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Effect of manual therapy on pain, disability and neural mobility in patients of lumbar prolapsed intervertebral disc: a randomized controlled trial

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Abstract

Introduction: Lumbar prolapsed intervertebral disc (PIVD) is a common health issue affecting young and middle-aged populations. The aim of the present study was to determine the effect of manual therapy interventions on pain, disability, and neural mobility in lumbar PIVD patients.

Material and methods: Eighty-eight participants were assigned to four groups (n = 22 in each); “Spinal Mobilization with Leg Movement” (SMWLM) group, “High-Velocity Low Amplitude” (HVLA) thrust group, “Neural Mobilization” (NM) group and “Control Treatment” (CT) group. The outcomes measures, viz. changes in pain, disability, and SLR ROM (“straight leg raise range of motion”), were assessed at baseline, after four weeks of treatment, and after a six-week follow-up.

Results: Data analysis was performed using SPSS 21.0 software. The greatest mean improvement was seen in the SMWLM group, with a VAS score of 6.05 ± 1.32 , compared to the HVLA group (3.68 ± 0.75), NM group (3.2 ± 0.62) and CT group (1.91 ± 1.22), ODI score of 15.65 ± 2.43 compared to the HVLA group (11.89 ± 1.29), NM group (10.85 ± 1.53) and CT group (3.77 ± 2.43) and a SLR ROM score of 15.06 ± 3.1 compared to the HVLA group (7.89 ± 2.21), NM group (7.07 ± 2.58) and CT group (1.59 ± 2.58).

Conclusions: SMWLM group showed the most significant mean change for VAS (“Visual analog scale”), ODI (“Oswestry Disability Index”), and SLR ROM compared to other groups. SMWLM may be a better viable choice in conservative management of lumbar PIVD.

Keywords: intervertebral disc herniation, manipulation therapy, physical therapy

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Introduction

Lumbar prolapsed intervertebral disc (PIVD) is a common spinal ailment that affects young and middle-aged populations [1]. It may be defined as the displacement of disc material beyond the standard intervertebral disc space [2]. It is the commonest cause of low back pain with a 60-80% lifetime prevalence, and is among the most common causes of radiating lower limb pain [3]. Lumbar radiculopathy, referred to as radiating pain to the lower limb, accompanies 10% of cases of low back pain. Prevalence is common in the 30- to 50-year age group [4]. Herniation of disc content causes pain, weakness, or numbness in the corresponding myotome or dermatome [5]. Common risk factors associated with lumbar radiculopathy are obesity, smoking, sedentary lifestyle, and socioeconomic conditions [6]. The most common level of disc herniation at the lumbar level is L4-L5 and L5-S1 [6,7]. The Intervertebral disc herniates mostly in the posterolateral direction, leading to compression of the nerve root [8]. Asymptomatic individuals might have radiological findings of disc herniation, protrusions, and annular tear [9]. Disc herniation causes compression of spinal nerve roots that, causes pain [10]. The degree of disc herniation is not correlated with the severity of pain [11].

Although surgical management gives faster short-term relief in symptoms compared to conservative management [12], it is associated with complications such as dural tear, and superficial wound infection [13] and re-operation may be required [14]. Before undergoing surgery, in the absence of worsening neurological symptoms, studies recommend conservative therapy of lumbar radiculopathy [15,16]. Therefore, different types of non-surgical treatment approaches, such as manual therapy interventions, have been developed and put to the test to treat this ailment [17,18].

Moreover, international guidelines [19,20] and systematic reviews [21–23] support the clinical importance of manual therapy interventions in short-term and long-term pain and disability management related to lower limb symptoms associated with back pain. Despite this, there are no standard guidelines for specific manual therapy intervention in lumbar radiculopathy, this creating a research gap to find more treatment options to ameliorate lumbar radiculopathy [19–23].

One such manual therapy intervention is ‘Spinal Mobilization with Leg Movement (SMWLM)’. It has been found to significantly improve outcomes when combined with exercise and electrotherapy in lumbar radiculopathy as compared to exercise and electrotherapy alone [24]. Manipulations using rapid thrust technique result in relief from local and radiating acute low back pain [25]. Research evidence also suggests that neural mobilization (NM) is effective at managing spinal radiculopathy by decreasing intra-neural edema and restoring neural

mobility [26]. Therefore, it is possible that these manual therapy interventions may also be effective in the treatment of Lumbar PIVD.

However, no study has yet compared the efficacy of these three manual therapy techniques in the treatment of lumbar PIVD. As these three techniques use different biomechanical and physiological mechanisms, the aim of the present study is to determine the effect of these manual therapy interventions on pain, disability and neural mobility in patients of lumbar PIVD with radiculopathy; it is hypothesized that they will be effective in improving the symptoms of lumbar PIVD.

Material and methods

A “double-blinded, randomized controlled trial” was conducted with “intention to treat analysis”. It was performed according to the “Consolidated Standards of Reporting Trials (CONSORT) 2010”. “The Institutional Ethics Committee (IEC) approved the research protocol (vide letter no. PTY/2019/1014, dated 11.09.2019)”. The trial was registered in the “Clinical Trial Registry of India (trial number CTRI/2020/01/023037)”.

Participants

The sample size was determined before the group allocation. Sample size (total 88 individuals, 22 in each group) was calculated based on a 99% confidence interval and 80% power with a pooled standard deviation of 2.2 [27] and ‘minimal clinically important difference (MCID)’ of 2.09 [28] for primary outcome measure, i.e. pain, considering a dropout rate of 20%.

To decrease the drop out rate, participants were offered convenient schedule, comfortable environment and treatment sessions being free of cost. Participant screening and selection is shown in the flow diagram as per CONSORT guidelines (Fig. 1). In accordance with the Helsinki declaration (2013), the participants clearly informed of the study's procedures in their “local vernacular language” and their informed consent was taken before admission.

Inclusion criteria: patients with lumbar PIVD causing pain, disability, and limitation in “straight leg raise range of motion” (SLR ROM), unilateral radiating pain to the leg below the knee, having radiological evidence of PIVD and nerve root compression by “Magnetic Resonance Imaging (MRI)” with age group between 18-50 years.

Exclusion criteria: sequestrated disc, osteoporosis, trauma, recent sprain, hypermobility, pregnancy, tuberculosis or previous history of lumbosacral surgery.

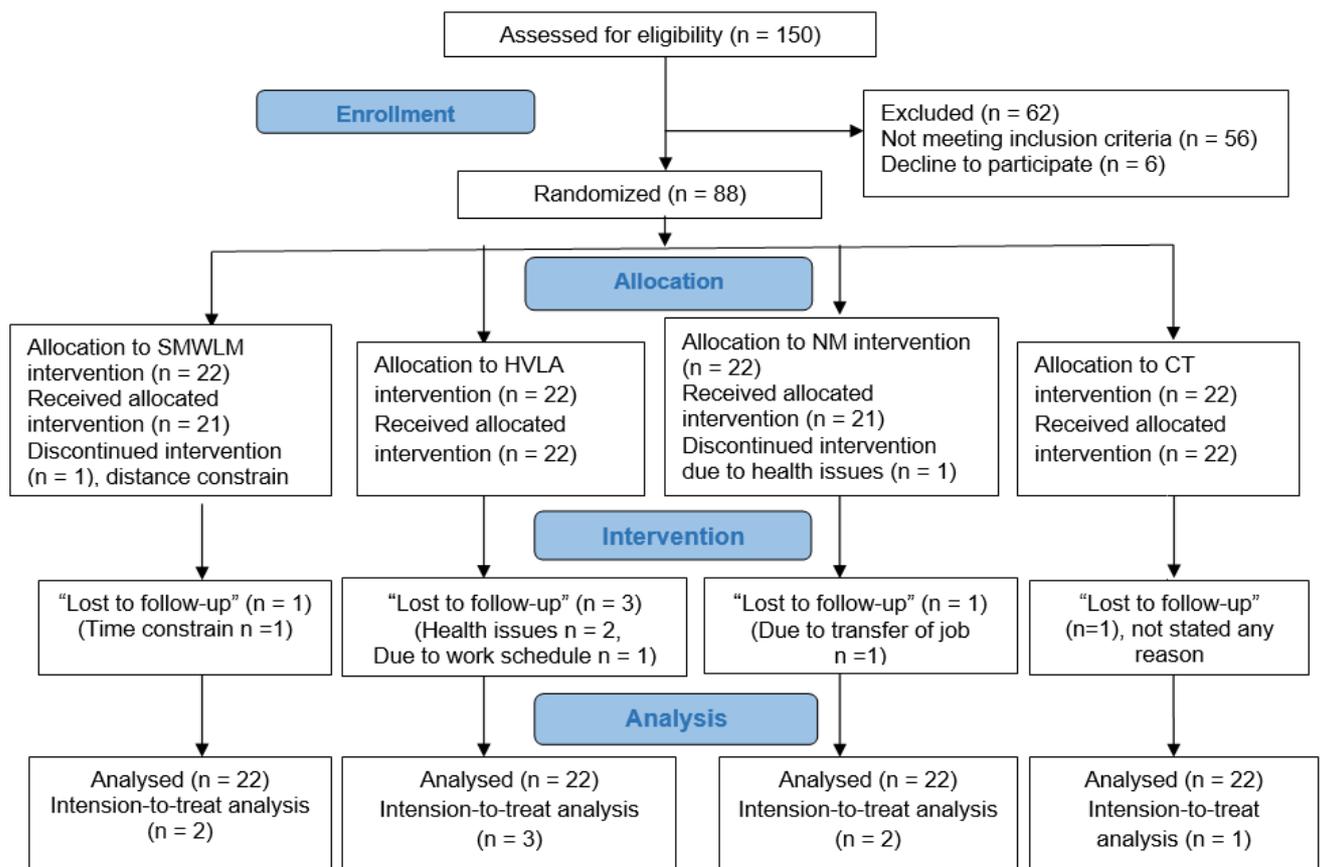


Fig. 1. Flow diagram as per CONSORT guidelines

CT- control treatment, HVLA- high velocity low amplitude, NM- neural mobilization, SMWLM- spinal mobilization with leg movement

PIVD was determined as the source of leg pain by physiotherapists (authors of this study) in consultation with the referring physician and the radiologist who confirmed the MRI findings. Patients were referred from general outpatient department to “the Department of Physiotherapy, Guru Jambheshwar University of science & Technology, Hisar”. Written informed consent was taken from all the subjects. They were free to withdraw from the study at any point and full anonymity was maintained. Participants were randomized into four groups; experimental groups: SMWLM group, “High-Velocity Low Amplitude” (HVLA) group, NM group and a “Control Treatment” CT group. A random computer-generated sequence of numbers was used for allocation among groups.

Procedure

SMWLM Group

The participant lay on their side with the involved leg upwards. An assistant supported the involved leg. The therapist bent forward over the patient and placed one thumb on the side of the spinous process reinforced by another thumb. The therapist pressed down the chosen spinous process. The participant was asked to perform a straight leg raise actively with the affected side leg in pain-free zone, and the therapist maintained pressure on the spinous process. After maintaining this position for 30 seconds, the therapist removed the pressure from the spinous process and the patient lowered the supported leg on the treatment table. Three repetitions were performed on the first visit, and three sets of six repetitions in consequent treatment sessions, applying a slight passive overpressure at the end of the range of motion [24,29]. Passive overpressure was maintained for 30 seconds.

HVLA Group

The participant lay down in lateral recumbent position (affected side leg up), with his/her upper foot in the popliteal fossa of the lower leg [30]. The therapist rotated the upper trunk to produce rotation and lateral flexion at the lumbar, followed by counter-rotation to manipulate a specific segment by HVLA thrust within anatomical limits.

NM Group

The participant was in a supine position. The therapist raised the participant's affected leg through a pain-free range from the couch, maintaining extension at the knee joint. The nerve was mobilized using gentle oscillations. The amplitude of these oscillations was increased as per patient response. Three sets of ten oscillations with a maximum range of pain-free SLR were given in every session. "Intermittent lumbar traction (ILT)" (traction force 30% of body weight) and "interferential therapy" (IFT) (four electrodes crossed pattern) were also applied to all groups for 15 minutes [31,32].

Any increase in leg pain during treatment session was reported as an adverse event. If an adverse event was reported, no further treatment was delivered on that day. All the participants were advised to do "lumbar stabilization" and "stretching exercises" as a home program after completion of the four-week intervention.

Outcomes measures

The primary outcome measures of this study were pain and disability. SLR ROM was secondary outcome measure. Pain and disability were assessed by using VAS and ODI respectively. SLR ROM was assessed where leg symptoms were noted, using a digital goniometer. Outcome measures were assessed at baseline, after four weeks of interventions, and after six weeks follow-up. All the outcome measures were recorded by a blinded assessor.

Statistical analysis

Statistical analysis was performed using SPSS 21.0 software. The “Kolmogorov-Smirnov test” was used to check the normality of data. *Post hoc* analysis was performed to determine treatment effects. One-way ANOVA was used for comparison between groups. Treatment effects within each group were calculated using repeated measures ANOVA. Level of significance was set at .05 (p-value).

Results

Baseline Comparison

Eighty-eight subjects participated in the study. Eight participants dropped out from the study (Fig.1). Intention-to-treat analysis was performed and the missing data was imputed by carrying forward the last recording of the participant who dropped out from the study. Table 1 depicts the baseline data characteristics. No significant differences were in the pre-intervention scores of all four groups, indicating that all the groups were similar at baseline.

Tab. 1. One-way ANOVA for baseline characteristics

	SMWLM Mean \pm SD	HVLA Mean \pm SD	NM Mean \pm SD	CT Mean \pm SD	F	P Value
VAS	8.1 \pm .97	8 \pm .88	7.8 \pm 1.15	8.1 \pm .77	0.438	0.726 ^{NS}
ODI	26.75 \pm 2.4	27.84 \pm 1.68	27.6 \pm 1.6	27.76 \pm 1.18	1.615	0.193 ^{NS}
SLR ROM	48.44 \pm 1.17	47.87 \pm 1.16	48.72 \pm 1.53	48.56 \pm 1	1.719	0.17 ^{NS}

CT- control treatment, F- post hoc, HVLA- high velocity low amplitude, MD- mean difference, NM- neural mobilization, NS- non significant, ODI- oswestry disability index, P- significance at $\leq 0.05^*$, F- post hoc, SD- standard deviation, SLR ROM- straight leg raise range of motion, SMWLM- spinal mobilization with leg movement, VAS- visual analog scale

Comparison among groups

The mean change in VAS scores differed significantly between the groups. *Post hoc* analysis showed significant improvement in VAS score in the SMWLM group (6.05 ± 1.32) as compared to the HVLA group (3.6 ± 0.75), NM group (3.2 ± 0.62) and CT group (1.91 ± 1.22) (Tab. 2).

Tab. 2. *Post hoc* analysis (one-way ANOVA) for mean change in outcome variables between different groups

Variables	SMWLM MD \pm SD (95%CI)	HVLA MD \pm SD (95%CI)	NM MD \pm SD (95%CI)	CT MD \pm SD (95%CI)	F	P
Mean VAS change	6.05 ± 1.32 (5.43 to 6.67)	$3.68 \pm .75$ (3.32 to 4.04)	$3.2 \pm .62$ (2.91 to 3.49)	1.91 ± 1.22 (1.35 to 2.46)	57.94	0.0001*
Mean ODI change	15.65 ± 2.43 (14.51 to 16.79)	11.89 ± 1.29 (11.27 to 12.51)	10.85 ± 1.53 (10.13 to 11.57)	3.77 ± 2.43 (2.66 to 4.87)	126.62	0.0001*
Mean SLR ROM change	15.06 ± 3.1 (16.51 to 13.61)	7.89 ± 2.21 (8.95 to 6.82)	7.07 ± 2.58 (8.28 to 5.86)	1.59 ± 2.58 (2.76 to 0.41)	89.66	0.0001*

95%CI- confidence interval, CT- control treatment, F- post hoc, HVLA- high velocity low amplitude, MD- mean difference, NM- neural mobilization, ODI- oswestry disability index, P- significance at $\leq 0.05^*$, SD- standard deviation, SLR ROM- straight leg raise range of motion, SMWLM- spinal mobilization with leg movement, VAS- visual analog scale

The results indicate a statistically significant difference between groups for mean change in ODI scores. *Post hoc* analysis showed a significantly greater improvement in ODI in the SMWLM group (15.65 ± 2.43) compared to the HVLA group (11.89 ± 1.29), NM group (10.85 ± 1.53) and CT group (3.77 ± 2.43) (Tab. 2).

The results indicate a statistically significant difference between groups for mean change in SLR ROM scores. *Post hoc* analysis showed a significant improvement in SLR ROM in the SMWLM group (15.06 ± 3.1) compared to the HVLA group (7.89 ± 2.21), NM group (7.07 ± 2.58) and CT group (1.59 ± 2.58) as shown in Table 2.

No significant differences were found between the HVLA group and NM group for all three variables. Therefore, it can be inferred that SMWLM was most effective in improving VAS, ODI and SLR ROM in lumbar PIVD. The results also suggest that HVLA and NM were effective at improving VAS, ODI and SLR ROM and in decreasing pain and disability compared to the control group.

Pre-intervention, post-intervention and follow-up comparison

Within group comparisons showed statistically significant improvements in “post-intervention scores” and “follow-up scores” in all groups compared to pre-intervention scores (Tab. 3). No significant difference was found between “post-intervention scores” and “follow-

up scores". These results suggest that patients improved after the application of treatment, and that this improvement was maintained during the follow-up period (Tab. 3).

Tab. 3. Repeated measures for VAS, ODI and SLR ROM scores of all groups at different levels of protocol

Groups		Pre-intervention	Post-intervention	Follow-up	F	P
		Mean \pm SD				
SMWLM	VAS	8.1 \pm 0.97	2.05 \pm 1.05	1.8 \pm 1.32	305.742	0.0001*
	ODI	26.75 \pm 2.4	11.1 \pm 0.85	11.15 \pm 1.14	778.633	0.0001*
	SLR ROM	48.44 \pm 1.17	63.5 \pm 3.67	63.72 \pm 4.68	333.034	0.0001*
HVLA	VAS	8 \pm 0.88	4.32 \pm 1.34	4.32 \pm 1.7	242.975	0.0001*
	ODI	27.84 \pm 1.68	15.95 \pm 0.91	16.05 \pm 1.35	1283.527	0.0001*
	SLR ROM	47.87 \pm 1.16	55.76 \pm 2.47	55.72 \pm 2.5	230.264	0.0001*
NM	VAS	7.8 \pm 1.15	4.6 \pm 0.94	4.65 \pm 0.88	208.793	0.0001*
	ODI	27.6 \pm 1.6	16.75 \pm 2.05	16.6 \pm 2.06	816.590	0.0001*
	SLR ROM	48.71 \pm 1.53	55.79 \pm 2.18	55.68 \pm 2.12	153.051	0.0001*
CT	VAS	8.1 \pm 0.77	6.19 \pm 1.08	6.29 \pm 1.15	38.779	0.0001*
	ODI	27.76 \pm 1.18	24 \pm 1.95	24.19 \pm 1.69	53.330	0.0001*
	SLR ROM	48.56 \pm 1	50.14 \pm 2.57	50.17 \pm 2.8	7.013	0.0002*

CT- control treatment, F- post hoc, HVLA- high velocity low amplitude, NM- neural mobilization, ODI- Oswestry disability index, P- significance at $\leq 0.05^*$, SD- standard deviation, SLR ROM- straight leg raise range of motion, SMWLM- spinal mobilization with leg movement, VAS- visual analog scale

Discussion

The objective of the present study was to determine the effects of different manual therapy techniques on pain, disability, and neural mobility in the lumbar PIVD. The study confirms that SMWLM, HVLA and NM interventions applied in combination with ILT and IFT effectively reduce pain and disability and improve SLR ROM. All outcomes improved after four weeks of intervention, and treatment effects were maintained after a six-week follow-up period. Our study findings showed that SMWLM is most effective in treating lumbar PIVD among all the interventions.

Our findings are corroborated by Satpute et al. [24]. SMWLM repositions the affected segment. SMWLM may correct small positional fault [26,29,33]. SMWLM has the ability to relieve nerve compression through increased intervertebral disc space gapping and nucleus deformation [29,34]. The use of SMWLM may be associated with activation of pain inhibition via the descending suppression pathway in the periaqueductal grey matter of the midbrain [35]. SMWLM also induces a sympatho-excitatory response that produces pain relief, possibly due to the SLR and slight passive overpressure components of the technique [36]. The greater improvement observed in the SMWLM group may be due to the combination of spinal mobilization and active SLR followed by slight passive overpressure; this has been confirmed

in several published randomized controlled trials [24,34,37]. However, these published randomized controlled trials have limited outcome measures and follow-ups, which are addressed by the present study.

The HVLA thrust applied in lumbar PIVD improves intervertebral disc space height and reduces intra-discal pressure. In addition, the enhanced intervertebral disc space height improves the lumbar range of motion [38]. Pain inhibition occurs at the dorsal horn level by altering neuroplasticity and central sensitization. Spinal manipulation produces a novel stimulus that acts as a counter-irritant to C fibre-mediated pain [39,40]. However, unilateral mobilization at the lumbar spine may result in changes in “sympathetic nervous system” activity to an extent [41]. Changes in the “sympathetic nervous system” may activate a descending pain inhibitory system by activating the periaqueductal grey matter mechanism. Our findings regarding the effects of manipulation in lumbar PIVD are corroborated by those of previous studies [25,30].

NM improve the gliding of the nerve, thus relieving symptoms [26]. Bertolini et al. [42] report that nerve root compression causes compromised microcirculation leading to demyelination and neural edema. Inflammatory response and neural tissue hypoxia is resolved by the oscillations applied during NM. The oscillations applied within a pain-free zone during NM also reduce mechano-sensitivity [42]. Our findings are confirmed by those of Gupta et al. which indicate that NM is effective in pain management in lumbar radiculopathy [43]. NM breaks adhesions [33] and facilitates neuro-dynamics, thereby decreasing pain and increasing SLR in lumbar PIVD patients [26,33].

“Minimum clinically important difference (MCID)” can be used as a threshold value to assess a clinically meaningful and significant changes in outcome measures. For VAS, the MCID has been reported to be 2 [44]. Mean improvements in VAS were 6.05 in the SMWLM group, 3.68 in the “HVLA group,” and 3.2 in the “NM group”, which exceed the MCID. An MCID value of 10 has been reported for ODI [44]. Mean improvements of ODI were 15.65 in the SMWLM group, 11.89 in the “HVLA group” and 10.85 in the “NM group” which exceed MCID. “Minimal detectable change (MDC)” for SLR has been reported to be 5.7 [45]. Mean improvements in SLR were 15.06 in the SMWLM group, 7.89 in the “HVLA group” and 7.07 in the “NM group”, which exceed MDC. Therefore, it can be postulated that improvements in experimental groups were not only statistically significant but also clinically significant.

The present study has significant practical implications. Lumbar PIVD is one of the common reasons for workplace absenteeism and disability [46]. It places a heavy economic burden on society and reduces work output. Patients getting pharmacological and surgical

management experience a number of associated possible complications, together with high cost. Manual therapy interventions can minimize the need of medicines and surgical procedure.

The study has several notable strengths. This is the first randomized controlled trial that compares different manual therapy interventions with control group. Blinding and sample size calculation were performed to decrease the bias. Results are not only statistically significant but also clinically important.

The study has some limitations. The study data was collected in only one clinical research laboratory; however, the population was stratified on the basis of gender and age group before random allocation to different groups to decrease research bias. In future studies should aim to optimize dose, and improve efficacy in bilateral radiculopathy and combination therapy with long-term follow-up.

Conclusions

The manual therapy interventions SMWLM, HVLA and NM, combined with ILT and IFT, are effective in treating lumbar PIVD with radiculopathy. Our findings indicate that of these techniques, SMWLM is most effective at reducing pain and disability and improving SLR ROM in patients of lumbar PIVD with radiculopathy.

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Conflicts of Interest

The authors have no conflict of interest to declare.

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