LETTER TO THE EDITOR

IS EXTRACORPOREAL SHOCKWAVE THERAPY EFFECTIVE EVEN IN THE TREATMENT OF PARTIAL ROTATOR CUFF TEAR?

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To the Editor,

Rotator cuff tear is a major cause of pain and shoulder dysfunction, with a prevalence of 21% in the general population (1). The lesion may be partial (with an estimated prevalence of around 13%) or total (7%). A theory of degeneration and micro-traumas has been postulated, proposing that repeated stresses could be responsible for small lesions of the tendon without the ability to heal, which should follow a more important traumatic event, responsible for the onset of a symptomatic lesion. Forty percent of rotator tears increase in size if left untreated, while none of these cases show a decrease in the tear size or spontaneous healing.

Contrasting results are reported regarding the choice of treatment. Some studies support surgical treatment, especially in the early stages of the disease, in order to prevent the progression of rotator cuff tendon degeneration and the involvement of the gleno-humeral joint (2). Other works suggest a conservative treatment such as physiotherapy to reduce pain and to prevent the progressive loss of function (3). The success rate of conservative treatment ranges from 33% to 82%.

Currently, very few data are available regarding the evidence of clinical outcome of partial rotator cuff tear treated with Extracorporeal Shockwave Therapy (ESWT). Shock waves (SW) are energy sound waves produced under water with a high voltage explosion and evaporation. In musculoskeletal diseases ESWT is able to improve blood supply and to increase cell proliferation, inducing tissue regeneration of tendons and bones (4).

The end point of the study is to verify the effects of shockwave therapy in the presence of injured tendon, also monitoring the clinical and functional aspects and the size of the lesion. The starting hypothesis is null; in fact, to date, there has been no study describing shockwave treatment of tendons with partial lesions.

MATERIALS AND METHODS

We conducted a prospective randomized clinical trial. The study was approved by the local Ethics Committee. Patients who came to our clinic with a diagnosis of a partial lesion of the rotator cuff were included in our study and gave written informed consent to participate.

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DISCLOSURE: ALL AUTHORS REPORT NO CONFLICTS OF INTEREST RELEVANT TO THIS ARTICLE.

The following were used as inclusion criteria: age > 18 years, capable of understanding; partial tear of supraspinatus, with lesion size in each of the three axes ≤ 11 mm, diagnosed by using ultrasound; symptoms for at least 1 month; indication of conservative treatment (3); no neurological condition that could compromise muscle strength or activity; no history of shoulder surgery during the previous 6 months; no abnormal findings on simple radiography. Exclusion criteria were: contra-indications of SW therapy (tumors, clotting diseases, anticoagulant therapy, history of epilepsy, the presence of pacemaker or defibrillator, pregnancy); massive tendon lesion of supraspinatus (> 11 mm); infiltrative and/or rehabilitative treatment in the three months prior to recruitment; rotator cuff tears which had undergone prior surgical repair or arthroscopy; pre-existing conditions associated with upper extremity pain; difficulties in follow-up; patients in a different on-going trial that would interfere with the assessment; any other reason in the judgment of the researchers. Patients were randomized 1:1 to receive shockwave treatment (ESWT) or therapeutic exercise. Treatments were divided according to a sequential randomization list using Stata MP12 statistical software. Possible adverse effects were monitored for both treatments: increased pain, joint lock, petechiae and hematoma formation, vagal crisis.

ESWT group

ESWT was applied with a Minilith SL1 (Storz Medical, Tägerwilen, Swiss) electromagnetic generator equipped with in-line ultrasound-guidance Aloka SSD 900 (Aloka Co., Ltd. Tokyo, Japan), during three sessions, at 7-day intervals, emitting 2000 impulses with an energy flux density (EFD) of 0.05 mJ/mm^2. No local anesthesia was required.

Exercise group

Patients underwent 12 weeks of therapeutic exercise for strengthening the rotator cuff and shoulder mobility. They were instructed to perform 2 different exercises 5 times a week. The program included an exercise for the anterior deltoid and an exercise for the teres minor muscle, with 2-3 min of warm up before starting the exercise program. Every week the physiotherapist graduated the exercises in relation to each patient's ability according to the pain during and after the exercise.

Sample size

The present study aimed to test the equality of VAS score in the two treatment groups: ESWT group *vs* exercise group. To test this hypothesis a significance level (alpha) was set at 0.050 and a 2-tailed test was used. We proposed a sample size of 11 patients for each group of treatment. With this sample size and assuming both a mean difference of 1.5 point (corresponding to the smallest effect that would be important to detect) between the shockwave and exercise groups and a common within-group standard deviation of 1.3, the study had to have power of 82% to yield a statistically significant result.

Outcome

The assessment times were at the time of recruitment (T0) and 3 months after recruitment (T1). The outcomes were the visual analogic scale (VAS), the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES) and the manual muscle strength testing scale (MMT). Moreover, the size of the lesion on the three axes (longitudinal, transverse and antero-posterior) was measured by ultrasound.

Epidemiological and clinical outcomes data were put in a database built with Office Excel Software (Microsoft Corporation, Redmond, USA) and analyzed with Office Excel and STATA SE14 Software (Microsoft Corporation, Redmond, USA). Continuous variables were expressed as mean ± standard deviation and range, while categorical variables as proportions. The normality of the continuous variables was evaluated and, for those not distributed normally, a normalization model was constructed using a logarithmic function. The *t*-student test was used for independent (parametric) samples to compare the normal or normalized continuous variables between groups; the ANOVA test was performed to compare groups and timing; Fisher's exact test was used to compare the categorical variables between groups.

A simple linear regression was used for every single outcome, in order to evaluate the relationship between pain referred to T1, MMT value at T1, ASES value at T1 and the respective variable at T0, age, gender, group (ESWT/exercise), BMI, affected shoulder (right/left), time between the onset of symptoms and the recruitment (months) between lesion size on the three axes at T1. For each of the previous outcomes, a multivariate linear regression model was constructed, using as determinants those variables that have been shown to be associated to the respective outcome in simple linear regression. The correlation coefficient was indicated calculating 95% CI and the Student's *t*-test. For all tests a value of $p < 0.05$ was considered significant.

RESULTS

The sample of the study was made up of thirty subjects, of whom 15 (50%) belonged to the ESWT group and the remaining 15 (50%) to the exercise group. Twenty (66.7%) patients were female and there were no statistically significant differences in the distribution of females per group (X2=0.0; p=1.000); the mean age of the group was 65.2±8.7 years (range = 45-81) and no statistically significant differences were observed in the comparison of the mean age between groups (t = 0.2; p=0.807). No drop-out occurred. All patients reported that they did not use drugs to manage the pain during the study period. No patient reported adverse effects. No statistically significant differences were observed between groups for anthropometric variables of weight (mean value: 71.6±10.5 kg; t=0.4; p=0.697), height (mean value: 162.2±8.6 cm; t =0.2; p =0.82) and BMI (mean value: 27.3±4.0 kg/cm^2; t=0.3; p=0.773). Three patients (10%) were tobacco smokers and there were no statistically significant differences in the distribution of smokers per group (X^2=0.4; p=1.000). On average, patients had experienced symptoms for 12.6±8.2 months (range=2.0-24.0) prior to enrollment, and no statistically significant differences were observed between groups (t=1.4; p=0.186). No statistically significant differences were observed in the distribution of right limb patients affected by right shoulder injury(p> 0.05). ANOVA analysis for repeated measurements showed that there was a statistically significant difference in the comparison between variable times (T0-T1) of the

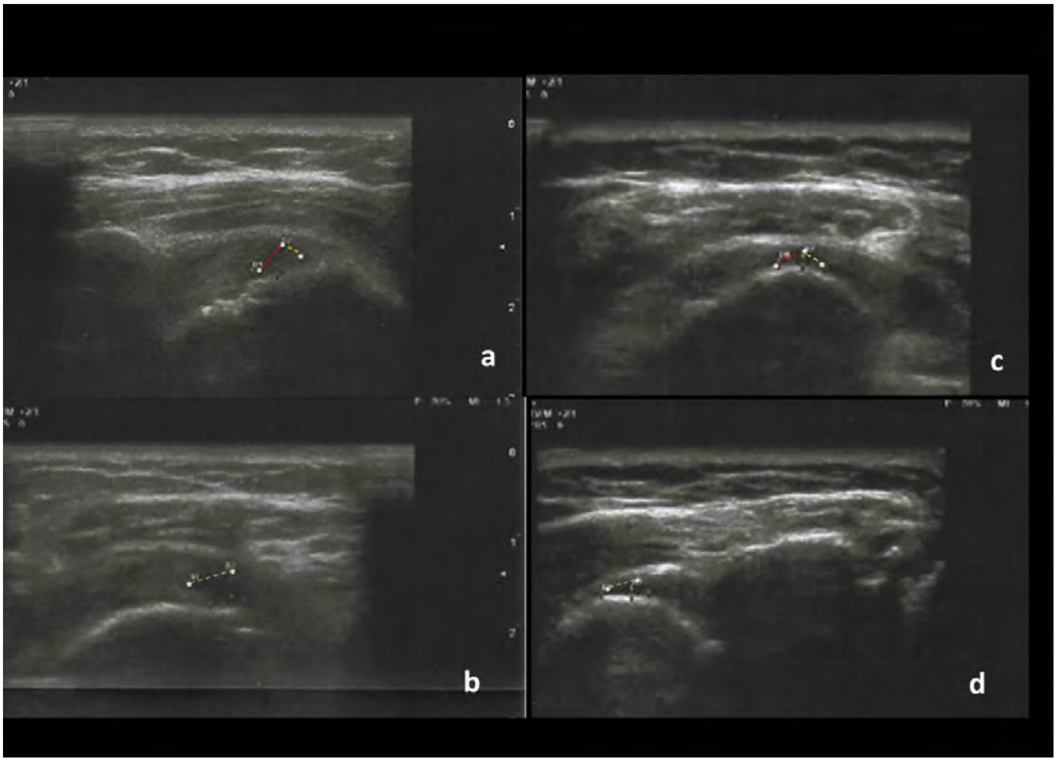

Fig. 1. *The sonographic images of a 71 year-old female showing the tear of the rotator cuff tendon at T0. The tear size is 5.5 mm on the longitudinal axis, 3 mm on the transversal axis (**a**) and 6.4 mm on the antero-posterior axis (**b**). Three months after ESWT the tear size in the same patient is 5.4 on the longitudinal axis, 0.74 mm on the transversal axis (**c**) and and 4.7 mm on the antero-posterior axis (**d**).*

Table I. *Clinical-functional results of the study groups at two follow-ups*

Variable	ESWT group	Exercise group	Total population
T 0			
Pain (VAS)	7.4±1.4 (5.0 – 10.0)	7.5±0.8 (5.0 – 8.0)	7.4±1.1 (5.0 – 10.0)
MMT	2.7±0.7 (1.0 – 4.0)	3.3±0.7 (2.0 – 5.0)	3.0±0.8 (1.0 – 5.0)
ASES	32.2±14.2 (8.4 – 51.6)	31.6±11.3 (18.3 – 54.9)	31.9±12.6 (8.4 – 54.9)
Lenght of lesion (longitudinal axis) (mm)	6.3±1.5 (3.2 – 8.9)	6.4±1.9 (3.2 – 10.7)	6.4±1.7 (3.2 – 10.7)
Length of lesion (transversal axis) (mm)	5.2±1.5 (3.5 – 7.8)	5.5±1.8 (2.6 – 9.1)	5.4±1.6 (2.6 – 9.1)
Lenght of lesion (antero-posterior axis) (mm)	2.9±0.8 (1.5 – 4.3)	2.9±0.8 (1.5 – 4.5)	2.9±0.8 (1.5 – 4.5)
T 1			
Pain (VAS)	3.9±2.2 (1.0 – 8.0)	6.9±1.2 (4.0 – 8.0)	5.4±2.3 (1.0 – 8.0)
MMT	3.3±1.1 (1.0 – 5.0)	3.1±0.6 (2.0 – 5.0)	3.2±0.9 (1.0 – 5.0)
ASES	54.9±21.8 (28.3 – 93.3)	35.3±12.4 (18.3 – 54.9)	45.1±20.1 (18.3 – 93.3)
Lenght of lesion (longitudinal axis) (mm)	5.3±2.4 (2.0 – 10.0)	6.2±1.8 (3.5 – 10.6)	5.8±2.1 (2.0 – 10.6)
Length of lesion (transversal axis) (mm)	4.1±2.1 (1.5 – 8.9)	5.4±3.4 (1.2 – 16.7)	4.7±2.9 (1.2 – 16.7)
Lenght of lesion (antero-posterior axis) (mm)	1.9±0.9 (0.5 – 3.1)	2.5±1.0 (0.7 – 4.5)	2.2±1.0 (0.5 – 4.5)

(T0: at enrollment; T1: after 3 months) (data are expressed as mean +/- standard deviation and range).

VAS value (F=17.4; p=0.000), of the ASES value (F=19.7; p=0.000) and of the size of the lesion (on longitudinal axis: F=5.5, p=0.027; on a transverse axis: F=9.5, p=0.005; on an antero-posterior axis: F=22.9; p =0.000) (Table I). There was a significant difference between groups for the VAS value (F=6.7, p=0.016).

A significant difference was observed in the interaction between time and group for VAS value (F=7.0; p=0.013), for MMT value (F=6.5, p=0.016), for ASES value (F=9.6, p=0.005, Table I) and for the size of the lesion on the antero-posterior axis (F=4.2; p=0.049). Simple linear regression analysis showed a statistically significant link between VAS value at T1 and group (coefficient = -0.7; 95% CI = -1.0 - -0,4; t=4.7; p=0.000). The MMT value at T1 had a statistically significant association with the MMT value at T0 (coef.=0.5; 95% CI=0.1-0.9; t =2.8; p = 0.009). The ASES value at T1 was associated both with the ASES value to T0 (coef. = 0.8; 95% CI=0.2 -1.3; t = 2.9; p = 0.008) and with group (coefficient = 6.5; 95% CI = 6.4-32.9; t =3.0; p = 0.005). The size of lesion at T1 was associated with the size at T0 on the same axis (on longitudinal axis: coef. = 0.9; 95% CI=0.6 - 1.3; t=5.9; p=0.000) (on axis transverse: coef.=0.2; 95% CI=0.1-0.3; t=4.8; p=0.000) (on antero-posterior axis: coef.=0.7; 95% CI=0.3 - 1.0; t=3.7; p=0.001) (Fig. 1).

There were no further associations between the outcomes and the remaining determinants in analysis ($p>0.05$). From the multivariate linear analysis we observed an association at the limits of the statistical significance between the MMT value at T1 and the MMT value at T0 (coef. = 0.4, t = 2.0, p=0.055). Multivariate linear analysis showed an association at the limits of statistical significance between ASES value at T1 and ASES value at T0 (coef. = 0.7; t = 3.3; p = 0.003) and group (coefficient = 19.2; t = 3.5; p = 0.002).

DISCUSSION

Our data show that in the treatment of RCT, shockwave therapy allowed to obtain both improvement and reduction in the size of the tendon lesion (on the antero-posterior axis). Our results support the interest of comparing the effects of shock waves with surgery, using either mini-open or arthroscopic methods, which are increasingly popular for the management of tendon lesions (2). Until now, shockwave treatment for rotator cuff tendinopathy has been reserved almost exclusively for cases of calcific tendinosis, in the presence of calcific deposits in phase I and II according to Gartner (5, 6), achieving excellent/good results in 90.9% of the patients. Only recently the indication of shockwave therapy has been extended to different pathologies of the shoulder, such as the sub-acromial conflict syndrome (7) and (non-calcific) tendinosis (8). Unlike calcific tendinopathy, in which a medium-high EDF is used, a lower EDF would be more appropriate for the tendon lesion, in relation to the greater susceptibility of the tissue.

We hypothesize that an important role of shock waves in the treatment of tendon lesions is the anti-oedema and anti-inflammatory effect, which could slow the progression of degeneration and tendon injury (9). Simultaneously, the shock waves determine a trophic and reparative effect on the tendon tissue, improving the differentiation of precursor cells towards tenoblast-like cells, modulating cell morphology and increasing collagen synthesis of type I (10).

The weak points of this study are the short follow-up period, the absence of MRI monitoring, the absence of a placebo or untreated control group. The strength is verification of the effect of shock waves in a new clinical picture, such as tendon tear. It might be interesting to check whether shockwave therapy can also be effective for a preventive action in different clinical conditions in which co-morbidities (for example of a metabolic type, such as thyroid pathologies) (11) or drug administration (e.g. corticosteroids) (12) are responsible for ischemic suffering and degenerative overload of musculoskeletal tissues.

In conclusion, ESWT could be indicated for the treatment of cuff tendon injury. We have excluded that the mechanical stimulation of the shock waves speeds up the opening of the tendon lesion, and we found a stabilization with size reduction on one of the axes. Further studies will allow to verify the effects on longer times and in association with exercise.

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