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# Treatment for Symptomatic Calcific Tendinopathy of the Shoulder: Ultrasound-Guided Needling Lavage and Extracorporeal Shock Wave Therapy *vs* Extracorporeal Shock Wave Therapy. A prospective observational study

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**SUMMARY**

**Objective.** To compare combined treatment ultrasound guided needling (UGL) and extracorporeal shockwave therapy (ESWT) *versus* ESWT alone in symptomatic calcific tendinopathy of supraspinatus.

**Methods.** It is a prospective observational study. The participants were 50 consecutive patients with painful (NRS > 5) calcific tendinitis of the shoulder. Clinical and radiological data were collected before treatment (T0) at one (T1) and three months (T2) follow-up.

Eligible patients were assigned to the Intervention Group (IG) with combined treatment and 3 sessions of focused ESWT (23 patients). Patients not willing to undergo UGL were considered as the Control Group (CG) and treated with 3 sessions of ESWT alone (27 patients). 36 patients reached T2.

**Results.** Combined treatment was more effective in NRS reduction at one (T1) month follow up ($p < 0.001$). Moreover, in IG, it was observed a statistically significant difference in NRS ($p < 0.001$) and in the CMS ($p < 0.001$) at three months follow-up (T2). Calcific deposit was eradicated more effectively by combined treatment, with total resorption in 79 % at T2 ($p < 0.001$).

**Conclusions.** Combined treatment ultrasound-guided needling lavage and shockwave therapy is a rapid, safe and effective treatment in patients with painful calcific tendinopathy, in pain reduction at one month follow-up.

**KEY WORDS**

*Barbotage; calcific deposit; calcific tendinopathy; eccentric exercise therapy ESWT; rotator cuff; shock wave therapy; shoulder pain; ultrasound-guided needling lavage; ultrasound-guided percutaneous irrigation.*

## INTRODUCTION

Rotator cuff calcific tendinopathy (RCCT) is one of the most frequent causes of pain in the shoulder and is characterized by the presence of calcific deposits in the rotator cuff; it usually occurs during the fifth and sixth decades of life, with a prevalence varying from 2.7% to 22%, and it is more common in females (60%)(1). In almost 50% of cases, it involves the supraspinatus tendon at 1.5-2 cm from its insertion site on the greater tuberosity (2).

Clinical symptoms occur in 34% to 45% of patients with RCCT, mostly shoulder pain, variably associated with acute or gradual reduction of the articular range of motion (3). However, calcific deposits have also been described in asymptomatic individuals (4).

Its pathogenesis is not fully understood, but it seems to be the results of an active cell-mediated process. Uhthoff and colleagues have proposed a model which divides the evolution of the disease into three distinct stages: the pre-calcific, calcific and post-calcific stages. They hypothesize that a favorable environment allows for an active cell-mediated calcification process, usually followed by spontaneous phagocytic resorption, and the time scale of these different stages can be anything from a few months to several years (5).

Based on radiographic findings, Gartner classified the calcification into three types: well-circumscribed and dense (Type 1), soft counter/dense or sharp/transparent (Type 2), and translucent and cloudy with no precise circumscription (Type 3) (6). Softer calcifications may not be visible on radiographs, and in these cases, ultrasound (US) can be considered as a tool for diagnosis. Ultrasound can define calcific locations in the tendon, as well as their size and texture, and has proved helpful in determining associated tendon tear (7, 8), with 98% sensitivity and 94% specificity (9).

Rotator cuff tear is found in approximately 25% of patients with calcific tendinitis, although such tears tend to be associated more with small calcific deposits than with large calcific deposits (10).

Conservative management is the first line of treatment, which entails a combination of medication (non-steroidal anti-inflammatory drugs – NSAIDs), subacromial corticosteroid injections, and physical therapy. Other non-operative treatments include extracorporeal shockwave therapy (ESWT) and ultrasound-guided needling and lavage/barbotage (UGL). Surgical intervention is indicated in severe or refractory cases (11, 12).

A combined approach to calcific tendinopathy using UGL and ESWT could lead to the quicker reduction of pain and size of calcification deposits, along with functional recovery (13).

The primary objective of this study is to evaluate the safety and the short-term effects of combined treatment with UGL and ESWT when compared to ESWT alone in terms of pain reduction at one month follow-up (T1) in patients with symptomatic calcific tendinopathy of the shoulder.

The secondary objective of the study is to investigate pain reduction at three (T2) months follow-up, to assess functional recovery at one (T1) and three (T2) months follow-up, and to assess calcific deposit resorption at three months follow-up (T2) in the patient's sample.

## MATERIALS AND METHODS

### Study design

This is a prospective observational study conducted according to good clinical practice and the ethics of the Helsinki Declaration and approved by the Institutional Review Board of the University of Rome La Sapienza (RS 6532/2021 – Date of approval: October 15, 2021).

### Eligibility criteria and enrollment

Participants were recruited between October 2021 and January 2022, among patients affected by painful calcific tendinitis of the shoulder diagnosed after clinical and radiological assessment.

The total number of patients evaluated was 53. Three patients were excluded: one patient had received a subacromial injection (SAI) and two patients had received ESWT, three weeks and one month previously, respectively. 50 patients were found eligible, and they all agreed to participate. 27 refused to undergo UGL for personal reasons and were therefore allocated to the control group. Overall, 23 patients were enrolled in the intervention group (IG) and 27 patients in the control group (CG). The Consort Flow Diagram is shown in **figure 1**.

The inclusion criteria were as follows: age greater than or equal to 18 years, shoulder pain lasting for more than 6 months, Numeric Rating Scale (NRS) greater than or equal to 5, radiographic finding of calcific deposits in the supraspinatus larger than 5 mm.

Exclusion criteria were Magnetic Resonance Imaging (MRI) or US diagnosis of rotator cuff tendon tear, subacromial injection with a corticosteroid or ESWT in the previous 3 months, history of prior allergic/hypersensitivity reactions relating to the study medications, coagulation disorders, therapy with oral anticoagulants, rheumatic diseases, fibromyalgia, pregnancy, and magneto-compatible devices. Eligible patients who agreed to participate signed written informed consent. Fifty-three patients met the inclusion criteria.

After completing the baseline data, eligible patients were assigned to the Intervention Group (IG) with combined treatment UGL and ESWT. Those patients not willing to undergo UGL were considered as the Control Group (CG) and treated with ESWT alone (**figure 1**).

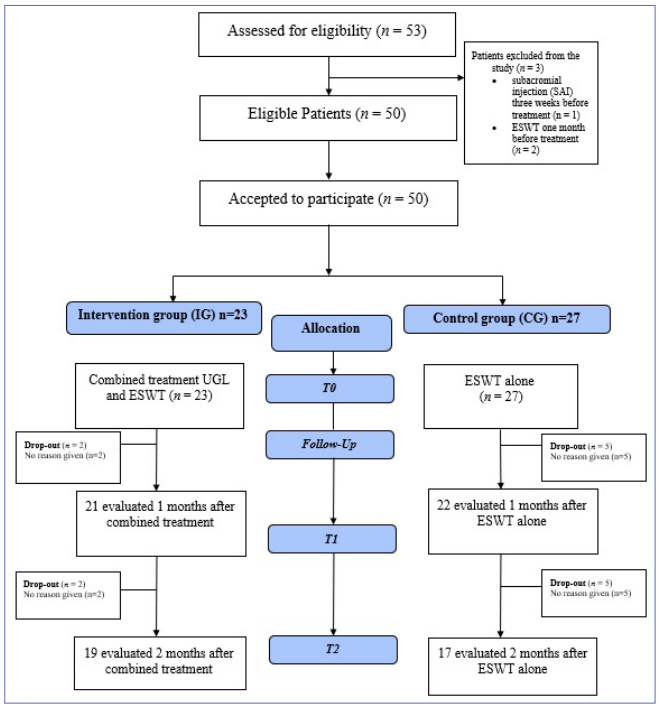


**Figure 1.** Consort flow diagram.

## Outcome measures

The Numeric Rating Scale (NRS) was used to assess pain, (14) and the Constant and Murley Score (CMS) was used for functional assessment (15).

Calcific deposit size was collected from standard X-ray projections (anterior-posterior, lateral and acromioclavicular views) by measuring the larger diameter.

Clinical data were collected before treatment (T0) and at one (T1) and three months (T2) after the last ESWT session. At T0, diagnostic US of the supraspinatus tendon (Sonoscape X5 with linear probe 4-16 MHz) was performed to determine the characteristics of calcific deposits, including position, morphology and Power/Color Doppler signal. Calcific deposits were classified according to radiographic morphology, and size was ascertained by measuring the larger diameter, with standard shoulder radiographs performed not more than four weeks prior to the intervention. Furthermore, an X-ray of the shoulder was repeated to evaluate the presence or the modification of calcific deposits at T2.

## Intervention group

The IG underwent UGL performed by a medical team with experience in both interventional and diagnostic musculoskeletal sonography, on an outpatient setting, with the patient in a supine position, their arm lying across their abdomen. After sterilization of the skin, the calcific deposit was identified with a 4-16 MHz probe wrapped in a sterile drape; under US guidance the subacromial-subdeltoid bursa was anaesthetized with 5 ml of 2% lidocaine hydrochloride, injected with a 21-gauge 40 mm needle. After 10 minutes, an 18-gauge single needle was positioned in the center of the calcification under sonographic guidance and connected to a sterile tube filled with 8 ml of saline solution 0.9% and 1 ml of 2% lidocaine hydrochloride. The other end of the tube was linked to a 5 ml syringe, after which the operator started to flush the calcification out by applying constant force on the syringe plunger until the calcific material started to back-flow into the connection tube as a milky substance. To avoid calcium reinjection, the liquid in the tube was emptied several times into a sterile container, until the calcification was entirely or partially removed and the back flow in the tube was free of visible calcium detritus. At the end of the procedure, the needle was gradually extracted and re-directed towards the subacromial-subdeltoid bursa, which was injected with 1 mL of triamcinolone (40 mg). The entire procedure took no longer than 30 minutes. Analgesic therapy with 1 gram of acetaminophen was recommended if needed, and broad-spectrum antibiotic therapy was prescribed to avoid bacterial infections.

Immediately afterwards, patients underwent the first session of ESWT with a focused electromagnetic shock wave device (Modulith SLK, STORZ Medical, Switzerland) with in-line sonographic guidance on the supraspinatus tendon area. The number of impulses administered was 2,400, with an energy flux density of 0.15 to 0.25 mJ/mm$^2$. Each participant received two more ESWT sessions with the same treatment parameters, one per week.

## Control group

The CG underwent three sessions of focused ESWT (Modulith SLK, STORZ Medical, Switzerland) on a weekly basis, with in-line sonographic guidance on the supraspinatus tendon area using the same parameters as the IG group. Patients in both groups were advised to rest and to avoid overhead movements and overloading on the treated shoulder. They were also given a home-based exercise program consisting of eccentric exercise for the shoulder, to recover and maintain the full range of motion (ROM).

## Statistical methods

### *Statistical analysis*

Continuous variables are presented as mean and standard deviation (SD), while categorical variables are presented as frequency and percentage. Repeated measures ANOVA were used to analyze changes in mean NRS and CMS during the follow-up periods. The independent samples t-test was used to test the statistical difference in the maximum size of shoulder calcification before and after treatment. The Paired t-test was used to assess intra-group changes in all outcome measures. All tests were two-tailed with a level of significance of $p < 0.05$. All analyses were conducted with IBM SPSS Statistics for Mac, version 25. The eligibility rate was assessed by the number of eligible patients divided by the total number of elements on the sampling frame. The enrollment rate was assessed by the number of patients included in the study divided by the total number of eligible patients. Safety was assessed by monitoring any serious adverse events that occurred during follow-up.

# RESULTS

## Demographic, clinical and radiographic variables

The mean age of the intervention group was 51.1 years (41.0-74.0); 34.8% were male and 65.2% female. The mean age of the control group was 51.3 years (44.0-70.0); 44.4% were male and 55.6% female. The mean BMI of the IG was 23.9 ± 2.7; the median BMI of the CG was 24.1 ± 3.2. 21.7% of IG and 12% of CG were found to have a smoking habit. The right side was affected in 56.5% of IG and 59.3% of CG. No significant intergroup differences were found at baseline assessment except for calcific size ($p < 0.01$). Patients' demographic, clinical-pathological features, onset of symptoms, NRS, Constant Murley Score, calcific deposit size at baseline are summarized in **table I**.

## Clinical results

### *Primary outcome*

At the evaluation times between groups, a statistically significant difference ($p < 0.01$) in the NRS was found at T1 in favor of the intervention group (IG) (**table II**).

**Table I.** Baseline characteristics of patients.

| | IG (n = 23) | CG (n = 27) | P-value |
|---|---|---|---|
| Age, mean (SD) years | 51.1 (10.4) | 51.3 (11.1) | 0.96 |
| Gender, female, n (%) | 15 (65.2) | 15 (55.6) | 0.49 |
| Side, right, n (%) | 13 (56.5) | 16 (59.3) | 0.85 |
| BMI, mean (SD) | 23.9 (2.7) | 24.1 (3.2) | 0.37 |
| Smokers, n (%) | 5 (21.7) | 3 (12) | |
| Gartner Classification, n (%) | | | |
| Type I | 6 (26.1) | 9 (33.3) | 0.57 |
| Type II | 12 (52.2) | 15 (55.6) | |
| Type III | 5 (21.7) | 3 (11.1) | |
| Symptom onset, mean (SD) months | 13.5 (9.4) | 13.5 (9.7) | 1.00 |
| NRS T0, mean (SD) | 6.9 (1.6) | 6.5 (1.1) | 0.21 |
| Constant Murley Scale T0, mean (SD) | 65.5 (20.2) | 68.8 (9.9) | 0.46 |
| Calcific deposit size T0, mean (SD) mm | 1.9 (0.7) | 1.3 (0.5) | **< 0.01** |

**Table II.** Primary outcome.

| NRS T1 | | | | | | | | 95% Confidence Interval | |
|---|---|---|---|---|---|---|---|---|---|
| | Mean | SD | Statistic | df | P-value | Mean difference | SE difference | Lower | Upper |
| IG | 2.7 | 2.3 | -3.4239 | 41.0 | **0.001** | -2.15 | 0.628 | -3.421 | -0.882 |
| CG | 4.8 | 1.8 | | | | | | | |

### Secondary outcome

*Comparison between groups*

At the evaluation times, a statistically significant difference in the NRS was maintained at T2. Significant differences between IG and CG were not observed in CMS at T1, but were found at T2 (p = 0.005). In calcific deposit resorption, a statistically significant difference at T2 was found, with total resorption in 15 patients (79%) of the IG and 3 (17.6%) patients of the CG (p < 0.001) (**table III**).

*Intra-group analysis*

In the intervention group, a statistically significant difference in the NRS and CMS at T0 *vs* T1 (p < 0.001) was observed. No significant difference was found at T1 *vs* T2 in either NRS (p = 0.15) or CMS (p = 0.34). At T0 *vs* T2, a statistically significant difference in NRS (p < 0.001), CMS (p < 0.001) and calcific resorption (p < 0.001) was observed.

In the control group, a statistically significant difference in the NRS and CMS at T0 *vs* T1 (p < 0.001) was observed. No significant difference was found at T1 *vs* T2 in either NRS (p = 0.15) or CMS (p = 0.34). No statistically significant difference was observed in CMS at T1 *vs* T2 (p = 0.51) or T0 *vs* T2 (p = 0.06). At T0 *vs* T2, a statistically significant difference in NRS (p = 0.002) and calcific resorption (p < 0.001) was observed (**tables IV** and **V**).

**Table III.** Between group differences in secondary outcomes.

| | | Mean | SD | Statistic | df | P-value | Mean difference | SE difference | 95% Confidence Interval | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | Lower | Upper |
| NRS T2 | IG | 2.3 | 1.9 | -2.7432 | 34.0 | **0.010** | -2.03 | 0.740 | -3.536 | -0.526 |
| | CG | 4.3 | 2.5 | | | | | | | |
| CMS T1 | IG | 84.9 | 13.7 | 1.9666 | 41.0 | 0.056 | 7.23 | 3.674 | -0.194 | 14.645 |
| | CG | 77.7 | 10.2 | | | | | | | |
| CMS T2 | IG | 87.2 | 9.9 | 3.0320 | 34.0 | **0.005** | 11.00 | 3.628 | 3.628 | 18.375 |
| | CG | 76.2 | 11.8 | | | | | | | |
| Calcific deposit size T2 | IG | 0.13 | 0.3 | -4.514 | 34.0 | **< 0.001** | -0.62 | 0.137 | -0.897 | -0.340 |
| | CG | 0.75 | 0.5 | | | | | | | |

**Table IV.** Intragroup differences in the outcome's measures.

| | IG | CG |
|---|---|---|
| NRS, mean (SD) | | |
| T0 | 6.9 (1.6) | 6.5 (1.1) |
| T1 | 2.7 (2.3) | 4.8 (1.8) |
| T2 | 2.3 (1.9) | 4.3 (2.5) |
| P-value T0-T1 | **< 0.001** | **< 0.001** |
| P-value T0-T2 | **< 0.001** | **0.002** |
| P-value T1-T2 | 0.153 | 0.441 |
| Constant Murley Scale, mean (SD) | | |
| T0 | 65.5 (20.2) | 68.8 (9.9) |
| T1 | 84.9 (13.7) | 77.7 (10.2) |
| T2 | 87.2 (9.9) | 76.2 (11.8) |
| P-value T0-T1 | **< 0.001** | **0.001** |
| P-value T0-T2 | **< 0.001** | 0.063 |
| P-value T1-T2 | 0.340 | 0.512 |

**Table V.** Calcific deposit size variation at T2.

| | IG (n = 23) | CG (n = 27) | P-value |
|---|---|---|---|
| Size variation, n (%) | | | |
| Unvaried | 0 | 8 (47.1) | |
| Reduction | 4 (21) | 6 (35.3) | **< 0.001** |
| Resorption | 15 (79) | 3 (17.6) | |

*Safety*

No adverse effects were observed in either group at each follow up. Nonetheless, 6 patients from the IG suffered from pain exacerbation, which was resolved with the administration of NSAIDs (4 patients) or SAI (2 patients).

In the CG 12 patients required additional treatment due to pain exacerbation, which was resolved with the administration of NSAIDs (10 patients) or SAI (2 patients).

## DISCUSSION

Rotator cuff calcific tendinopathy is a self-limiting disorder of the shoulder characterized by deposition of calcium in the rotator cuff tendons. Its pathogenesis is not fully understood, but it seems to be the results of an active cell-mediated process (2, 16).

In this work we found that combined treatment UGL and ESWT was more effective in pain relief at one month follow-up (T1) if compared to ESWT alone. In our sample, the intervention group also showed greater improvements in pain, function and calcific resorption at T2 compared to the control group.

These findings were partly expected, in fact according to the literature such as Ioppolo *et al*., when UGL is combined with other procedures, such as ESWT, it has proved to be more effective and faster than ESWT alone in terms of pain reduction, functional recovery and calcific deposit resorption (17).

UGL is a technique that uses sonographic guidance to aspirate calcium deposits from a particular area. It is performed under local anesthesia, is fully accepted as a safe and effective treatment. Moosmayer *et al*. described positive outcomes in terms of pain reduction, functional recovery and calcific resorption, with a low complication rate (0-10%) (18, 19); Del Castillo *et al*. showed that these outcomes last in the medium and long term (20).

In our study we have treated all type of calcification because, while UGL is always indicated in type 2 or type 3 calcification of the shoulder, it should be also considered for harder symptomatic calcification (Type 1) like Oudelaar says (21, 22). Furthermore, the combined treatment showed no difference in terms of side effects when compared to those involving ESWT, UGL or SAI alone (13, 23).

In the IG, 13 patients at T1 (61.9%) and 14 patients at T2 (73.7%) achieved a variation > 2.5 points on the NRS scale; in the CG only 6 patients (27.2 %) at T1 and 5 patients (29.4%) at T2 achieved such a variation, which is described in literature as the minimal clinically important difference (MCID) for NRS in RCCT patients (24).

Functional recovery improved in both groups at T1 without any statistically significant difference, but we observed a variation > 17 points - described as the MCID for CMS (25) - in 12 patients (57.1%) of the combined group, while in the control group only 5 patients (22.7%) achieved this result.

The therapeutic exercise could positively contribute in the management of RCCT, even if there are no available studies that outline a specific protocol for this pathology (26). Patients of both groups were administrated a home-based exercise protocol, and we can hypothesize that an early pain relief allows a faster ROM recovery and avoid the under-stimulation of the upper limb. This may have contributed to the functional improvement we observed at each follow-up time in both groups, but more in the IG than in the CG. Moreover, in order to achieve an early mobilization and to manage post-intervention pain and the risk of bursitis, a subacromial injection (SAI) with triamcinolone was also administered at the end of the treatment.

UGL has been shown to be quite effective in calcium removal (27). In our study, calcific deposit was eradicated more effectively by combined treatment, with total resorption in 15 patients (79%), even if baseline calcification size was larger than in the control group.

In the CG we observed a variation in calcific deposit, but total resorption was achieved in 3 patients only (17.6%). In fact, there is no complete agreement on the role of ESWT in the resorption of calcification (28), even though clinical improvements in shoulder function and pain are shown in the literature at a mid-term follow-up (29). We also can hypothesize that some participants were not symptomatic because of the calcification deposit. In fact, calcification in the middle of the tendon or at the articular surface could be less symptomatic than calcification on the bursal surface of the tendon (30).

Calcification size > 15 mm and Type I according to Gartner classification seem to be poor outcome prognostic factors when ESWT is performed (31), hence the idea to perform combined treatment with UGL.

In fact, ESWT stimulates proliferation, migration, and differentiation of supporting cells, all of which contribute to tendon self-healing (32-34).
Different energy levels and a different number of sessions can be performed, but there is no agreement on the gold standard (11, 35, 36).
All the patients treated in the study were symptomatic, with functional impairment and radiographic evidence of calcific deposits in the supraspinatus ≥ 5 mm (37).
For the UGL, an 18-gauge single needle was chosen, being easier to use than the double-needle technique, less invasive and equally effective (38-40).
Pain seems to be exacerbated in the resorption phase of the natural calcific tendinopathy cycle, probably sustained by bursal inflammatory reaction, leading to the remodeling of calcium deposit (41). It can be easily managed with NSAIDs or SAI, but it demands an accurate monitoring of the patient in the weeks after the procedure.
Based on our hypotheses and our data, combined UGL and ESWT treatment may be effective, safe, and rapid in patients with painful calcific tendinopathy.

### Study limitations

The most important limitation in our work is the short time follow-up; in fact, ESWT expected effects, in particular tendon self-healing could take more than three months to be observed. Other limitations are the lack of randomization, and the drop-out rate: 14 patients (28%) were lost to follow-up from T0 to T2, no reasons given. COVID-19 promulgated restrictions, and patients' reluctance to go to hospital in a pandemic might also have played a role.

## CONCLUSIONS

The combined treatment UGL and EWST is safe and more effective in reducing pain at one month follow-up than ESWT alone. Patients of both groups achieved pain relief, functional improvement and calcific deposit reduction, although patients in the IC had better results. We suggest that the combined treatment, which exploits the washing of the UGL and the biological effects of the EWST, could maintain the positive effects we observed for a longer period of time.
These results should be confirmed by future high-quality randomized clinical trials.

## FUNDINGS

None.

## DATA AVAILABILITY

Data are available under reasonable request to the corresponding author.

## CONTRIBUTIONS

DDR, SZ, AAB, MV: conceptualization, design. DDR, SZ, MM, LP, DT, MCV: data collection. DDR, SZ, MV: results analysis and interpretation. DDR, SZ: writing – original draft. All authors: writing – review & editing.

## CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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