Section: Orthopedics

Original Research Article

COMPARISON OF FUNCTIONAL OUTCOME AND PAIN RELIEF OF EPIDURAL TRIAMCINOLONE VS CONSERVATIVE MANAGEMENT FOR LUMBAR DISC DISEASE

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Abstract

Background: Low back pain is a global health issue affecting males and females, with a lifetime prevalence of 60-85% and an annual prevalence of 15-45%. The study compares the functional outcome and pain relief of epidural triamcinolone vs conservative management for lumbar disc disease. **Materials and Methods:** This randomized controlled study was conducted at the GIRM and RGGGH Madras Medical College Chennai for one year, from June 2016 to August 2017. Four hundred patients with chronic low back pain were divided into two groups of 200, one group undergoing conservative management as control and the other as an experimental group undergoing epidural steroid injection. A general physical examination, local spine examination and neurological assessment were done. X-ray of the Lumbosacral Spine (AP and lateral view) and MRI of the lumbar spine were done in all the cases. **Result:** The demographic characteristics, including distribution of sex (p=1) and mean age (p=0.628), were comparable in both groups. Patients in Group A had significantly lower mean VAS scores and ODIS, NRS, and SLRT scores than those in Group B. The mean VAS scores decreased at all follow-ups, while SLRT scores showed better activity levels. The ODIS scores were also lower in Group A compared to Group B. The first and second follow-ups showed better improvement in spinal motion. The self-reported satisfactory occupation resumption was comparable in groups A and B (90% and 80%). **Conclusion:** The present study concluded that epidural steroids and conservative management were beneficial in managing chronic low back pain at the end of the final follow-up.

INTRODUCTION

Low back pain is the most common condition and major health problem worldwide. It can affect everyone in life; both males and females are affected.[1] The lifetime prevalence of low back pain is 60-85%, while the annual prevalence is 15-45%.[2] The annual incidence of back pain in the general population is 10%-15%.[3] Majority of patient's low back pain is a self-limiting condition; 90% are expected to recover in about six weeks.[4] However, annual recurrence rates of 60% have been reported. In the United States (US), Low back pain (LBP) is the second most common cause of disability in adults, and the most common reason for loss of work, which affects the socio-economic status.[5,6] Working populations are at higher risk of developing LBP, 80% of the population will experience it during their lives. In working populations, lifetime recurrences of up to 85%.[7] In India, nearly 60% of people have significant low back pain at some time or another in their lifespan. Epidemiological studies provide information regarding various risk factors such as lifestyle, occupation, habit, socio-economic status and smoking associated with a history of low back pain.[8]

Lumbar disc disease is characterized by lumbosacral radicular pain, characterized by back pain radiating into the lower limbs. The nerve root compression usually causes it due to lumbar disc herniation or spinal stenosis. Common nonsurgical treatments for lumbosacral radicular pain involve lifestyle modification, education, analgesic medication, physical therapy, exercise, or epidural steroid injections (ESIs). ESIs are the most commonly performed procedures for relieving lumbosacral

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radicular pain. They may be performed to deliver steroids or local anaesthetics to the site of pathology in the epidural space via a transforaminal, interlaminar, or caudal approach. Many conservative treatment options for lumbosacral radicular pain include bed rest, pharmacologic therapy with NSAIDs, and questionable exercise.[9-12]

Since lumbar radicular pain may originate from inflammation of the epidural space and the nerve root, analgesic effects of corticosteroids are most likely related to the inhibition of PLA2 and inflammation, inhibition of neural transmission in nociceptive C fibers and reduction of capillary permeability. The epidural steroid acts this way, and the most commonly used steroids for epidural injections are triamcinolone acetonide, betamethasone, and methylprednisolone. Our study is based on triamcinolone steroids. Injected Triamcinolone has been reported to remain in situ for approximately two weeks. The clinician should consider waiting approximately two weeks after the injection to assess the patient's response. However, suggests that up to 3-4 injections may be used for acute radicular pain syndromes. Thus, this study investigated whether ESI was better than conservative treatment for achieving clinical outcomes such as pain control and functional improvement in patients with lumbosacral radicular pain.

MATERIALS AND METHODS

This randomized controlled study was conducted at the GIRM and RGGGH Madras Medical College Chennai for one year, from June 2016 to August 2017. Four hundred patients with chronic low back pain were divided into two groups of 200 each. The control group underwent conservative management, and the experimental group were given epidural triamcinolone injection.

Inclusion Criteria

Age > 20 years to < 65 years, male and female, back pain over six months duration, physician diagnosis of discogenic back pain, one- or two-level disc degeneration on MRI scan, and low back pain with or without radiculopathy were included.

Exclusion Criteria

Cases with a history of previous lumbar spine surgery, cases with motor weakness, rapidly progressing neurological deficits, cauda equina syndrome, neurogenic claudication, local infection at the site of injection, use of steroids three weeks or less before the study, allergy to steroids, bleeding diatheses, pregnancy, and patients with uncontrolled hypertension, uncontrolled diabetes mellitus were excluded.

Before the commencement, the study was approved by the Ethical and Research Committee of Madras Medical College. Patients fulfilling the selection criteria were selected and briefed about the nature of the study. Written informed consent was obtained from the selected patients.

After obtaining written informed consent from the selected patients, demographic data, chief complaints, presentation and history were obtained through an interview. A general physical examination, local spine examination and neurological assessment were done. X-ray of the Lumbosacral Spine (AP and lateral view) and MRI of the lumbar spine were done in all the cases.

Pain intensity was assessed using a Visual analogue scale (VAS) score. Further, these patients were subjected to a straight leg raise test. The patients were also evaluated for the Oswestry Disability Index Score (ODIS). The control group was advised conservative management, and the experimental group was given an epidural steroid injection. Clinical evaluations were performed immediately post-injection, two weeks (First follow-up), two months (Second follow-up), four months (Third follow-up) and six months (final follow-up). The immediate post-injection evaluation included VAS and SLRT, NRS and ODI. During the first, second and third follow-ups, patients were assessed for the Numerical Rating scale, Visual Analogue Score, Oswestry Disability Index score, and the Straight Leg Raising Test (SLRT).

Statistical Analysis

The data obtained was entered into a Microsoft Excel spreadsheet. The categorical data was expressed as rate, ratio and percentage, and the comparison was done using the chi-square test. The continuous data was expressed as mean ± SD, and comparison was done using an independent sample t-test. A p-value of less than or equal to 0.05 at a 95% confidence interval was considered statistically significant.

RESULTS

The commonest age group in group A was 41- 50 (53.19%), while in group B, 50% of patients were aged between 31-40. Most patients were male, with a male-to-female ratio 1.5:1 in both groups. The participants' mean age was 47.47±14.22 years in group A and 48.83±12.15 years in group B (p=0.691). The demographic characteristics, including distribution of sex (p=1) and mean age (p=0.628), were comparable in both groups. The range of motion (flexion, extension and lateral bending), SLRT, VAS, ODIS, BDIS, and NPIS scores pre-injection were comparable in patients with group S and NS (p>0.05).

Sensory symptoms in Group A were 44.1%, and Group B was 55.9%. Group A comorbidities were 51%, and Group B was 48.5%, with no spinal deformity. Spinal tenderness in Group A was 48%, and Group B was 52%. Paraspinal spasm was present in 48.3% of Group A and 51.7% in Group B. There is no significant difference in symptoms between groups [Table 1].

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Duration of back pain in both groups A and B is 4.9 months, finding in ROM and SLRT in a patient with groups A and B. There is no significant difference in pain between groups [Table 2].

The mean VAS scores were significantly low, and the mean ODIS, NRS, and SLRT were significantly lower in group A compared to group B ($p<0.001$). In pain and activity at immediate post-injection, ODI, VAS, and NRS were insignificant [Table 3].

The mean VAS scores in patients with group A reduced at immediate post-injection ($p<0.001$), first ($p=0.001$), second ($p=0.001$) and third follow-up ($p<0.001$) and were significantly low at all the intervals compared to group B.

Post injection, the SLRT scores revealed better activity levels (>60) in both groups. A similar trend was noted at the first, second and third follow-ups. The ODIS at immediate post-injection revealed significantly lower scores in patients with group A compared to group B ($p<0.05$), and the same pattern was observed during the first, second, and third follow-up ($p<0.05$).

During the first (80.33%) and second (80.12%) follow-ups, the improvement in spinal motion was reported to be significantly better in patients with group A compared to group B ($p<0.05$).

The intensity of pain and disability of the patients during the final follow-up shows that the mean VAS score was significantly low, and the mean ODIS, NRS, and SLRT were significantly less in group A compared to group B ($p<0.001$), respectively.

There are no significant complications; only one patient required surgeries in group A. The self-reported satisfactory occupation resumption was comparable in groups A and B (90% and 80%; $p=0.278$). [Table 4]

Table 1: Symptoms and Comorbidities

Characteristic		Group A		Group B		P value
Sensory symptom	Yes	49	44.1%	62	55.9%	0.138
	No	151	52.4%	137	47.6%	
Motor symptom	Yes	0	0	0	0	0.073
	No	200	50%	200	50%	
Comorbid	Yes	34	51.5%	32	48.5%	0.788
	No	166	49.7%	168	50.3%	
Scoliosis	Yes	0	0	0	0	1
	No	200	50%	200	50%	
Spinal tenderness	Yes	154	48%	167	52%	0.103
	No	46	58.2%	33	41.8%	
Paraspinal spasm	Yes	157	48.3%	168	51.7%	0.159
	No	43	57.3%	32	42.7%	

Table 2: Characteristic of pain

Characteristic	Group A		Group B		P value
	Mean	SD	Mean	SD	
Duration month	4.9	1.28	4.9	1.29	0.969
Flexion	51.03	7.25	51.1	7.3	0.918
Extension	26.64	3.13	27	2.94	0.237
Lateral bending	31.26	3.45	31.77	2.74	0.102
Active left	52.03	9.84	51.98	9.81	0.959
Passive left	65.2	7.05	65.2	6.98	1
Active right	52.78	11.49	52.83	11.56	0.965
Passive right	63.58	8.87	63.63	8.95	0.955

Table 3: Duration and pre-treatment evaluation

Immediate follow-up	Group A		Group B		P value
	Mean	SD	Mean	SD	
VAS	2.35	0.85	5.57	0.97	<0.001
ODI	19.86	7.28	27.13	7.94	<0.001
NRS	2.34	0.84	5.44	1.08	<0.001
SLRT RIGHT	82.68	6.1	68.33	5.66	<0.001
SLRT LEFT	83.08	5.53	69.25	5.95	<0.001
Pain and activity at immediate post-injection					
ODI	37.25	2.25	37.1	2.25	0.505
VAS	7.65	0.77	7.74	0.59	0.19
NRS	7.58	0.82	7.55	0.84	0.717

Table 4: Improvement follow-ups

		Group A		Group B		P value
		Mean	SD	Mean	SD	
1st follow-up	VAS	2.11	0.65	3.48	0.76	<0.001
	ODI	19.86	7.28	27.13	7.94	<0.001
	NRS	2.23	0.78	3.45	0.74	<0.001
	SLRT RIGHT	87.2	3.77	84.83	3.89	<0.001
	SLRT LEFT	83.21	16.34	81.46	13.99	0.251

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2nd follow-up	VAS	2.12	0.65	3.48	0.76	<0.001
	ODI	21.04	5.93	28.63	5.39	<0.001
	NRS	2.12	0.65	3.49	0.76	<0.001
	SLRT RIGHT	87.18	3.77	84.83	3.89	<0.001
	SLRT LEFT	87.2	3.77	84.83	3.86	<0.001
3rd follow-up	VAS	2.12	0.65	3.48	0.76	<0.001
	ODI	21.04	5.93	28.62	5.38	<0.001
	NRS	2.12	0.65	3.48	0.76	<0.001
	SLRT RIGHT	87.2	3.77	84.8	3.88	<0.001
	SLRT LEFT	87.23	3.77	84.78	3.92	<0.001
4th follow-up	VAS	2.35	0.85	5.57	0.97	<0.001
	ODI	20.41	5.63	31.15	5.16	<0.001
	NRS	2.35	0.85	5.57	0.97	<0.001
	SLRT RIGHT	83	6.06	68.28	5.62	<0.001
	SLRT LEFT	83.2	5.61	69.3	5.91	<0.001

DISCUSSION

Epidural steroid injections for lumbar radiculopathy have been used since 1953. Along with mechanical compression of nerve roots, lumbar radiculopathy can be triggered by different proinflammatory chemical agents, causing ectopic neuron firing. Steroids injected into the epidural space or around the affected nerve root are thought to inhibit these inflammatory mediators. However, there is conflicting evidence for the potential benefit of epidural steroid injections. Some studies have shown a moderate short-term benefit, whereas others have shown little difference between epidural steroid and placebo injections.[13,14] The large volume of fluid injected into the epidural space (i.e., normal saline or water for injection) is known to cause adhesinolysis surrounding inflamed nerve roots and washing out of inflammatory mediators, thus helping relieve symptoms. Various studies have compared the effect of steroids and normal saline in epidural injection, but the results were inconclusive.[15]

In our study, 68% of the patients in Group A and 68% in Group B were males with a male-to-female ratio of 1.5:1. A similar study by Sayegh et al. on 183 patients (steroid group: 93, WFI-group: 90) reported male preponderance (64.51% and 70% respectively).[16] The demographic characteristics, including distribution of sex (p=1) and mean age (p=0.628), were comparable in both groups. The clinical characteristics viz, duration of pain (p=0.969), radiation, cause of the pain due to injury, paraspinal muscle spasm spine flexion (p=0.918), extension (p=0.237), lateral bending (p=0.102), active left (p=959), passive left (p=1.00) active right (p=0.965) passive right (0.955) were comparable in both the groups. Further, the pre-injection pain pattern in terms of VAS score (p=0.190) and NRS (p=0.717) activity levels in terms of disability index, including ODIS, were also comparable (p=0.505).

The mean VAS scores in patients with group A and group B reduced at immediate post-injection (2.35 vs 5.57) (p<0.001), first (2.11 vs 3.48) (p<0.001), second (2.12 vs 3.48) (p<0.001) third follow up (2.12 vs 3.48) (p<0.001) and final follow up (2.35 vs 5.57) (p<0.001) compared to immediate pre-injection and significantly low at all the intervals in Group A compared to Group B. These findings suggest that the pain relief offered by epidural steroid injection was superior to conservative management.

After injection, the SLRT scores revealed better activity levels (> 60) in both groups. The score in group A for the right side was significantly higher (87.00 ± 4.32 vs. 68.37) compared to group B, but the SLRT score for the left assessment was comparable in both groups (83.07 ± 4.51 vs. 69.67 ± 14.83). A similar trend was noted at the first, second and third follow-ups. Thus, the activity levels based on SLRT showed improvement. Both groups were statistically comparable regarding their demographic data and the cause and duration of symptoms. The straight leg raising test improved in both groups; this improvement was faster among the steroid group's patients.

In our study, the ODIS index at immediate post-injection revealed significantly lower scores in patients with group A compared to group B (21.90 ± 8.33 vs. 30.03 ± 5.38; p<0.001) and the same pattern was observed during the first and second third and final follow up (19.47 ± 6.90 vs. 27.17 ± 5.42; p<0.001). These findings suggest that the disability observed in patients with epidural steroid injections was significantly lower than in conservative management. A similar study reported that the mean Oswestry Disability Index questionnaire score of steroid-group patients was statistically significantly lower than that of the WFI group at all post-injection re-evaluations. Patients receiving epidural steroids experienced faster relief during the first post-injection week. The study concluded that an epidural containing local anaesthetic and steroids treats patients with LBP and sciatica. The findings of the present study agreed with the results of this study.[16] The present study showed better outcomes in patients with epidural injections using ODIS for six months.

In this study, the patients were asked to report improved spinal motion. During the first (63.33%) and second (80%) follow-up, the improvement in spinal motion was reported to be better significantly in patients with group A compared to group B (p<0.050).

In the present study, self-reported satisfactory resumption of occupation was comparable in groups A and B (90% and 80%, respectively), suggesting a comparable effect of study drugs on the occupation.

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Overall, the present study showed that chronic low back pain treated with epidural steroid or conservative management has a beneficial effect in pain relief and improvement in activity levels, thereby lowering the disability and resumption of occupation. But, the outcome with the epidural steroid group was immediate and long-lasting.

CONCLUSION

The present study concluded that epidural steroid and conservative management had beneficial effects at the end of the final follow-up in managing chronic low back pain. However, results are more favourable with the steroid group than the conservative group. The positive effect was fast and longer pain relief and better activity levels, easing disability as VAS, NRS SLRT and ODIS assessed. Epidural injections are safe, effective, and less expensive with fewer complications and are an acceptable alternative to surgery in properly selected patients.

Limitations:
There was no long-term follow-up of more than 26 weeks, and radiological follow-up was not done. Pathological improvement/arrest was not documented, and the improvement in spinal motion and occupational resumption was subjective.

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