



Effects of Myofascial Release with and without taping on the pain, disability, and Range of motion of female patients with non-specific lower back pain: a randomized clinical trial

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ABSTRACT

Study design: Single-blinded, randomized parallel trial with concealed allocation and treatment intention analysis.

Objective: To determine the effects of Myofascial Release (MFR) with and without taping on the pain, disability, and Range of motion of female patients with non-specific lower back pain (LBP).

Summary of background data: Myofascial release is often used to treat the pain syndromes of the human body. It is a part of manual therapy, which is used to treat the skeletal muscles that are causing immobility or disability and control their pain by providing relaxation to the contracted muscles, thus improving blood circulation and lymphatic circulation. Taping is also an evident way to treat and relieve non-specific lower back pain.

Methods: Fifty female patients with non-specific LBP were randomized to the MFR group (n=25), receiving a total of nine sessions of MFR, each lasting for 40 minutes 3 weeks, and to the MFKT group (n=25), which received MFR in combination with taping. The studied variables were pain measured by the Numeric Pain Rating Scale (NPRS), disability measured by the Oswestry Disability Index (ODI), and Range of Motions measured by a goniometer.

Results: Subjects that received MFR with taping (MFKT) group showed more significant improvement than MFR alone in Pain [NPRS: mean difference (MD): 4.52, $p < 0.000$], disability [ODI (MD=42.08, $p < 0.000$)] and in Range of motions [(Flexion: MD=9.68, $p < 0.000$), (Extension: MD=4.8, $p < 0.000$), (Rt Lateral Bending: MD=4.56, $p < 0.000$) (Lt Lateral Bending: MD=5.04, $p < 0.000$).

Conclusion: Myofascial Release alone also improved the pain, disability, and Range of motion, but when given with taping, the results were better than those shown alone. However, for how long these results will last, the procedure's sustainability still needs to be discovered.

INTRODUCTION

Lower back pain has been a very prevalent condition in our society. The pain in the lower back is the pain that happens on the side of an individual's body posteriorly, which radiates from the last ribs of the body to the lower levels of the gluteus or the creases of the buttocks. According to the studies, non-specific lower back pain comprises 90% to 95% of the reported cases. (1) a study was conducted throughout 195 different countries in which the impact of lower back pain was studied. The study concluded that there is a 54% increase in years living with a disability associated with lower back pain. (2)

According to the studies, the point prevalence occurs to be of lower the back pain is somewhat 18%, however the prevalence of the lifetime of the lower back pain occurs to be 39%. And lower back pain is more prevalent among women aged between 40 and 69 years. (3)

Usually, whenever lower back pain occurs, a precise cause for it or any fundamental reason causing the pain is not identified or looked for; this is because it is thought that the pain might be arising from any perfunctory problem, which includes any muscle or joint strain or sprain, which is also called non-specific lower back pain (4), however, if the pain does not subside with any conventional treatment or physical therapy management then one should look for possible red flags and perform additional test and measures to identify the problem. (5)

If females are considered and their chronic pain problems are studied, it was concluded that lower back pain is one of the most common clinical and public health problems affecting the female population significantly around the globe. And it also came into notice that post-menopausal women pertain a more considerable risk and a higher incidence of developing non-specific lower back pain than the male population. (6)

Multiple lines of intervention are used when discussing the management of lower back pain. Most importantly, when we discuss non-specific lower back pain, it is usually prescribed that after addressing the nature of the lower back pain, it is suggested that the individual should avoid bed rest and try to remain active. Furthermore, patient education, as well as strategies to manage their pain, are also suggested. (7) Mentioning the treatments for managing the non-specific lower back pain, it is also suggested to receive different physical therapy management and regimens as, according to the studies, they are supposed to be highly effective in the management of non-specific lower back pain. (8) according to the studies, different management techniques are utilized to manage non-specific lower back pain, and myofascial release is one of them. Myofascial release is often used to treat the pain syndromes of the human body. It is a part of manual therapy, which is used to treat the skeletal muscles that are causing immobility or disability and control their pain by providing relaxation to the contracted muscles, thus improving blood circulation and lymphatic circulation. (9) There is strong evidence regarding treating musculoskeletal conditions through myofascial release. It is noted that the pain is reduced significantly when an individual receives myofascial release therapy for lower back pain conditions. (10) Taping is also an evident way to treat and relieve lower back pain of non-specific nature. Studies were conducted to find out the effects of taping on the pain as well as disability of the lower back, and the results concluded that taping reduces the pain as well as disability and improves the flexion of the lower back too. (11) Taping can be an effective tool for treating non-specific lower back pain. (12)

So, the purpose of this study was to figure out the comparative effects of MFR with taping as well as without taping on the disability, pain, and Range of motions of the lower back among the patients which are suffering from lower back pain of non-specific nature, as this combination treatment is not addressed in different studies as per our knowledge.

MATERIAL AND METHODS

Study Setting and Design

This study is supposed to be a parallel-group, two-arm superiority trial. The allocation ratio was 1:1 and balanced randomization was conducted in this study. The study was conducted in the outpatient setting of Al-tibri Medical College and Hospital and Body Works Physical Therapy Center.

Eligibility Assessment

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Screening of the patients was done before including them in this study. Patients with lower back pain persisting for more than 3 months were included. Patients who have back pain that progresses to any neurological deficit, any persistent or intensified back pain combined with appetite loss, inexplicable weight loss, fever, nausea, and chills, and any known pathology related to the spine or lower back (such as a spinal tumor or underlying spinal cord diseases, such as ankylosing spondylosis or spondylolisthesis), Participants in this trial were excluded if they had received any therapy of the steroid for lower back pain within the previous three months, had an inflammatory rheumatic disease, had sensitive skin, a skin allergy, or had a dermatological problem. The study also eliminated any patient who has received rehabilitation therapy for non-specific lower back pain within the previous two months. For this study, only female patients aged 25 to 38 were chosen.

Trial Population

The CONSORT flow diagram demonstrates the flow of participants, randomization, allocation and follow-up (Figure1). The sample size was calculated through the Primer of Biostatistics, with the value of $\alpha = 0.050$. The mean detectable difference was 2, and the power was 0.800, which calculated the sample size as 23 participants in each group. Due to the loss of follow-up and other patient errors, we collected a sample of 25 participants for each group. There was no loss to follow up. Hence 50 participants' data were analyzed. The level of significance of this study was $P < 0.05$.

For this study, 50 females were recruited who suffered from non-specific lower back pain.

Ethical Consideration

Ethical Approval was taken from the Institutional Bioethical Committee (Dated: 23rd September, 2021, Approval no: IBC KU-223/2021). It was focused that the study should follow the guidelines of ethics developed in the Helsinki Declaration of 1964 and its revision in 2008. (13) The procedure was clearly explained to all the participants, and the participants signed a consent form. Data were coded, and the participants had every right to withdraw from the study anytime they wanted. It was also advised that if the participants feel any extensive discomfort because of the treatment, they should report to the department immediately and might discontinue the treatment. The protocol of the study was approved by clinicaltrial.gov (Registration no: NCT05649774)

Randomization

The participants were assigned randomly into each group, MFR (n=30) and MFKT (n=30), with the help of a computer-generated random sequence of numbers. (14) The block size used was 6 to assign participants into MFR and MFKT groups. The allocation concealment was preserved.

Interventions

A physical therapist and a certified Kinesio taping practitioner applied the intervention. The blinding was not possible for the therapist as she provided the manual therapy intervention. Myofascial release was provided 3 times per week to the patients, with each session lasting for around 30 minutes. The intervention was given to the patients for overall 3 weeks.

The following techniques was applied to the patients.

MFR Group

For the MFR group, the myofascial release of thoracolumbar fascia was performed. The therapist place their hands on the T12-L1 levels and the sacrum. A cross-handed hold was performed along the fascia. The technique was applied for almost five minutes. The therapist then stood facing the participant's leg and near the greater border of the participant's pelvis to work on the gluteus medius and gluteus maximus muscles. The therapist stabilizes the patient's pelvis by placing the palm on the surface that is anterior and letting the fingers rest on the gluteal muscles' outer fibers. In an open pack position, permit the participant to do flexion of their knee while offering sufficient stretch to the hip joint. Hold, let go, and then extend once more. 15 repetitions of this motion were done with both legs. Gross relaxation of the tensor fascia latae was also carried out for the tensor fascia latae muscle. The therapist applies pressure to the distal muscle fibers with the other hand's fingers and the superior fibers proximal to the insertion on the thumb

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and anterior superior iliac crest with several of the hand's slightly adducted fingers. Hold, let go, and then extend once more. On each limbs, do the release procedure fifteen times.

MFKT Group

For the Myofascial Release with the Taping group, the same myofascial release was provided, and at the end, taping for the lower back pain syndrome was performed. The lumbar star correction technique was applied. Four tapes and one strip was cut. The paper from the center was torn. The targeted area was stretched as tolerated at the lumbar region. Over the target tissue, the therapist applied a tension of between 25% and 35% to the strip inside the therapeutic zone. Release the tension from the end of the strip and turn on the glue. Adjust the posture for the second strip in order to modify the tissue's stretch. In the middle of the tape, attach the second strip with 25% to 35% tension, and finish with no tension. Turn on the glue. Flex your trunk now and turn to one side. In the middle of the tape, apply the final tape strip with a tension of 25% to 35%. Apply the fourth tape strip with 25% to 35% tension, flexion, and rotation on the opposite side once more. Three times a week, following each myofascial release therapy, the tape will be changed.

Outcome Measures

The primary focus of this study was to check the pain level among the patients, while the secondary outcome was disability and Range of motion. For all these variables, a baseline measure was taken on the initial first day of treatment (PRE), and a reading was obtained at the end of the treatment after 3 weeks (POST).

For the perception of pain, the scale that is used is the Numeric Pain Rating Scale (NPRS).

NPRS is considered to be a numeric version but segmented of the Visual Analogue Scale (VAS). It has whole numbers from 0 – 10, which reflects the intensity of pain the respondent is experiencing. (15) It is an 11 – point scale with the numeric range "0," which indicates one extreme of the pain that is no pain, and "10," representing the other extreme of the pain that is the pain worst imaginable or as bad as it can be. (16) The higher the score, the greater the pain intensity. (17) The Minimal Clinically Important Difference (MCID) for the NPRS is suggested to be a reduction of 2 points. (18)

For the disability of lower back pain, Oswestry Disability Index (ODI) was used. This index gives a subjective percentage of the function level (disability) in different daily activities among individuals suffering from lower back pain. (19) it targets ten daily activities and has six answering statements, scored from 0 to 5, where 0 is pain or difficulty-free while 5 is the worst imaginable moment. All these ten sections are then completed, and the score calculation is done. Adding all the responses together out of 50, multiply it by the number of questions answered and then multiply by 100 and report the result in percentage. 0% to 20% is considered a minimal disability, 21% to 40% is considered a moderate disability, 41% to 60% is considered a severe disability, and 61% to 80% is considered crippled. In comparison, 81% to 100% are either bedbound or just exaggerating their symptoms. (20) The MCID for ODI is a decrease of 4 to 10 points. (21)

For Range of motion, a goniometer was used. To check the degrees of flexion and extension, the patient's iliac crest was taken as a fixed reference point, and the fixed end of the goniometer was placed on it while the moveable end was with the body's axillary line. The subjects were asked to stand in an upright position with their knees extended and their arms placed in front of their bodies. (22) The degrees of flexion and extension were noted in the respective movements. For lateral bending, the patient is asked to stand upright, and the therapist stabilizes the patient's pelvis. The center of the goniometer is placed at the spinous process of the S1 vertebrae, while the immobile end of the goniometer will be perpendicular to the ground. The moveable arm lies in line with the C7 spinous process. The patient then moves in the lateral bending on both the left and right side, and the readings are recorded. For the Range of Motions, the effect size is considered. Any increase in the Range of motion is considered clinically significant. (23)

Statistical Analysis

Version 26 of SPSS was employed to analyze the data. To determine whether the pre- and post-readings differed, a paired sample t-test was run. ANOVA was used to determine the difference between the groups, whereas the mean difference within the group was computed to determine relevance with the MCID.

RESULTS

50 participants were involved in this study and were divided into two groups at random: group MFKT, with a mean age of 30.9 (2.41) years, and group MFR, with a mean age of 31.32 (3.13) years. Table 1 lists the participants' baseline characteristics in summary form. Figure 1 provides an explanation of this study's flow diagram.

Data analyzed for both groups about different variables are mentioned in Table 2.

Pain

According to Table 2, a significant difference was found within the group at the end of the treatment in MFR (Mean: 4.36; 95% CI: 3.86 – 4.86) and in MFKT (Mean: 2.2; 95% CI: 1.84 – 2.56).

The pain level was significantly decreased in both groups ($p < 0.000$). However, between the groups, the mean difference at the end of the treatment was (mean difference MFR – MFKT: 2.16; 95% CI: 1.40 – 2.92) ($P \leq 0.05$).

ODI

There was a significant difference reported within the group at the end of the treatment. In MFR (Mean: 41.76; 95% CI: 36.13 – 47.38) and in MFKT (Mean 11.36; 95% CI: 9.04 – 13.67). Disability was also decreased in both groups, but a significant decrease was noted in the MFKT group after the treatment. (Mean difference MFR – MFKT: 30.40; 95% CI: 39.46 – 21.33). ($p \leq 0.05$).

Range of Motion

Flexion was analyzed first. In MFR (Mean: 56.20; 95% CI: 51.71 – 60.68) and in MFKT (Mean: 80.04; 95% CI: 77.63 – 82.44). Flexion increased by both techniques, but MFKT results were greater than MFR when compared between the groups. (Mean Difference MFR – MFKT: 23.84; 95% CI: 30.83 – 16.84). In extension, the MFR (Mean 17.72; 95% CI: 15.96 – 19.47) and MFKT (22.32; 95% CI: 21.25 – 23.28) were compared. There was an increase in extension, but when the comparison was made between the groups, there was an increase in the response of MFKT. (Mean difference MFR – MFKT: 4.60; 95% CI: 1.71 – 7.48).

For the lateral bending of the Right side within the group, a comparison was reported for MFR (Mean 19.48; 95% CI: 17.90 – 21.05) and MFKT (Mean 24.40; 95% CI: 22.79 – 26.00). A comparison was made between the groups which reported an increase in response to the MFKT. (Mean difference MFR – MFKT: - 4.92; 95% CI: - 8.01 – -1.82).

For the lateral bending of the left side within the group, a comparison was reported for MFR (Mean 19.96; 95% CI: 18.16 – 21.75) and MFKT (Mean 24.00; 95% CI: 22.41 – 25.58). The group comparison revealed an increased response from MFKT (Mean difference MFR - MFKT: 4.04; 95% CI: 7.32 – 0.75).

DISCUSSION

A study was conducted in which the effects of MFR were compared with the Muscle Energy technique (MET) in individuals having non-specific lower back pain. The study concluded that both techniques were beneficial and brought positive results among the patients. The disability, as well as pain, was reduced with the techniques mentioned above. Still, after following-ups, it was concluded that MET proved better than the MFR. In our study, the effects of MFR individually and in combination with taping significantly reduced pain and disability. (24)

Also, in another study, the effects of taping alone were discussed, whether it helps patients with disability or pain. The results of that study concluded that disability, as well as pain, was reduced by taping. Still, the effects were not clinically worthwhile and were too small to be statistically significant. Because of this, we combined our taping technique with MFR, and the obtained results were highly significant. The pain, as well as the disability of the patients with non-specific lower back pain, were highly reduced. Hence we can say that taping can bring promising results when used in combination with any other technique. (25)

The research was conducted in which the effects of taping, myofascial release, and another exercise technique were studied on the forward head posture. The disability of the neck was studied in this case. According to the study, all of the techniques brought improvement in pain as well as disability. Still, none

of their outcomes was statistically significant, while in our studies, both the techniques resulted significantly, and the effects from MFKT are with a high mean difference. Hence it can be used as a combination for the reduction of lower back disability as well as pain. (26)

Effects of myofascial release were also studied on the Range of motion of the individuals. According to a study, because of myofascial release, there was an increase in the Range of motion of the knee joint without putting any deficit in the performance of the muscle, similar to our study of how all the three ranges of the lower back were significantly improved by both the techniques, out of which the MFR has done with taping rendered better results. (27) Also, according to another study, taping has improved various problems in individuals with lower back pain. That included Range of motion and other physiological problems. Flexibility was also significantly improved because of taping, whereas in our study, taping brought significant results when applied in combination with myofascial release. However, there is still room to apply to tape individually and compare the results with and without MFR. (28)

CONCLUSION

The above study concluded that MFR, as well as MFKT (MFR with the combination of taping), are significant techniques for bringing promising results to patients with non-specific lower back pain. Still, the results of MFKT are better than MFR. Hence this technique can be utilized in the future to treat patients as well as decrease their pain as well as the level of disability and pain as well as help in the improvement of their Range of motion.

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Conflict of Interest:

We have no conflicts of interest to disclose. All authors declare that they have no conflicts of interest.

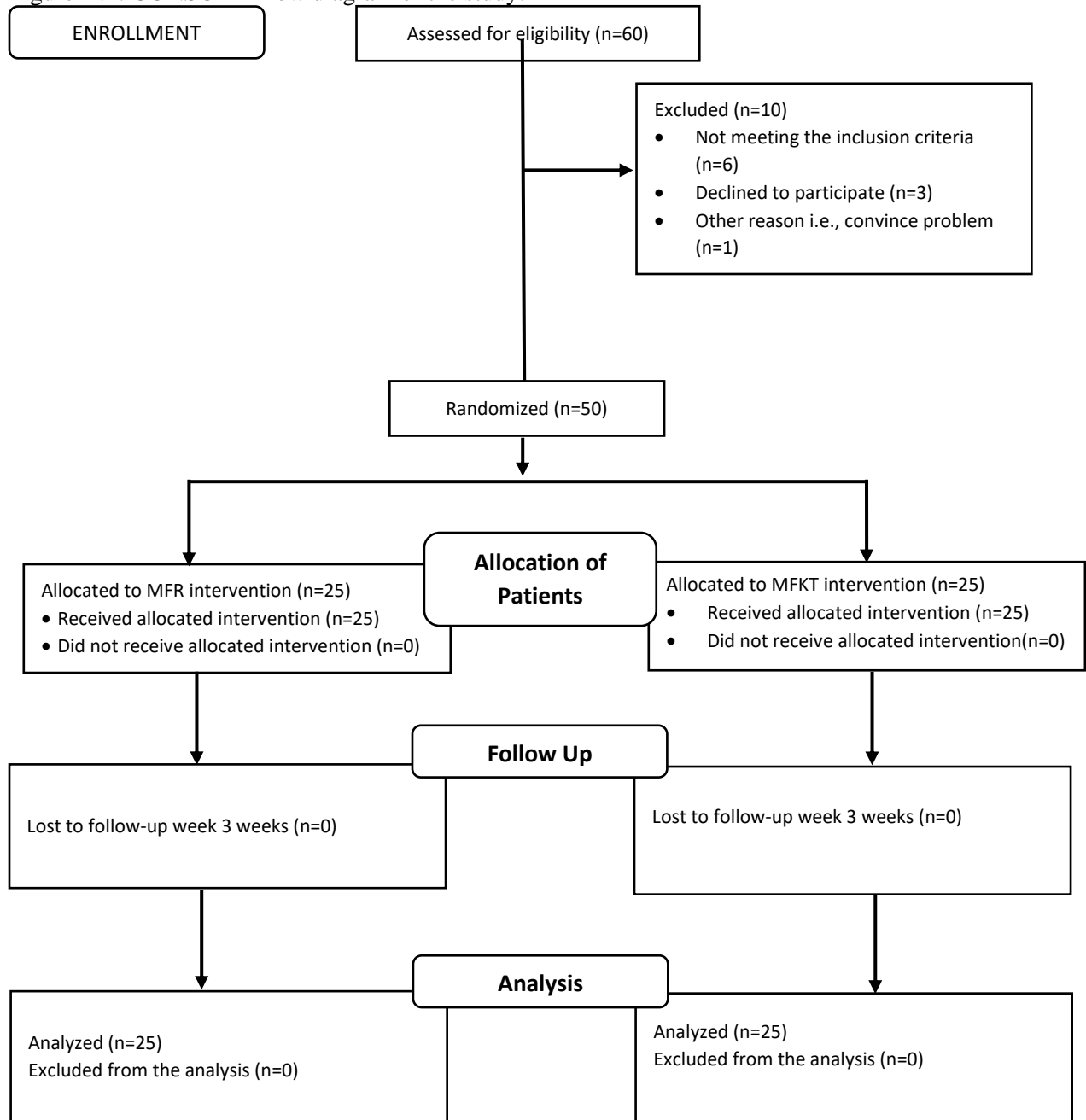
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APPENDIX A : FIGURE

Figure A.1: CONSORT Flow diagram of the study.



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APPENDIX B: TABLES

Table B.1: **baseline demographic and clinical characteristics**

Parameters	MFR	MFKT
	(n=25)	(n=25)
Age (yr)	31.32 (3.13)	30.92 (2.41)
Gender(female)	25	25
NPRS (0-10)	6.28 (0.61)	6.72 (0.89)
ODI (0-100%)	55.6 (9.43)	53.44 (12.24)
ROM Flexion (degrees)	50.48 (11.09)	70.36 (6.23)
ROM Extension (degrees)	14.48 (3.89)	17.52 (3.67)
ROM Rt Lateral bending	16.12 (4.10)	19.84 (4.30)
ROM Lt Lateral bending	17.16 (4.70)	18.96 (5.63)

Data are mean (SD). NPRS; Numeric Pain Rating Scale; ODI; Oswestry Disability Index; ROM; Range of Motion; Rt; Right; Lt; Left

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Table B.2: Differences between the groups of the outcome measures.

Outcome	Group				Difference between the groups
	Baseline		Week 3 (end of protocol)		Week 3 (end of protocol)
	MFR	MFKT	MFR	MFKT	MFR minus MFKT
NPRS	6.28 (6.03 – 6.53)	6.72 (6.35 – 7.09)	4.36 (3.86 – 4.86)	2.2 (1.84 – 2.56)	2.16 * (1.40 – 2.92)
ODI	55.60 (51.70 – 59.49)	53.44 (48.38 – 58.49)	41.76 (36.13 – 47.38)	11.36 (9.04 – 13.67)	30.40 * (39.46 – 21.33)
ROM Flexion	50.48 (45.90 – 55.05)	70.36 (67.78 – 72.93)	56.200 (51.71 – 60.68)	80.040 (77.63 – 82.44)	23.84 * (30.83-16.84)
ROM Extension	14.48 (12.87 – 16.08)	17.52 (16.00 – 19.03)	17.72 (15.96 – 19.47)	22.320 (21.25 – 23.28)	4.60 * (1.71 – 7.48)
ROM Lateral Bending (Right)	16.12 (14.42 – 17.81)	19.840 (18.06 – 21.61)	19.48 (17.90 – 21.05)	24.400 (22.79 – 26.00)	4.92 * (8.01 – 1.82)
ROM Lateral Bending (Left)	17.16 (15.21 - 19.10)	18.96 (16.63 – 21.281)	19.96 (18.16 – 21.75)	24.000 (22.41 – 25.58)	4.04 * (7.32 – 0.75)

Data are mean (CI 95%). *P≤0.05. NPRS; Numeric Pain Rating Scale; ODI; Oswestry Disability Index; ROM; Range of Motion