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Research protocol

Evaluation of Efficacy of Spencer Technique, Kaltenborn, Mulligan, and Maitland mobilization on Pain, Range of Motion and Functional Disability in Patients with Frozen Shoulder

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ABSTRACT

Shoulder pain is a common complaint, with prevalence studies showing that 7-20 percent of the adult Indian population suffers from it. Functional disability is one of the most common complaints for patients with shoulder pain. The aim of shoulder pain treatment is generally to reduce pain and strengthen functional disabilities. So, this study will be conducted to compare the efficacy of Spencer technique, Kaltenborn, Mulligan, and Maitland mobilization in frozen shoulder. A total of 80 samples will be included and they will be divided into four group 20 in each. They will receive treatment 5 times a week for 3 weeks. On completion of the treatment in the third week, post interventional assessment and scores of VAS, ROM, and SPADI will be revaluated and follow-up and assessment of these outcomes will be revaluated on completion of 2nd month, 3rd month and 6th month and the data will be taken for analysis. Result will be drawn post the conduction of study.

Keywords: Frozen Shoulder, Rehabilitation, Spencer technique, synovial joints, Hypertonic muscles.

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INTRODUCTION

The glenohumeral joint (shoulder joint) is a ball and socket joint that connects the scapula and the humerus. It is the main link between the upper limb and the trunk. It is one of the most flexible joints in the human body, but it comes at the expense of joint stability ^[1]. The glenohumeral joint is constructed by the articulation of the head of the humerus with the glenoid cavity of the scapula. This gives rise to the alternate name for the shoulder joint ^[2]. The articulating surfaces, including those of most synovial joints, are coated in hyaline cartilage. Since the head of the humerus is much larger than the glenoid fossa, the joint has a wide range of motion but is also unstable ^[3]. Flexion, extension, abduction, adduction, internal rotation, and external rotation are all possible movements with a ball and socket synovial joint, the same applies for shoulder joint [1,4].

Shoulder pain is a common complaint, with prevalence studies showing that 7-20 percent of the adult Indian population suffers from it ^[5,6]. The prevalence of this disorder in the general population is estimated to be between 2% and 5%. It is more common in women between the ages of 40 and 60^[7]. Pain, loss of movement, and loss of joint range of motion are all symptoms of the disease (ROM) [8,9]. Its etiology isn't fully understood. Synovial inflammation, joint capsule hypertrophy, and the formation of fibrous structures are all part of the

pathology of frozen shoulder ^[10]. The disease usually manifests itself as a feeling of strain when performing vital movements, as well as joint pain while moving in some direction. Functional disability is one of the most common complaints for patients with shoulder pain. The aim of shoulder pain treatment is generally to reduce pain and strengthen functional disabilities [11]. As a result, outcome assessments should provide a tool (such as a questionnaire) for assessing functional disabilities. There are some self-administered questionnaires for shoulder pain and disability ^[12]. The Shoulder Disability Questionnaire (SDQ) and the Shoulder Pain and Disability Index (SPADI) were deemed the most useful questionnaires by patients as evidence suggests ^[13,14].

Patients with chronic adhesive capsulitis cases have been confirmed to react well to therapeutic mobilizations (Maitland's, Kaltenborn's, Mulligan's, MET) [15], resulting in pain relief and improved functional efficiency.

The Spencer technique consists of seven gentle stretching maneuvers that are used to treat shoulder restrictions caused by adhesive capsulitis, hypertonic muscles, and a variety of other painful or degenerative conditions that require increased mobility. These are low-velocity, moderate-to-high-amplitude methods that carry the joint



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into its full range of motion. Springing motion or repetitive concentric movement of the joint through the restrictive barrier is the activating force ^[16].

The main objectives of osteopathic shoulder girdle manipulation are to regain movement and avoid motion loss. A need arises as to develop a standard specialty physiotherapy protocol towards management of patients with frozen shoulder. So, this study will be conducted to

Compare the efficacy of Spencer technique, Kaltenborn, Mulligan, and Maitland mobilization in frozen shoulder.

METHODOLOGY

The study is approved by the Clinical Trials Registry-India with reference number CTRI/2022/01/039290. This study will be carried out with the sample size of 80 in the department of Musculoskeletal Physiotherapy, Ravi Nair Physiotherapy College, Sawangi (Meghe), Wardha after approval from the Institutional Ethics Committee of Datta Meghe Institute of Medical Sciences, Deemed to be University.

Study type is Interventional study and the sampling design was probability sampling with the sampling technique of simple random sampling using computer generated randomization. A total of 80 samples will be included ^[17]. The study will be conducted in

Musculoskeletal Physiotherapy OPD, Acharya Vinoba Bhave Rural Hospital, Sawangi (Meghe),Wardha on patients with frozen shoulder. Study duration is 24 months

Sample size was calculated using the formula given below.

$$n = \frac{(Z_{1-\alpha/2} + Z_{1-}\beta)^2 p_1(1-p_1) + p_2(1-p_2)}{(p_1 - p_2)^2}$$

As there are four groups, each group will consist of 20 samples.

Inclusion criteria

Patients diagnosed with Frozen Shoulder. (Stage 2 and 3). Both male and female diabetic with $\geq 6.5\%$ HbA1c level between the age group of 40-60 years ^[18]. Frozen Shoulder patients with painful, stiff shoulder for at least 3 months. Frozen Shoulder with at least 25% restricted shoulder range of motion ^[19]. Patients with unilateral frozen shoulder. Patients who are able to comprehend command and willing to participate in the study.

Exclusion criteria

Patients with recent history of surgery on particular shoulder. Post traumatic shoulder pain and stiffness. Patients with Paraesthesia. Patients with previous history of fracture at the shoulder complex, rib fracture. Patients with rotator cuff pathology, tendon calcification. Frozen Shoulder secondary to Brachial Plexus Injury, Parkinsonism, Ankylosis, Infection or Arthroplasty.



Procedure

After obtaining clearance from the institution ethics committee, patients with shoulder pain visiting AVBRH, Sawangi (Meghe), Wardha and MSK OPD, RNPC will be screened for frozen shoulder and confirm diagnosis based on investigations and physical evaluation. Out of the selected population those fulfilling the inclusion and exclusion criteria will be asked to participate in the study. Total n=80 patients will be selected and an informed written consent will be obtained. Demographic data will be collected along with initial assessment of VAS, ROM, and SPADI score. After this initial evaluation, they will be allocated randomly into 4 groups group (A), group (B), group (C), and group (D). All four techniques will be performed according to the standard operative procedure. All the groups will receive the selected treatment for 5 sessions/week for 3 weeks. On completion of the treatment in the third week, post interventional assessment and scores of VAS, ROM, and SPADI will be revaluated and follow-up and assessment of these outcomes will be revaluated on completion of 2nd month, 3rd month and 6th month and the data will be taken for analysis.

Patients will be divided into four groups: Group A will receive Hot Moist Pack (for Shoulder), Spencer Technique, and Codman's Exercises: 20 Patients. Group B: will receive Hot Moist Pack (for Shoulder), Kaltenborn Mobilization, and Codman's Exercises: 20 Patients. Group C will receive Hot Moist Pack (for Shoulder), Mulligan's Mobilization, and Codman's Exercises: 20 Patients. Group D will receive Hot Moist Pack (for Shoulder), Maitland's Mobilization, and Codman's Exercises: 20 Patients.

Outcome measure

1) Subjective – Visual Analogue Scale (VAS) - For pain [14]

2) Functional - Shoulder Pain And Disability Index (SPADI).

3) Objective – Shoulder Range Of Motion (Rom) – Shoulder active and passive ROM ^[20].

Data management

Data collection and reporting will be performed under the guidance of the primary investigators. Documentation for the analysis will be carefully scrutinized for accuracy. The Excel spreadsheet will be issued to an allocation blinded statistician at the end of the study to perform the required analysis. The trial's data will be stored in a safe, locked storage area for later analysis by a biostatistician and the primary researcher.

Data analysis

The SPSS latest version will be used to perform statistical analyses. Student 't' test will be used to test for the significance of difference between the 4 groups. Paired 't' test will be used to comparison of the parameters between three groups. Repeated measures ANOVA will be used for the significance of difference before and after treatment at various time intervals mentioned. Descriptive statistics and frequency distribution will be used for demographic details. To determine the impact of, all statistical tests will be performed with a 95 percent confidence interval (p-value 0.05). **DISCUSSION**

The study will be conducted to compare the effect of Spencer Technique, Kaltenborn, Mulligan, and Maitland mobilization on Pain, Range of Motion and Functional Disability in Patients with Frozen Shoulder. Frozen shoulder is a disorder characterized by stiffness and pain around the shoulder complex. Frozen shoulder results in pain, restricted joint mobility which in turn affects the basic activities of daily living which finally impacts the quality of life mainly involving overhead activities

Various methods of therapeutic interventions have being recommended for frozen shoulder. To regain the range of motion, strength Maitland's, Kaltenborn's, Mulligan's mobilization and Codman's exercises have been recommended for patients with frozen shoulder. Raghav S. et al Compared Mulligan MWM Technique and Kaltenborn Mobilization Technique on Pain and End Range of Motion in Patients with Adhesive Capsulitis of Shoulder Joint reported Kaltenborn mobilization and mulligan's mobilization are equally effective in patients with frozen shoulder to reduce pain and improve range of motion.

CONCLUSION

Conclusion will be drawn post data collection and statistical analysis

Patient Consent

Principal Investigators will obtain the written informed consent from the participant on a printed form (local language) with signatures and give the proof of confidentiality.

Confidentiality

The study program will be explained to the participant, the principal investigator will take subjective information. The consent form will include the confidentiality statement and signatures of the principal investigator, patient and a witnesses. If required to disclose some information for the study, consent will be taken from the patient with complete assurance of his confidentiality

Declaration of interests

The authors declare no conflicting interest.

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