Research Protocol

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Impact of Spiral Stretch Technique on Range of Motion, Pain, and Disability in Patients with Adhesive Capsulitis: A Study Protocol for a Randomised Clinical Trial

Physiotherapy Section

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ABSTRACT

Introduction: Adhesive Capsulitis (AC) of the shoulder is a progressively painful condition that gradually limits both passive and active movement in the glenohumeral joint. It affects 3% to 5% of the general population annually, but in individuals with diabetes, the rate can reach up to 40%. The Spiral Stretch technique is a unique method that incorporates Proprioceptive Neuromuscular Facilitation (PNF) into an assessment and treatment sequence, modified to include Muscle Energy Technique (MET) principles. Although preliminary research suggests a potential role for managing AC, further research is needed to confirm its effectiveness as a standalone or adjunctive therapy.

Need of the study: The spiral stretch technique shows promise for managing AC, but its benefits, best use, and long-term effects are not yet clear. More research is needed to understand it better and improve patient outcomes.

Aim: To develop a protocol to evaluate the efficacy of the spiral stretch technique in treating pain, Range of Motion (ROM), and disability in patients with AC.

Materials and Methods: This is a pre-test post-test Randomised Controlled Trial (RCT) that will be conducted at MM Super-specialty Hospital, Mullana from August 2024 to February 2025. Patients will be recruited based on specific inclusion and exclusion criteria. Subjects will be randomly allocated into two groups through computer-based random allocation techniques. Group 1 will receive spiral stretch and conventional physiotherapy treatment, whereas Group 2 will receive only conventional physiotherapy treatment. Pre-test and post-test assessment will be done using the Numerical Pain Rating Scale (NPRS), shoulder ROM measurements, and the Shoulder Pain and Disability Index (SPADI). The physiotherapy treatment will be given for 40 minutes each session, three times a week for four weeks.

Keywords: Range of motion, Shoulder joint, Shoulder pain

INTRODUCTION

AC is the most prevalent shoulder joint condition and is also known as frozen shoulder [1]. This condition, where inflammation in the shoulder joint results in scapulohumeral pain, causes a loss of both active and passive ROM and leads to limitations in daily activities [2]. This condition affects 3-5% of the general population, with a higher prevalence of 20% among diabetics, and is most frequently observed in manual workers between the ages of 40 and 60 [3]. The exact cause of the condition isn't completely understood.

The pathology of frozen shoulder involves synovial inflammation, thickening of the joint capsule, and the development of fibrous tissues. Typically, the condition presents as discomfort during essential movements and joint pain when moving in certain directions [4]. Conservative management for frozen shoulder to alleviate pain and inflammation includes physical therapy interventions such as cold and hot packs, range-of-motion exercises, Codman's exercises, mobilisation, stretching, strengthening exercises, TENS, ultrasound, and interferential therapy, which are also used to manage pain and restore function [5].

MET is a non-invasive method used to stretch and lengthen inflexible muscles and fascia. It primarily targets soft tissues and aids in joint mobilisation, enhancing joint ROM and muscle extensibility by increasing tolerance to stretch [5]. The primary effects of MET are attributed to two distinct physiological mechanisms: Post-Isometric Relaxation (PIR) and Reciprocal Inhibition (RI) [6]. PNF is a crucial rehabilitation method that increases muscle flexibility and ROM. PNF helps restore movement and strength, but its effects on the structure of the shoulder joint are still little understood. Research has mostly focused on treating symptoms [7].

The spiral stretch technique is a distinctive approach for enhancing shoulder ROM. In this technique, PNF methods are integrated into the assessment and treatment process, with modifications to incorporate the principles of MET [8]. There are two methods: Spiral MET method 1 (shoulder spiral stretch into extension to increase ROM in flexion, adduction and external rotation) and Spiral MET method 2 (shoulder spiral stretch into flexion to increase the ROM in extension, abduction and internal rotation) [8]. There is limited literature available on the spiral stretch technique, and its long-term effects have not been documented. Therefore, the aim of this study will be to evaluate the effects of the spiral stretch technique in treating patients with AC.

Primary objective: To determine the efficacy of the "Spiral stretch" technique to improve ROM in patients with AC.

Secondary objective: To determine the efficacy of the "spiral stretch" technique to improve pain and disability in patients with AC.

Null hypothesis: There will be no significant effects of the spiral stretch technique in patients with AC.

Alternate hypothesis: There will be significant effects of the spiral stretch technique in patients with AC.

REVIEW OF LITERATURE

Alagingi NK and Rayudu GM conducted a study to compare the effectiveness of Mulligan's technique and MET in individuals with AC. Eighty patients were recruited and randomised into two groups.

Group A (n=30) received Mulligan's technique, and Group B (n=30) received MET, with both groups performing exercises thrice weekly for three weeks. The study found that both Mulligan's technique and MET were similarly effective in reducing pain and improving shoulder function for individuals with AC [5].

In a study conducted by Patel B and Dibyendunarayan BD, the study aimed to compare the effectiveness of MET and Mulligan's Technique in AC patients. A total of 42 participants diagnosed with AC were divided into two groups of 21 individuals each. One group received a combination of MET and conventional therapy, while the other group underwent a combination of Mobilisation with Movement and conventional therapy. Both groups participated in a 4-week treatment program, 5 days per week. Group B (MWM) showed significantly greater improvement than MET [9].

Umaria H et al., evaluated the added benefits of Spiral Stretch MET combined with conventional treatment in AC patients within a two-week protocol. Thirty pre-diagnosed AC patients were randomised into Group A, receiving MET with conventional treatment, and Group B, receiving only conventional treatment. The intervention enhanced pain, ROM, and function, with the spiral stretch MET group demonstrating significantly superior outcomes compared to the control group [10].

Ghaffar T et al., aimed to compare the effectiveness of PNF stretching and MET in reducing pain and disability among individuals with AC. 30 participants aged 30 to 60 years were enrolled in the study. Group A received PNF stretching, while Group B underwent Spencer MET for one month. The study concluded that Spencer MET proved to be more effective [11].

MATERIALS AND METHODS

In this pre-test post-test RCT, participants will be selected from MM Super-specialty Hospital, Mullana from August 2024 to February 2025, where they sought physiotherapy for shoulder pain and discomfort, presenting with capsular pattern restriction in shoulder ROM and diagnosed with AC. Ethical clearance has been obtained from the Institutional Ethics Committee (IEC) of Maharishi Markandeshwar Institute of Medical Sciences and Research, Mullana, Ambala, under project number IEC-2994. This trial has been officially listed on ClinicalTrials.gov (ID: CTRI/2024/08/072699).

To maintain transparency and confidence, participants will receive an informed consent form in their language. The principal researcher will be the only one with access to the codes assigned for data collection, ensuring confidentiality. After consent is obtained, participants will undergo additional eligibility checks.

Inclusion criteria:

1. Age 30-60 years.
2. Both males and females.
3. Patients in the second and third stages of frozen shoulder.
4. Diabetic population.

Exclusion criteria:

1. Subjects with a recent history of surgery on the affected shoulder.
2. Rheumatoid arthritis.
3. Subjects with a history of any trauma/fracture around the shoulder complex.
4. Osteoporosis and malignancies in the shoulder region.
5. Neurological deficits affecting shoulder function.
6. Subjects with rotator cuff lesions and tendon calcification.
7. Pain or disorders of the cervical spine, elbow, wrist, or hand on the affected side.

Sample size: A pilot RCT will be conducted with a total of 12 participants, evenly distributed with six participants in each group, to calculate the effect size. These participants will also be included in the main study.

Randomisation, Allocation and Blinding

Participants will be randomly assigned to two groups using computer-generated randomisation software: Group 1 will receive the Spiral Stretch technique along with conventional treatment, while Group 2 will receive only conventional treatment. All participants will be blinded to their group assignments. The therapist will establish baseline characteristics for each participant through a standardised assessment form, recording details such as sex, age, body mass index, and current occupation. Primary and secondary outcome measures will be documented before the intervention begins.

Intervention

The intervention will start once the baseline measurements and standardised evaluations are complete. Over the course of four weeks, each participant will receive therapy three times a week for 40 minutes each time. Participants will be forbidden from taking any pain medication during this time.

Group 1: Participants will receive the "spiral stretch" technique and conventional treatment. There are two methods in spiral stretch; each method will be applied for two sets of five repetitions each.

Method 1: Shoulder 'spiral' stretch into extension to increase the ROM in flexion, adduction and external rotation [8]. The patient lies supine and ensures that their shoulders remain in contact with the table throughout the procedure and their head is turned left. Next, the patient flexes, adducts and externally rotates the (right) arm fully, maintaining the elbow in extension (palm facing the ceiling) while the practitioner stands at the head of the table and supports the patient's arm at the proximal forearm and elbow. The patient is instructed to begin the process of returning the arm to their side, in stages, against resistance, and the amount of force used by the patient should not exceed 25% of their available strength.

The first instruction is to pronate and internally rotate the arm ('turn your arm so that your palm faces the other way'), followed by abduction and then extension ('bring your arm back outwards and to your side'). All these efforts are combined by the patient into a sustained effort which is resisted by the practitioner so that a 'compound' isometric contraction occurs, involving infraspinatus, middle trapezius, rhomboids, teres minor, posterior deltoid and pronator teres. On complete relaxation, the practitioner, with the patient's assistance, takes the arm further into flexion, adduction and external rotation, stretching these muscles to a new barrier. This procedure is repeated two or three times [5].

Method 2: Shoulder 'spiral' stretch into flexion to increase the ROM in extension, abduction and internal rotation [5]. Firstly, the patient lies supine and ensures that their shoulders remain in contact with the table throughout the procedure. The patient extends, abducts and internally rotates the (right) arm fully, maintaining the elbow in extension (wrist pronated) while the practitioner stands at the head of the table and supports the patient's arm at the proximal forearm and elbow. Next, the patient is asked to begin the process of returning the arm to their side, in stages, against resistance, and the amount of force used by the patient should not exceed 25% of their available strength.

The first instruction is to supinate and externally rotate the arm ('turn your arm outwards so that your palm faces the other way'), followed by adduction and then flexion ('bring your arm back towards the table, and then up to your side'). All these efforts are combined by the patient into a sustained effort that is resisted by the practitioner, so that a 'compound' isometric contraction occurs, involving the

clavicular head of pectoralis major, anterior deltoid, coracobrachialis, biceps brachii, infraspinatus and supinator. On complete relaxation, the practitioner, with the patient's assistance, takes the arm further into extension, abduction and internal rotation, stretching these muscles to a new barrier. This procedure should be repeated two or three times [8].

The conventional physiotherapy treatment consists of moist heat packs, ultrasound therapy, Codman's pendular exercise, wand exercise and finger ladder exercise [9].

Group 2: Patients will receive only conventional physiotherapy treatment. Firstly, a moist heat pack will be applied over the affected shoulder for a duration of 10 minutes. Next, ultrasound therapy will be administered in continuous mode, with a frequency of 1 MHz and an intensity of 1.5 W/cm^2, for a duration of 7-8 minutes. The transducer head will be applied in concentric circles over the superior, anterior, and inferior aspects of the affected shoulder.

To perform Codman's pendular exercise [9], the patient is instructed to stand and lean forward slightly to allow the affected arm to hang freely (holding a bottle), with the unaffected arm supported on a table, and gently swing the arms back and forth, sideways like a pendulum and in circles (clockwise and anticlockwise). Next, finger ladder exercises are performed by instructing the patient to stand in front of a wall, extending their affected arm and placing their fingers on the lowest mark on the ladder, keeping elbows extended. Next, the patient is instructed to slowly climb the ladder, by lifting each finger one at a time, moving upwards sequentially, followed by lowering the fingers back to the starting position, each time attaining a new range.

Lastly, wand exercises are performed to increase range in all directions of the restricted capsular pattern [9]. To increase shoulder abduction, the patient is instructed to stand and hold the wand with both hands, palms facing down and arms by their sides. Then, the patient is instructed to start lifting the affected arm sideways to the affected side, keeping both elbows straight. To increase external rotation, the patient is instructed to hold the wand with both hands, with palms facing up, keeping elbows at their sides and 90° flexed and rotate the wand away from the body. To increase internal rotation, the patient is instructed to hold the wand behind their back, with the affected hand at the lower end (palms out) and the unaffected hand at the top (palms in). Using the unaffected hand, they are instructed to pull the wand upwards and then slowly lower it, gradually increasing the ROM. Finally, to increase the flexion ROM, the patient is instructed to hold the wand with both hands, palms facing down, keeping elbows by their sides, and then slowly raise the wand in front of them, keeping both elbows straight. All exercises are performed for three sets of 10 repetitions each.

Outcome Measures

Primary outcome measures:

Range of Motion (ROM): The shoulder ROM, covering flexion, extension, abduction, internal rotation, and external rotation, is measured using a universal goniometer. Each movement is evaluated three times, and the average measurement is used for outcome analysis [12].

Secondary outcome measures:

Numerical Pain Rating Scale (NPRS): The NPRS, which ranges from 0 to 10, is used to measure pain severity. A score of 0 indicates no pain, 1 to 3 reflects mild pain, 4 to 6 denotes moderate pain, 7 to 9 represents severe pain, and a score of 10 indicates extremely severe pain [13].

Shoulder Pain and Disability Index (SPADI): The SPADI is a self-administered questionnaire consisting of 13 items that evaluate pain levels and the difficulty of performing daily activities involving the upper extremities. It includes a 5-item pain subscale and an 8-item disability subscale. The patient is asked to pick the number that best describes their pain level and how hard it is to use the affected shoulder. The pain scale adds up to 50 points, and the disability scale adds up to 80 points. The total SPADI score is shown as a percentage, where 0 is the best and 100 is the worst. A higher score means more disability [14].

STATISTICAL ANALYSIS

SPSS statistical software, version 26, will be used for statistical analysis. The normality of the data will be assessed using the Shapiro–Wilk test. If the data are normally distributed, parametric tests will be used: a paired t-test for within-group analysis and an unpaired t-test for between-group analysis. If the data are not normally distributed, non-parametric tests will be employed: the Wilcoxon Signed Rank test for within-group analysis and the Mann–Whitney U test for between-group analysis.

Trial status: The trial is currently recruiting patients. Participant recruitment started in August 2024 and is expected to end in November 2024. The intervention is expected to start in November 2024.

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