

*Efficacy of Capacitive-Resistive Therapy on
the Treatment of Myofascial Pain*
Study Protocol and Statistical Analysis Plan

Material and Methods

Thirty six volunteers with active myofascial trigger points in the upper trapezius and neck were included the study after being examined by sports medicine specialists between 12 December – 1 March. During the examination, the reproduction of the daily life complaints and the presence of a tense muscle band, hypersensitive point, which was characterized by reflected pain and local twitch findings, was evaluated diagnostically. Exclusion criteria were fibromyalgia, discal hernia, radiculopathy, myelopathy, having received trigger point injection and physical therapy within the last 1 month, neck or back surgery, rheumatismal diseases, pregnancy. The study was approved by the Istanbul Faculty of Medicine Ethics Committee. All participants were informed of the study and signed written informed consent. The study was designed as a prospective, randomized, placebo-controlled double-blind trial (NCT04287517). The patients were divided into two groups by a physician who did not participate in patient evaluation using the block randomization method. The Sports Physician who made the evaluations carried out blindly until all data was collected. Patients likewise received their treatment blindly at different times throughout the entire study. The entire randomization process was carried out in accordance with Consort Statement.

Treatment

After the patients were divided into two groups, capacitive resistive therapy and exercise were applied to one group, and placebo (sham) therapy and exercise were applied to the other group by an experienced physiotherapist for 10 sessions. The sessions were continued for 3 weeks with an interval of 24-48 hours. All sessions were planned for 16 minutes (8 minutes to one side and 8 minutes to the other). Individuals who received a placebo treatment were administered sham in empty mode without energy transfer. The patients were reported not to understand that they received a placebo they were working without heating the system. In each session ten minutes capacitive mode six minutes resistive mode was used. Since myofascial trigger points are predominantly located in superficial muscle tissue, capacitive therapy was preferred. It was also benefited from resistive treatment to achieve deep tissue effect. Physiotherapist after applying capacitive and resistive therapy or placebo to patients; The patients performed neck stretching exercises (for Trapezius and Levator Scapula muscles) and isometric neck exercises 10 repetitions and 3 sets. Each exercise was carried out under the supervision of the same physiotherapist, after each session.

Outcomes

Visual Analog Scale (VAS), neck disability index (NDI), short form - 36 (SF-36) questionnaire, ROM and algometer, Pain Pressure Threshold (PPT), were evaluated blindly by an experienced sports medicine clinician before and after the treatment. In each evaluation, all measurements were repeated 3 times and their averages were calculated at the end. VAS, SF-36 and Neck Disability Index were filled under supervision before each individual started treatment. Subsequently, neck range of motion (ROM) measurement were performed with inclinometer and Pain Pressure Threshold measurement were performed with the algometer.

Pain intensity was evaluated by VAS and Algometer. VAS: A tool used to help a person rate the intensity of certain sensations and feelings, such as pain. The visual analog scale for pain is a straight line with one end meaning no pain and the other end meaning the worst pain imaginable. A patient marks a point on the line that matches the amount of pain he or she feels. The most simple VAS is a straight horizontal line of fixed length, usually 100 mm. The ends

are defined as the extreme limits of the parameter to be measured (symptom, pain, health; in this study pain will be studied) orientated from the left (worst) to the right (best). Lower scores mean better outcome. The validity and reliability study of the scale was determined by Price et al. It has a good degree of validity and reliability. PPT is defined as the minimum force applied which induces pain. This measure has proven to be commonly useful in evaluating tenderness symptom. It has been shown to be a reliable method of evaluating myofascial trigger points. Studies have shown high consistency among clinicians (ICC 0.80 - 0.92).

NDI was used for neck disability assessment. Vernon et al. developed NDI as the neck version of Oswestry Low Back Pain Scale. Turkish version of the study was made by Aslan et al. The test-retest reliability value of the questionnaire was found ICC: 0.979 (excellent). Neck Disability Index (NDI) is a self-report questionnaire used to determine how neck pain affects a patient's daily life and to assess the self-rated disability of patients with neck pain. Each question has six statements, the first statement is marked the section score = 0, if the last statement is marked it = 5. Maximum score is 50 and minimum is 0. Lower scores mean better outcome.

The Short Form (36) Health Survey is a 36-item, patient-reported survey of patient health. The SF-36 is a measure of health status and an abbreviated variant of it. The SF-36 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale on the assumption that each question carries equal weight. The lower the score the more disability. The higher the score the less disability i.e., a score of zero is equivalent to maximum disability and a score of 100 is equivalent to no disability.

Normal joint movements of the cervical region are important for many activities in daily life. In our study, inclinometer was preferred for the evaluation of cROM. Evaluation of passive joint movements in the cervical region is also used to determine the capsular pattern and final sensation of the joint. In the previous study, the ICC value was found to be 0.89 - 0.94 with the inclinometer. Flexion, extension, lateral rotation in both directions and flexion ROM examinations were performed. The normal cervical spine's range of motion is approximately 80° to 90° of flexion, 70° of extension, 20° to 45° of lateral flexion, and up to 90° of rotation to both sides.

Statistical Analysis Plan

Average values were compared statistically. Evaluations were made both within the group before and after treatment (TO) and also for intergroup before and after treatment. Descriptive statistics of the numerical variables in the study are given as mean, median, min-max, standard deviation. Descriptive statistics for categorical variables were given as numbers and percentages. Numerical variables were analyzed with the Shapiro Wilk test. Student t Test was used for group comparison of variables with normal distribution, and Mann Whitney U test was used for group comparisons of non-normally distributed variables. For dependent groups, Paired t Test was used for mean comparisons and Wilcoxon test was used for median comparisons. In calculations, 0.05 was taken as the level of significance. SPSS (version 21) package program was used in the analysis.