sup>4</sup>

<sup>1</sup>Associate Professor, Department of Orthopedics, Mahaveer Institute of Medical Sciences, R.M. Dhariwal Hospital, Bhopal, MP, India.

<sup>2</sup>Assistant Professor, Department of Orthopedics, Kakatiya Medical College, MGM Warangal, Telangana, India.

<sup>3</sup>Assistant Professor, Department of Orthopedics, Government Medical College, Jangaon, Telangana, India.

<sup>4</sup>Associate Professor, Department of Orthopedics, Kakatiya Medical College, MGM Warangal, Telangana, India.

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### Corresponding Author:

**Dr. Kodam Rammohan,**  
Associate Professor, Department of  
Orthopedics, Kakatiya Medical  
College, MGM Warangal, Telangana,  
India.  
Email: dramkohankodam@gmail.com

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### ABSTRACT

**Background:** Low back pain (LBP) is a major health and socioeconomic problem in modern society. It constituted about 37% of occupational risk factor and occupies first rank among the disease complications caused by work. **Aim:** To study the effectiveness of epidural steroid injection in alleviating symptoms caused by prolapsed intervertebral disc.

**Materials and Methods:** It was a prospective study, Patients with low backache visiting Mahatma Gandhi Memorial Hospital, Warangal, from October 2023 to September 2024.

**Results:** Out of 60 cases, 30 were given Epidural steroid and 30 were given Normal saline among them 36 were interlaminar, 13 were transforaminal and 11 were caudal approach. In our study the mean age of the patients was 47.7. In our study out of 60 patients 40 were females and 20 were males. Significant results were seen when patients were followed at 2<sup>nd</sup>, 3<sup>rd</sup> and 4<sup>th</sup> month when observed with VAS and ODI scores. Epidural steroid injection has also shown significant improvement compared to saline on SLRT. In case of SF36 bodily pain, general health and role of emotional showed a significant outcome at 6 months, however by 1 ½ years not much difference was seen. Interlaminar approach is found as the best approach for ESI (Interlaminar > Transforamina 1 > Caudal). The only one patient that shifted from epidural to discectomy did so due to worsening deficits and pain.

**Conclusion:** The present study concluded that ESI is a viable modality for selected patients, the evidence is good for radiculitis secondary to disc herniation with local anesthetics and steroids, involving minimal risk.

**Keywords:** Epidural Injection, VAS, Low back pain, SLRT, ODI.

## INTRODUCTION

Low back pain (LBP) is a major health and socioeconomic problem in modern society. It constituted about 37% of occupational risk factor and occupies first rank among the disease complications caused by work. Such high prevalence of complications at international level has made the World Health Organization to name the first decade of the third millennium as the “decade of campaign against musculoskeletal disorders (as the silent epidemic)” (WHO, 2005).

In Indian population the prevalence of LBP has been found to vary between 6.2% (in general population) to 92% (in construction workers). The prevalence of LBP has been found to increase with age and to be

more common among females. Age  $\geq$  35 years was found to have 9 times more risk as compared to <35 years.

Low socioeconomic status and poor education have been found to be associated with LBP. Present episode of LBP was found to be associated with previous history of LBP.

Heavy Physical work in terms of lifting heavy loads, repetitive job, prolonged static and awkward Posture have been found to be some of the risk factors of LBP.<sup>[1]</sup> It is also an important Cause of sickness absenteeism in our country, therefore finding an appropriate treatment for it is prudent. Degenerative disc disease is an important cause of low back pain, L3-L4 and L4-L5 intervertebral level showed the greatest area of disc degeneration.<sup>[2,3]</sup> Disc prolapse

amounts for 5% of all low back aches. Treatment for lumbar disc herniation can be conservative or surgical and which one is effective is always controversial. Conservative treatments are physical therapy, epidural steroid injection, cheirography, anti-inflammatory agents & opioid analgesics which are a lot cheaper and less invasive than surgical techniques.<sup>[5]</sup>

Epidural steroid injection is very popular & low risk alternative to surgical intervention in lumbar disc herniation.<sup>[6]</sup> The term 'epidural steroids', refers to injection of corticosteroids in the epidural space, it is one of the most commonly used interventions in managing chronic low back pain.

The debate continues regarding the efficacy of epidural steroid injections via the various approaches in the 3 regions because of the varying opinions rendered in multiple systematic reviews and guidelines.<sup>[7,8,9,10,11]</sup>

Epidural steroid injection (ESI) is primary indication for radicular pain associated with herniated nucleus pulposus, this study would evaluate the change in quality of life and symptoms of patients who have symptomatic lumbar disc herniation and seen on MRI and the associated postoperative complications. The patients will be questioned using the SF 36 and visual analogue scale (VAS) and Oswestry score over a period of 2 years.

#### **Aims and Objectives of the Study**

1. To study the effectiveness of epidural steroid injection in alleviating symptoms caused by prolapsed intervertebral disc,
2. To know the effectiveness of epidural steroid in low back pain.
3. To compare the outcome with other modalities of management in the literature.
4. To study the complications following epidural steroid injection.

## **MATERIALS AND METHODS**

#### **Source of data**

Patients with low backache visiting Mahatma Gandhi Memorial Hospital, Warangal, from October 2023 to September 2024.

**Type of study:** Prospective study.

#### **Study period**

Over a period of two years from October 2023 to September 2024.

**Method of Statistical Analysis:** Statistical analysis

**Sample size:** 50

#### **Inclusion Criteria**

1. Back pain for more than 6 weeks in an adult with evidence of lumbar disc herniation on MRI
2. Failed conservative management (tractions, analgesics, physiotherapy).
3. Disc herniation with radiculopathy.
4. Lumbosacral radiculopathy.

#### **Exclusion Criteria**

1. Back painless than 6 weeks.
2. Patient with focal neurological deficits.
3. Patient with multiple level intervertebral discs involvement.
4. Those without evidence of lumbar disc herniation on MRI.
5. Osseous cause for lumbar canal stenosis on MRI.
6. Signs of lumbar disc degeneration without lumbar disc herniation on MRI.
7. Presence of other associated spinal pathologies.
8. Those with Cauda equina syndrome.
9. Those with prior spine surgery and discectomies

Collection of data from patients who had low backache as follows:

- a. History by verbal communications.
- b. Clinical examination both local and systemic.
- c. Blood investigations like Complete blood picture, Erythrocyte sedimentation rate, C-Reactive protein, Clotting time, Bleeding time, Random blood sugars, Renal function test and Serum electrolytes
- d. Radiological examination—x ray lumbo sacral spine antero posterior, lateral, and oblique views, chest x ray PA view, MRI.
- e. Pre anaesthetic check-up.
- f. Written and informed consent.
- g. Photographic documentation of epidural steroid injection.
- h. Templating data.
- i. Postoperative care.
- j. Postoperative functional outcome evaluation, by Visual analogue scale and Oswestry Disability Index, before the start of treatment and later at the time of follow up.

#### **Post procedure advice**

Post procedure patients advised bed rest, avoid straining and bending. Patient is advised to sleep in propped up position and consume plenty of oral fluids.

#### **Number and Frequency of ESI**

If the first injection fails to relieve symptoms, further injections can be given at 2-week intervals. The number of injections is a matter of personal choice, but three injections would appear to be a reasonable limit.

#### **Follow-up period**

Clinical follow-up at 1st month, 2nd month, 3rd month, 6th month, 1 year, 1½ year intervals for assessment of pain, gait, sensory evaluation, motor evaluation & any complications.

Assessment of improvement with the help of VAS (pain), ODI (functional outcome), SF 36 score is done. When no improvement is seen with a single injection, a second and third injection can be given after a 3-week interval. If there is no improvement, the patient is considered for surgery.

## RESULTS

A total of 68 patients with low backache are taken in this study out of which only 60 patients were available for follow-up, of which 30 were given steroid 30 were given normal saline, the patients with low back ache presented in the outpatient department with pain in the back radiating to one or both the lower limbs with paraesthesia and difficulty in performing daily activities like washing clothes, sweeping the floor and lifting a heavy object. All or few of these activities caused pain in their back. These patients had a failed trial of conservative line of management. They included patients who used medications, pelvic traction, physiotherapy and other treatment modalities for more than 6 weeks. The patients were analysed clinically and radiological by taking an x-ray lastly by taking an MRI for all those who fulfilled our inclusion and

exclusion criteria were planned for epidural steroid injection

The evaluation of scores that is VAS, ODI and SF36 before and after injections was done, later the patients were followed at 1 month, 2 month, 3 month, 6 months, 1 year and 1½ year after injection.

The following results were analysed, and they have proven to be highly significant statistically at 2nd, 3rd and 6th month, after 3 months, there was no significant differences between the groups, and among the approaches interlaminar was superior to transforaminal which is again superior to caudal approach. Epidural steroid injection has showed good, short-term improvement in patients with intervertebral disc herniations.

The following are the results obtained in the study.

### SOCIODEMOGRAPHIC DATA

#### AGE DISTRIBUTION OF PATIENTS WHO WERE GIVEN EPIDURAL STEROID

In our study, the mean age was 47.7 with maximum patients lying in the age group between 41-50 years.

**Table 1: Distribution of study subjects according to their age with low backache**

PT.AGE GROUP	NO. OFPATIENTS	PERCENT (%)
20-30	5	10
31-40	11	22
41-50	22	44
51-60	7	14
61-70	5	10
Total	50	

#### Sex distribution of patients who were given steroid

In our study, 16 female patients and 14 male patients are given steroid

**Table 2: Distribution of study subjects according to their sex with low backache**

Sex	No ofpatients	Percent (%)
Male	26	52
Female	24	48
Total	50	100

**Table 3: Distribution of study subjects according to their Risk factors for low backache**

Risk factors	No of patients	Percent(%)
Repetitive job	12	24
Prolonged static andAwkward posture	8	16
heavy manual labour (lifting, torsional loading and 2020 twisting)	30	60
Total	50	100

#### DURATION OF PAIN

In our study out of 60 patients, there were many patients with chronic pain about 34 patients

**Table 4: Duration of pain**

Type of pain	Duration of pain	No of patients	Percent (%)
Sub acute	6wks.-3months	8	16
Acute	<12 weeks	15	30
Chronic	>7-12wks.	27	54
	TOTAL	50	

#### MRIFINDINGS

Distribution of study subjects according to their MRI findings LEVEL OF DISC:

In our study all were lumbar disc herniation's, nocervical or thoracic among 60 cases, 4 have L2-L3, 7 have L3-L4, 11 have L4-L5 and 9 have L5-S1 level of disc.

**Table 5a: Distribution of study subjects according to the level of disc**

Level of disc	No of patients	Percent (%)
L2-L3	5	10
L3-L4	28	56
L4-L5	6	12
L5-S1	11	22
Total	50	

**TYPE OF DISCS**

In our study among 60 cases,34 cases have disc bulge,18 have protrusion of disc, and extruded and sequestered discs were not included in my study.

**Table 5b: Distribution of study subjects according to the type of discs**

Type of discs	No of patients	Percent (%)
Disc bulge	28	56
Protrusion	17	34
Extrusion	3	6
Sequestration	2	4
Total	50	

**TYPE OF APPROACHES**

In our study among 60cases, 31 cases were treated by inter laminar,15 were treated by transforaminal and 14 by the caudal approach.

**Table 6: Distribution of study subjects according to type of approaches**

Type of approaches	No of patients	Percent (%)
Inter laminar	32	64
Transforaminal	7	14
Caudal	11	22
TOTAL	50	

**OUTCOME MEASURES**

nce collected, the data was exported to Statistical Analysis System (SAS Institute Inc., Cary,N.C.) for statistical analysis. Repeated ANOVA was used to study the effectiveness of treatment, and to compare treatments.

**VAS Scale**

The patients were followed at 1st month,2 ndmonth,3rd month,6 thmonth,1 year and 18 months and mean and standard deviation were calculated

**Table 7: Descriptive statistics of VAS in IVDP**

Before ESI VAS		N	Mean	SD	Pvalue
	<b>Interlaminar</b>	<b>32</b>	<b>5.06</b>	<b>1.43</b>	<b>.46</b>
	Transforaminal	7	5.71	.73	
	Caudal	11	5.45	1.57	
1mthVAS	Interlaminar	32	2.19	.78	.61
	Transforaminal	7	2.00	.00	
	Caudal	11	2.00	.00	
2mthVAS	Interlaminar	32	1.63	1.29	.48
	Transforaminal	7	2.00	.00	
	Caudal	11	2.00	.00	
3mthVAS	Interlaminar	32	1.50	1.34	.31
	Transforaminal	7	2.00	.00	
	Caudal	11	2.00	.00	
6mth VAS	Interlaminar	32	3.69	.74	.22
	Transforaminal	7	4.00	.00	
	Caudal	11	4.00	.00	
1yr VAS	Interlaminar	32	4.00	.51	.04
	Transforaminal	7	4.57	.98	
	Caudal	11	4.00	.00	
18 mth VAS	Interlaminar	32	4.25	.84	.28
	Transforaminal	7	4.57	.98	
	Caudal	11	4.73	1.00	

**SLRT**

The patients were followed at 1st month,2 nd month, 3rdmonth, 6thmonth, 1year and18 months and mean and standard deviation and P-values were calculated.

**Table 8: Descriptive statistics of SLRT in IV**

		N	Mean	SD	P value
Before ESI	Interlaminar	32	1.84	.369	.369
	Transforaminal	7	1.86	.378	
	Caudal	11	2.00	.000	
1mth SLRT	Interlaminar	32	3.28	.457	.262
	Transforaminal	7	3.00	.000	
	Caudal	11	3.18	.405	
2mth SLRT	Interlaminar	32	3.44	.504	.420
	Transforaminal	7	3.00	.000	
	Caudal	11	3.18	.405	
3mth SLRT	Interlaminar	32	3.56	.504	.004
	Transforaminal	7	3.00	.000	
	Caudal	11	3.18	.405	
6 mth SLRT	Interlaminar	32	2.56	.504	.004
	Transforaminal	7	2.00	.000	
	Caudal	11	2.18	.405	
1yr SLRT	Interlaminar	32	2.28	.457	.262
	Transforaminal	7	2.00	.000	
	Caudal	11	2.18	.405	
1.5Yr SLRT	Inter laminar	32	2.28	.457	.262
	Transforaminal	7	2.00	.000	
	Caudal	11	2.18	.405	

**SF36 SCORE:**

The patients were followed at 1stmonth, 2ndmonth, 3rdmonth, 6thmonth, 1year and 18 months and mean and standard deviation were calculated.

**Table 9: Descriptive statistics of SF36 in IVDP**

		N	Mean	SD	Pvalue
Role limitations due to emotional problems	Interlaminar	32	62.19	31.47	0.169
	Transforaminal	7	47.29	32.47	
	Caudal	11	75.45	26.41	
Pain	Interlaminar	32	57.45	9.75	0.793
	Transforaminal	7	56.57	14.13	
	Caudal	11	54.86	11.98	
General health	Interlaminar	32	47.19	5.95	0.095
	Transforaminal	7	42.14	10.75	
	Caudal	11	49.09	4.91	

**COMPLICATION FOLLOWING ESI**

In our study among 60 patients, 5 of the mh ad immediate hypotension following ESI and 5 had a post-injection headache. There were no complications like infection, HPA axis suppression, dural puncture, nerve injury and spinal arachnoiditis following ESI.

**Table 10: Distribution of study subjects according to different complication following ESI**

COMPLICATION	NO OF PATIENTS
Injection site pain	4
Transient headache	3
Steroidal side effects(hypotension)	2
Dural puncture	-
PDPH(post dural puncture headache)	-
Nerve injury	-
Others	-

**Case1**

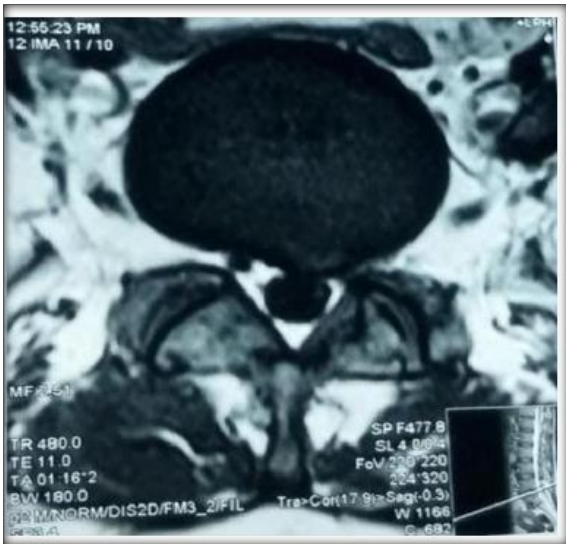
Name	Renuka
Age/Sex	33yr/F
Diagnosis	L5-S1PIVD
Typeofapproach	Caudal

**Outcome measures**

	VASScore	ODI	SLRT
PRE-ESI	8	31	2
1MonthofESI	4	26	4
1 <sup>1/2</sup> yr.ofESI	4	17	3



(a)



(b)



(c)

## DISCUSSIONS

Epidural steroid injections are commonly used to relieve pain and radicular symptoms caused by lumbar disc herniations and have shown good short-term improvement without surgery. Its use in chronic degenerative disc disease with canal stenosis due to other causes is still debatable [95]. Epidural steroid injection showed better results compared to normal saline in our follow up.

Epidural steroid injection is one of the therapeutic interventional therapies. There are a multitude of interventional techniques in the management of chronic pain, including not only neural blockade but also minimally invasive surgical procedures such as peripheral nerve blocks, trigger-point injections, facet joint injections, sympathetic blocks, neuroablation techniques, intra discal thermal therapy, disc decompression, morphine pump implantation, and spinal cord stimulation.

In our study we have laid emphasis on treating radiculopathy and pain caused by intervertebral disc prolapsed with epidural steroid injection. This is the simple and relatively effective method in improving the symptoms of the patients. We have conducted our study on 60 patients. By careful evaluation of the effects of these injections the drawbacks and advantages of this procedure could be concluded.

All patients were clinically showed improvement in pain, disability status, quality of life and functional status who were given steroid injection compared to saline.

Outcome was assessed using Visual analogue score on a scale of 0 to 10 for pain, Oswestry disability index 98.99 for function, SLRT for functional outcome and SF36 for assessing the quality of life. Outcome was measured at consecutive months and lastly 1yr, 1.5yrs. Two-way Anova test was used to analyse these results as the data is normally distributed.

These results are similar to several other systematic reviews performed recently, whereas they have some similarities to others and are in contradiction to other systematic reviews.

### Age distribution

In our study the mean age of the patient was 47.7 with the maximum patients between 41-50 years, according to the literature intervertebral disc prolapse occurs above >35 years of age. Age appears to be one of the important factors in the etiology of this condition. The age incidence in our study is similar to that of Renato Santiago Gomez.<sup>[13]</sup>

### Type of ESI approach

In our study out of 60 patients 36 patients were tried with interlaminar approach, out of 60 patients 13 were tried with transforaminal approach and 11 out of 60 patients were tried with caudal approach. In a study conducted by Ackerman et al., 12 a total of 90 patients were included, were he equally distributed in to 2 approaches, making 30 in each approach.

Ackerman et al,<sup>[13]</sup> compared the efficacy of caudal epidural injections with lumbar interlaminar and transforaminal epidural injections. This was a relatively small study showing the superiority of both lumbar interlaminar epidural injections and transforaminal epidural injections over caudal epidural injections at both 3mths and 6mths follow up period.

#### **Various scores used**

The effect of epidural steroid injection in intervertebral disc prolapsed can be assessed with the help of various pain and functional scores evaluated before and after the injection.

In our study we have used the universally accepted VAS (visual analogue score) for the assessment of pain in low back ache patients it is more subjective, simple and easily evaluated with easy understanding by all the patients, they have to select a point on the scale ranging from 0 (no pain) to 10 cm (severe pain) respectively.

For the functional assessment we have used ODI (Oswestry disability index), for quality of life assessment we have used SF36 (short form) questionnaire which includes a series of questions to be filled by the patient.

There are several others cores which have been used in various studies to evaluate the effect of epidural steroid.

BECKDEPRESSIONINVENTORY(BDI-21),MCGILLBPQUESTIONNAIREINDEX (MPQ), LOW BACK PAIN RATING SCALE (LBPRS), PROGRESSIVE ISOINERTIAL LIFTINGEVALUATION(PILE), LUMBARTEST,QUEBEC BACKPAINDISABILITY SCALE (QBPD), ROLAND-MORRIS DISABILITY QUESTIONNAIRE (RDQ), WADDELL DISABILITY INDEX (WDI)36, MILLION VISUAL ANALOGUE SCALE (MVAS)38, LOW BACK OUTCOME SCORE (LBOS).<sup>[14]</sup>

In our study it was easy for us to educate our patients about the VAS score as it was a simple linear scale including a single dimension which is the pain. Figures representing a smile to frown with scaling done below were shown to the patient. Depending on the type of pain they are facing, they mark that level. The scores were evaluated from 0 to 10 pre and post injection. ODI and SF36 questionnaire took about 10 min to be filled and were easier to understand. it was difficult for few patients during early recall.

#### **Comparison of VAS scores**

The VAS score has ranged between 2 to 8 per patient with the mean for IL, TF and Cas 5.533±1.55, 5.429±1.69 and 5.611±1.420. The patients were followed after 1month, 2 months, 3 months, 6 months,1 year and 1½ year respectively.

When statistical analysis was done comparing the mean VAS scores before and after injection for different approaches the results obtained were highly significant at (p<0.01) 2nd, 3rd and 4th follow ups.

When statistical analysis was done by multiple comparisons in between 3 approaches, at 2nd, 3rd,4th follow ups has shown inter laminar approach to be superior when compared to transforaminal and caudal approach.

When compared to other studies, in Candido et al,<sup>[15]</sup> the VAS was compared pre and post injection. Follow-up was at 3<sup>rd</sup>and 6<sup>th</sup> months, the VAS scores were converted to a scale of 100 in his study. In Ghai Et al,<sup>[16]</sup> a study on transforaminal epidural injection the VAS was compared to pre and post injection, follow up was at 3rd month, 6th month and finally at 1 year, he noticed >50% pain relief from baseline using VAS, the VAS scores were also converted to a scale of 100 in his study.

Comparison of ODI with different studies Oswestry disability index The Oswestry Disability Index ranges from 0 to100, with lower scores indicating less severe symptoms.

The ODI for LBA patients ranged between 13% to 42% per patient with a mean ODI for different approaches IL,TF and C is 32.762±5.8,31.286±4.1 and 34.333±6.2respectively. The patients were followed after 1month,2months, 3 months, 6 months,1year and 1½ year respectively.

When statistical analysis was done comparing the mean VAS scores before and after injection for different approaches the results obtained were highly significant at (p<0.01) 2nd,3rd and 4th follow ups. When statistical analysis was done by multiple comparisons in between 3 approaches, at 2nd, 3rd, 4th follow ups has shown interlaminar approach to be superior when compared to transforaminal and caudal approach, in between TF and C, TF was superior at 2nd ,3rd and 4th follow ups.

When compared to other studies, in Laxmaiah Manchikanti et al,<sup>[17]</sup> the ODI was compared pre and post injection. Follow up was at 6th months, 1 and 1.5 years, both the IL and C showed superior results but when compared Inter laminar approach was better than caudal approach.

#### **Comparison of SLRT with different studies**

Mohammad Taghi Mortazavi et al,<sup>[18]</sup> conducted a double-blind randomized clinical trial among 40 patients SLRT before and after the treatment showed significant results with the steroid group, in our study when compared with the baseline values results were significant after the ESI at 3months follow up. In our study only 3 components were selected from SF36 score they include Role limited due to emotional problem, Bodily Pain(BP) Score and General health, at6mths follow-up p-value for

Inter laminar approach is 0.031, for transforaminal approach is 0.001and for caudal approach is 0.014.

In a study conducted by McGrath et al it was a RCT study among 1667 patients 9 of them had injection site pain. Wewalka et al<sup>[19]</sup> conducted a cohort study a total of 37people were included in his study out of 37 people 2 developed hypotension with TF ESI. Manchikanti et al,<sup>[20]</sup> conducted a RCT a total of 120 people were included in the study, out of 120

people 9 of them developed nerve injury with TF approach.

In a study conducted by V.G.Murakibhavi et al,<sup>[21]</sup> which was a RCT, a total of 50 patients got admitted, among which 9 of them had transient headache, 12 out of 50 had hypotension following ESI. In our study among 60 patients 3 of them had injection site pain, 2 out of 60 had transient headache and 1 out of 60 developed hypotension.

Similar to previous studies our results suggest that epidural steroid injections are associated with surgical avoidance (a 41% rate of crossover by surgically assigned patients who received epidural steroid injection compared with a 12% rate of crossover by surgically assigned patients who did not receive an epidural steroid injection), although this is heavily influenced by the baseline preference for surgery.

Among patients who had a baseline preference for surgery, epidural steroid injection was associated with a higher rate of crossover from surgical to nonsurgical treatment.

Furthermore, surgical avoidance may not be an ideal goal in the absence of a long-term improvement in outcome with nonsurgical treatment or even equivalence in outcome Between surgical and nonsurgical treatment. Our results suggest that patients who avoided surgery may have had less improvement than they would have otherwise had.

These results indicate no significant difference in outcome at one, two, three, or four years between patients who received an epidural steroid injection and those who did not receive an epidural injection for the treatment of lumbar disc herniation in the SPORT study.

However, an increased rate of surgical avoidance was noted in the group treated with an epidural steroid injection.

## CONCLUSION

The present study concluded that ESI is a viable modality for selected patients, the evidence is good for radiculitis secondary to disc herniation with local anesthetics and steroids, involving minimal risk.

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