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US-guided percutaneous irrigation of calcific tendinopathy of the rotator cuff in patients with or without previous external shockwave therapy

Ezio Lanza[1] · Francesca Piccoli[2] · Cristina Intrieri[2] · Riccardo Muglia[2] · Letterio Salvatore Politi[1,2] · Mario Borroni[3] · Alessandro Castagna[2,3] · Luca Maria Sconfienza[4,5]

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Abstract

Objectives To compare the outcome of US-guided percutaneous irrigation of calcific tendinopathy (US-PICT) of the rotator cuff in patients with or without previous external shockwave therapy (ESWT).

Methods We analyzed all patients treated with US-PICT from March 1, 2016, to October 1, 2019, with shoulder pain refractory to conservative management for rotator cuff calcific tendinopathy, diagnosed with ultrasound. Each patient was examined using the Constant–Murley Score (CMS) questionnaire (score 0–100) before and after treatment. We tested CMS differences using the Mann–Whitney *U* (Wilcoxon rank-sum) test in the two groups. US-PICT was performed placing two or multiple 14G needles, according to the calcification size, inserted under US guidance to create a circuit of irrigation in the calcified tendon. NaCl solution at 38 °C was then injected from the entry needle in a variable amount to hydrate and fragment the calcification, finally allowing for its expulsion through the exit needle. All patients also received an intrabursal steroid injection.

Results From 2016 to 2019, 72 US-PICT treatments were performed on 70 patients (females = 46; males = 26) with a mean age of 49.7 years (SD = 8.7. Thirty-three (47%) underwent previous ESWT, while thirty-seven (53%) had no previous treatments. No treatment-related complications were observed. Follow-up was averagely 14.4 months (median = 11.6, SD = 11.9, range 1–45); 37 patients had a follow-up shorter than 12 months (1–11.6); 35 patients were visited after more than 1 year (12.2–45.6, Table W). Before treatment, the mean CMS was 35 (SD = 21); after treatment, it reached 75.4, with an average CMS improvement of 40.3 points (SD = 23.7, $p < 0.001$). The comparison of improvement between the ESWT and non-ESWT group yielded no significant difference ($p = 0.3$).

Conclusions US-PICT of the rotator cuff is an effective procedure to reduce shoulder pain and increase mobility in patients with calcific tendinopathy, both in short- and long-term time intervals. Previous unsuccessful ESWT does not affect the outcome of US-PICT.

Keywords Shoulder · Calcific tendinopathy · Ultrasound-guided percutaneous irrigation · Rotator cuff

✉ Ezio Lanza
eziolanza@gmail.com

1 Radiology Department, Humanitas Clinical and Research Center - IRCCS, Rozzano, Milan, Italy

2 Department of Biomedical Sciences, Humanitas University, Pieve Emanuele, Milan, Italy

3 Shoulder and Elbow Unit, Humanitas Clinical and Research Center - IRCCS, Rozzano, Milan, Italy

4 IRCCS Istituto Ortopedico Galeazzi, Milan, Italy

5 Department of Biomedical Sciences for Health, Università degli Studi di Milano, Milan, Italy

Introduction

Calcific tendinopathy of the rotator cuff (CTRC) is a common condition with an estimated prevalence of 42.5% in adults with shoulder pain [1] and higher frequency in females in their fifth decade. Disease etiopathogenesis is characterized by hydroxyapatite crystal deposition, often in the supraspinatus (SSP) and infraspinatus (ISP) muscle tendons [2], secondary to the metaplastic transformation of tenocytes into chondrocytes [3].

Shoulder pain may range from mild to severe, often resistant to anti-inflammatory drugs and painkillers, typically

increasing at night and may result in functional impairment. Treatment options include extracorporeal shockwave treatment (ESWT) [4], ultrasound-guided percutaneous irrigation (US-PICT) [5], and surgery [6]. US-PICT, a percutaneous treatment aimed at fragmenting and flushing with saline the calcific deposit using needles placed under ultrasound guidance [7–10], is reported to be more efficient than ESWT alone [11]. Recent reports indicate that patients who have a poor outcome after ESWT should seek a different treatment [4]; however, they are frequently addressed to ESWT monotherapy [12]. Moreover, the effect of the previous ESWT on patients subsequently undergoing US-PICT is unknown.

Thus, our purpose was to compare the outcome of US-PICT of the rotator cuff in patients with or without previous external shockwave therapy.

Materials and methods

This retrospective analysis aimed at comparing the efficacy of US-PICT between patients with a history of previous unsuccessful ESWT and those with no previous therapy.

The study protocol was approved by the local Institutional Ethics Committee (-blinded for review-). The study was conducted in accordance with the ethical standards laid down in the Declaration of Helsinki. Informed consent was obtained before every treatment from all patients.

We analyzed all patients treated with US-PICT from March 1, 2016, to October 1, 2019, with shoulder pain refractory to conservative management due to rotator cuff calcific tendinopathy, diagnosed with ultrasound. The inclusion criteria were: a well-formed intratendinous calcification diagnosed at ultrasound (US) with associated shoulder pain not attributable to other pathology (Fig. 1). The exclusion criteria were: calcification size < 5 mm [13]; fragmented calcifications; evidence of extrusion in the subacromial bursa; coagulation disorders or anticoagulant therapy.

Patients were mostly referred by orthopedists or physiatrists who acted later as referring physicians. In accordance with our standard protocol, all patients underwent a preoperative visit one to 7 days before treatment to confirm the indication, followed by US-PICT and a follow-up visit in 1 month. In the preoperative setting, shoulder investigation by conventional imaging (i.e., x-ray) was not requested as US was considered the first choice imaging technique, in line with the current guidelines of the European Society of Skeletal Radiology [14]. Successive visits were decided on a case-by-case basis, according to clinical evaluation, patient symptomatology, and compliance. All patients were asked to return for a long-term follow-up visit at the end of October 2019 to collect data for this report.

Preoperative visit

All patient's data were recorded on an electronic database. We routinely noted age, gender, and previous ESWT treatments. All patients who underwent at least three sessions of ESWT in the 3 months preceding treatment were considered part of the ESWT subgroup. Clinical examination was performed in order to fill the Constant–Murley Score (CMS) questionnaire, which is a reliable 0–100 points scoring system introduced to determine functional postoperative outcomes after a shoulder injury. CMS has been widely used and tested, showing good interobserver and intraobserver reliabilities [15–18] and comparable outcomes regardless of being patient-derived or clinician-derived [19].

The questionnaire is divided into subscales, including pain (0–15 points), activity level (0–10), arm positioning (2–10), external rotation (2–10), internal rotation (0–10), forward flexion (2–10), lateral elevation (2–10), and strength (0–25). An overall low score indicated worse disability.

The patients were asked to perform the requested movements while facing the operator. The strength section was approximated by asking the patients whether they preferred to avoid load on the affected arm (0 points), carried

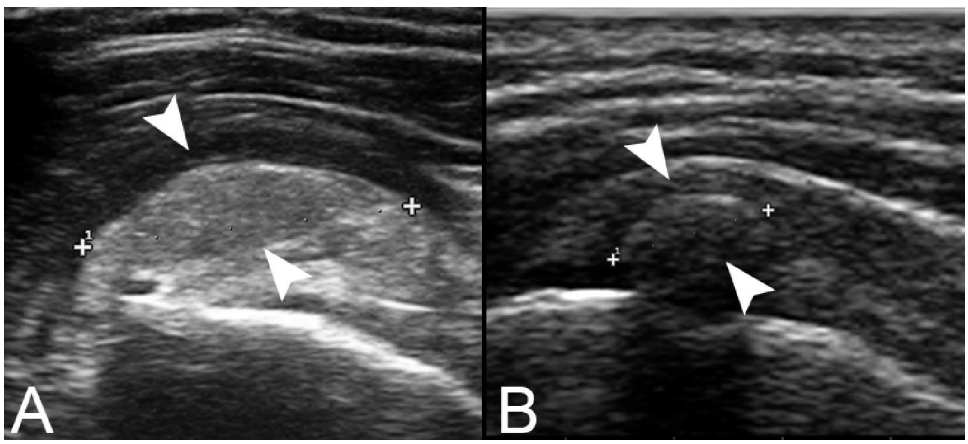

Fig. 1 Ultrasound of the supraspinatus tendon in two different patients affected by diverse CTRC types: **a** 27 mm "soft "calcification never treated before (white arrowheads); **b** a "hard" 10 mm calcification, previously treated by ESWT, showing increased acoustic shadowing (white arrowheads)

only light weights (10 points) or could carry normal weights (25 points).

Calcification number, size, and location were recorded utilizing US imaging (Esaote MyLab25, Genova, Italy). The patients were instructed to avoid strain on the affected arm until US-PICT.

US-PICT

The treatments were performed by the same single operator with 5-years' experience (E.L.). On the scheduled day for treatment, US evaluation was repeated to confirm the indication. US-PICT was performed in a single session, in a room dedicated to diagnostic US, in an outpatient setting with the previously described technique [10]. In brief, it started with the administration of subcutaneous and intrabursal anesthesia (9 ml Mepivacaine Chlorhydrate, Angelini Pharma, Italy plus 1 ml bicarbonate); then, a single or multiple 14 gauge needles were placed under US guidance (Fig. 2), according to calcification size [20]. Saline solution heated at 42 °C [21] was injected and flushed through the needles (Fig. 3) in order to hydrate and break down the calcification. Calcium deposits were expelled from the exit needle. The procedure was deemed complete when the calcification core was completely flushed, and fluid was free from visible calcium; any residual presence of the calcification shell alone was considered acceptable. Finally, intrabursal injection of methylprednisolone (Depo-Medrol 40 mg, Pfizer, New York, USA) was administered to reduce post-procedural inflammation. All patients were instructed to start a rotator cuff and shoulder conditioning program supervised by a physiotherapist.

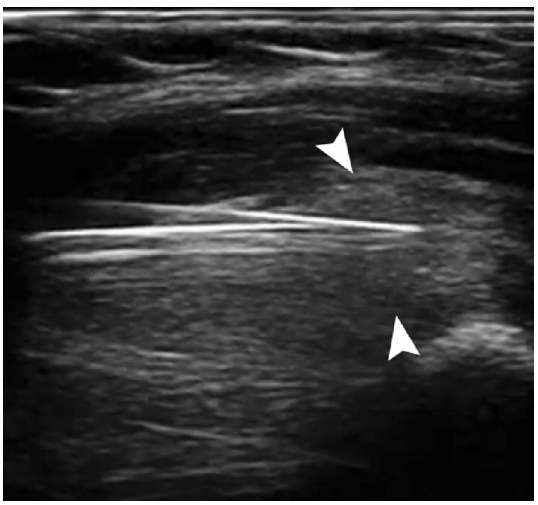

Fig. 2 Ultrasound image of the "two needles" technique; two 14G needles are seen facing each other inside a soft 13 mm calcification (white arrowheads)

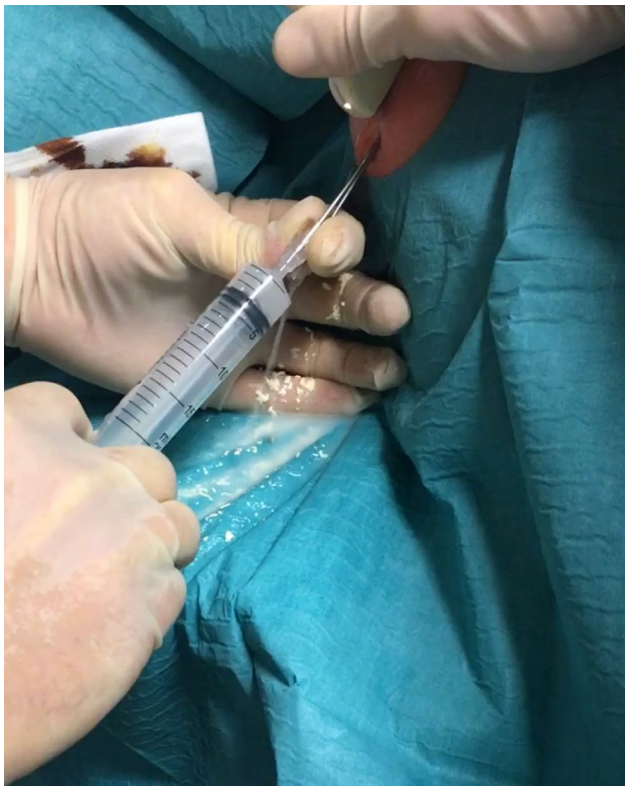

Fig. 3 Photography of the two needles inserted in the shoulder tendon and calcification irrigation (milky fluid with calcific deposits is visible on the surgical linen)

Follow-up

All patients were directed back to their referring physician 1 month after US-PICT for the planning and implementation of a rehabilitation program. In case of refractory pain in the short term (e.g., before 30 days), the patients were re-assessed earlier and, in case of any post-procedural residual bursitis, they underwent a cycle of intrabursal steroid injection (three injections in 3 weeks). The referring physician was asked to complete and provide a post-procedural CMS using the same methodology. All patients with missing data were recalled for a visit in October 2019 for completion.

Statistical analysis

All statistical analyses were performed by E.L. who has 5 years of experience in biostatistics, using Stata 13 (StataCorp LP, Texas, USA). Wilcoxon rank-sum tests were performed to compare the CMS before and after treatment in all subgroups. Mann–Whitney *U* test was used to compare the CMS in the ESWT and non-ESWT group. Statistical significance was set at $p < 0.05$.

Results

From 2016 to 2019, 72 US-PICT treatments were performed on 70 patients (females = 46; males = 26) with a mean age of 49.7 years [standard deviation (SD) = 8.7, Table 1]. Two patients received bilateral treatment. Tendons affected were: SSP = 42, ISP = 8, ISP-SSP = 14, Subscapularis (SSC) = 5, SSC-SSP = 2, SSC-SSP-ISP = 1.

Thirty-three (47%) underwent previous ESWT (at least three sessions), while thirty-seven (53%) had no previous treatments. Forty-nine treatments were performed on the right shoulder, twenty-three on the left. Seventeen shoulders were treated using a single needle (24%), 35 using two needles (49%) (Fig. 1), 10 using three needles (14%), 9 using four needles (12%), and one patient with a 4 cm calcification required the use of six needles (1%). The mean calcification size was 15 mm (SD = 6, range 7–40 mm).

No treatment-related complications were observed, including bursitis or capsulitis.

Follow-up was averagely 14.4 months (median = 11.6, SD = 11.9, range 1–45); 37 patients had a follow-up shorter than 12 months (1–11.6); 35 patients were visited after more than 1 year (12.2–45.6 months, Table 2).

All patients showed a significant improvement after US-PICT (Fig. 4). Before treatment, the mean CMS was 35 (SD = 21); after treatment, it reached 75.4, with an average CMS improvement of 40.3 points (SD = 23.7, $p < 0.001$).

The ESWT group included 33 patients (34 shoulders, 18 females and 15 males, Table 2). They had a mean CMS of 38 (SD = 21) before treatment and of 76 after treatment (SD = 12). The mean improvement observed was 37 (SD = 25, $p < 0.001$).

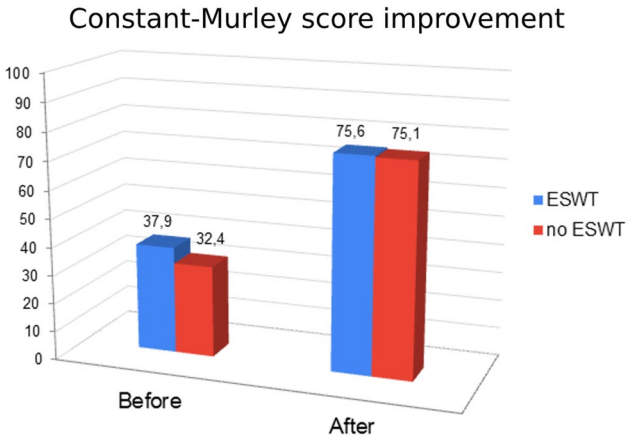

Fig. 4 Column chart showing on the left mean Constant Score before US-PICT treatment in patients who underwent previous ESWT (blue) and who did not (red) and on the right, mean Constant Score after US-PICT treatment in the two groups of patients

The non-ESWT group consisted of 37 patients and 38 shoulders (26 females and 11 males), with a mean CMS before treatment of 32 (SD = 21). After treatment, there was a mean improvement of 43.5 (SD = 25, $p < 0.001$), with a mean post-procedural score of 75.1.

The comparison of improvement between the ESWT and non-ESWT group yielded no significant difference ($p = 0.3$). The detailed results are shown in Table 3.

Discussion

Our main finding is that a previous ESWT in patients with calcific tendinopathy does not affect the outcome of subsequent US-PICT. Currently, there is no consensus regarding the standard treatment of CTRC. According to different studies, rest, physical therapy, and oral NSAIDs administration with or without corticosteroid injection are considered the initial treatment of choice [3]. Failure of conservative management, defined as the persistence

Table 1 Patients and US-PICT characteristics

	ESWT	Non-ESWT	*p* value
Females	19	27	0.181
Males	15	11	
Mean age	49	50	0.761
Calcification size	15 mm (7–40)	15 mm (8–40)	0.873
Needles used	2 (1–6)	2(1–4)	0.757

Table 2 Subgroup analysis of response to US-PICT according to the length of follow-up and previous ESWT treatment (Wilcoxon rank-sum test; $p < 0.05$ is considered significant)

Follow-up	Non-ESWT				ESWT			
	Subgroup	CMS score		*p*	Subgroup	CMS score		*p*
		Before	After			Before	After	
≤ 12 months Mean	*n* = 18 5.6 (1–11.6)	33 (2–56)	76 (24–86)	< 0.001	*n* = 19 6.5 (1–11.6)	40 (2–76)	76 (56–86)	< 0.001
> 12 months Mean	*n* = 20 24 (12.2–45.6)	32 (2–76)	74 (44–86)	< 0.001	*n* = 15 21.7 (12.6–45.6)	35 (2–76)	75 (44–86)	< 0.001

Table 3 Constant–Murley score data comparison of patients who underwent US-PICT with or without previous extracorporeal shockwave treatment

Mean values	ESWT group ($n=34$)		Non-ESWT group ($n=38$)	
	Before	After	Before	After
Pain	2 (0–5)	12 (5–15)	1 (0–5)	12 (0–15)
Activities	3 (0–4)	4 (4–4)	3 (0–4)	4 (4–4)
Arm positioning	7 (2–10)	10 (10–10)	6 (2–10)	10 (6–10)
External rotation	1 (0–2)	2 (2–2)	1 (0–2)	2 (2–2)
Internal rotation	4 (0–10)	9 (0–10)	3 (0–10)	9 (0–10)
Forward flexion	5 (0–10)	9 (0–10)	4 (0–10)	9 (0–10)
Lateral elevation	6 (0–10)	10 (4–10)	4 (0–10)	9 (4–10)
Strength	9 (0–25)	21 (10–25)	8 (0–25)	20 (0–25)
Total Score	38 (2–76)	76 (44–86)	32 (2–76)	75 (24–86)
Improvement	37 (SD = 25, $p<0.001$)		43.5 (SD = 25, $p<0.001$)	
Calcification size (mm)	15 (SD = 6)		15 (SD = 7)	

of symptoms for more than 3 months after therapy start, prompt noninvasive (ESWT) or minimally invasive (US-PICT) treatments. There are currently no criteria to define whether a patient should undergo ESWT rather than US-PICT. One study depicts US-PICT as the preferred treatment in the case of grade II or III calcification (according to Gartner and Heyer classification [13]). In the same paper, contraindication to US-PICT treatment is defined as calcification size < 5 mm or migration of the calcification into the bursal space [22]. Surgical approach with arthroscopy is reserved for chronic cases in which any other treatment has failed.

Although treatment choice is based on own experience and skill, ESWT is frequently preferred for its less invasiveness and wider availability [23]. However, De Boer et al. [24] showed that US-PICT resulted in better clinical outcome improvement and observed a substantial increase in CMS and a faster dissolution of calcium deposits within the treated tendons at 6 weeks from the procedure. Furthermore, US-PICT allows for the cleansing of the diseased tendon [25] by means of needling and saline flushing, preventing dehydration and long-term hardening. The significant CMS improvement observed in both groups of this study suggests that US-PICT is highly effective and may be proposed to all patients complaining of shoulder pain due to calcification, including those with a history of prior unsuccessful ESWT. These, added to the fact that ESWT has little effect on reducing calcification size [24], which may lead to recurrent shoulder pain [4], are all reasons for which US-PICT may be preferred as the first-line treatment.

Notably, US-PICT can be performed in patients previously undergoing ESWT only in those cases where the calcification still maintains its original ovoidal shape inside the tendons with no substantial fragmentation. This is the reason why in our analysis, we did not consider patients in whom previous ESWT determined a fragmentation of the deposit, who were not eligible for US-PICT. However, it is acknowledged that ESWT in addition to US-PICT significantly improves CMS, when compared to ESWT alone [26].

As an exclusion criteria, we decided to omit fragmented calcifications from our analysis, since US-PICT is usually less efficacious in this setting [27]. Indeed, the absence of a formed shell increases risk of intrabursal calcification spread [27]. Moreover, smaller deposits are more difficult to target and fragment [2]. However, US-PICT has been used successfully also in these circumstances [3]; hence, this is acknowledged as a limit of our study.

Noteworthy, in our experience, no treatment-related complications occurred after the 72 procedures performed, as an additional confirmation that US-PICT is a safe technique with very low risk of adverse events [28].

As a technical note, some authors prefer lidocaine for both local anesthesia and calcium aspiration [14, 29], while in our experience mepivacaine is used for anesthesia and warm saline for dissolving the calcium core. Our choice of saline over lidocaine was based on the evidence that is at least as effective at core fragmentation [21], while mepivacaine is the standard local anesthetic in use in our Institution.

Nonetheless, the following limitations to this study are to be acknowledged. First, as a retrospective analysis, there is a lack of direct comparison between US-PICT and ESWT. In particular, we did not register the time elapsed between the last ESWT session and US-PICT; thus, we cannot report on the potential short-term benefits experienced by our patients after ESWT. Moreover, none of our patients underwent ESWT after US-PICT, preventing us from performing an inverse comparison. Afterward, our patients received the second CMS scoring after very different time intervals. On the one side, this allowed to create two subgroups and compare short-term with long-term results (Table 2); on the opposite side, it may have represented a confounding factor which should be avoided by planning a rigorous follow-up with CMS scoring at exact time intervals before directing the patients back to their referring physician. Third, we did

not classify calcification according to their stiffness (Fig. 1), for example, with elastosonography, to test whether ESWT may be linked to calcification hardening.

The main strengths of this report are the use of a standardized questionnaire as previously recommended in a recent systematic review [5], the highly significant evidence resulting from all tests executed and having the same operator performing all treatments.

Conclusion

US-PICT is efficient for the treatment of CTRC regardless of previous ineffective ESWT treatment on the affected shoulder and can be recommended in cases refractory to shockwave therapy. Further studies aimed at a direct and prospective comparison of ESWT vs. US-PICT are needed to achieve a consensus for the first-line treatment of this widespread condition.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical standards All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Ethics approval Ethics approval was obtained by the IRB of Humanitas Research Hospital IRCCS.

Informed consent Informed consent was obtained from all individual participants included in the study.

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