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Surgery Sparing Effect of Epidural Steroid and Gravity Lumbar Reduction Therapy in Conservative Treatment of Prolapsed Lumbar Intervertebral Disc

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ABSTRACT

Background: Conservative treatment is the first choice in treatment of prolapsed lumber inter-vertebral disc (PIVD). Surgery is indicated when conservative treatment fails.

Objective: To study the effectiveness of two conservative methods: epidural steroid (ESI) and Gravity lumber reduction therapy (GLRT) program in sparing back surgery.

Material and methods: 141 patients, male: female 59:82, of mean age – 51+/- 11.6 years; suffering from PIVD, for mean duration of 10.58 +/ - 3.8 weeks were included.

Intervention: Epidural steroid injection under fluoroscopic control was done 2 times in 2 weeks time. If there was no adequate improvement after 2 doses, GLRT was given 3 times daily; each session lasting for 30 minutes at the tolerated degree for 3 months.

Outcome-measures: Improvement was assessed by using physician-specific parameters, like pain by VAS, degree of SLRT positivity, restriction of forward flexion in inches and claudication distance in meters, patient-specific functional score: ODI. At least 50% improvement in these scores was considered adequate.

Statistical tools: Analysis of results was done by students' t test and chi square test. **Results:** mean base-line VAS score 6.48 reduced to 3.15 at 3 weeks, mean SLRT degree increased from 61.43 to 80.54 , mean claudication distance increased from 89 meters to 237, mean restriction of forward flexion of spine decreased from 11 to 3.1 inches; and spine-specific function ODI decreased from 11.09 to 3.08. The subjects were followed for minimum of 6 months (Mean- 7.4 +/_2.3). Of 104 patients available to follow-up, 9 (8.6%) fail to improve. Of 9 cases who did not improve 4 were subjected to surgery within 2 months.

Conclusion: Conservative management of PIVD with epidural steroid injection and GLRT was effective in avoiding back surgery in about 90% cases.

KEYWORDS	prolapsed lumber inter-vertebral disc, epidural steroid injection, gravity lumber reduction therapy, back surgery.

Introduction

Low back pain and radicular leg pain are common problems reported in the PMR OPD. Most common diagnoses of low back and leg symptoms are intervertebral disc herniation, spinal stenosis, intervertebral disc degeneration without disc herniation, degenerative spondylolisthesis with stenosis, and post lumbar surgery syndrome.[1,2,3]

Commonly employed management techniques are medications, physical modalities in the form of lumbar traction, heat therapies, exercise and manipulations, acupuncture, epidural steroid injections, ozone discectomy and surgery as last option.

Despite several studies demonstrating that surgery offers early benefit in terms of pain relief, non-surgical conservative management should be the first line of therapy. Epidural steroid injections (ESI) are an increasingly employed nonsurgical intervention. [4-12]

The effect of fluoroscopy guided epidural steroid injection in lumbosacral radicular syndrome, on pain and disability is small but significant. Moreover, ESI can be performed at a fraction of the cost of surgical intervention and there is no reported major complications or adverse effects.[14,15]

Lumbar traction is widely used treatment for Low back pain and there are different forms like auto-traction, mechanical traction, continuous lumbar traction, intermittent lumbar traction, pneumatic traction, and gravity dependent lumbar traction etc.[16]

Gravity lumbar reduction therapy provides enough traction force to distract the lumbar vertebrae, thereby reducing intra-discal pressure and alleviates pain in patients with low back pain or lumbar disc problems. This method uses gravity and patient's own body weight to produce traction for lumbar reduction with a vest around the chest.

Many patients report of good improvement after traction but

there is no clear cut documentation on which type of traction and for how long to continue and specially gravitational lumbar reduction therapy has been overlooked while very expensive and invasive treatment have dominated in the treatment of low back pain with leg pain.

The objective of our study is
To see the effectiveness of epidural steroid injection along with gravity lumbar reduction therapy in patients with lumbar inter-vertebral disc herniation with leg pain and who are potential candidates for surgery.

To develop a very inexpensive and minimally invasive treatment protocol that can be easily done in a rural setting and home environment.

Material and methods
Type of study was a prospective observational study. One hundred forty one (141) patients diagnosed as PIVD, admitted in PMR department, JNIMS, during April 2014 to July 2015. And **confirmed by MRI study** were included. Majority of the patients have been treated in other centers, and were advised surgery.

Patients were in the age group of 40 to 65 years with the most common age group 40 to 50 yrs, sex Male: Female 59:82, having symptoms more than 6 weeks.

Exclusion criteria
Patients with cauda equina syndrome, rapidly progressive sciatica or neurological deficit, previous disc surgery or epidural steroid injection within one year, other causes of nerve root compression like traumatic, neoplastic, infective, autoimmune or metabolic, developmental spine deformities were excluded from the study. The conditions like pregnancy, obesity and comorbid conditions like heart disease, stroke, bleeding disorder, uncontrolled HTN, hernia, hemorrhoids, recent abdominal surgery were taken as relative contraindications as GLRT may be difficult in some of the cases.

Patients were explained about the procedures and written consent was obtained from each. Prior ethical approval was taken from the IEC of JNIMS.

Under proper aseptic and antiseptic precautions, all the selected patients received ESI under fluoroscopic guidance with 80 mg methyl prednisolone acetate (Depomedrol) given twice in two weeks time. Patients were allowed to lie on prone position for few minutes in the idea of promoting ventral spread. If there was no significant improvement after 2 injections patients were given GLRT 3 times a day for consecutive three months.

Patient outcome measures were assessed 1. Clinically by using VAS (visual analog scale) for pain, SLRT (Straight Leg Raising Test) in degrees, claudication distance in meters, Forward flexion ROM of spine expressed as distance of finger tip from floor in inches, other ROM lateral flexion, rotation measured in grades of no, mild, moderate or severe restriction. 2. Bio-psycho-socially by using spine specific function Oswestry Disability Index (ODI) and patient satisfaction in grades as subjective improvement in terms of percentage.

Adequate response was taken as 50% reduction in VAS pain score, 30 degrees increase in SLRT, 2 grade improvement in ODI, 50% improvement in ROM, and 50% improvement in self satisfaction after second ESI. Improvement less than the set criteria as above were classified as inadequate response.

Assessment was done initially and after one week of first, and second dose of ESI. Those who did not respond to ESI were given additional treatment of GLRT. Patients were advised to continue GLRT three times a day for 3 months. Follow up program after completion of treatment were done monthly for three months and six months.

ILESI (Inter-laminar epidural steroid injection) was administered under fluoroscopy guidance using a C-arm under aseptic and antiseptic precautions. Patients were laid down recumbent on the side of leg pain and 80 mg of methyl prednisolone acetate (Depomedrol) was injected after confirming the needle tip position at epidural space by injecting radiopaque dye (Omnipaque). Patients were observed for one day after injection to see any unwanted side effects of injection and discharged with back care advices. Pic.1.

GLRT was done by suspending the patient on a tilt table using a chest harness. Usually starting from 35 degree and gradually increasing the inclination by 5 to 10 degrees, in subsequent sessions, and as the patient can tolerate, till it reaches 90 degree for 30 minutes. If patient cannot tolerate higher degree of inclination, he or she should be able to attain at least 60 degree of inclination for 30 minutes to have an effective traction. Patients were demonstrated how to suspend themselves at home environment at the achieved tolerable inclination and discharged with advice to continue traction at home for three months and to come for regular assessment. Pic.2, Pic.3

Statistical analysis
Means of initial VAS score (pain), ODI scores, SLRT degree, claudication distance and forward flexion of spine were compared with the intermediate and final scores by using student's paired t-test. Using chi square test compared normal variables like neurological deficits. Data were analyzed by using SPSS version 14.0.

Results
Out of 141 cases enrolled for the study 104 patients completed the program 37 patients did not complete as they did not turn up for follow up.

The mean age in the study group was 51+/- 11.6 with commonest age group 41 to 50 years (31%), Male : Female ratio 59:82, Disease duration 10.58 +/- 3.8 wks, mean VAS score (pain) 6.48(1.28), mean ODI score of 54.40 (13.67), mean SLRT 61.43 (20.39) in degrees, mean claudication distance 86.98 (95.12) in meters, ROM spine forward flexion restricted 10.90 (9.40) in inches. Level of prolapse was most common at L4-L5 with no striking side preference. Table 1.

The change in scores from the initial assessment at 3 wks and at 6 mths (shown in the Table) VAS score 3.15 (1.72) and 1.23 (0.49), ODI score 27.60 (15.61) and 8.83 (6.01), SLRT degree 80.54(14.56) and 89.17 (4.78), claudication distance 237.27 (86.71) and 295.4(20.9), ROM spine forward flexion 3.08 (6.48) and 0.44 (1.70). Table 2.

Summary
In this study 63 patients (66.3%) improved with ILESI only and this population of patients did not require any further treatment in one year follow up. 32 patients (33.7%) who were not improved with ILESI only, showed significant improvement after adding GLRT. 9 patients (8.7%) did not show any significant improvement with both the modalities and were advised surgical intervention. 4 of the 9 patients underwent surgery. At 6 months follow the statistically significant improvement in pain and disability scores (p-value = 0.00), that had been achieved, were found to be maintained.

Pic.1 Proper needle position and Dye spread in epidural space

Pic. 2 GLRT (Gravity Lumbar Reduction Therapy) at Hospital

Pic.3 GLRT at Home environment

Table 1: Epidemiological Parameters

Parameter	Values
Mean Age in Years	51 (11.6)
Sex- Male:Female	59:82
Duration of disease in weeks	10.58 (3.8)
Mean VAS Score	6.48 (1.28)
Mean ODI Score	54.40 (13.36)
Mean SLRT in degree	61.43 (20.39)
Mean claudication distance	89.68 (95.12)
ROM Spine Forward flexion (inches)	10.90 (9.40)

Table 2: Changes of out-come scores from initial to assessment at 3 weeks and 6 months

Characteristics: Mean Scores	Baseline	At 3 weeks	At 6 weeks	p-value
VAS Score	7.30 (3.58)	3.15 (1.72)	1.23 (0.49)	.00
ODI Score	54.40 (13.67)	27.60 (15.61)	8.83 (6.01)	.00
SLRT Degree	61.43 (20.39)	80.54 (14.56)	89.17 (4.78)	.00
Claodication Distance (meter)	89.68 (95.12)	237.27 (86.71)	295.4 (20.9)	.00
ROM Spine forward flexion (inches)	10.90 (9.40)	3.08 (6.48)	0.44 (1.70)	.00

Discussion

Epidemiologic studies indicate that low back pain with leg pain is very common problem at 85-95% of lifetime incidence. Of these 2-5% have symptomatic prolapse intervertebral disc. On population per year basis 0.5 – 1.0% develop sciatica due to PIVD.[17,18] Upto 70% of PIVD resolve by itself in 6 weeks without any intervention and most guidelines recommend considering surgery for the remainder 30%.[19,20] On the other hand spontaneous resorption is a well established phenomenon as reported by many authors like Kim ES et.al[21], Chiriac A et.al[22]

Studies have shown that conservative and surgical management has the same outcome in the long run and many authors compared the effectiveness of conservative treatment with surgery in the management of PIVD. In a landmark study by Weber and same cohort by Mather, in a randomized control trial 128 patients were followed for ten years with conservative and surgical treatment. The results tend to become similar at one year and beyond two years, there was no statistically significant difference between the two groups. [23]

In another study by Wilco C Peul et.al [24] on prolong conservative care vs early surgery in patients with sciatica caused by lumbar disc herniaton. 283 patients in 9 Dutch hospital divided into two groups with early surgery and conservative treatment with 2 years follow up and concluded that early surgery give more rapid pain relief but outcomes were similar at 1 year and outcome in pain and disability were same or maintained at two years follow up. Conservative management was done by family physicians and there were no physiatrist or physiotherapist mentioned who could have provided better management.

Question arises what should be the components of conservative management frequently used and how long should we continue. **Traction, mainly the pelvic traction is no more effective than placebo; physiotherapy exercises, control movement advices, spinal manipulation no evidence base support and spinal braces are useful only for temporary pain relief.[25]

Many studies[26] have reported usefulness of epidural steroid in reducing pain and inflammation but they concluded that they are no more effective than a placebo

There have been reports [27], that blind epidural injections that is without fluoroscopy guidance, even in experienced hands, the injectate may be misplaced in up to 30% of the cases.

Derby and colleagues,[28,29] developed the fluoroscopically guided transforaminal injection techniques for diagnostic and therapeutic purposes to allow precise delivery of high concentrations of the injectate directly at the ventral aspect of the nerve root sleeve and posterior annulus.

Spiiker-Huiges A et al[30] studied the cost effectiveness of epidural steroid and concluded that effect on pain and disability is small but significant and at lower costs with no serious side effects.

Manchikanti L et al[15] in a randomized double blind, active control trial of effectiveness of lumbar interlaminar epidural injections in disc herniation concluded it as an effective modality.

Manson NA et al[31] in a retrospective case series concluded transforaminal epidural steroid injections are an important treatment tool, preventing the need for surgery in 56% of patients with LDH.

Lutz GE et al[32] long term effectiveness of fluoroscopic transforaminal lumbar epidural steroid injections in patients with refractory radicular leg pain and opined that the procedure is an effective nonsurgical treatment option.

Manchikanti L et al[33] again in another systemic review concluded that fluroscopically directed epidural injections provide long term improvement in back and lower extremity pain in patients with lumbar discogenic pain with no limited evidence showing the potential effectiveness of surgical interventions compared to nonsurgical treatments.

Bicket MC et al[34] in a systemic review and meta-analysis of randomized controlled trials remarked that epidural steroid injections may provide a small surgery-sparing effect in the short term compared with control injections and reduce the need for surgery in some patients who would otherwise proceed for surgery.

In a 3 large trials of 120 patients comparing caudal, interlaminar and transforaminal approaches to epidural injections for low back pain and lower extremity pain patients, by Manchikanti L et al, a similar portion of patients showed significant improvement in the three trials: 76% with caudal, 71% with interlaminar and 73% with transforaminal approaches at 2 years.[35]

Autotraction was defined as the use of one's own weight to create the traction force and GLRT is one of its kind. Telso and Merlo[16] (1993) from Italy reported of superiority of autotraction to conventional passive traction.

Oudenhoven RC[36] presented 121 case of low back and extremity pain treated with GLRT that relieved pain.

Although some form of spinal traction/distraction has been used for centuries, the results were erratic and inconsistent, so that most spine specialists began to abandon this approach in the 1960s.[37]

Gravity Lumbar Reduction therapy was first introduced in Minneapolis: Sister Kenny Rehabilitation Institute in 1976. The effective distraction force is 40 to 50% of body weight and this force effectively assist in reducing the intra-discal pressure and enhances the regression of prolapsed disc. It was Burton and Nida[38] who introduced the concept of Gravity Lumbar Reduction Therapy 3

Tekeoglu I et al[13] in their study also found GLRT as an effective method of distracting intervertebral disc space by about 3mm. which had been shown by pre and post rontgenograms.

On the other hand Janke AW et al[39] had demonstrated effectiveness of gravitational traction in distracting IV disc space by pre and post traction rontgenograms in different studies.

The advantage of gravity induced lumbar reduction have been recognized and such treatment had been advanced by Dr Charless V Burton.[40]

A Cochrane review on traction for LBP with or without sciatica (Clarke et al, 2007)[41] found that autotraction was moderately more effective than mechanical traction for global improvement in patients with sciatica.

GLRT system uses weight of the lower half of the body to provide a traction force and is low cost and means for support can be made easily in the home environment through an overhead strap and some discomfort experienced by the patients during traction can be overcome by some adjustment in the corset and by slowly increasing the inclination to a tolerable angle of inclination. It effectively distracts the vertebral bodies by providing a traction force more than 25% body weight thereby reducing the intra-discal pressure, enhances reduction in size of prolapsed disc and relief mechanical compression of nerve root and provides long term pain relief.

Conclusion

It can be concluded that short term improvement can be achieved by some form of epidural steroid injection which can be administered without much difficulty in rural setting and long term improvement can be achieved by some form of gravity traction preferably GLRT which can be done any where in home environment. And this is good option in the rural population. Minimum of 6 months wait n watch policy is judicious before considering invasive options, including minimally invasive ones and reconsider again before advising surgery.

Limitation of our study

Our study was simple prospective observational study, a randomized control trial is definitely needed. A longer period of follow up in years is required to obtain a reliable data on long-term effectiveness of the treatment methods. It could be more significant if we classified the type of disc prolapse and study the respective outcomes. For self reported satisfaction more reliable tools like 7-point Likart scale could be better. Drop out rate were a little on higher side.

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