European Journal of Physical and Rehabilitation Medicine 2018 June;54(3):333-40
DOI: 10.23736/S1973-9087.17.04749-9

ORIGINAL ARTICLE

Effectiveness of Extracorporeal Shock Wave Therapy and kinesio taping in calcific tendinopathy of the shoulder: a randomized controlled trial

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ABSTRACT

BACKGROUND: Extracorporeal Shock Wave Therapy (ESWT) is effective in the treatment of calcific tendinopathy of the rotator cuff, eliciting an analgesic/anti-inflammatory action and promoting tissue regeneration. Kinesio taping (KT), another recently-introduced rehabilitative tool, exerts an analgesic and biomechanical action on joints and muscles. ESWT and KT may have a synergic effect when used in combination, but the effectiveness of the association has not been established.

AIM: The aim of this study was to test if the association of KT with ESWT is superior to ESWT alone in the treatment of rotator cuff calcific tendinopathy.

DESIGN: Randomized controlled trial.

SETTING: Rehabilitation Institute outpatients.

POPULATION: Forty-two patients with rotator cuff calcific tendinopathy were randomly assigned to the experimental group (ESWT+KT, N.=21) or control (ESWT, N.=21).

METHODS: In the experimental group, patients underwent three sessions (once a week for 3 weeks) of ESWT with KT applied at the end of each session. Controls underwent three sessions of ESWT only. All patients were assessed before treatment (T0) and at 1 (T1), 4 (T2) and 12 weeks (T3) after the end of treatment with the following outcome measures: a visual analogue scale (VAS), the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire, Subjective Shoulder Rating Questionnaire (SSRQ), and Oxford Shoulder Score (OSS).

RESULTS: Both groups showed significant improvement in all outcome measures, but the time course differed between the two groups. At T1 *vs*. T0, the improvement was significantly better in ESWT+KT than ESWT on VAS (P=0.007), DASH (P<0.0001) and SSRQ (P=0.0001). Successive improvements at T2 *vs*. T1 and T3 *vs*. T2 did not differ significantly between the groups. At the end of follow-up, ESWT+KT still showed significantly greater improvement than ESWT on VAS (P=0.02) and SSRQ (P=0.038).

CONCLUSIONS: KT associated with ESWT seems to improve the recovery in rotator cuff calcific tendinopathy with a faster therapeutic response compared to ESWT only.

CLINICAL REHABILITATION IMPACT: Our results suggest the effectiveness of using KT as adjuvant therapy to ESWT in rotator cuff calcific tendinopathy, through enhancing the short-term analgesic action and the medium- to long-term biological-regenerative effects.

(*Cite this article as:* Frassanito P, Cavalieri C, Maestri R, Felicetti G. Effectiveness of Extracorporeal Shock Wave Therapy and kinesio taping in calcific tendinopathy of the shoulder: a randomized controlled trial. Eur J Phys Rehabil Med 2018;54:333-40. DOI: 10.23736/S1973-9087.17.04749-9)

KEY WORDS: Shoulder pain - Rotator cuff - Tendinopathy - Extracorporeal shockwave therapy - Athletic taping.

Shoulder pain constitutes about 16% of all symptoms regarding the musculoskeletal system, with an annual incidence of 15 new episodes per 1000 patients.[1] A frequent cause of shoulder pain is calcific tendinopathy of the rotator cuff, which usually affects working-aged adults.[2] The etiology and pathogenesis of this disease are still controversial: degenerative changes, hypovascularization of the cuff, metabolic disorders and functional overload have been cited over time as possible causes of calcific deposit formation and thickening of the tendons (calcific metaplasia).[3, 4]

The conservative treatment includes diverse therapeu-

tic options: local infiltrations of corticosteroids and/or anesthetic, ice/heat therapy to reduce the pain, and manual therapy with massages or manipulations associated with therapeutic exercise for functional recovery.[5-9] In recent years, Extracorporeal Shock Wave Therapy (ESWT) has been successfully employed in the treatment of musculoskeletal diseases.[10] ESWT induces, through a mechanism of mechanotransduction, an analgesic and anti-inflammatory action in the short term and promotes tissue regeneration in the long term.[11-13] "Wash out" of the chemical mediators of inflammation, nociceptive inhibition (gate control theory) and neovascularization have been identified as the main biological effects of ESWT on tissues.[11, 14] ESWT treatment has proven to be particularly effective in calcific tendinopathy of the rotator cuff, reducing the pain and facilitating functional recovery over a period of weeks.[15-22]

Another treatment that has recently gained increasing attention in rehabilitation is kinesio taping (KT).[23] Its use is widespread in the prevention and treatment of sports injuries and reports in the literature confirm its usefulness as an adjuvant therapy in neuromuscular rehabilitation.[24-26] The potential mechanisms through which KT produces its beneficial effects have not been clearly demonstrated as yet. As a rehabilitative tool, KT is claimed to have four main physiological effects: facilitation or inhibition of muscle function, increase of the blood/lymphatic circulation, an analgesic effect, and corrective action on a wrong articular alignment.[23, 27-31] In the treatment of shoulder pain related to rotator cuff calcific tendinopathy and impingement syndrome, KT has demonstrated a positive effect on functional recovery by acting on pain and favoring the correct articular kinematics.[32-37] Moreover, in the short term, KT has been shown to provide greater relief from pain than other therapeutic approaches, but better results in the medium-long term have so far not been demonstrated.[38-42]

ESWT and KT may have a synergic effect when used in combination, thanks to several mechanisms suggesting their therapeutic effectiveness. But to our knowledge, studies on the combined use of ESWT and KT have so far not been performed. Hence, we aimed to assess whether the association of KT with ESWT in the treatment of shoulder pain due to rotator cuff calcific tendinopathy could be superior to ESWT alone in improving the short- and medium-term clinical and functional status and in reducing recovery time.

Materials and methods

This was a parallel-group, 1:1 allocation ratio, single-center, randomized, superiority trial, carried out at the Scientific Institute of Montescano, Istituti Clinici Scientifici Maugeri, Italy. All patients referred to our clinic from July 2013 to January 2016 for assessment for treatment with ESWT for calcific tendinopathy of the shoulder were screened.

Inclusion criteria were: age >18 years, pain and shoulder range of motion limitation in activities of daily living (ADL) for at least 2 weeks, signs of rotator cuff calcific tendinopathy on imaging (musculoskeletal ultrasound, standard radiography, magnetic resonance) and positivity to specific tests of functionality (Jobe, Lift-off, Patte, Palm up, Yocum, Neer), the absence of cognitive impairment and impaired consciousness which could prevent the subject from expressing free and informed consent.

Exclusion criteria were: treatment with intra-articular infiltration therapy (corticosteroids or corticosteroids/anesthetic) and/or physical therapy to the affected shoulder within 4 weeks prior to the study, ongoing cortisone or non-steroidal anti-inflammatory (NSAID) therapy, partial or complete tear of the tendons of the rotator cuff on imaging, severe glenohumeral and/or acromioclavicular osteoarthritis, surgery for direct shoulder injury, concomitant cervical symptoms consistent with radiculopathy, outcomes of neurological diseases involving the shoulder, dermatological diseases, damaged skin (scars, infections, or ulcerations not fully healed) involving the affected shoulder, blood coagulation diseases or anticoagulant therapy, decompensated diabetes, tumors, bone infections, pregnancy, presence of a pace-maker, rheumatoid arthritis or other connective tissue diseases, and allergy to adhesive tape.

The study design and protocol were approved by the institutional Review Board and Ethics Committee (approval # CE 928, 27/06/2013, chair: Carlo Pasetti) and the study was carried out in accordance with the World Medical Association's code of Ethics (Declaration of Helsinki, 1967). A written informed consent was obtained from all patients before their participation in the study.

Enrolled patients were randomly assigned to the experimental (ESWT+KT) or control (ESWT) group using a computer-generated list of random numbers obtained with the Matlab random numbers generator (MATLAB version 7.14.0.739, MathWorks Inc., Natick, MA, USA). The sequence was concealed until assignment, and the person-

nel enrolling participants did not know in advance which treatment the patient was assigned.

Patients assigned to the ESWT+KT group underwent three sessions of ESWT, once a week for three consecutive weeks, according to the treatment protocol. KT was applied at the end of each session. Patients assigned to the ESWT group underwent three sessions of ESWT, following the same procedure as in the ESWT+KT group but without KT application at the end of each session.

All patients were evaluated before treatment (T0) and at 1 (T1), 4 (T2) and 12 weeks (T3) after the end of treatment.

During all visits, patients underwent anamnestic and clinical evaluation. The pain was carefully evaluated according to the site, irradiation, typology, intensity, periodicity, evolution and exacerbation. Furthermore, all patients underwent specific functionality tests for rotator cuff (Jobe, Lift-off, Patte, Palm up, Yocum, Neer).

For each patient four outcome measures were considered: the intensity of pain (assessed by Visual Analog Scale [VAS]),[43] the Disabilities of the Arm, Shoulder and Hand questionnaire (DASH),[44] the Subjective Shoulder Rating Questionnaire (SSRQ) [45] and the Oxford Shoulder Score (OSS) [46] for the assessment of daily life activities.

In addition, side effects, complications and adverse reactions have been reported.

ESWT

The device used for ESWT was DUOLITH® SD1 Tower (Storz Medical AG, Tägerwilen, Switzerland). The treatment protocol consisted of 3 sessions, once per week for 3 consecutive weeks, in which ESWT was delivered at 4 Hz, with 1800 pulses, and energy flux density ranging from 0.07 to 0.15 mJ/mm^2. No local anesthesia was given and a common gel was placed between the patient's skin and the probe. The treatment was carried out without any anesthesia in order to use pain perception as feedback both for the amount of energy to be delivered and localization of areas to be treated. The treatment was performed with the patient in sitting position and the affected arm extended alongside the body and rotated max 15° internally and externally. Patients were informed about the possible, but infrequent, side effects, for which they gave their informed consent.

KT

KT is a 100% cotton tape which is a breathable, adhesive and sensitive to heat, latex-free and not containing drugs. It is elastic only in the longitudinal direction, with a stretch capacity of approximately 40-60% more than its resting length. It is applied directly on the skin and can be worn 24 hours/day for 3-5 days. Before applying the tape, the skin was cleaned accurately. For decompression taping, the length of the strip was equal to that of the muscle to be treated with the addition of a few more centimeters serving as the base and tail to anchor it. For compression taping, the length of the strip was less than that of the muscle, considering that the percentage of extension is about 40%. Anchor strips were applied without tension. Application on the deltoid muscle: the tape was cut in a V shape in decompression. It was fixed at approximately 5 cm below the humeral insertion point of the muscle (with the arm extended alongside the body, the head facing towards the contralateral side). Once the anchoring point was located, with the shoulder abducted at 90° and at maximal external rotation and extension, one tail of the tape was anchored at the origin of the muscle on the clavicle, covering the anterior deltoid fibers, without applying traction to the tape. The other tail was applied to the back side of the muscle, with the arm in anterior flexion and adduction and the elbow in 90° flexion.

Application on the supraspinatus muscle: the tape was cut in a V-shape in compression, with the starting anchor on the greater tubercle of the humerus. One tail of the tape was positioned, with a 40% tension, under the spine of the scapula; the other tail was positioned with a tension of 40% over the supraspinous fossa, surrounding the upper corner of the scapula.

Statistical analysis

Sample size computation was based on the outcome measure DASH. We wanted to detect a difference equal to 8 (the minimal clinically important difference reported in the literature for patients similar to ours is 10.2).[47] Published studies report a standard error of measurement (SEM) for the DASH of 5.22. Hence, to highlight the established difference with a two-tailed type I error of 0.05 and a power of 80%, the estimated sample size was 15 patients per group. Making a conservative choice that takes into account both possible drop-outs and patients lost to follow-up, we increased the sample size to 20 patients per group.

The normality of the distribution of all variables was assessed with the Shapiro-Wilk test, supported by visual inspection. Descriptive statistics are reported as mean±SD and 95% confidence interval for the mean for continuous

variables and N. (%) for categorical variables. Between-group comparisons were carried out by independent samples *t*-test or by the χ^2 test, for continuous and categorical variables, respectively. Within-group comparisons were performed using the *t*-test for paired data.

To assess differences between groups in the time course of the outcome measures, two-factor analysis of variance (ANOVA) was used, with treatment as the between-factor (ESWT+KT *vs*. ESWT) and time (T0, T1, T2, T3, T4) as the within-factor, with repeated measures in the time factor. Since the two treatments were expected to show differences over time, in the case of a significant interaction the differences T1-T0, T2-T1 and T3-T2 in the outcome measures were compared between the two groups, while the values of the outcome measures were compared between groups at observation times T1 (short-term effect) and T3 (end of follow-up effect). The level of statistical significance was set at $P<0.05$. All tests were two-tailed. The Holm-Bonferroni correction method for multiple comparisons was applied, when appropriate. All analyses were carried out using the statistical package SAS /STAT, release 9.2 (SAS Institute Inc., Cary, NC, USA).

Results

A total of 108 patients suffering from shoulder pain were screened for inclusion in the study. Of these, 50 met the inclusion criteria and agreed to take part in the trial. After randomization, 24 were assigned to the ESWT+KT group and 26 to the ESWT group. Eight patients (3 of ESWT+KT and 5 of ESWT) did not come to the follow-up visit for personal reasons and were considered drop-outs. Hence, 21 patients of ESWT+KT and 21 of ESWT underwent further analysis. During a 12-week follow-up after the end of the treatment, only 1 subject showed skin redness after the application of the tape (flow chart, Figure 1).

Table I presents patients' demographic and anthropometric characteristics: there was no significant difference between groups. Table II reports the baseline scores (T0) of the outcome measures (VAS, DASH, SSRQ and OSS). No between-group differences were observed.

The time course of each outcome measure in the two groups is summarized in Figures 2-5.

Repeated measures ANOVA revealed a highly significant time factor for all outcome measures ($P<0.0001$ all), indicating an important global improvement. Moreover, the time x group interaction factor was significant for all the considered outcomes ($P=0.013$, $P=0.0004$, $P<0.0001$ and $P=0.048$ for VAS, DASH, SSRQ and OSS, respectively), indicating a different time course of improvement in the two groups.

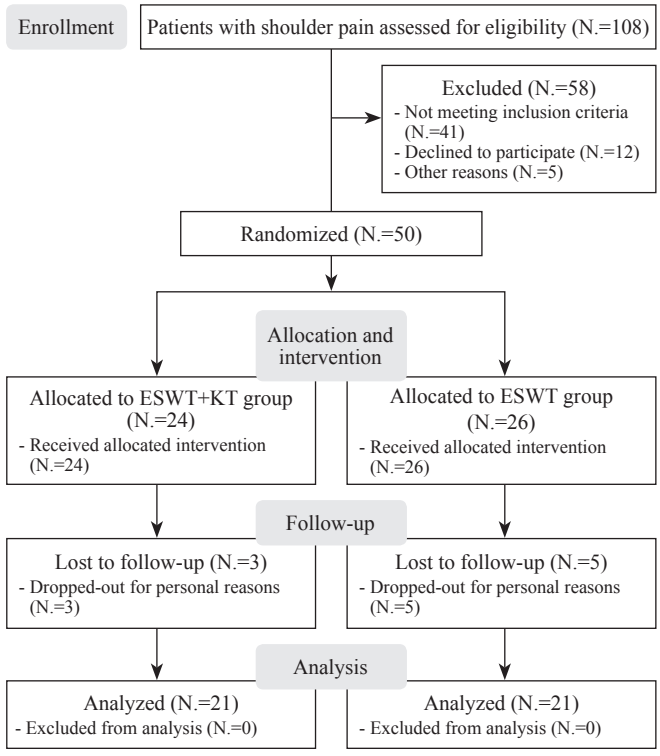

Figure 1.—Study flow chart.

To gain insight into the time course of the outcome measures and into the significant between-group differences, we compared the progressive improvements, analyzing the differences between the observation time-points for each outcome measure in the two groups (Table III). For all measures and for both groups, the improvement

TABLE I.—*Patients' demographic and anthropometric characteristics at baseline (T0).*

	ESWT+KT (N.=21)	ESWT (N.=21)	P
Age, years	54.1±10.3	48.7±11.9	0.125
Male gender, N. (%)	7 (33)	9 (43)	0.525
Right shoulder affected, N. (%)	12 (57)	10 (48)	0.537
Right-handed, N. (%)	18 (86)	16 (76)	0.432
Dominant shoulder affected, N. (%)	13 (62)	11 (52)	0.533

P values refer to between-group comparisons.
ESWT: extracorporeal shock wave therapy; KT: kinesio taping.

TABLE II.—*Baseline values (T0) of the considered outcome measures for the two study groups.*

	ESWT+KT (N.=21)	ESWT (N.=21)	P
VAS	6.6±1.5 (6.0, 7.2)	6.7±1.1 (6.2, 7.1)	0.906
DASH	33.6±12.1 (28.4, 38.8)	31.1±8.9 (27.3, 34.9)	0.459
SSRQ	49.8±14.5 (43.6, 56.0)	50.7±8.8 (47.0, 54.5)	0.802
OSS	32.3±8.3 (28.8,3 5.9)	29.8±7.3 (26.6, 32.9)	0.295

P values refer to between-group comparisons.
Data reported as mean±SD (95% confidence interval for the mean).
ESWT: extracorporeal shock wave therapy; KT: kinesio taping; VAS: Visual Analogue Scale; DASH: Disabilities of the Arm, Shoulder and Hand questionnaire; SSRQ: Subjective Shoulder Rating Questionnaire; OSS: Oxford Shoulder Score.

between T1 and T0 was generally more marked than that for the following time-points (T2 *vs*. T1 and T3 *vs*. T2), but the improvement was significant for all measures only in the ESWT+KT group (P<0.005 for all comparisons, after Bonferroni-Holm correction); in the ESWT group, only VAS showed an improvement that was significant after correction (P=0.014). These results indicate that the short-term period plays a very important role in the global improvement. Moreover, comparing the improvements obtained in the short term (T1 *vs*. T0) between the two groups, we found that ESWT+KT showed a significantly greater improvement than ESWT on VAS (P=0.007), DASH (P<0.0001) and SSRQ (P=0.0001), but not on OSS where the difference had only borderline significance (P=0.057). The progressive improvements at the following times (T2 *vs*. T1 and T3 *vs*. T2) were not significantly different in the two groups, with p-values ranging from 0.21 (DASH: T2 *vs*. T1) to 0.90 (SSRQ: T3 *vs*. T2).

Finally, at time T1 the ESWT+KT patients had significantly better values for VAS, DASH and SSRQ (P=0.005,

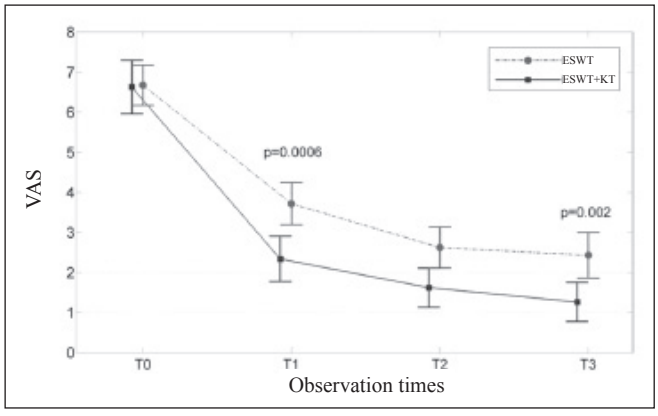

Figure 2.—Time course of VAS for ESWT+KT and ESWT groups. The P values reported are for the between-group comparisons (raw values).

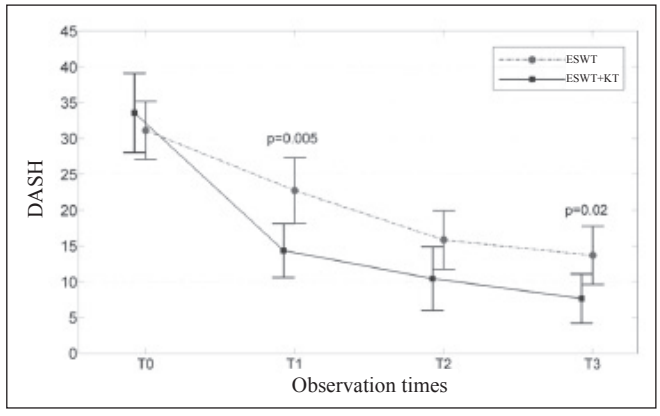

Figure 3.—Time course of DASH for ESWT+KT and ESWT groups. The P values reported are for the between-group comparisons (raw values).

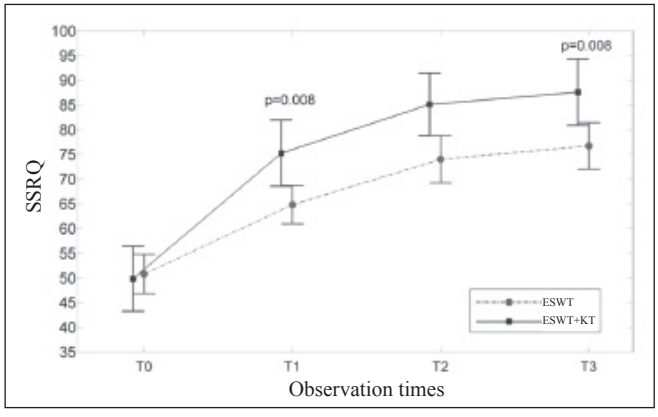

Figure 4.—Time course of SSRQ for ESWT+KT and ESWT groups. The P values reported are for the between-group comparisons (raw values).

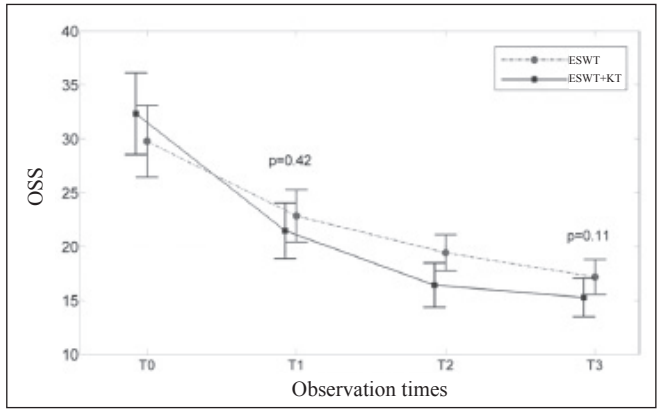

Figure 5.—Time course of OSS for ESWT+KT and ESWT groups. The P values reported are for the between-group comparisons (raw values).

TABLE III.—*Differences (D) between observation times for each outcome measure (VAS, DASH, SSRQ, OSS) in the two groups.*

	T1-T0 ESWT+KT	T2-T1 ESWT+KT	T3-T2 ESWT+KT	T1-T0 ESWT	T2-T1 ESWT	T3-T2 ESWT
Δ VAS	-4.3±1.4 (-4.9, -3.7)†^	-0.7±1.0 (-1.1, -0.3)	-0.4±0.9 (-0.8, 0.0)	-3.0±1.6 (-3.6, -2.3)‡	-1.1±1.3 (-1.6, -0.6)	-0.2±1.2 (-0.7, 0.3)
Δ DASH	-19.2±7.0 (-22.2, -16.2)†^	-3.9±5.8 (-6.4, -1.5)	-2.8±4.6 (-4.7, -0.8)	-8.4±5.9 (-10.9, -5.8)	-6.9±9.1 (-10.8, -3.0)	-2.1±8.2 (-5.6, 1.3)
Δ SSRQ	25.4±10.1 (21.1, 29.7)†^	9.9±9.6 (5.8, 13.9)	2.5±3.5 (1.0, 4.0)	14.0±6.8 (11.1, 16.9)	9.2±8.2 (5.7, 12.7)	2.7±7.2 (-0.4, 5.8)
Δ OSS	-10.9±6.6 (-13.7, -8.1)^	-5.0±5.5 (-7.4, -2.7)	-1.1±2.5 (-2.2, -0.1)	-6.9±6.5 (-9.7, -4.1)	-3.4±5.7 (-5.9, -1.0)	-2.2±3.3 (-3.7, -0.8)

Data reported as mean±SD (95% confidence interval for the mean).
ESWT: extracorporeal shock wave therapy; KT: kinesio taping; VAS: Visual Analogue Scale; DASH: Disabilities of the Arm, Shoulder and Hand questionnaire; SSRQ: Subjective Shoulder Rating Questionnaire; OSS: Oxford Shoulder Score.
†P<0.01 compared to T1-T0 ESWT (between-group); ^P<0.005 compared to T2-T1 ESWT+KT and T3-T2 ESWT+KT (within-group); ‡P=0.014 compared to T2-T1 ESWT and T3-T2 ESWT (within-group).

P=0.03 and P=0.04 respectively, after Bonferroni-Holms correction). At the end of the 12-week follow-up (T3), VAS and SSRQ scores were still significantly better in ESWT+KT patients than ESWT (P=0.02 and P=0.038, respectively).

Discussion

The aim of this study was to assess if the association of KT with standard ESWT yields better results than the use of ESWT alone in the treatment of shoulder pain due to calcific tendinopathy of the rotator cuff, both in the short and medium-long term.

We showed a reduction in pain and functional improvement with a significant clinical change already after the first week in both groups. Hence, our study confirms the effectiveness of ESWT in reducing the inflammatory response in patients suffering from calcific tendinopathy, decreasing pain in the short-term period and improving functional capacities in the affected joint area in the long term. This effect seems to be due to particular mechanotransduction pathways which activate a series of cellular events (largely unknown till now) linked to cell metabolism and the natural regenerative power of tissues.[48] Our data support claims in the literature that ESWT can be considered as the gold standard in the treatment of rotator cuff calcific tendinopathy. In the randomized trial of Cosentino *et al.*[49] and in the 2013 review of Ioppolo *et al.*[50] it is highlighted that, besides its significant anti-inflammatory/antalgic role, ESWT leads to reabsorption of the calcifications which persists over a period of 6 months.

In our study, however, the ESWT+KT group showed a more marked improvement in the short-term period than the ESWT group, with statistical significance in all measures and a trend for maintenance of the good results at 12-week follow-up. This means that the therapeutic action proposed (KT+ESWT) had a beneficial effect on patients which persisted over time. The application of KT as adjuvant therapy determined a marked pain reduction in the short term and a faster recovery of functional capacities compared to use of ESWT alone. These effects were similar in the medium-long term.

Thelen *et al.*[38] evaluated the short-term effect of KT in a prospective, randomized double-blind study on patients diagnosed with rotator cuff tendinopathy: a significant improvement in pain-free articulation was found with the SPADI and VAS scales in the group treated with KT. According to a meta-analysis carried out by Lim *et al.*,[39] KT may provide greater pain relief than other therapeutic approaches in the short-term period, but there is no evidence showing that KT is better than other approaches at reducing pain and disability in the medium-long term period. In the short-term period and in a patient in severe clinical conditions, KT had an analgesic effect, enhancing the functional recovery.[33-42] The results obtained in our study show that KT reinforced the analgesic and regenerative action of ESWT in the short term and promoted a faster therapeutic response in the medium-long term. We speculate that KT performs its therapeutic functions mainly by proprioceptive feedback, through an immediate and constant stimulation of the mechanoreceptors in the skin, protecting the joint and reducing wrong movements. While correcting the postural attitude, KT would perform both a biomechanical correction of the articulation and have effects on the neurologic activation of the muscles.[31] Through this elastic bandage, it is possible to reduce in the short-term period the mechanical stress that is often present in painful shoulders.[41]

By improving the effectiveness of ESWT, KT accelerated the recovery time. The most important point that emerges from this study, in fact, is the faster response in terms of pain reduction and the faster functional recov-

ery in ADL of the patients treated with KT in addition to ESWT, significantly shortening the response time to treatment. Hence, KT could represent a valid therapy supporting the rehabilitation

Conclusions

Besides determining a significant reduction of pain and inflammation, ESWT in association with KT seems to be able to shorten the recovery time. The results of this study are encouraging, suggesting the effectiveness of KT as adjuvant therapy for the treatment of these diseases in the short-term period, and its capacity to enhance the biological-regenerative effects of ESWT in the medium-long term. Added to these positive findings is the almost complete absence, we found, of complications and side effects.

KT is a non-invasive, non-pharmacological, localized therapy that can, hence, be considered effective as an adjuvant therapy in association to ESWT, and able to enhance the rehabilitation of rotator cuff calcific diseases. Moreover, thanks to its low cost, it may offer greater advantages from an economic point of view over other standard drug therapies. While further research is necessary to define the therapeutic indications, identify the best application methods, and clarify which factors determine the clinical result, our findings suggest that ESWT in association with KT is a valid therapeutic option in patients suffering from shoulder pain due to calcific tendinopathy.

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Conflicts of interest.—The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

Article first published online: November 29, 2017. - Manuscript accepted: November 28, 2017. - Manuscript revised: November 21, 2017. - Manuscript received: March 22, 2017.