Efficacy of spinal mobilization in the treatment of patients with lumbar radiculopathy due to disc herniation: A randomized clinical trial

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ABSTRACT

Introduction: Lumbar radiculopathy (LR) secondary to disc herniation is the most disabling clinical condition amongst people with low back pain. The objective of this study was to evaluate the efficacy of spinal mobilization in the treatment of patients with LR in addition to standard physiotherapy treatment. Materials and methods: The study is an observerblinded randomized clinical trial with concealed allocation and block randomization performed on 24 patients (13 male, 11 female) with age 51.45 ± 12.32 years and 3.83 ± 1.12 years of duration of lumbar radiculopathy. Control group received moist heat therapy and intermittent lumbar traction while the experimental group received spinal mobilization (transverse vertebral pressure) in addition to control treatment. Both groups received back care, postural advice and ergonomic advice. Outcome measures of pain on visual analogue scale (VAS), Quebec back pain disability index (QBPDI) and passive straight leg raise (PSLR) were collected pre-, post-3-days treatment and post-6-weeks follow-up. Two-way ANOVA was used with Bonferonni test for post-hoc analysis using SPSS version 11.5 for Windows at 95% confidence interval. **Results:** There was significant (p<.05) changes observed in all three measures- VAS (1.67 \pm 4.08), QBPDI (7.17 \pm 4.31) and PSLR (62.50 \pm 5.00) in the experimental group at immediate follow-up. The between-group difference in changes for long-term follow-up was not significant. Conclusion: Spinal mobilization in addition to standard physiotherapy comprising of moist heat and lumbar traction produced significant immediate effects on pain, disability and straight leg raise in patients with LR.

Key words: Maitland's concept, mobilization/manipulation, manual therapy, physiotherapy, rehabilitation, sciatica.

INTRODUCTION

Back pain is one of the most common musculoskeletal complaints seen in

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physiotherapy. Of it, the inter vertebral disc prolapse or disc herniation accounts for 15% of all back complaints [1], 38% of all hospital admissions in back pain [1], 50% of all the spinal surgeries [1], 50% of greater than 6 months work absence from back trouble [1], 58% of greater than 2 years work absence from back trouble [1], 80% of people disabled by the back complaints [1], and 76% of occupationally induced low back pain [2].

Disc protrusion and its resulting nerve root compression at the intervertebral foramen leads to sensory. Motor and reflex changes corresponding to the spinal segment, together with production of shooting pain along the

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specific dermatome, the condition termed as radiculopathy [3].

In spite of the growing conservative treatment techniques, there are quite a large number of patients with disc herniation opting for surgery either due to lack of effective relief or due to risks of developing chronicity. Conventional treatment techniques [4-8] never focused to that extent on restoring the rotational dysfunction asymmetrical associated with discogenic lumbar radiculopathy and they were more of indirect methods, without any proven clinical effectiveness. Various physical modalities [4-8] have been recommended in the literature for the treatment of low pack pain and / or lumbar radiculopathy such as therapeutic heat, therapeutic cold, TENS, ultrasound, interferential therapy, intermittent lumbar traction, etc. There is insufficient evidence to support the effectiveness of the physical modalities in the treatment for lumbar radiculopathy.

Various exercise regimens [4-8,12] have been recommended in the literature [10,11] for the treatment of low pack pain and / or lumbar radiculopathy such as, flexion exercises, extension exercises or both. There is little evidence to support the efficacy of any single therapeutic exercise regime and studies with controlled trials are lacking.

Maitland - Lumbar traction can be applied in a variety of ways, with the patient in a range of postures. The traction force may be sustained or intermittent, and may be applied manually or by machines. The most commonly used position is the fowler's position. The use of a split table eliminates the frictional force between the body and the couch and this has now become a very common clinical practice.9 Colachis and Strohm did a radiographic study on the effect of traction and concluded that it generally caused decreases in anterior disc heights and increases in posterior disc heights and these changes were associated with the flattening of the lordosis. The effect was reversible after 10 min [13]. Twomey found that the elongation of the spines was lost 30 min after traction [13]. Reilly et al found that changes in disc heights were greater as the angle of hip flexion increased [13]. Cyriax believed that the mechanical effect of traction was to produce negative pressure in the intervertebral disc which would "suck" back a disc protrusion [13]. Lee and Evans studied the loads on the lumbar spine during traction therapy and they concluded that traction produces a flexion moment as well as axial distraction of the lumbar spine. In addition, the spine will be subjected to anterior shear [13]. Meszaros et al [14] studied the effect of 10%, 30%, and 60% body weight traction on the Straight Leg Raise test of symptomatic patients with low back pain, and found that both the 30% and 60% body weight traction significantly improved the post-treatment SLR and the pain on the VAS.

Studies say that the presence of a neurological deficit does not contraindicate manipulation or mobilisation [15-17], and that it should always be an option before going for a surgical consult because of the reported successes with its use in clinical practice. With proper knowledge of the possible complications [15], and necessary precautions, a thorough pre- manipulative testing should be advised to prevent complications.

There are widely published case studies stating the effectiveness of flexion- distraction manipulation [17-23] and side posture rotary manipulation [24-28] in the treatment of sciatica due to disc herniation, when used in combination with other modalities ranging from general anesthesia [24], epidural steroid injection [25] to exercises for strength [19], flexibility [20], endurance [21], stabilisation [22] and sensory- motor training [18], electrical stimulation [18], moist heat [19], trigger point therapy [22], nutritional advice and back education [28].

Ottenbacher and Difabia [29] did a quantitative review – meta analysis for the efficacy of spinal manipulation or mobilisation therapy and concluded that it was effective when used with other forms of treatment or when measured immediately following therapy. The results however provided only empirical support when SMT was used to treat pain, flexibility limitations, and impairment in physical activity. Another comprehensive systematic review done by Bronfort [30], on the recent studies showed that there is moderate evidence for short-term efficacy of spinal manipulative therapy in the treatment of acute and chronic low back pain. There is insufficient data available to draw conclusions regarding the efficacy for the treatment of lumbar radiculopathy.

Passive movement [31] as a treatment technique can be broadly divided into its use as mobilization (passive oscillatory movements) or manipulation (small amplitude thrust / stretch performed at speed at the limit of a range of movement). Mobilization [31] is the method of choice for most lumbar disorders because it can be used as a treatment for pain or for restoring movement in a hypomobile joint. It can be adapted to suit the severity of the pain, the irritability of the disorder, and the stages and the stability of the pathology.

The Maitland concept [9,31-34] requires open-mindedness, mental agility, and mental discipline linked with a logical and methodological process of assessing cause and effect. The central theme demands a positive personal commitment (empathy) to understand what the person (patient) is enduring. The key issues of the concept that require explanation are personal commitment, mode of thinking, techniques, examination, and assessment [31].

Maitland's approach to treatment consists of a thorough subjective examination to determine the severity, irritability, nature and the stage of the patient's complaints. Here the patient has the control over the techniques performed, and hence it reduces the possibility of any undue harm. Treatment was progressed or modified depending on continuous methodical reassessments throughout the treatment process. Maitland also describes the importance of the Slump test and the SLR for evaluating the neural tissues in patients with back complaints [32].

Coxhead et al [35], studied the effect of four treatments for sciatic symptoms- traction, exercises, manipulation (as laid down by Maitland), and corset in a randomized controlled trial in 322 outpatients. There was thus sixteen treatment groups, enabling a comparison of combinations of methods as well as of individual methods. Progress was measured by the patient's account of symptomatic improvement or deterioration and by return to work or normal activities. They found that there was a significant increase in symptomatic improvement with increasing numbers of treatments used in combination. There were no beneficial effects of treatment detectable at four or sixteen months. Also, in the short term, active physiotherapy with several treatments appears to be of value in the outpatient management of patients with sciatic symptoms, but it does not seem to offer any longer term benefit.

Maitland describes rotational mobilisation techniques and also reports cases [9] stating their effectiveness in the treatment of sciatica due to disc herniation and nerve root pain in lumbar radiculopathy. He classifies these techniques as either passive physiological or the passive accessory techniques. Of the passive accessory rotational techniques, transverse pressure over the spinous process and the unilateral postero- anterior pressure over the transverse process are described, as effective [9]. Maitland's school of thought is universally accepted as an evidence based clinical reasoning program for the assessment and the treatment of patients and further advantages of this approach is found in various other literature [9,36]. Maitland's approach may prove an answer to these questions by unilateral rotational mobilization techniques, which can restore the vertebral position and also can decompress the nerve root by opening the intervertebral foramen [9].

The purpose of the study is to compare the effectiveness of Maitland's segmental mobilisation technique and conventional physical therapy in the treatment of lumbar radiculopathy due to disc herniation, to develop an effective and an efficient nonoperative treatment method in physical therapy for patients with unilateral lumbar radiculopathy caused due to disc herniation, and to evolve a method of treatment which will show better immediate and long- term relief for patients with unilateral lumbar radiculopathy caused due to disc herniation.

We initially hypothesized that Maitland's segmental rotational mobilisation would be more effective than the conventional physical therapy in the treatment of unilateral lumbar radiculopathy in reducing the pain intensity; improving the range of straight leg raise (SLR); and improving the Quebec Back Pain Disability Index (QBPDI) score.

MATERIALS AND METHODS

Ethical clearance

The study protocol was approved by the scientific committee of Manipal College Of Allied Health Sciences (MCOAHS), Manipal. All participants were required to provide a written informed consent prior to their screening and participation in the study.

Study design

Observer-blinded randomized clinical trial.

Study setting

Out-patient treatment setting in a multispecialty university-affiliated teaching hospital.

Study location

Dept of Physiotherapy, Manipal College Of Allied Health Sciences (MCOAHS), Manipal.

Sampling

Convenient sampling.

Subjects

Out- patients referred by a physician to the physical therapy department in Kasturba Hospital, Manipal, for conservative treatment of leg pain and/ or low back pain or discomfort.

Participant selection

The participants were selected based upon the following criteria.

Inclusion criteria

Age between 20 and 50 yrs; medical and provisional diagnosis of lower lumbar intervertebral disc prolapse $(L_4 - L_5 \text{ or } L_5 - S_1)$ with lumbar radiculopathy; sudden onset, acute, stable, non-irritable and mechanical symptoms; sensory and / or motor and / or reflex changes indicative of a single level of root involvement; painful and limited POSITIVE SLR within the first 70 degrees, with the radiating pain of the same nature as that of the subjective complaint. The leg pain should be more than the back pain during the test;³⁷ painful and restricted unilateral posteroanterior pressure on the ipsilateral or the contralateral transverse process; Grade II or a Grade III transverse vertebral pressure on the spinous process directed from the painfree side to the painful side SHOULD be restricted and also mimic the exact nature of the perceived complaint, compared to the other side.

Exclusion criteria

Subjects who underwent earlier course of physical therapy or manipulation in the past 6 months from the day of assessment; worsening neurological signs and symptoms found during reassessment in treatment; presence of cord signs and symptoms; subjects who took analgesics or anti-inflammatories other than that prescribed, during the study period; subjects screened as having non- spinal aetiologies or inflammatory aetiologies for lumbar radiculopathy; obesity, pregnancy; history of intake of anti- coagulants or steroids; and h/o depression or any other psychotic illnesses.

Participant recruitment

The subjects were randomly assigned to receive either the control or the experimental treatment using block randomization. The allocation method was concealed from the Efficacy of spinal mobilization in the treatment of patients with lumbar radiculopathy due to disc herniation: A 69 randomized clinical trial

therapist using sequentially numbered sealed opaque envelopes.

Procedure

The subjective and the objective examination of the patient clinically evaluated as a lumbar radiculopathy was done based on the assessment format described by Maitland, in Vertebral Manipulation [9], and is given in the appendix- VII. Pre- treatment and post- treatment outcome measurement for both groups include:

Pain severity, measured by the Visual Analogue Scale- VAS

The Scale is a 100mm scale from zero to hundred where zero indicating no pain and hundred indicating the intensity of maximum pain. The patients were asked to point out the reading corresponding to the perceived intensity of pain on the scale and were recorded. The VAS was found to be the most reliable and valid tool for assessment of intensity of pain [38].

Degree of positive SLR, on physical examination, measured by goniometry

The patient was positioned in supine. The axis of the goniometer was kept along the greater trochanter and the stable arm along the lateral line of the trunk and the mobile arm along the long axis of the thigh. The degree was measured directly from the readings on the protractor at the axis of the goniometer. The reliability and the validity of goniometer for the measurement of range of motion of joints has been well established and were also done as part of the study. The leg was passively raised by the examiner / tester until the patient's symptoms were reproduced and it radiated till the knee and at that position, the neck flexion and ankle dorsiflexion was added to confirm the increase in the pain. This point at which the pain was reproduced was measured as the degree of positive SLR. The SLR was considered negative if it was positive greater than 70 degrees, for the purpose of the study [37]. The SLR was stated as a sensitive

tool to measure the prognosis in lumbar disc herniations [39].

Score of perceived disability, measured by the Quebec Back Pain Disability (QBPD) Index

The patients were given a detailed explanation about the QBPD index [40,41] and the 20 items. Subjects, who felt any particular item was inapplicable to them, were instructed to imagine their own in that situation and were supposed to score that item. The score for each item is from zero to five and thus the minimum score is zero and the maximum is hundred for a subject, for all the twenty items together.

Treatment- control group

The Control group received the conventional physical therapy treatment, for three sessions on three days including the day of assessment, in following order;

• Five minutes of intermittent lumbar traction in the fowler's position. Pull of 60% of the body weight for 45 sec, with a rest period of 15 sec, with a sweep of minimum 30% of body weight, for 15 mins [14].

• Application of therapeutic heat to the low back through hydrocollator packs for 15 min. in the prone position with a pillow under the legs.

Treatment- experimental group

The experimental group received (in addition to the control group treatment) Maitland's transverse vertebral pressure [9] on the spinous process under consideration, from the painfree side to the painful side, in the following order in treatments for three sessions on three days including the day of assessment:

• Grade I transverse vertebral pressure on the spinous process under consideration 5 reps 2 sets;

• Grade II transverse vertebral pressure on the spinous process under consideration 5 reps 2 sets.

Re assessment of the significant objective findings: severity of pain on the Visual Analogue Scale; neurological Signs and SLR

Subjects with the presence of worsening neurological signs and symptoms were analyzed for the purpose of the study and then they were given the control group treatment protocol. Subjects who had good results in the significant objective findings were given, in order;

• Grade II transverse vertebral pressure on the spinous process under consideration 5 reps 2 sets.

• Grade III transverse vertebral pressure on the spinous process under consideration 5 reps 2 sets Re assessment of the significant objective findings.

• Grade IV transverse vertebral pressure on the spinous process under consideration 5 reps 2 sets, if indicated.

Home Programme (given as hand- outs) includes: advice about back care, postural control and ergonomics. Home programme was provided for both treatment groups and patient log was provided to ensure compliance.

Data analysis

The pain on VAS, the SLR in degrees and the disability score in QBPD index were taken as dependent variables. The variables were measured pre- and post- treatment and were also measured during the follow up period approx. after 6 weeks. The groups were taken independent variables. The values were recorded and analyzed within subjects as well as between groups using two-way analysis of variance (ANOVA) and post-hoc testing using Bonferonni test. The results were considered significant if p < .05.

The comparison between 3 days- post treatment and the pre- treatment variables was taken as the immediate post- treatment results. The comparison between 6 weeks-post treatment and the 3 days- post treatment variables was taken as the long- term post treatment results, for the purpose of the study.

RESULTS

A total of 160 subjects were assessed for the purpose of the study. Of these, 136 were excluded because, 23 were excluded in the screening examination on the absence of the specific inclusion criteria on physical examination, 18 had associated sacroiliac dysfunction,17 had lost follow up during the study period, 14 had both level herniations, 14 had associated piriformis syndrome, 11 had bilateral radiculopathy, 10 had co- existing hamstring tightness, 9 had cord involvement, 9 were treated conventionally before using physical therapy, 8 took unprescribed

	Overall	Control group	Experimental group	Level of significance p-value 1.000 (NS)	
Samplesize	24	12	12		
Gender	13 (11)	6 (6)	7 (5)	1.000 (NS)	
Male (female)					
Side of	17 (7)	10 (2)	7 (5)	.182 (NS)	
symptoms			. ,		
Right (left)					
Age (years)*	51.45 ±12.32	48.75 ± 8.66	54.16 ± 15.04	.292 (NS)	
Duration of	3.83 ± 1.12	4 ± 1.04	3.66 ± 1.23	.482 (NS)	
symptoms					
(years)*					

* Values in mean and standard deviation, NS- not significant at p <.05 level

Groups	Control group			Experimental group			p-value
Outcome	Pre-	Post-3-	Post-6-	Pre-	Post-3-	Post-6-] -
measures	treatment	days	weeks	treatment	days	weeks	
		treatment	treatment		treatment	treatment	
Pain severity	73.33 ±	51.67 ±	$40.00 \pm$	68.33±	10.00±	$1.67 \pm$.000* & .525
(VAS)	8.16	7,53	6.32	9.83	8.94	4.08	
0-100mm							
Passive SLR	27.50 ±	37.50 ±	42.50 ±	30.00 ±	52.50±	62.50 ±	.029* & .312
(degrees)	3.53	3.53	3.53	8.16	5.00	5.00	
QBPDI score	75.00 ±	60.33 ±	49.83 ±	52.50±	22.83±	$7.17 \pm$.007* & .085
(0-100)	6.23	9.24	13.41	11.71	7.08	4.31	

Table 2. Between-group comparisons for the three outcome measures at three levels ofmeasurement during the study

All values are in mean and standard deviation

*Significant at p < .05 level

VAS- visual analogue scale

SLR-straight leg raise

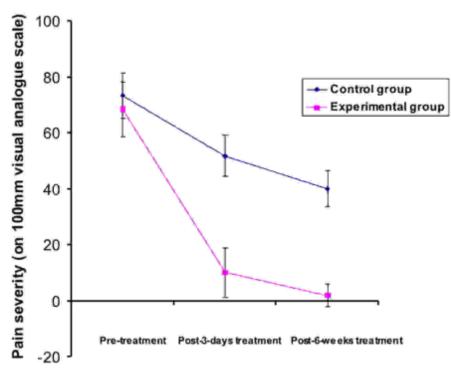
QBPDI-Quebec back pain disability index

medications before treatment, 2 were undiagnosed associated systemic illness, and 1 had diabetic neuropathy.

The overall and group-wise demographic characteristics of 24 included participants were provided in table-1.

Maitland group improved significantly greater than the conventional group in pain reduction (figure-1) in the immediate post-treatment period (p=.000) and was not significant in the long term post- treatment (p=.525). Maitland group also improved

Figure 1. Between-groups comparison of changes in pain severity



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Figure 2. Between-groups comparison of changes in passive SLR

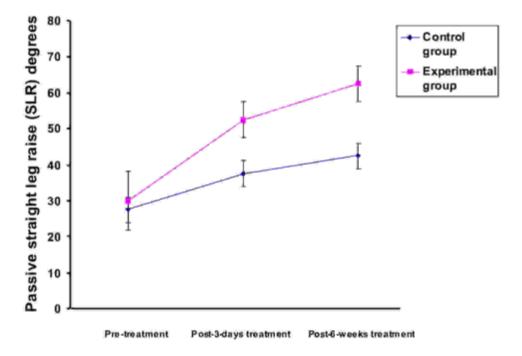
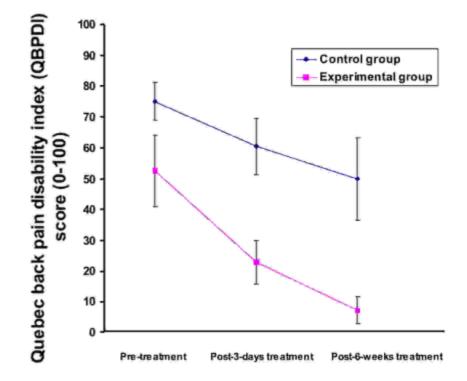


Figure 3. Between-groups comparison of changes in QBPDI score



significantly in the passive SLR (figure-2) than the conventional group in the immediate post treatment (p=.029) compared to the long term post treatment (p=.312). Maitland group also improved significantly in the QBPDI scores (figure-3) immediate post treatment (p=.007) compared to the long term post treatment (p=.085) compared to the conventional group.

DISCUSSION

The study results confirmed that Maitland's segmental rotational mobilisation using the transverse vertebral pressure improved the pain, disability and the SLR as a short-term effect of treatment and the effect is carried on till 6-wks post-treatment. But the improvement found in the long-term was not significant. The study results also disproved that manual therapy could not be effective in the long-term and its short- term effects are reversible [29,30]. The significant reduction in pain on VAS which is a subjective scale, in the maitland group could be explained by the possible effect that placebo had on the subjects because of the therapist's "hands-on" treatment on the spine.

The significant improvement in SLR is in agreement with the earlier studies stating that it is a sensitive tool to detect the prognosis [39] in disc herniation in comparison to the crossed SLR which is more specific to diagnosis. The SLR also very strongly correlated with the severity of pain and thus it also showed improvement. The initial significant improvement in the SLR could be because of the mechanical compression of the nerve root especially at the dorsal root ganglion, which is more mechanosensitive, could have been relieved by the rotation produced, manually [42,43].

Traction had been shown to decrease the degree of disc herniation, subsequently decreasing pressure on the nerve root and the dura mater. This reduction in pressure may restore some of the normal slack of the neuromeningeal pathway, allowing an increase in motion of the lower extremity and thus an improved SLR. Traction also has a stretching effect on the disc, ligaments, muscles, and the facet joints. In addition, stimulating the mechanoreceptors within these structures would cause an inhibition of pain impulses. The traction movement of ligamentous and osseous structures may also improve local nutrition to impinged and inflammed neural and ligamentous tissues, resulting in decreased pain transmission, which might also have improved the SLR [14].

The reason why SLR did not improve in the long term could be the "irritation" of the nerve root that accompanies the inflammatory process secondary to the compression or on exposure to the nucleus pulposus or the blood vessels in the annulus [39]. The significant correlation (p<.05) noted between the variables chosen for the study could be because of their higher sensitivity and responsiveness to clinical change.

Another point about this study was the adoption of an outcome measure, which is an indication of subjective well being, and health related quality of life. It is the ultimate goal of our therapy. The reason why Quebec Back Pain Disability Index was chosen in our study was because it is a reliable, valid, and responsive measure of disability in back pain, compared to the other outcome measures like the Roland- Morris, Oswestry, and SF- 36 scales [40,41].

The conventional group also showed improvement in all the three variables clinically which might be because of the type of clinical presentation (mechanical) of the disc herniation chosen for the study and also traction was an effective treatment tool. The flexion moment [13] produced by traction must not be overlooked, as it may produce mechanical effects (posterior tissues stretching, intervertebral foramina opening [44] on the lumbar spine that have significant clinical implications.

Lee R Y [42] measured the movements of the lumbar spine produced by rotational mobilisation and studied the effects of different grades of mobilisation on the movements produced, using a electromagnetic tracking device in 14 healthy volunteers. He found that rotational mobilisation produced oscillatory movements of the lumbar spine in all three anatomical planes and he concluded that rotational mobilisation may be able to restore lost movements of the lumbar spine in any of the three anatomical planes.

Rotation also creates simultaneous tension and approximation in alternate layers of the annulus. The theoretical basis for the application of rotational techniques for dysfunction of discal origin is varied. Structurally, when torque is applied in the form of rotation to the lumbar motion segment, the collagenous structure, particularly the alternate layers of the annulus, are stretched. Further if rotation of the segment reduces the mechanical deformation of injured annular collagen fibers and their associated nociceptive endings, symptom reduction should follow [43]. Pain reduction through the use of rotational techniques is thought to be achieved through the effects of manipulation- induced analgesia [43,49-52] and mechanoreceptor stimulation.

Finally, the Maitland group's significant improvement could and must only be mainly attributed to the "clinical reasoning" process [9,51] involved in manual therapy. The reason must be attributed to the chosen inclusion criteria for both the groups that is, restricted rotational excursion at the affected vertebral level made sure that mobilisation was given to those who presented with restriction and also the homogeneity between the groups was thus maintained.

Further studies could be done on the effectiveness of combined- traction and rotational mobilisation- therapy, auto-traction [45], gravitational lumbar reduction [46,47], inverted spinal traction [48] on a larger sample size, on other types of herniations, at other levels of herniations compared to other conservative treatments.

CONCLUSION

The Maitland group showed significant improvement in the pain, SLR, QBPD Index score when compared to the conventional treatment in the immediate post treatment compared to the pre treatment. The improvement in the long-term post treatment however, was not significant.

Maitland's segmental rotational mobilisation might prove as an effective alternative to conventional physical therapy (traction and moist heat) in the treatment of lumbar radiculopathy due to disc herniations.

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Disclosure

The study was performed as a post-graduate thesis of the first author during his course of study at Manipal College Of Allied Health Sciences, Manipal.

Conflicts of interest

None identified and/or declared

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