Title: Effect of scapula-focused treatment with additional motor control exercises on pain and disability in patients with subacromial pain syndrome: A Randomized Controlled Trial

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BACKGROUND

Subacromial pain syndrome (SPS) is a shoulder pain condition in which individuals report pain or discomfort associated with excessive overhead movements.[1,2] It corresponds to 44%-65% of all shoulder pain complaints[2,3] resulting in increased disability and reduced quality of life.[4] Factors associated with SPS include: disorders of scapula and clavicle kinematics,[5] glenohumeral stiffness and instability,[6] muscle weakness or disorders in motor control.[7]

The scapula plays an important role in absorption and energy transfer to maximize levels of upper limb freedom.[8] Periscapular muscles act synergistically to allow scapulohumeral coupled movements. In the last decade scapula assessment and treatment focused on “motor control exercises” has become ubiquitous for the rehabilitation process of painful shoulder. The latest systematic review with meta-analysis on the on the efficacy of exercises demonstrated that interventions focused on the scapula should be considered in treating SPS, provide benefits with short-term results for shoulder pain, function[9] and abduction ROM.[9,10]

The studies included in the meta-analysis that observed the additional effects of motor control exercises or scapula stabilization present important methodological limitations such as the absence of concealed allocation, blind subjects, blind assessor and absence of intention-to-treat analysis[11,12] that contribute to the low quality of evidence.Therefore, there is a need for further research through high-quality RCT that adequately assess the effects of scapula motor control exercises on clinical outcomes.

OBJECTIVE

Determine the effect of adding scapular motor control exercises to a scapula-focused program on disability, pain, muscle strength, and ROM in patients with Subacromial Pain Syndrome.

DESIGN OVERVIEW

Controlled, randomized, superiority clinical trial, prospectively registered, two-arms, parallel, blind assessor, blind patient, and allocation concealment. All methodological steps were described by Consolidated Stands of Reporting Trials (CONSORT).

METHODS

Setting and Participants

Individuals with SPS were recruited from March 2016 to June 2017 by the local health system. The trial was conducted in an outpatient physical treatment service provided by the local health system. This study was approved by the University Research Ethics Committee (CAAE:52563216.0.0000.5414). All participants were informed about the procedures and signed the consent form.

Inclusion Criteria: participants with a history of shoulder pain for more than one week, located in the shoulder anterior-proximal region, with positive results for 3 out of 5 SPS tests: 1) Neer; 2) Hawkins-Kennedy; 3) painful arc; 4) pain or weakness resistant to external rotation, and 5) Jobe.[13]

Exclusion criteria: history of shoulder trauma or surgery; total rotator cuff or biceps brachii tendon rupture (imaging exam or self-report); practitioners of sports activities involving the upper limbs; individuals with neurological disorders and alterations in cognitive function (e.g. stroke, epilepsy, multiple sclerosis, Parkinson's disease and peripheral neuropathy); shoulder pain for of primary involvement in the cervical or thoracic region; systemic disease involving the joints (e.g. rheumatoid arthritis); carpal tunnel syndrome; and those who underwent physiotherapeutic treatment of the shoulder in the last six months.

Randomization and Intervention

Simple randomization was carried out using a computer-generated schedule in Microsoft Excel (Microsoft Corporation, Redmond, Washington). Allocations were sealed, sequentially numbered envelopes, prepared by an individual not involved in the recruiting, assessment or treatment of the patients, and kept in a central locked location.

The envelopes were opened on the first day of the treatment, and the participants were randomly allocated into two treatment groups: the scapula-focused group (SFG) and the scapula motor control group (MCG). The subjects were treated individually and blinded regarding treatment allocation. Due to the nature of the interventions, it was not possible to blind the physical therapists that conducted the interventions.

The exercises for each group were based in a previously proposed protocol[14]. The patients assigned to the SFG performed 6 exercises with a focus on the periscapular muscles: 1) side lying external rotation with abduction at 0°[15,16]; 2) prone horizontal abduction with external rotation from 90º to 135º[17,18]; 3) Scapular punch[19]; 4) Knee Push[20]; 5) Full Can[17,20]; 6) Diagonal D1[17]. The exercise load was 60% of the one-repetition maximum (1-RM) during the first week because it was their first exposure to the exercises.[21] The weekly load progression averaged about 2.5% increase/wk up to -80% of 1-RM, according to the strength of each participant[21]. The exercises were performed in 3 series of 10 repetitions, with a 1-minute interval between repetitions during the first and fourth week.

From the fourth week on, the exercises were increased to 12 repetitions, and from the fifth to eighth week, to 15 repetitions.[21] The Push up plus[17,22] exercise with the feet flat on the floor was considered the progression exercise of the knee push.[20] The load progression for the push-up plus exercise takes place by lifting the feet on supports and could reach a height of 47.5 cm[23].

The patients allocated to the MCG performed the scapula-focused exercises with the same progression, and six motor control exercises were added to this group. For this study, Motor control exercises were defined as retraction and depression movements of the scapula without external load (e.g., dumbbells and an elastic band) and associated with visual, verbal and kinestetic feedback in maintaining the posture. The six motor control exercises were always performed at the beginning of each session: A) Towel Slide[24]; B) Scapular Clock[24]; C) PNF Scapular[24]; D) Modified Inferior Glide[25,26]; E) Scapular Orientation Exercise (SOE)[27,28]; F) Protraction and retraction in front of a mirror. From the first to the third week, three series of 10 movements were performed for each exercise with verbal, visual, and kinesthetic feedback. On the fourth week, the exercises were increased to 12 movements, and visual feedback was removed. From the fifth to the eighth week, the exercises progressed to 15 repetitions, while verbal feedback was carried out only by the therapist. In both groups, the series of exercises were randomized into blocks at the beginning of each week.

Outcomes measures and Follow-up

Shoulder function was considered the primary outcome; pain, treatment effect perception, satisfaction, kinesiophobia, strength, ROM, and scapula position were all considered the secondary outcomes.

Function and pain: The Brazilian version of Shoulder Pain and Disability Index (SPADI-Br) is valid and reliable for assessment of individuals with shoulder disorders[29] The Minimally Important Difference (MID) considered for the questionnaire was 10 points.[30] Higher scores indicated the worse condition.

A verbal, numerical pain rating scale was applied to measure the intensity of the pain. The values range from zero to ten and must be answered based on the pain intensity at the time of the test.[31,32]

Treatment effect perception, satisfaction, and kinesiophobia: The global perceived effect scale assessed patient perceptions of the effect of the treatment. For the assessment of patient satisfaction, The MedRisk[34] questionnaire was used. For assessment of the kinesiophobia level, the Tampa Scale of Kinesiophobia was applied.

Strength, ROM, and scapula position: Isometric strength assessment was carried out using a hand-held dynamometer (Lafayette®, Lafayette Instrument Company, Ind., USA). Muscle strength measurements were performed in abduction, adduction, internal and external arm rotation[36] and for specific muscles, of the serratus anterior, upper, middle and lower trapezius[37].

For the ROM assessment, a digital inclinometer (Lafayette®, Lafayette Instrument Company, Ind., USA) was used during flexion, abduction and internal and external rotation active movements[38]. Upward rotation and scapula anterior/posterior tilt movements were also evaluated[37,39,40] .

STATISTICAL ANALYSES:

Sample size calculation: Was performed with G*Power 3.1 for Windows (Universität Kiel, Germany) based on the primary study outcome assessed by SPADI-Br questionnaire. The sample was calculated based on the questionnaire's capacity to detect a 10-point difference in the global outcome score (SD=11.7), considering the clinically relevant difference, alpha 0.05, power 80% and considering a 20% sample loss.

Statistical analysis: Statistical analysis followed the intention-to-treat concept[41,42] using the Statistical Package for the Social Sciences Software (SPSS). The linear mixed-effect model was applied for the primary and secondary variables. In the model, "Time" and "group" were considered fixed effects, whereas the participants were considered the random effect. The time by group interaction was included in the analysis to assess the difference effect between the groups at each follow-up, and the dependent variable baseline value was included as a covariate for the correction of possible differences. The significance level was 0.05 for all analyses. The calculations of the effect size (ES) and Minimal Important Difference was carried out according to Armijo-Olivo et al[43]. The ES is calculated by dividing the difference between group mean scores by the pooled standard deviation of the 2 groups.

$$ES - \frac{X_{G1}\text{-}X_{G2}}{S\text{pooled}} \quad \text{and} \quad S_{\text{pooled}} - \frac{\sqrt{S_1^2(n1-1)+S_2^2\,(n2-1)}}{n1+n2-2}$$

The effect size values were considered small (up to 0.2), moderate (0.5), and large (equal or above 0.8)[44]. Statistical analysis followed the intention-to-treat concept and was carried out by a researcher not involved in the evaluation and treatment protocols. The strength measures were examined with normalization to body weight (strength in kilograms/ kilogram of body weight X 100).

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