Effect of Neural Mobilization Techniques on Pain, and Hip and Knee Range of Motion on Lumbosacral Radiculopathy Patients with Peripheral Sensitization

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Methods and Materials

1.1. Study design and setting

This study was a double-blind case-control trial. In this study, the investigator was blind to the participant's measurements, the examiner and the observer were blind to the participant group. The study was conducted at the Security Forces Hospital in Dammam (SFHD), King Fahd Hospital of the University (KFUH) and Dammam Medical Complex (DMC) in Dammam, Saudi Arabia. This study was approved by the Institutional Review Board (IRB) at Imam Abdulrahman bin Faisal University (Appendix A).

1.2. Participants

The sample size was calculated using G*power software Version 3.0.10. Data from Tambekar et al. (2016) was used (effect size 0.82, $\alpha = 0.05$, power= 0.95). The calculation resulted in a total of 51 participants. Lumbosacral radiculopathy patients with dominant peripheral sensitization of unilateral leg pain were recruited. The patient was diagnosed with peripheral sensitization if they fulfilled the criteria suggested by Schäfer et al. (2009) which included: S-LANSS score < 12, negative sensory and motor examination, and positive neural tissue provocation tests (straight leg raising test, slump test). The inclusion criteria were: adult, pain duration of more than 3 months, patients were diagnosed with peripheral sensitization. Patients with one or more of following criteria were excluded from this study: S-LANSS score ≥ 12, motor or sensory deficits, history of back or lower extremity surgeries, bilateral referred pain, patients with TENS contraindications as described in Jones and Johnson (2009) such as pacemakers and cardiovascular problems, epilepsy, active malignancy, dermatological conditions, and diminished pain sensation.

At SFH, KFHU and DMC outpatients' clinics, the physician referred patients diagnosed with lumbar radiculopathy or lumbosacral radiculopathy with negative dermatomes, myotomes and reflexes examinations finding to the primary investigator. In the initial appointment, the primary investigator explained to each participant the aims and the general procedures of the study. If agreed to participate, the patient signed the consent form (Appendix B, C). The independent examiner started the examination for eligibility with S-LANSS assessment (Appendix D) and an

examination of SLR and slump tests. If eligible, the patient was assigned alternatively to one of the three study groups: tensioner group (T- group), slider group (S- group), or control group (C-group). Patients were blinded to the intervention details until they were assigned to one of the study groups. In the alteration type of allocation of groups allocation, the first patient was assigned to slider group, the second was assigned to the tensioner and the third to control group. This order continued even if there was any withdraw until we reached the end of the list then we started filling the gaps in the list from the top with new participants.

1.3. Outcome measurements

Evaluation procedures were carried out exactly the same for all the three group by an independent examiner. Another observer helped the examiner in recording hip and knee ROM during the examination. Both the examiner and observer were blinded to the study groups. The following measurements undertaken were carried out on four different occasions: baseline, after 1st session, after 3rd session, and after 6th session.

*1.3.1. **Pain** intensity*

Visual analog scale (VAS) was used to measure pain intensity. It consisted of a 10-cm horizontal line with 'No pain" at one end and "Worst imaginable pain" at the other end. The patient was asked to mark his current leg pain level on the line. The Minimal clinically important difference (MCID) for VAS was reported to be 1.8 - 1.9 cm (Hägg et al., 2003). VAS is a valid and reliable measurement of pain intensity (Ferreira-Valente et al., 2011).

1.3.2. Hip ROM with SLR

The patient was in supine position with their head in neutral and flat on the bed without pillows. The examiner supported the knee in full extension using his proximal hand, whereas distal hand was used to maintain the ankle position in a neutral position. The examiner passively raised the examined leg until the patient reported reproduction of his symptoms, or until the examiner felt significant resistance to SLR (Martin et al., 2014; Walsh and Hall, 2009a).

The independent examiner performed the SLR test for asymptomatic then symptomatic limb. A bubble inclinometer (Fabrication Enterprise Inc., White Plains, New York 10602, and U.S.A) was secured just proximal to the ankle joint using double adhesive tape. The inclinometer was directed towards the medial aspect of the leg so that the examiner could not see it. The observer adjusted the fluid to zero level before testing. The observer recorded the ROM when the patient started feeling reproduction of his symptoms or the examiner felt significant resistance (Figure 1).

3.3.3 Knee flexion ROM with the Slump test

In the slump test, the patient seated at the edge of the bed with legs dangling freely and knee at an angle of 90^{o} flexion. The patient's trunk was placed in slumped position with cervical flexion and hands were together behind the back. The distal hand of the examiner was used to maintain the ankle in neutral position. The examiner proximal hand was used to maintain the slump position of the patient trunk. The examiner instructs the patient verbally to maintain his head in flexed position. The examiner used his distal hand to passively extend the examined knee until the patient felt his symptoms, or until the examiner felt significant resistance (Walsh and Hall, 2009a). The measurement of knee flexion ROM in a slump was taken for the asymptomatic then symptomatic limb.

A bubble inclinometer was secured just proximal to the ankle joint using double adhesive tape. The inclinometer was directed towards the medial aspect of the leg so that the examiner could not see it. The observer adjusted the fluid to zero level before testing and recorded the angle during the test. The observer recorded the measurement of the inclinometer at the point of symptoms reproduction or the feeling of resistance (Walsh and Hall, 2009b) (Figure 2).

Figure 1: Straight leg raising test. showing the placement of inclinometer to measure hip range of motion from starting position (A) to end position (B).

Figure 2: End position of the slump test. during which the observer was recording knee range of motion and the examiner performed the test.

1.4. Interventions

Each patient received therapeutic sessions over 2 weeks (3 sessions/ week). All patients in all groups received Transcutaneous Electric Nerve Stimulation (TENS). In addition, T-group received tensioner neural mobilization technique and S-group received slider neural mobilization technique.

1.4.1. TENS (All study groups)

TENS device (Sonicplus 692V, ENRAF-NONIUS, Rotterdam) was applied at a pulse frequency of 100 Hz (Thiese et al., 2013). A single channel, two surface electrodes, were used for stimulation over a session period of 15 minutes (Itoh et al., 2009). The device electrodes were placed on the painful paraspinal areas of the back. The intensity was set to enable a clear tingling sensation above the sensory threshold of the patient (Barker et al., 2008; Itoh et al., 2009) (Figure 3).

Figure 3 : Transcutaneous electrical nerve stimulation (TENS).

1.4.2. T-Group (Tensioner technique)

This technique was done in a sitting slump position. The patient sat on the edge of the bed with the neck and trunk in neutral, hips and knees in 90^{o} flexion and ankles in resting plantar flexion. The back of the patient's knees touched the bed edge. The patient was asked to move the neck and trunk into flexion slouched position, the treated knee in extension, and ankle in dorsiflexed simultaneously (Phase 1). Then the patient extended the neck and trunk, flexed the knee, and plantarflexed the ankle simultaneously (Phase 2). Tensioner technique was performed for 10

repetitions over 2 sets. The patient was given a 2-minutes resting time between the sets (Herrington, 2006; Shacklock, 2005) (Figure 4).

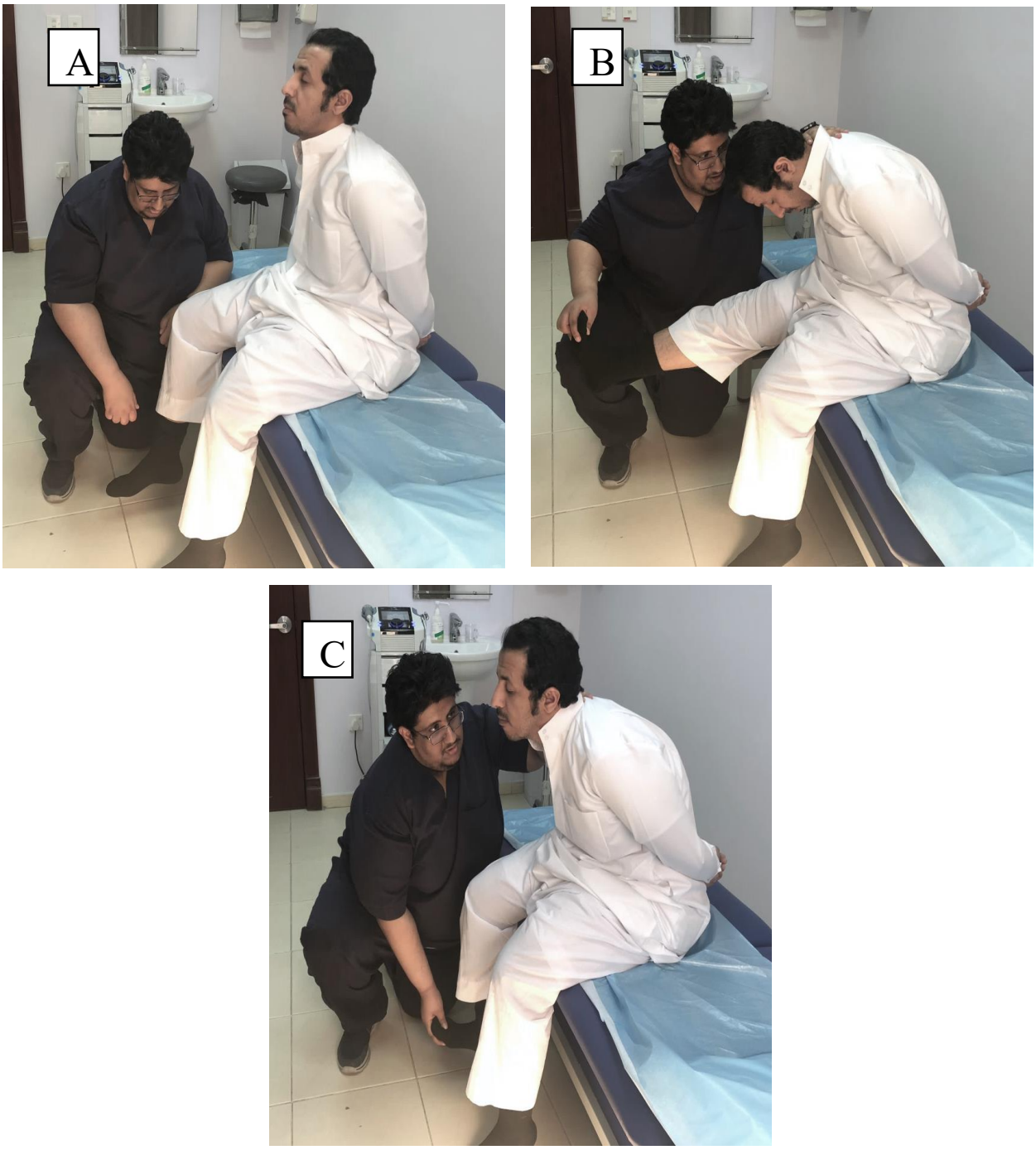

Figure 4 : The tensioner technique: A) starting position, B) phase 1, and C) phase 2.

S - Group (Slider technique)

This technique was also done in a sitting slump position. The patient sat on the edge of the bed, with the neck and trunk in flexion, hips, and knees in 90^{o} flexion and ankles in resting plantar flexion. The back of patient's knees touched the bed edge. The patient was asked to move the neck into extension, the treated knee in extension, and ankle in dorsiflexion simultaneously (Phase 1). Then the patient flexed the neck and trunk, flexed the treated knee and plantarflexed the ankle Simultaneously (Phase 2). Slider technique was carried out for 10 repetitions over 2 sets. The patient was given a 2-minutes resting time between the sets (Herrington, 2006; Shacklock, 2005) (Figure 5).

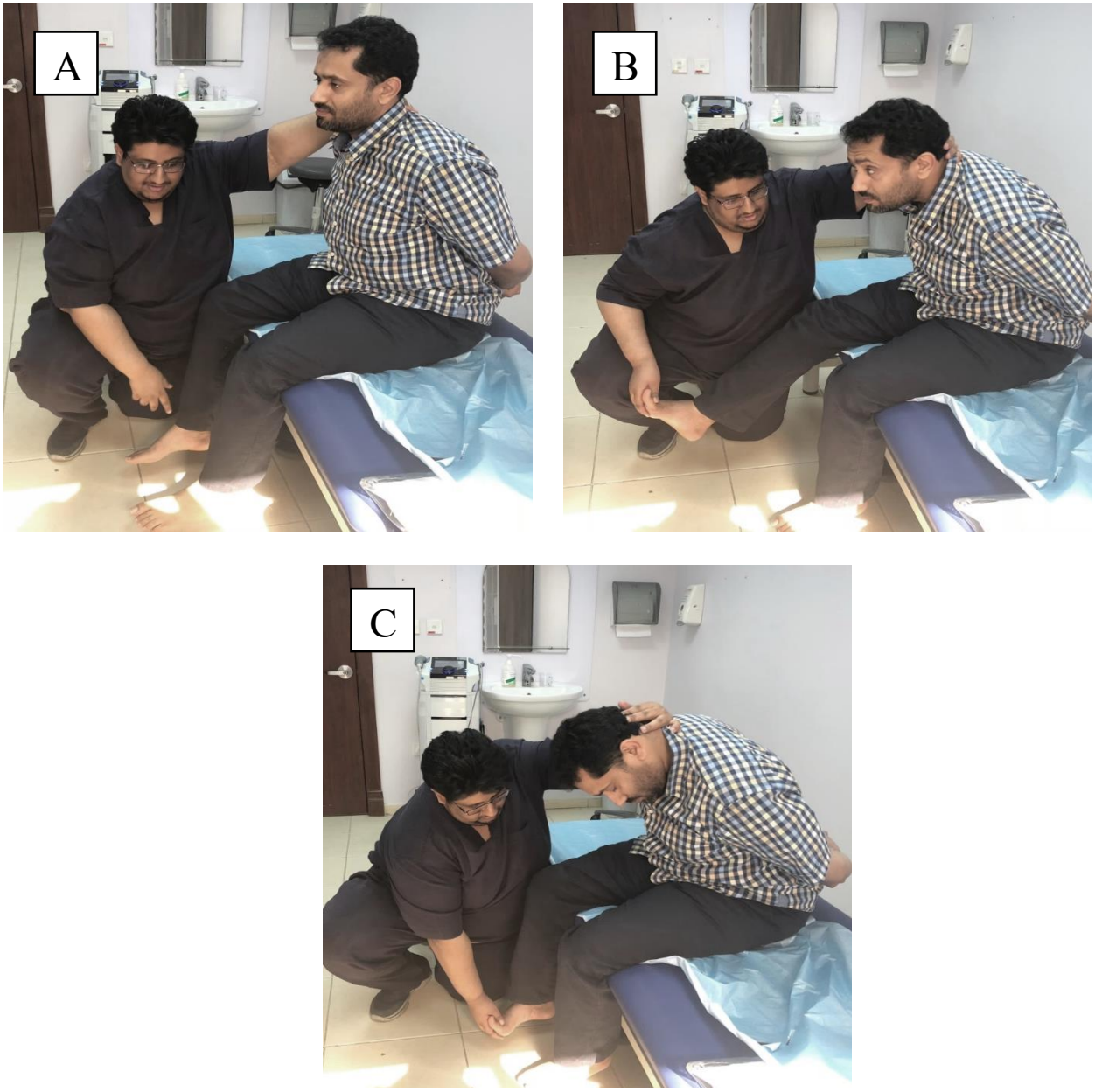

Figure 5 : The slider technique: A) starting position, B) phase 1, and C) phase 2.

1.5.Statistical analysis

SPSS software (version 23, IBM Corporation, New York) was used for statistical analysis. Descriptive data of mean and standard deviation was obtained for all data. The baseline between groups' comparisons on clinical and demographic variables (BMI, age, and VAS) was performed using one-way analysis of variance (ANOVA). A two-way mixed design ANOVA (MANOVA) with post-hoc (Bonferonni Correction) was used to calculate the differences in outcomes measurements with TIME (baseline, 1^{st}, 3^{rd}, and 6^{th} session) as a within-groups factor and GROUP (control, slider, and tensioner) as a between-group factor. The effect size was also calculated with Cohen's *d* to estimate the magnitude of differences within and between groups [small (d = 0.2), medium (d = 0.5), and large (d = 0.8)]. Pearson's correlation was performed to assess the relationship between pains, hip flexion ROM in SLR, knee flexion ROM in slump. The significant level was set at $P < 0.\ 05$.