STUDY PROTOLOL

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Brief Title: Percutaneous Microelectrolysis on Myofascial Trigger Points Pain. (MEP)

Official Title: Effectiveness of Percutaneous Microelectrolysis in the Decrease of Pain in Myofascial Trigger Points: Evaluation Through Algometry and Visual Analog Scale. Randomized Controlled Trial.

ABSTRACT.

Background: Percutaneous electrotherapy is today a therapeutic alternative in musculoskeletal conditions. In that sense, percutaneous microelectrolysis (MEP) stands out as treatment for tendinopathies and musculoskeletal pain, such as myofascial trigger points (MTrPs), although more studies are needed to support it.

Objective: Investigate effectiveness of MEP in reducing painful pressure threshold (PPT) and pain intensity (PI) in MTrPs.

Method: Controlled randomized clinical trial. Research was performed at Physiotherapy Laboratory of Andrés Bello University. Participants were forty-eight volunteers with MTrPs presence in upper trapezius muscle. Both groups received a baseline ultrasound treatment, adding MEP to experimental group. Intervention consisted of a MEP intervention and tree

reevaluation sessions (at day one, three and seven). Direct current was delivered with acupuncture needle directly to MTrP and PPT and PI was reevaluated before and after application. Main outcomes were PPT and PI differences (PPTdiff and PIdiff) between evaluation sessions.

Results: MEP demonstrated positive changes increasing PPT (PPTdiff1-1, p=0,0000, PPTdiff2-1, p=0,0000, PPTdiff3-1, p=0,0000) and decreasing PI (PIdiff1-1, p=0,0001, PIdiff2-1, p=0,0001, PIdiff3-1, p=0,0008) in experimental group, and significant differences in PPT at second reevaluation session compared to control group (PPTdiff2-1, p=0,0032).

Conclusion: MEP is a good analgesic treatment for MTrPs compared to therapeutic ultrasound, although neither of two therapies seems to be better than other in long term. Two treatments improvements PPT and PI, so MEP can be considered as an effective alternative treatment for MTrPs pain.

Keywords: electrotherapy; electrolysis; pain threshold; myofascial pain syndromes; analog visual scale.

Material and Methods

Present design represents a randomized double-blind clinical trial. Study was approved on June 18, 2019 by Eastern Metropolitan Health Service of Santiago (SSMO) ethics committee. Study was registered at www.clinicaltrials.gov. Participants were divided in two groups assessed in both presences of MTrPS in shorter upper trapezius muscle. It was recording the PPT and PI before and after intervention. Both groups received therapeutic ultrasound as baseline treatment. Experimental group received microelectrolysis additionally. A reassessment of PPT and PI was done on day one, three and seven post intervention.

Subjects. forty-eight healthy volunteers were recruited (23 men, 25 women, average age 22 years). Participants were students of Science Rehabilitation Faculty (SRF) of Andrés Bello University, Santiago de Chile. Number of participants was selected by convenience. An invitation was extended to students through formal communication channels (mailing), student representatives and social networks, summoning two hundred and seven potential participants. Selection was based on a survey whose first part was structured in relation to general demographic participant's data, including name, age, sex, body mass index (BMI), career year, and personal information contact (e-mail and cell phone number). Second part of survey consisted of closed questions constructed by eligibility criteria. Inclusion criteria considered participants over 18 years old, students of SRF and positive hypersensitive MTrPs. Exclusion criteria include neck or shoulders pathologies in the last 6 months (as fractures, sprains, tendinopathies, dislocations or muscle tears), cervical pain, sensitivity alterations such as hyposthesia, anesthesia or hyperesthesia in neck, shoulders and/or arms, wounds or skin alterations in shoulder as psoriasis, scars or keloids, fear to electrotherapy application and analgesic pharmacological treatment at recruitment time (non-steroidal anti-

inflammatory or steroidal drugs). Elimination criteria considered non-tolerance electrotherapy intervention and non-completion of evaluation protocol (attendance at all scheduled sessions). Demographic data were tabulated in Microsoft excel® 2016 program (Table 1, characterization of study groups).

Variable	MEP (n = 24)	Control (n = 24)	p-value	Sample distribution
sex (%) **men** **women**	 11 (22,9%) 13 (27,1%)	 12 (25,0%) 12 (25,0%)	*p = 0,7730**	*Normal**
Age *(mean,+/-DS)*	22,5+/-1,9	22,0+/-1,6	*p = 0,2993***	*Normal***
BMI (Kg/m2) ***(mean +/-DS)***	24,5 +/- 3,4	22,9+/-2,3	*p =0,0616***	*Normal***
Short trapezius muscle laterality (%) ***right*** ***left***	 17 (70,8%) 7 (29,2%)	 20 (83,3%) 4 (16,7%)	*p = 0,2470****	*Normal****
SP-AC distance (cm) ***(mean+/-DS)***	9,2+/-1,8	8,4+/-1,7	*p = 0,1241***	*Normal***
PPTpre 1 (Kg/cm2) ***(mean +/-DS)***	1,4+/-0,2	1,4+/-0,2	*p = 0,5734***	*Normal***
PIpre1 (mm) ***(mean +/- DS)***	32,1+/-13,6	31.4 +/- 15.1	*p = 0,8729***	*Normal***

Table 1. Characterization of study groups. Variable sex and short trapezius muscle laterality is represented in frequencies (%). Values for continuous variables are in means with their corresponding standard deviation (DS). Variable sex was analyzed using xi2 test*. For the analysis of continuous variables, the T-Student test was used**. Variable short trapezius laterality was analyzed with the F-Fishertest***.
BMI: body mass index, **SUTL:** short upper trapezius muscle laterality, **SP-AC distance:** distance spinous process from C7 to acromion, **PPTpre:** pain pressure threshold pre intervention at day one, **PIpre:** pain intensity pre intervention at day one. **p > 0.05******

Secondary variables as short upper trapezius muscle laterality (SUTL) and sex were represented as frequencies, while MTrP location distance (MLD) and age was represented as median and BMI in averages. Primary variables included PPT and PI pre-intervention

(PPTpre and PIpre) were expressed as averages with their corresponding standard deviation (x, SD). Data were analyzed to compare homogeneity of groups with STATAv.13 program.

Equipment. GYMNA´s COMBI 500 electric stimulator was used for ultrasound application at 1MHz, 1.5Watts/cm^2, 100% duty cycle, 5cm^2 ERA and 15 minutes.[24] SVELTIA´s DC equipment was used for MEP application. It was used a dispersing electrode (area 28.26cm^2) and an acupuncture needle (0.3x25millimeters). Circuit was closed by placing dispersing electrode in contralateral arm to trapezius muscle to be treated. Current intensity was 600µA at the needle (current density of 1.71mA/cm^2).

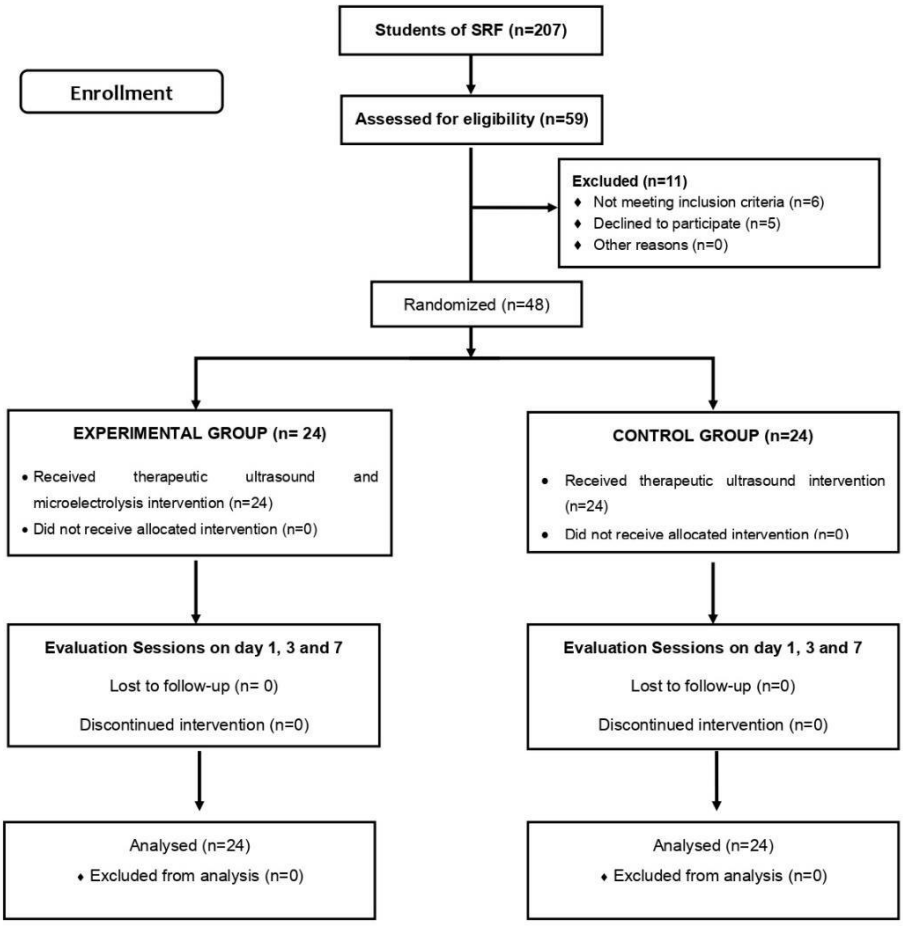
Measurement tools. BASELINE® pressure algometer was used to measure PPT (1cm^2 surface area).[25] Algometry was applied after shortness upper trapezius assessment by placing algometer at the MTrP exerting a perpendicular pressure until user reported pain. Kilograms of pressure per square centimeter (Kg/cm^2) was registered. PI was evaluated with VAS. VAS was applied after algometry recording pain perceived with algometry test.

Procedure.

1. Participants

207 surveys were analyzed obtaining 59 potential participants, dropping out five. 54 participants agreed to participate and gave their written consent. Six participants were excluded due absence of MTrPS, obtaining 48 participants (23 men, 25 women). Principal investigator assigned a number to each participant to perform randomization. Conformation of groups was carried out by simple randomization by dark envelopes. Participants didn´t know assigned group and were individually cited in following two weeks to physiotherapy laboratory of SRF to be evaluated.

Figure 1. Subject recruitment and flow through the study



2. Groups.

Sample was divided by a simple randomization process performed with a random number table, assigned participants to one of two study groups. Sequence of randomization and participants of each group was only known by principal investigator. Working groups were designated as experimental (MEP group, n = 24) and control group (n = 24). None subjects knew the treatment that would be applied. Each participant was evaluated registering their age, BMI and SUTL. Location of MTrP was determined at shortness trapezius muscle, taking as reference a line between superior acromion´s midpoint surface and C7 spinous process (PE-AC distance). Algometry and VAS was subsequently applied obtaining the PPT and PI

pre intervention (PPTpre y PIpre). Variables described were compared between groups to assess the homogeneity of them (Table 1). Data reflect the homogeneity of groups at the beginning of the study.

3. Pain pressure threshold (PPTpre) and pain intensity (PIpre) preintervention evaluation.

A blinded physiotherapist registered PPT and PI before and after participant's intervention. Evaluation station consisted of a chair and a table with the algometer and VAS. The subjects sat with their backs supported with both feet on the floor. Evaluator proceeded to measure both upper trapezius muscles length manually, choosing the shortest. Subsequently a line was drawn between C7 spinous process and upper acromion midpoint face of ipsilateral shoulder. Most sensitive palpation´s point was searched on the line and then marked with a cross measuring distance from C7 to this point. Algometry was applied at selected point exerting a perpendicular pressure until the user referred pain. Participants were instructed to raise slightly contralateral hand when feeling pain in algometry test. A PPT less than $3Kg/cm^2$ was recorded as a positive MTrP. This was same protocol used for participants pre-selection where 6 of 54 were excluded. Next pain intensity was assessed with VAS, recording pain magnitude in millimeters produced by algometry. PPTpre and PIpre data were tabulated in Microsoft excel® program sheet.

4. Therapeutic ultrasound application.

Participants of both groups received a therapeutic ultrasound treatment. Experimental group received first ultrasound and subsequently MEP, while control group was treated only with ultrasound. Ultrasound intervention protocol was performed in the same way for both groups. Application was performed in an adjoining room by another physiotherapist who didn´t know

groups. Treatment was carried out with participant in sitting position applying ultrasound at sensitive point marked by examiner of evaluation station. Ultrasound therapy was delivery at 1MHz, 1.5 Watts/cm^2, 100% duty cycle (SATP: 1.5Watts/cm^2 and SATA:1.5W/cm^2), ERA 5cm^2 and 15 minutes.[24] Once ultrasound intervention was finished, participants of MEP group were taken to microelectrolysis box, while participants of control group returned to evaluation station.

5. Microelectrolysis application.

Microelectrolysis was performed by another physiotherapist. Before intervention, puncture area was cleaned with alcohol. Procedure was performed with latex gloves. Acupuncture needle was introduced perpendicular to demarcated point of trapezius with 0.14mA intensity. Dispersing electrode was placed in external surface of contralateral arm once chosen trapezius muscle. Inside tissue intensity was raised to 0.6mA. Each participant was instructed to indicate to physiotherapist appearance of burning, pain or great local pressure in order to pause emission. Emission time was recorded until symptoms appeared, indicating T1 time, pausing emission for 30 seconds. Then a second emission was made until participant referred again discomfort symptoms. Second emission time was recorded as T2, pausing application again for 30 seconds. Third and last emission was delivered for same time obtained for T2 or if discomfort appeared before completing that time.

6. Pain pressure threshold (PPTpre) and pain intensity (PIpre) postintervention evaluation.

Completing intervention, participants returned to evaluation station. Evaluator repeated the same assessment protocol made before ultrasound and MEP application, recording PPT and PI postintervention. Variables PPTdiff1-1 and PIdiff1-1 were created based on differences

between algometry and pain intensity measurements before and after intervention. Participants were cited for a reevaluation on day three and seven obtained variables PPT2, PI2, PPT3 and PI3. This allowed to create PPTdiff2-1, PPT3-1, PIdiff2-1 and PIdiff3-1 variables, that represented differences obtained between the measurements of days three and seven with those obtained on day one before intervention.