



## Gross myofascial release of trunk with leg pull technique on low back pain with radiculopathy — A randomised controlled trial

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**Background:** Lower Back Pain (LBP) with radiculopathy is a potentially more serious form of mechanical low back pain. A paucity of literature exists about the effect of the gross myofascial release (MFR) technique on the management of LBP.

**Objective:** The study aimed to evaluate the effect of gross MFR when given as an adjunct to conventional physical therapy in subjects with low back pain with radiculopathy.

**Methods:** Forty subjects ( $n = 40$ ) clinically diagnosed with LBP with radiculopathy were enrolled and randomly allocated to either the control group ( $n = 20$ ) or the experimental group ( $n = 20$ ). Both study groups received 5 sessions of intervention. The control group received conventional physical therapy while the experimental group received gross MFR of the trunk and lower limb along with conventional physical therapy. The outcome measures included were pressure pain threshold for the lower back and lower extremity, lumbar flexion and extension range of motion (ROM), percentage disability, and patient satisfaction towards the treatment which were measured pre-intervention (day 1) and post-treatment (day 5). The interaction between group and time was analysed using two-way mixed ANOVA.

**Results:** The results suggested that the experimental group was statistically significant over the control group in terms of pressure pain threshold in the lower back ( $p < 0.001$ ) and lower limb ( $p = 0.003$ ), disability

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( $p < 0.001$ ), and patient satisfaction ( $p = 0.034$ ) and lumbar flexion ( $p = 0.002$ ) except lumbar extension ROM ( $p = 0.973$ ).

**Conclusion:** When given as an adjuvant to conventional physical therapy, gross myofascial release proved to provide a significant and faster short-term improvement over conventional treatment alone in subjects diagnosed with low back pain with radiculopathy.

**Keywords:** Soft tissue; manual therapy; myofascia; lumbar spine; radiculopathy; trigger points.

## Introduction

Low back pain (LBP) has been considered one of the important causes of disability in the general population.<sup>1</sup> It is a complex multifactorial condition affecting most people at some point in their life. The condition has been identified as the leading contributor to years of life lived with disability in the world. Estimates of the 1-year prevalence range from 0.8% to 82.5%.<sup>2</sup> The occurrence of LBP in India is also alarming with nearly 60% of the people in India having suffered from LBP at some time during their lifespan.<sup>3</sup>

LBP may sometimes be associated with complaints of radiating or referred pain. The radiating pain in either or both the lower extremities follows a specific dermatome or myotome with a rough estimate of the prevalence being 3% to 5% commonly caused by lumbar disc herniation, piriformis syndrome, myofascial pain, spondylolisthesis, facet joint pathology, etc.<sup>4–7</sup> The LBP that is associated with referred pain is defined as pain that spreads to the surrounding area not following a particular dermatome or myotome pattern on palpation that usually is the pain arising from either the viscera or myofascial fibrous bands that are formed within the muscles due to pathological conditions. These painful bands are referred to as myofascial trigger points (MTrP) that develop as a result of neuromuscular and musculoskeletal issues including chronic repetitive strain injuries, postural problems, systemic disease, or strain, sprain, degenerative joint conditions, disc lesions, etc. These MTrPs can often be identified in the muscular fascia of the trunk and lower limb muscle on palpation which causes a referred pain or pseudoradiculopathy.<sup>8–10</sup> Fascia has been described as a body-wide tensional network, which consists of all fibrous, collagenous, and soft connective tissues, whose fibrous architecture is dominantly shaped by tensional strain rather than compression. This continuous network envelops and connects all

muscles and organs.<sup>11–13</sup> The hyperirritable (hypersensitive) spots in a taut band of skeletal muscle fibers are defined as myofascial trigger points.<sup>8,14</sup> Patients with trigger points in the hamstring muscle mimic symptoms of sciatica/or pseudo sciatica/extraspinal sciatica because pain extends down the posterior thigh within the distribution of the sciatic nerve. Among patients with LBP, tightness of the hamstring muscles in one or both lower limbs is common.<sup>1,10</sup>

The clinical practice guidelines by American Physical Therapy Association recommend a combination of manual therapy, trunk exercises including endurance, coordination and strengthening exercises, traction, and nerve mobilisation. Studies support the application of electrotherapeutic modalities to manage pain for the treatment of LBP with radiculopathy or referred pain.<sup>15–17</sup>

Myofascial release (MFR) therapy is a hands-on technique, meaning that the therapist applies pressure with the hand onto, and into the client's body.<sup>11,16</sup> MFR can be given in two forms, Direct release and Indirect release. The Direct release method uses force or weight, with practitioners using tools, knuckles, or elbows to slowly stretch the fascia, hoping to bring about elongation and mobility. The indirect release is a gentler method where the practitioner applies less pressure, encouraging the fascia to slowly "unwind" itself until greater movement is achieved.<sup>11,18,19</sup> The gross MFR for trunk (abdomen and lower back) and lower quarter Leg Pull are gross MFR techniques, which are used to release the myofascia of the anterior abdominal wall, lower back, and lower limbs.<sup>13</sup>

Studies have been done on the effect of gross myofascial release on mechanical neck pain, cervical radiculopathy, and non-specific low back pain.<sup>10,20,21</sup> There is a paucity of literature regarding gross myofascial release techniques in reducing lower back pain with lower limb radiculopathy. Hence, the need arises to identify

the effect of the gross myofascial release technique in subjects with low back pain with radiculopathy on the trigger point, lumbar range of motion (ROM), and function.

## Materials and Methods

### Study Subjects:

The study was a single-blinded randomised controlled trial where the assessor who took outcome measurement was blinded from the group allocation of the study subjects. The study was conducted at a tertiary care center in Belagavi city,

Karnataka, India between March 2017 and February 2018.

A total of 73 subjects with low back pain were assessed for eligibility to participate in the study. Forty subjects who met the inclusion criteria were randomly assigned with concealed allocation to one of the groups: the Control group ( $n = 20$ ) and the Experimental group ( $n = 20$ ). The subjects randomly chose one of the two labelled and sealed envelopes to determine their group allocation (Fig. 1). The sample size was calculated using the formula  $n = 2(z\alpha + z\beta)^2/d^2$ , where  $z\alpha$  is the Z value for  $\alpha$  error that is 1.96,  $z\beta$  is 0.84 with a

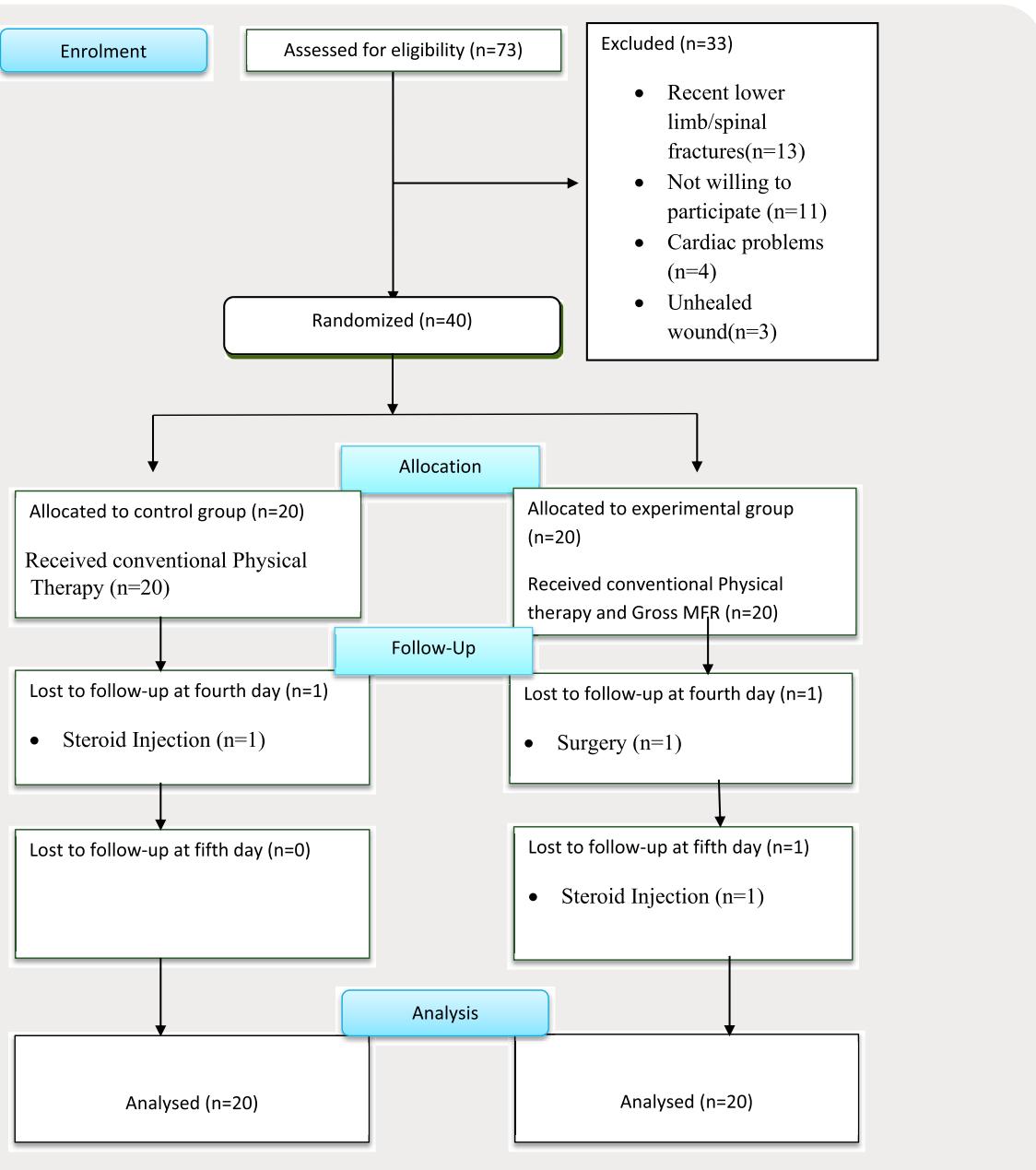


Fig. 1. CONSORT flow diagram.

power of 80% and  $d$  is the mean difference of 4 on pain reduction score using the visual analog scale (VAS) taken from the reference article.<sup>20</sup> To be included in the study the subject needed to fulfill two or more of the following inclusion criteria: (1) Subjects with low back pain associated with radiculopathy to unilateral lower limb between the age group of 20–60 years (2) Subjects with active/latent trigger point with grade 2 and above tenderness in any one of the Para-spinal areas: Thoracolumbar Fascia, Quadratus Lumborum, and Piriformis (3) Subjects with active/latent trigger point with grade 2 and above tenderness in any one of the Lower limb area: Hamstring muscle, Calf muscle and Gluteus with grade 2 and above. The study excluded subjects (1) If the individuals self-reported contraindications/precautions to MFR: unstable medical conditions (blood pressure fluctuations/blood sugar abnormalities; dermatitis; contagious or infectious disease; mentally unstable; inability to provide informed consent; the influence of drugs/alcohol; recent fractures/surgeries; wounds/ulcers; pregnancy<sup>13</sup> (2) individuals with unhealed open wounds at the treatment area assessed on basis of observatory finding (3) Cauda equina syndrome or myelopathy as assessed by the researcher on the basis of signs and symptom screening (4) Any self-reported systemic diseases (5) history of lower limb trauma/spinal trauma/fractures (6) Diagnosed cases of peripheral vascular disease as reported by the assessing/referring doctor. Ethical clearance was obtained from the Institutional Ethical Committee (KIPT/129/29.05.17). Written informed consent was obtained before the enrolment and the purpose of the study was explained to all the subjects. The present trial is registered in the Clinical Trial Registry of India (CTRI/2018/05/013852) dated 14/05/2018.

### *Procedures*

Pressure pain threshold (PPT) was the outcome used to assess the trigger point (Trp) pain of the low back and the lower limb muscles. For low back muscles assessment, the subject was asked to expose the low back region and lie down in a prone position. The examiner palpated and marked the trigger point in the lower back and lower extremity musculature following which the probe of a pressure algometer instrument (Baseline® Dolorimeter with Circular Probe) was placed perpendicularly to the point identified. Force is applied to the Trp through the pressure algometer up to the

maximum pain tolerated by the patient. If in the case of multiple Trps, the most painful Trp was taken for the outcome measurement. The pain pressure measurements were expressed in pounds (lbs). The readings were recorded pre-and post-intervention. The interrater ICC value for the measurements with pressure algometer was excellent at 0.91 for assessing pressure pain.<sup>22,23</sup>

Lumbar flexion and extension active ROMs were assessed using a modified Schober's test. For lumbar flexion ROM, subjects were standing with an erect posture and two landmarks marked on the skin, which includes the point bisecting a line connecting the two posterior superior iliac spines (PSIS) (baseline). A point was marked 15 cm superior to the baseline landmark and the subjects were then asked to perform flexion movement as much as possible. The range of movement of the lumbar spine was measured using a measuring tape from the superior landmark to the mid-point of the baseline in units of centimeters.<sup>24</sup>

For measuring lumbar extension ROM, the same landmarks were used. The range of movement measured was from the superior landmark to the mid-point of the baseline landmark by asking the patient to perform lumbar extension movement. Modified-modified Schober's method has moderate validity ( $r = 0.67$ ), and excellent reliability (intra: ICC = 0.95; inter: ICC = 0.91) to assess lumbar sagittal ROM.<sup>24</sup>

Oswestry Disability Index (ODI) consists of 10 items to assess the subject's pain, and functional affection so as to quantify the patient's level of disability that occurred due to low back pain. Under each of these items, there are six response options with each response scored from 0 to 5, with higher values interpreted as a greater disability giving a maximum score of 50. The total score is multiplied by 2 and expressed as a percentage. Scores are categorised as per the percentage of disability calculated as 0–20 as a minimal disability; 21–40 as a moderate disability; 41–60 as a severe disability; 61–80 as crippling back pain; 81–100 bed-bound disability. ODI has the reliability of ICC = 0.90.<sup>25,26</sup>

Global Perceived Effect Questionnaire (GPEQ) was used to assess patient satisfaction with the treatment received for the particular condition. The GPE scale asks the patient to rate, on a numerical scale, how much their condition has improved or deteriorated since some predefined time point. The subject was asked the following

question "compare your current complaints with 1 month ago?" GPE demonstrated an intraclass correlation coefficient value of 0.90–0.99 that points to excellent reproducibility of the GPE scale.<sup>27</sup>

The subjects who were allocated to the control group received conventional physical therapy, which included two-channel Transcutaneous Electrical Nerve Stimulation (TENS) applied in a sequential form for 20 min with frequencies ranging from 80–120 Hz with the electrodes placed at maximum painful points in the back and lower limbs to treat the radicular pain, thermotherapy in the form of Hot Moist Pack (HMP) placed on the lower back for 15 min for relieving paraspinal spasm. The static lower back exercise was taught for which the subject was in a crook lying position with a towel placed between the lower back and the plinth. The subject was asked to press the lower back against the towel. In addition, core strengthening exercises which included side bridging, bird dog exercise, and semi-squatting were also to be performed. Each strengthening exercise was given for 3 sets with 5 repetitions in each set with each exercise position to be held for 10 s with 5 s of rest time. The total duration of treatment session lasted approximately 45 min.

Subjects enrolled in the experimental group received gross myofascial release of the trunk and lower limb along with conventional physical therapy (as explained above) with 45 min of conventional followed by 15 min of MFR for each subject. The muscles targeted in this procedure were dorsiflexion of the foot, hip flexors, extensors, abductors, adductors, internal rotators and external rotators. The position of the subject and the therapist changed according to the muscle targeted.<sup>11</sup>

The procedure began with the patient supine, leg adducted to neutral, the patella and foot pointed up and the entire leg in neutral rotation, and stretch was applied using traction equal to the weight of the patient's leg. The heel of the foot was cupped with the therapist's dominant hand and the forefoot was held with the other hand. The therapist's thumb rested on the bottom of the patient's foot proximal to the metatarsal head. Using the body weight, the therapist leaned back until the elbows were fully extended till the weight of the subject's leg was counterbalanced ensuring no contact of the patient's leg with the treatment table. Then slowly the therapist began to dorsiflex

the patient's foot until resistance was felt. The position was held until release was felt and an increased angle of dorsiflexion was achieved. The technique was stopped with the patient's foot in neutral or 90° positions, and the traction was increased until the therapist felt resistance and the end feel was reached. From here if the subject's knee permitted, the therapist maintained traction and slowly worked to increase the movements of the hip in different planes until release was noted. The movement sequence of the hip was neutral — flexion — hip abduction — external rotation of knee — internal rotation of knee — external rotation of hip — internal rotation of hip with the knee in extension. The angle of motion was decreased at the point where the restriction was felt and the position was maintained until release occurred. Throughout the procedure, the therapist waited at the point of restriction until the release was felt and then applied the stretch again, repeating the sequence until the end feel is reached (Fig. 2).<sup>13</sup>

The procedure for the fascial unwinding technique started first with the myofascial release of the right-side Psoas muscle as well as Iliacus muscle and then proceeded with the release of the left Psoas and Iliacus muscle (Fig. 3(a)). For releasing the Psoas muscle and the lumbar spine, the subject was side lying position with their knee flexed. The position of the therapist was at the side of the treatment plinth facing the back of the subject. The caudal hand supported the subject's thigh with a flexed knee and the cranial hand contacted the lumbar region. By using the subject's thigh as a lever and the cranial hand as a fulcrum, myofascial unwinding was performed.<sup>10</sup>

For the release of the Iliacus muscle, the position of the subject was supine lying at the end of the plinth with both the lower extremities out of the plinth (Fig. 3(b)). The position of the therapist was at the contralateral side of the target muscle, that is if the therapist was releasing the right-side Iliacus muscle, then the position of the therapist was on the left side of the subject. A cross-handed hold was applied along with the psoas until the release was felt, with the cranial hand below the inferior costal margin and the caudal hand above the inguinal region.<sup>10</sup>

#### *Statistical analysis*

The statistical analysis was done using SPSS version 22 (SPSS Inc., Chicago, IL). The normality



Fig. 2. Lower quarter leg pull technique (a) Starting position (b) Flexion, (c) Hip abduction, (d) External rotation of knee (e) Internal rotation of knee, (f) External rotation of hip (g) Internal rotation of hip.



Fig. 3. (a) Fascial unwinding hold, (b) MFR hold.

of data was evaluated by skewness and Kurtosis Z values and the Shapiro-Wilk test, which indicated the data follows a normal distribution with 95% of confidence. In addition, the homogeneity of variances and covariance matrices was assessed by Levene's test for equality of variance and BOX's test, respectively. Intention-to-treat analysis was applied, and all 20 participants were included for data analysis since the 2 dropouts in the experimental group had completed 3 to 4 out of 5 sessions of intervention (> 50% of sessions). All the quantitative variables were compared within the group

for pre- and post-intervention values using paired samples *t*-test after checking for normal distribution within each group. In addition, the effect of the intervention between the experimental and the control group was compared by analysing the interaction between group and time on the outcome variables (ODI, PPT in low back and lower limb, lumbar flexion and extension ROM) using a two-way mixed method Analysis of Variance (ANOVA)/split-plot ANOVA was used. Probability-values less than 0.05 were considered statistically significant.

Table 1. Comparison of baseline demographic parameters between two groups ( $N = 40$ ).

Demographic	Study group		Chi-square	<i>p</i> -value
	Control ( $N = 20$ ) Mean ± SD	Experimental ( $N = 20$ ) Mean ± SD		
Age (Years) <sup>a</sup>	39.65 ± 10.41	39.95 ± 12.58	—	0.935
Gender <sup>b</sup>				
Male	10 (50%)	14 (70%)	1.667	0.197
Female	10 (50%)	6 (30%)	—	
Height (CM) <sup>a</sup>	164 ± 7.93	167.95 ± 6.19	—	0.087
Weight (Kg) <sup>a</sup>	62.34 ± 10.2	66.33 ± 12.42	—	0.274
BMI (Kg/m <sup>2</sup> ) <sup>a</sup>	23.85 ± 4.27	23.47 ± 3.85	—	0.769
Affected side <sup>b</sup>				
Right side	12 (60%)	13 (65%)	0.107	0.744
Left side	8 (40%)	7 (35%)	—	

Notes: \*Statistical significance (*p*-value < 0.05); a — Student's "t" test; b — Chi square test.

## Results

**Table 1** shows the comparison of baseline demographic characteristics between the two study groups. There was no statistically significant difference observed between the groups in the demographic characteristics.

Within the group analysis comparing pre-to post-intervention, values show statistically significant changes (*p* < 0.05) for all the outcome parameters for both intervention groups. The level of significance was *p* < 0.001 for the experimental group using ODI, PPT (lower back and lower limb), and lumbar ROM (flexion and extension). The *p*-value for the control group also showed significance for ODI (*p* < 0.001), PPT for lower back (*p* = 0.027), PPT for lower limb (*p* = 0.02), and lumbar flexion and extension ROM (*p* < 0.001) (**Table 2**).

The GPEQ mean score for the control group was  $2.2 \pm 1.24$  and for the experimental group was  $2.95 \pm 0.89$ . GPEQ values showed a statistically significant difference (*p* = 0.034). In comparison between groups, the experimental group displayed to be more beneficial than the control group.

The analysis between the study group and time showed significant interaction for ODI (*p* < 0.001), PPT for the lower back (<0.001), PPT of the lower limb (*p* = 0.003), and lumbar flexion ROM (*p* = 0.002). However, the lumbar extension ROM failed to show significant interaction (*p* = 0.973) (**Table 3**).

These results suggest that, with time under consideration, 5 sessions (short term) of gross myofascial release technique when administered in adjunct to conventional physical therapy intervention demonstrated a significant effect in the

Table 2. Within the group comparison of outcome measures of two group ( $N = 40$ ).<sup>#</sup>

Outcome measures	Group	Before intervention	After intervention	<i>P</i> -value
		Mean ± SD	Mean ± SD	
MODQ (In %)	Control	54.30 ± 8.81	40.95 ± 11.55	< 0.001*
	Experimental	56.55 ± 14.36	26.25 ± 10.46	< 0.001*
Pain in the low back (In lbs)	Control	9.90 ± 4.90	11.25 ± 5.25	0.027*
	Experimental	6.60 ± 3.66	10.75 ± 4.48	< 0.001*
Pain in the lower limb (In lbs)	Control	9.20 ± 5.09	11.10 ± 4.92	0.002*
	Experimental	5.60 ± 3.27	9.74 ± 3.61	< 0.001*
Lumbar Flexion ROM (In CM)	Control	6.27 ± 1.59	6.78 ± 1.46	< 0.001*
	Experimental	5.78 ± 2.03	7.23 ± 1.79	< 0.001*
Lumbar Extension ROM (In CM)	Control	1.97 ± 0.58	2.55 ± 0.59	< 0.001*
	Experimental	2.01 ± 0.66	2.58 ± 0.77	< 0.001*

Notes: \*Statistical significance (*p*-value < 0.05); MODQ — Modified Oswestry Disability Questionnaire; <sup>#</sup>paired *t* test.

Table 3. Interaction between group and time analysis.<sup>#</sup>

Outcome parameter	Interaction	Partial eta squared	F Statistic	P-value
MODQ (In %)	Time	0.765	123.369	< 0.001*
	Time * Study Group	0.329	18.603	< 0.001*
PPT in the low back (In lbs)	Time	0.613	60.152	< 0.001*
	Time * Study Group	0.291	15.590	< 0.001*
PPT in the lower limb (In lbs)	Time	0.663	74.674	< 0.001*
	Time * Study Group	0.213	10.270	0.003*
Lumbar flexion ROM (In CM)	Time	0.570	50.312	< 0.001*
	Time * Study Group	0.230	11.327	0.002*
Lumbar extension ROM (In CM)	Time	0.618	61.563	< 0.001*
	Time * Study Group	0.000	0.001	0.973

Notes: \*Statistical significance (*p*-value < 0.05); #Two-way mixed model ANOVA.

short term as compared to conventional physical therapy alone for the management of low back pain with radiculopathy.

## Discussion

The results of this study support the alternative hypothesis, which stated that gross myofascial release of trunk musculature and lower quarter leg pull technique in addition to conventional physiotherapy will demonstrate a change in the pain, mobility, and function of the lower back and lower extremities indicating significant short-term benefits.

In this study, the pain pressure threshold was evaluated on the trigger points present in the lower back and the lower limbs. The post-intervention values in both groups suggested that the pain sensitivity was reduced significantly in the experimental group. A meta-analysis on the effect of massage therapy suggested that the reason for the reduction of pain could be due to the mechanical stimulus in the form of pressure, applied through manual soft tissue manipulation. Myofascial release is one of the manual soft tissue manipulation techniques which have similar physiological effects on the body. The impulse of mechanical stimulus, which is known to travel faster as compared to the sensation of pain, may have blocked nociception at the level of the spinal cord.<sup>28</sup>

In this study on comparison between group analyses, MFR was found better than conventional physical therapy for lumbar flexion ROM. However, lumbar extension ROM was equally better in both study groups. The improvement in the range

of motion could be secondary to the overall reduction in pain levels.<sup>29,30</sup> Myofascial release has previously proven beneficial in improving soft tissue extensibility by reducing fascial adhesions and improving the local fluid dynamics.<sup>31,32</sup>

The sacral fascia is considered to be the structural centre of the superficial back line (SBL) which extends from the plantar surface to the ridge just above the eyebrows. A cadaveric study conducted to analyse force transmission across the lumbar fascia suggested that segmental motion can be influenced due to the low-level transmissions occurring in the middle and posterior lumbar fascia.<sup>33</sup> Fascial movements can be altered by the amount of force transmitted across the fascia. Since the lumbar fascia is a part of the superficial back-line, alterations in the movements of the lumbar fascia may influence the mobility of this entire fascial meridian since the lumbosacral fascia comprises a part of the structural centre of this fascial network.<sup>33,34</sup> Literature on the pathophysiological model for chronic low back pain integrating connective tissue and nervous system mechanisms states that the application of myofascial release produces a direct stretch on the contractile as well as non-contractile structures at the target site, which have an impact on this study.<sup>35</sup>

The analysis of ODI values indicated a significant reduction of functional disability in the participants of both study groups. However, the MFR group showed better results than the conventional group. Previous literature about low back pain stated that there is a high correlation between pain levels and functional disability. Precisely, the higher the pain levels, the higher the disability, and vice versa.<sup>21,29</sup> The reason attributing to this

correlation could be the restriction of activities because of pain. This may further lead to a reduction in the available range of motion, thus causing detrimental effects on daily task performance. Thus, pain reduction may have improved daily task performance, which may have further reduced the individual's activity limitation.

A statistically significant difference was observed on the analysis of GPEQ, which indicates that the individuals who received experimental group intervention were more satisfied as compared to those who received the conventional intervention. A reason for patient satisfaction could be a reduction in pain levels and an improvement in the overall functional status of the individual post-intervention. Another reason for an increased GPEQ score in the experimental group could be due to the additional tactile stimulation produced by the myofascial release in the experimental group which may have increased the serotonin levels in the body thereby producing a sense of well-being.<sup>36</sup>

This study had a few limitations. The treatment durations for both study groups varied due to the study design being a controlled trial. A lack of follow-up to analyse the long-term effect of the intervention was due to time constraints and owing to higher rates of dropouts. The strength of the back muscles was not assessed since only 5 sessions of treatment were given and to have any positive strength gains a minimum of 3 weeks of treatment is required. The calculation of sample size in this study was on the basis of a gross MFR technique applied on the neck and not on the lower back since the studies lacking in the literature.

In the future, the isolated effect of gross myofascial release can be assessed by comparing the MFR technique against sham MFR application or with other manual therapy techniques like neural mobilisation, dry needling, Mulligan's mobilisation, etc. in individuals with low back pain associated with radiculopathy. The effect of the intervention can be evaluated on the properties of the muscle and myofascial trigger points using more sophisticated tools like diagnostic ultrasonography or biochemical analysis of trigger points (neuropeptides and inflammatory mediators). It is also recommended to consider the application of gross MFR techniques for the treatment of other musculoskeletal conditions like neck pain, shoulder pains, restrictive chest expansions, etc.

## Conclusion

In conclusion, the study provides preliminary evidence for the short-term effects of gross myofascial release along with the leg pull technique to be effective for low back pain with radiculopathy. Hence, this technique can be included by manual therapy/physical therapy professionals as a promising technique in the management of back-pain patients.

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## Conflict of Interests

The authors declare that they have no competing interests.

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## Author Contributions

AR was a principal investigator in collecting and analysing the data along with performing the intervention. PG majorly contributed to the conception and design, interpretation of data, manuscript writing, and editing. Both AR and PG agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Both authors read and approved the final manuscript.

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