



INNOVATIVE MULTIDISCIPLINARY TREATMENT FOR LUMBOSACRAL RADICULAR PAIN – A LONG TERM FOLLOW UP STUDY

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ABSTRACT

Background: Back pain with or without lumbosacral radicular pain is the most common pain condition seen by doctors.

Aim: To evaluate results of multidisciplinary treatment for low back pain and lumbosacral radicular pain

Material and Methods: This prospective follow study was carried out at private in Pune city of India. Follow up of the patients, who underwent multidisciplinary treatment for low back pain and lumbosacral radicular pain done for over the period after obtaining written informed consent of the patients. Patients underwent Transforaminal epidural injection with Fluoroscopy guidance at level of disc herniation causing nerve compression followed by 12 days' rest. After 12 days, patient underwent multidisciplinary therapy as per protocol which included, physiotherapy, ergonomics, nutritional guidance, psychological counselling and complementary therapy. **Statistical analysis:** Data was analysed by using statistical software Primer of Biostatistics. Measurements were expressed as means and standard deviations for continuous variables and percentages for categorical variables and was analysed. Pre- and postoperative interventional values were compared using the one way Analysis of Variance (ANOVA) test. A p value less than 0.001 was considered statistically significant.

Results: Total 520 patients were included in the study. Mean follow up of the patient was 4.7 years (SD=3.6 years). Total female patients were 288 (55.38%) and male patients were 232 (44.62%). Straight leg raise (SLR) for right and left leg was significant for all patients ($p < 0.001$). The improvement in neurodeficit for L3L4 (right and left leg) was significant among those having neurodeficit ($p < 0.001$). Neurodeficit involving L4L5 had statistically significant improvement ($p < 0.001$). Patients with neurodeficit involving L5S1 also showed statistically significant improvement ($p < 0.001$). Patients with neurodeficit affecting S1S2 showed statistically significant improvement ($p < 0.001$). Patients had significant improvement in pain scores (Numerical rating scale) ($p < 0.001$). Lumbar spine movements, namely, Flexion, Extension, Lateral rotation improved significantly post treatment. Oswestry Disability Index (ODI) scores improved after treatment ($p < 0.001$).

Conclusion: Innovative multidisciplinary approach was found to be effective in for low back pain and lumbosacral radicular pain.

KEYWORDS : Back Pain, Lumbosacral radicular pain, Multidisciplinary Approach

INTRODUCTION –

Back pain with or without lumbosacral radicular pain is the most common pain condition seen by doctors. Each year in England, about 2.3 million people, 4.2% of the population, consult a general practitioner at least once for LBP and these individuals represent about 20% of those with LBP¹ UK costs associated with back pain to NHS were conservatively estimated in 1998 as £1.1 billion.² For countries like India, back pain and lumbosacral pain epidemiological data are not available. United Nations and WHO, endorsed 2000-2010 as the Bone and Joint Decade and declared low back pain as the most prevalent musculoskeletal problem. Low back pain and lumbosacral pain are medical disorders where there is no consensus for treatment despite numerous studies available in literature regarding their treatment. Surgery is definitive only for back pain with neoplasm, spinal infections, cauda equina syndrome. Majority of patients presenting with lumbar disc prolapse and lumbosacral radicular pain are treated by various techniques depending on the specialist doctor they visit. Various treatment options ranging from bed rest, medications, epidural injections, chiropractic manipulations, physiotherapy, acupuncture, Ayurveda (Indian traditional medicine), Massage therapy etc. have been used for

treatment. Lumbar spine surgery has given debatable results with few studies reporting surgery for Lumbosacral radicular pain giving good outcome.³ Substantial number of patients never have relief from surgery^{4,5}. Over 20% of patients are unsatisfied with treatment including surgery at 5 years follow up.⁶

Interventions like epidural steroid injections have been widely used for non-surgical treatment of lumbo Sacral Radicular pain. Epidural Steroid Injections are one of the commonest procedures performed in the UK, with 45,948 ESIs recorded in the National Health Service in 2002/2003.⁷ Literature has abundant studies on minimally invasive treatments particularly epidural steroid injections for lumbosacral radiculopathy. The study results are either in favour of epidural injections or negate it. Wang et al conducted a meta-analysis on surgical versus nonsurgical treatment of chronic low back pain and found that for chronic low back pain, nonsurgical treatment was shown to be effective, feasible, and safe.⁸ Luijsterburg et al conducted a systematic review on effectiveness of conservative treatments for the lumbosacral radicular syndrome in 2004. This review concluded that in long-term there was no evidence in favour of epidural steroid

injections when compared to placebo or NSAID apart from conflicting evidence for short-term pain relief.⁹

Lumbosacral radiculopathies due to herniated disc results from mechanical pressure on a nerve root by the disc and in addition the chemical mediators like prostaglandins released from herniated disc cause inflammation of the nerve root. The goal of an epidural steroid injection is to place corticosteroids in or near an area of inflammation surrounding the nerve root. Therefore, the efficacy of epidural injection improves with the targeted delivery of drug into anterior epidural space.^{10,11} Various studies have been done regarding the effectiveness of epidural steroid injection in terms of duration of pain relief.^{12,13} Sariyildiz, et al conducted a study on the effectiveness of fluoroscopically guided transforaminal epidural steroid injections on radicular pain (VAS scores), functionality (Oswestry disability index), psychological status (hospital anxiety and depression scale) and sleep quality (Pittsburgh sleep quality index (PSQI) in patients with lumbar disc herniation. They observed a 50 % improvement in VAS scores with a follow up of 12 months. Park et al compared the short-term effect and advantage of transforaminal epidural steroid injection (TFESI) performed using the Kambien's triangle and sub-pedicular approaches.¹⁴

The West Study published in 2005, by Arden et al emphasized the need for multidisciplinary treatment for sciatica.¹⁵ This was a multicentre randomized, double-blind, placebo-controlled, parallel-group trial in four secondary pain-care clinics in the UK. The main outcome measure was the Oswestry low back pain disability questionnaire. They derived the following conclusion from their study "In this pragmatic study, Epidural steroid injections offered transient benefit in symptoms at 3 weeks in patients with sciatica, but no sustained benefits in terms of pain, function or need for surgery. Sciatica is a chronic condition requiring a multidisciplinary approach. To fully investigate the value of epidural steroid injections, they need to be evaluated as part of a multidisciplinary approach." The literature shows variable results with epidural steroid injections done for lumbosacral radicular pain and long-term results are questionable with need for repeat injections. On extensive literature search, we were unable to find studies involving follow up of epidural steroid injections for at least 5 years. Considering the biopsychosocial model of chronic pain and diverse treatment options (including variable technique for epidural steroid injections) we decided to develop an innovative treatment plan for Lumbosacral radiculopathy based on multidisciplinary approach. Patients with diagnosis of prolapsed Lumbosacral intervertebral disc with radicular pain were treated with Transforaminal steroid injection followed by 12 days of active rest followed by 12 days Multidisciplinary treatment which included Physiotherapy, Complementary therapy, psychological therapies, ergonomic sessions, nutritional guidance. These patients were followed up over a period of 8 years to assess the long-term results.

METHODS:

We did a prospective evaluation and follow up of 520 patients, who underwent multidisciplinary treatment for low back pain and lumbosacral radicular pain. Study was carried out in a Private Speciality Center in Pune city of India.

The patients were enrolled in treatment and follow up was done from July 2010 to July 2018 (8 years). The minimum follow-up period was 3 years (119 patients enrolled in 2014). Maximum follow up was for 8 years (90 patients enrolled in 2010).

Patient inclusion criteria in study –

1. Clinically diagnosed and MRI confirmed L2 to S1 any disc with radiculopathy (unilateral or bilateral, single or multiple levels)

2. Either sex, 20 years to 75 years of age.
3. Patient giving written informed consent for entire treatment protocol.

Patient exclusion criteria in study –

1. Cauda equina syndrome
2. Sensory or motor neurodeficit present for more than 2 years.
3. Duration of symptoms more than 2 years
4. Complete lower limb paralysis
5. Coagulopathy
6. Allergy to dye/local anaesthetic/steroid
7. Local site skin infection.
8. Patients with impaired cognition or psychiatric ailments.

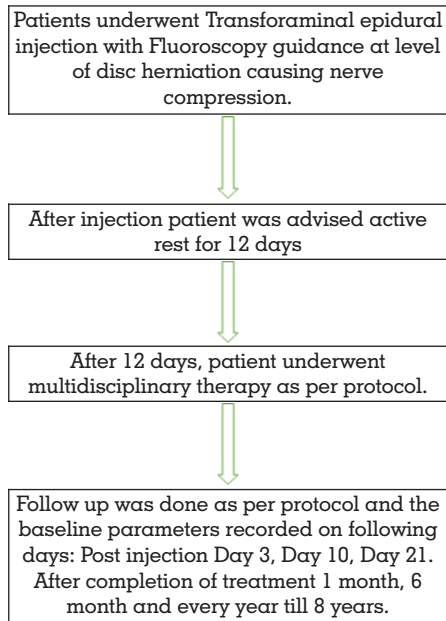
Before commencing treatment, a detailed evaluation of patients was done and following clinical parameters were recorded:

SLR right/left leg	SLR represents straight leg raise. Positive SLR for Lumbosacral nerve compression is between 30 to 70 degree. Beyond this value it can be false positive.
Neurodeficit L3-L4	This is assessed by knee extension. Motor power grading is done from 0 to 5. (right/left)
Neurodeficit L4-L5	This is assessed by Dorsiflexion foot at ankle. Motor power grading is done from 0 to 5 (right/left)
Neurodeficit L5-S1	This is assessed by knee flexion. Motor power grading is done from 0 to 5 (right/left)
Neurodeficit S1-S2	This is assessed by Plantar Flexion of foot at ankle. Motor power grading is done from 0 to 5 (right/left)
Pain scores	Pain was assessed using Numerical Rating Scale where 0 represents no pain and 10 is the worst possible pain
Spine movements Flexion	Normal range of Flexion of Lumbar spine is 50-60 degrees
Spine movement Extension	Normal range of Extension of Lumbar spine is 20-35 degrees
Spine movement right lateral flexion	Normal range of right lateral flexion of Lumbar spine is 20-25 degrees
Spine movement left lateral flexion	Normal range of Extension of Lumbar spine is 20-25 degrees
ODI (Oswestry Disability Index)	This tool is used to measure patient's functional disability due to low back pain. It is calculated as a percentage score based on daily activity performance. 0-20% represents minimal disability. 21-40% represents moderate disability. 41-60% represents severe disability. 61-80% represents crippled. 81-100% represents bed bound patients.

All patients underwent following treatment protocol:

Total 745 patients with lumbosacral radicular pain were enrolled for treatment. 50 patients were lost on follow up and hence excluded from study. 175 patients were found to have psychiatric illness requiring medications and active management. Hence excluded from study.





Transforaminal epidural injection:

All injections were done using the same technique in operation theatre under Strict aseptic technique. Patients were placed prone and C-arm fluoroscopy was utilized for level identification and needle placement. Lidocaine 2% was administered as local anaesthetic infiltration at injection site. 22G Quincke's needle was used for transforaminal epidural injection at affected level, images taken in AP and lateral view to confirm needle tip position. Before injecting drug, intravascular or intrathecal needle placement was excluded and proper needle placement as well as dye spread was confirmed by injecting Omnipaque 300 2-3 ml. A mixture of 0.125% Bupivacaine 3 ml with 20 mg Depot Methylprednisolone was then injected. The procedure was done at all affected levels (based on clinical and MRI correlation).

Multidisciplinary Treatment:

Physiotherapy:

Initial 4 days of Electrotherapy followed by Core strengthening, back muscle strengthening, Sciatic nerve flossing or stretches.

Ergonomics:

A detailed evaluation of posture in relation to patient's daily activities like computer use, sports, domestic chores was done and corrections were suggested to improve posture.

Nutritional guidance:

Dietary guidance was provided as per vitamin deficiencies and lifestyle.

Complementary Therapy:

This included Panchkarma and Basti treatment as per Ayurveda practices. Panchkarma is considered as one of the most important treatment for all diseases as per Ayurveda. Basti is one of the five procedures of Panchkarma for diseases resulting from "Vata". Vata dosha resides in large intestine and is found in patients suffering from Sciatica. Basti treatment is a herbal decoction of oils and medicines given per rectum to eliminate "Vata dosha" from its seat (large intestine).

Psychological counselling:

Psychological counselling and Cognitive Behavioural Therapy, Stress management sessions were given as per requirement.

STATISTICAL ANALYSIS:

Data was collected using a structured proforma on Excel

software (Microsoft, Seattle, USA). Data was analysed by using statistical software Primer of Biostatistics. Measurements were expressed as means and standard deviations for continuous variables and percentages for categorical variables and was analysed. Pre- and postoperative interventional values were compared using the one way Analysis of Variance (ANOVA) test. A p value less than 0.001 was considered statistically significant.

Ethical considerations:

The study was conducted according to the Declaration of Helsinki.. A written informed consent was taken from all patients after explaining the procedure.

RESULTS:

Total 520 patients were included in the study. Mean follow up of the patient was 4.7 years (SD=3.6 years). Total female patients were 288 (55.38%) and male patients were 232 (44.62%).

Age of the patients ranged from 19 years to 88 years. Majority of the patients were in the 41-60 years of age group (45.58%) followed by 19 to 40 years (33.85%) and above 60 years age group (20.57%).

Table No. 1: Gender-wise distribution of the patients

Sr. No.	Gender	Frequency	Percentage
1.	Male	288	55.38
2.	Female	232	44.62
	Total	520	100.00

Table No. 1: Age-group wise distribution of the patients

Sr. No.	Age Group	Frequency	Percentage
1.	19 to 40 years	171	33.85
2.	41 to 60 years	237	45.58
3.	Above 60 years	107	20.57
	Total	520	100.00

Improvement in outcome variable on multiple follow-up:

Straight leg raise (SLR) for right and left leg was significant for all patients (p<0.001). The improvement in neurodeficit for L3L4 (right and left leg) was significant among those having neurodeficit (p<0.001). Neurodeficit involving L4L5 had statistically significant improvement (p<0.001). Patients with neurodeficit involving L5S1 also showed statistically significant improvement (p<0.001). Patients with neurodeficit affecting S1S2 showed statistically significant improvement (p<0.001). Patients had significant improvement in pain scores (Numerical rating scale) (p<0.001). Lumbar spine movements, namely, Flexion, Extension, Lateral rotation improved significantly post treatment. Oswestry Disability Index (ODI) scores improved after treatment (p<0.001).

Table No. 3: Improvement in outcome variable on multiple follow-up

Sr. No.	Outcome Variable	F Value	P Value	Statistical Significance
1.	Straight leg raise (SLR) for right side	68.71	0.0001	Highly significant
2.	Straight leg raise (SLR) for Left side	67.10	0.0001	Highly significant
3.	Neurodeficit for L3,L4 – Right Side	10.80	0.001	Highly significant
4.	Neurodeficit for L4,L5 – Right Side	11.28	0.001	Highly significant
5.	Neurodeficit for L5,S1 – Right Side	9.42	0.001	Highly significant
6.	Neurodeficit for S1,S2 – Right Side	7.74	0.001	Highly significant
7.	Neurodeficit for L3,L4 – Left Side	8.07	0.001	Highly significant

8.	Neurodeficit for L4,L5 – Right Side	13.62	0.001	Highly significant
9.	Neurodeficit for L5,S1 – Right Side	10.82	0.001	Highly significant
10.	Neurodeficit for S1,S2 – Right Side	7.24	0.001	Highly significant
11.	Spine Movement Flexion	80.63	0.0001	Highly significant
12.	Spine Movement Extension	51.38	0.0001	Highly significant
13.	Spine Movement -Right Lateral Flexion	240.46	0.0001	Highly significant
14.	Spine Movement -Left Lateral Flexion	255.62	0.0001	Highly significant
15.	Pain Score	926	0.0001	Highly significant
16.	ODI	563.92	0.0001	Highly significant

DISCUSSION:

Lumbosacral radicular pain was initially thought to be due to nerve compression secondary to prolapsed lumbar disc. Studies have demonstrated the effects of leakage of contents of nucleus pulposus causing the release of several neuropeptides such as substance P, vasoactive intestinal peptide, calcitonin gene-related peptide and also nitric oxide, tumour necrosis factor, prostaglandins, thromboxanes, and leukotrienes. These biological components cause inflammation, ischaemia and sensitize the adjacent nerve root and dorsal root ganglion thereby creating radicular symptoms.¹⁶ Steroids (glucocorticoids) have anti-inflammatory action by inhibiting production of these mediators. Epidural injections strategically place steroids near the inflamed nerve root, thus decreasing local inflammation and ischaemia, reducing neuronal oedema and pain. Hence Lumbosacral radicular pain has been traditionally treated with epidural steroid injections since 1901. These injections mostly provide short – moderate term relief from symptoms. Bunavendra et al indicated that evidence for transforaminal lumbar epidural steroid injections is Level II-1 for short-term relief and Level II-2 for long-term improvement in the management of lumbar nerve root and low back pain.¹⁷ Manchikanti et al conducted a systematic review of literature on epidural steroids on lumbosacral radicular pain. They concluded that epidural injections have short-term benefits in terms of alleviating pain and disability of lumbar disc herniation and moderate long-term effects.¹⁸ Similar results have been found with other systematic reviews^{19,20,21,22,23} Alan Kaye et al conducted a systematic review of randomized controlled trials of epidural injections in managing chronic spinal pain.²⁴They concluded that the evidence in managing lumbar disc herniation or radiculitis is Level II for long-term improvement with epidural injections.

All the studies have evaluated isolated role of epidural injections in managing lumbosacral pain, studies using multidisciplinary approach to treat chronic pain is not available. The results of epidural steroid injections are short – moderate term as seen in most studies but our study has proved otherwise. Our multidisciplinary treatment approach has shown long term benefits to patient in terms of pain relief and functionality as it addresses the entire spectrum of Lumbosacral radicular pain, namely the primary and secondary associated pathologies. Lumbar disc prolapses and radicular pain is associated with secondary pathologies like poor core muscle strength, weak paraspinal muscles, tight hamstrings. In addition, certain pathologies like flat foot, poor ergonomics can be the precipitating factor for early Lumbar spine degeneration and subsequent events. In addition, the patient has fear of activity leading to secondary muscle weakness. None of the studies and treatment protocols have

evaluated the role of multidisciplinary treatment of Lumbosacral radicular pain.

We did not conduct a randomized control trial to see the effects of transforaminal epidural injection versus multi-disciplinary therapy and subsequent follow up. This is the major lacunae of our study. Being a private pain treatment centre where patients mostly come after previous unsuccessful treatments, we commit to provide the best treatment approach for patients which definitely is multidisciplinary. In future, randomized control trials in this direction would provide further insight in treatment of lumbosacral radicular pain.

CONCLUSION:

Innovative multidisciplinary approach was found to be effective in for low back pain and lumbosacral radicular pain. In future, randomized control trials in this direction would provide further insight in treatment of lumbosacral radicular pain

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