The efficacy of MPK device plus home-exercise for shoulder pain. Single blind, monocentric, randomized controlled trial

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Aim

Shoulder pain is one of the most common disorders of musculoskeletal system, with a prevalence estimated to be around 20-33% in general population.[1] Common causes of shoulder pain are impingement syndrome, tendons degeneration, scapula-humeral osteoarthritis. Conservative treatment that consists in non steroid anti-inflammatory drugs, physical therapy, and exercise therapy, is a common intervention in patients presenting shoulder pain.[2-4] The aim of the study was to investigate the effectiveness and safety of MPK device use combined with specific therapeutic home exercise compared with therapeutic home exercise alone in patient with shoulder pain.

Materials and methods

From November 2011 to April 2012, 66 patients between 30 and 65 years were recruited at the Department of Physical Rehabilitation of the University Hospital of Florence. The inclusion criteria were: more than one month of shoulder pain, clinical and instrumental diagnosis of one of the following: impingement syndrome, reversible tendonitis or partial tears involving one or more tendons and the signed informed concerned. Exclusion criteria were: recent conservative shoulder treatment, cervical brachial syndrome, full rotator cuff tears, history of shoulder dislocation, subluxation, fracture, adhesive capsulitis the glenohumeral joint or cervical/shoulder/upper back surgery, history of breast cancer on the involved side, pregnancy, and history of systemic inflammatory disorder. The study was conducted in concordance with the principles of Helsinki Declaration. MPK device is constituted by a printed circuit board and two electrodes having opposite polarity, characterized in that it operates according to a combination of sequential frequencies chosen amongst eight possible frequencies in the range between 8 Hz and 36 Hz. Device is powered by a battery. Electrostatic pulses waves, through mechanoreceptors skin, influence the extrapiramidal system that is responsible for muscular tone and posture control. Severe side effects are not known. Participants were randomly assigned to receive home-exercise and activated MPK device or home-exercise and inactivated MPK device. Concealed allocation was performed with a web-based procedure (www.eclintrials.org/ect/). Treatment allocation was performed at the first visit. The primary outcome measure was the change of Constant-Murley score (CMS) [5] after 5 weeks of treatment. Secondary outcomes measures were the change of Range of Motion and shoulder pain evaluated on a VAS scale. Patients were evaluated two times at the baseline visit: at the initial clinical evaluation (T0) and 5 minutes after wearing MPK device (T1). A third evaluation was made after 5 weeks of treatment (T2). The endof-study visit was carried out four months after the end of treatment (T3). In the present report only 5week results about CMS and shoulder pain evaluations are shown. During the first session, patients were instructed about the therapeutic home-exercise program, which was based on stretching exercise, concentric and eccentric exercise for the rotator cuff and scapula stabilizers, and proprioceptive exercises. In addition patients were provided with MPK device that patients had to wear on the wrist of the painful shoulder during day and night. According with the assigned treatment arm, a discharge or charge battery was inserted into the device and its feature was checked by a removable led. Finally, the device was positioned into a wristband and the patient wore it. We calculated our sample size according to the Constant-Murley score. We estimated that we needed 66 patients to detect a difference between groups equal or greater than 80% of the variability of the investigated phenomenon (=0.10, twosided =0.05) Unpaired Student t test was used to compare the differences between treatment arms. Adjusted analyses were performed with ANCOVA. All analyses were conducted according to the intentiontotreat principle. Last observed carry forward technique was applied for the imputation of missing values of primary and secondary endpoints.

Table I. – Average values of ConstantMurley score and shoulder pain before and after treatment and comparison of the results between trial arms.

	Arm A*(N=33)		Arm B#(N=33)
ConstantMurley score, mean (SD)			
Baseline (T0)			
At 5 weeks (T2)	60.0 (15.1)		56.7 (17.6)
Average change within arm (T2-T0)	69.1 (15.1)		76.1 (13.6)
Average diff. of change bw. arms (95% CI)	+9.1 (10.6)	+10.3 (+4.6 to +15.9)	+19.4 (12.2)
P value		<0.001	
Shoulder pain, VAS			
Baseline (T0)			
At 5 weeks (T2)	55.9 (20.8)		49.4 (20.8)
Average change within arm (T2-T0)	43.5 (20.5)		27.2 (19.7)
Average diff. of change bw. arms (95% CI)	-12.5 (19.6)	-9.6 (-0.5 to -18.8)	-22.1 (17.4)
P value		0.039	

Abbreviations: diff., difference; bw., between; VAS, visual analogue scale.
*Home exercise plus inactive MPK device
#Hom eexercise plus active MPK device

Results

A total of 66 patients were eligible for inclusion. There were no differences between the treatment arms in the clinical characteristics at baseline visit. Sixtyfive participants (98.5%) completed the 5week study visit. The average change in Constant-Murley score was +19.4 (95% CI: +15.1 to +23.7) in the home-exercise plus MPK device group and +9.1 (95% CI: +5.3 to +12.9) in the home-exercise group (Table I). The home-exercise plus MPK device group demonstrated a significantly greater improvement than the home-exercise group in the primary outcome, with a difference between groups of 10.3 points (95% CI: +4.6 to +15.9; P <0.001). The estimate of the treatment effect adjusted for baseline CMS, gender and age was equal to +9.3 (95% CI: +4.3 to +14.2; P <0.001). The decrease in visual analogue scale after 5 weeks of treatment was in average significantly higher in the home-exercise plus MPK device group (-22.1 [95% CI: -16.0 to -28.3] vs. -12.5 [95% CI: -5.5 to -19.4]), with a difference between groups equal to -9.6 (95% CI: -0.5 to -18.8; P=0.039). (Table I). The effect of experimental treatment adjusted for adjusted for baseline CMS, gender and age resulted equal to -11.4 (95% CI: -3.4 to -19.5; P=0.006). No adverse events and reactions were observed in both treatment arms.

Discussion

In our study, a significant clinical improvement was observed in the group of patients where therapeutic home-exercise were combined with the use of active MPK device, compared to patients in which MPK device was inactive. In fact, in average MPK device has been demonstrated to be able to increase CMS and decrease shoulder pain of about 10 points more than homeexercise alone, after 5 weeks of treatment. The value of this result is powered by the concomitant observation that the effect of the homeexercise alone was comparable with that reported in other several trials, where exercises were shown to be as effective as or more than NSAIDs, corticosteroids injections and arthroscopy treatment. According to our previous clinical experiences a 5week treatment period has been shown to be adequate to reach satisfactory therapeutic results. However, it is worth to note that in this study we also detected an early positive effect of the experimental treatment. At visit T2, patients assigned to the active MPK device arm reported a significantly sudden improvements in pain at rest, in particular during the night, and in shoulder range of motion. Overall, on the basis of the results reported by several authors that used in the past CMS as primary outcome, we retain our results clinically significant. The strengths of the present study are the prospective randomized study design and the good compliance of the participants. In addition, the standardised exercise protocol used in the study provides a valid guidance about content, dose, and progression of the treatment approach, which enables its implementation into the everyday practice. However, the study also has some limitations. Because of the new tested technologies, doctors were not blinded about the treatment arm to which patients were assigned, and that could have decreased the internal validity of the results. Moreover, the short-term follow-up cannot allow any inference about the good quality of the long term outcomes that this promising new device could guarantee for the treatment of shoulder pain.

Conclusion

MPK device was found to be safe and well-tolerated and, for the first time, it was demonstrated that patients suffering from shoulder pain may benefit from electrostatic pulses waves. Future investigations should be undertaken in order to evaluate the long-term effects of this technique.

References

1. Daniel I Rhon, Boyles RE, Cleland JA, Brown DL. A manual physical therapy approach versus subacromial corticosteroid injection for treatment of shoulder impingement syndrome: a protocol for a randomised clinical trial. BMJ Open 2011;e000137.
2. Johansson K, Oberg B, Adolfsson L, Foldevi M. A combination of systematic review and clinicians' beliefs in interventions for subacromial pain. Br J Gen Pract 2002;52:145-52.
3. Calis HT, Berberoglu N, Calis M. Are ultrasound, laser and exercise superior to each other in the treatment of subacromial impingement syndrome? A randomized clinical trial. Eur J Phys Rehabil Med 2011;47(3):375-80.
4. Dorrestijn O, StevensM, Winters JC, van derMeer K, Diercks RL. Conservative or surgical treatment for subacromial impingement syndrome? A systematic review. J Shoulder Elbow Surg 2009;18:652-60.
5. Constant CR, Murley AH. A clinical method of functional assessment of the shoulder. Clin Orthop Relat Res 1987:160-4.