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MUSCULOSKELETAL

US-guided percutaneous treatment and physical therapy in rotator cuff calcific tendinopathy of the shoulder: outcome at 3 and 12 months

Giulio Pasquotti[1] · Alex Faccinetto[2] · Umberto Marchioro[1] · Matteo Todisco[2] · Vincenzo Baldo[3] · Silvia Cocchio[3] · Giorgio De Conti[1]

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Abstract
Objectives To monitor the results of ultrasound (US)-guided percutaneous treatment of calcific tendinopathy of the shoulder at 12 months (T12) after treatment (T0). To verify the possible relations between some pre- and post-procedural variables with the clinical outcome at T12.
Methods Forty-seven patients (26 female and 21 male) were enrolled in the study. Patients' approval and written informed consent were obtained. Symptoms were assessed by Constant Shoulder Score (CSS) at T0 and T12. Thirty of these also underwent a CSS control at 3 months (T3). The treatment efficacy was statistically tested for relation with location and type of calcification, characteristics of the tendon and subdeltoid bursa, impingement, and rehabilitation treatments.
Results There was a significant increase in the average CSS value between T0 and T12 (40.7 vs. 75.3). The variables analysed did not show a statistically significant effect on the outcome at T12. A link was noticed only between patients' increasing age and score improvement, particularly among female subjects.
Conclusion US-guided treatment of calcific tendonitis is a viable therapeutic option. No pre- or intra-procedural parameters emerged which might help in predicting the outcome, apart from patients' needs in everyday life.
Key points
- *US-guided tcreatment of shoulder calcific tendinopathy is an excellent therapeutic option*
- *Long-term results seem greatly affected by patients' features and needs in everyday life*
- *No proven pre- or intra-procedural parameters emerged that might predict the outcome*

Keywords Calcific tendinitis of the shoulder · US-guided percutaneous treatment · Shoulder impingement · Subacromial bursal thickening · Rehabilitation

Abbreviations
SADB subacromial subdeltoid bursa
CSS Constant Shoulder Score

Introduction

Calcific tendonitis of the shoulder is a condition caused by hydroxyapatite deposits in the area of the tendons of the

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✉ Giulio Pasquotti
gpasquotti@libero.it

Alex Faccinetto
alexfaccinetto@gmail.com

Umberto Marchioro
umberto.marchioro@sanita.padova.it

Matteo Todisco
mat.todisco@gmail.com

Vincenzo Baldo
vincenzo.baldo@unipd.it

Silvia Cocchio
silviacocchio09@gmail.com

Giorgio De Conti
giorgio.deconti@sanita.padova.it

[1] U.O di Radiologia I, Azienda Ospedaliera Universitaria di Padova, via Giustiniani 2, 35100 Padova, Italy

[2] Istituto di Radiologia, Università degli Studi di Padova, Padova, Italy

[3] Department Molecolar Medicine Institute of Hygiene, Laboratory of Public Health, University of Padua, Padova, Italy

rotator cuff and is characterized by recurrent episodes of pain associated with functional limitation. Pain and limitation may vary from a moderate to a very severe degree, the latter being usually related to episodes of hyperacute inflammation triggered by the body in an attempt to spontaneously reabsorb crystals. Inflammation usually affects both the tendon and the adjacent subacromial subdeltoid bursa (SADB), sometimes also with calcium crystals passing through and depositing in the SADB itself. Several acute episodes may occur, depending on the size of calcification and on resorption efficacy, and pain may also become chronic due to persistent bursal inflammation (subacute/chronic bursitis). Conversely, in the absence of hyperacute phases, chronic symptoms may arise caused by the presence of the calcification with chronic irritation of adjacent structures [1–4].

Ultrasound (US)-guided treatment of intratendinous calcifications is an established therapeutic option, particularly effective against hyperacute pain, as it can be performed in a very short time in addition to giving immediate pain relief following the emptying of the calcification itself. Numerous studies in the literature have analysed and optimized its performance methods and also demonstrated that the treated tendon stays intact over time [5].

There are not many studies on the long-term efficacy of this procedure. Factors that can have an influence on the procedure have been studied very little as well. In theory, these factors might include both pre-procedural characteristics, such as the time from the onset of symptoms, calcificationand contiguous tissues features or the patient's clinical condition, and post-procedural variables. In support of this, the literature has reported that the extent of daily efforts (sports or work-related) or the development of incorrect posture as an antalgic reaction may be responsible for persistent bursal inflammation [6, 7]. However, little has been explored in the literature on the post-procedural management of the patient. An evaluation was attempted by Fusaro et al., who demonstrated the efficacy of a combined approach with percutaneous treatment and rehabilitative functional physiotherapy [4]. This study has limitations, though. For example, no comparative assessment was carried out between patients who underwent rehabilitative physiotherapy and those who did not.

Our work is aimed at monitoring the results at 3 (T3) and 12 months (T12) after treatment (T0), testing any possible relation between some parameters evaluated before the procedure and the outcome at T12, as well as between such outcome and any post-procedural physiotherapy treatments.

Materials and methods

Ninety-seven patients with calcific tendonitis of the shoulder (52 females, 45 males; age range 31–76 years; average age 45.4 years; total number of treated shoulders 99) were recorded between June 2011 and June 2013 at the US Interventional Service of our department. Patients had the diagnosis made previously, not only at our institution, and then confirmed just before scheduling.

All patients treated provided their written informed consent on a document previously approved by our department review board. Before treatment, each patient underwent US examination, as well as X-ray or MR examination, and completed Constant Shoulder Score (CSS) under the supervision of a physician. CSS is a widely used score specific to the shoulder and is based on a combination of objective tests and subjective evaluations (Table 1) [8–10].

Patients who had been previously treated with other types of injections or physical therapy, such as shock waves, were excluded from the study.

Pre-procedural U.S. study

The preliminary US evaluation was carried out with high-resolution linear transducers (9–14 MHz) by an experienced radiologist (at least 8 years of experience) in musculoskeletal US: US examination was recorded in AVI video format and archived. After that, the examination video was re-evaluated by two other radiologists (each with at least 4 years of experience) in order to achieve agreement in the evaluation of the parameters under study.

US parameters analysed: 1) Type of calcification based on Bianchi-Martinoli's classification [11]: type I, hyperechoic foci with a well-defined acoustic shadow (Fig. 1; Video 1); type II, hyperechoic foci with soft shadow; type III, hyperechoic foci without shadowing (Fig. 2). 2) Site of calcification by identifying two sub-groups: clear intratendinous calcifications; sub-bursal calcifications, focally deforming the contour of the tendon examined on the bursal side. 3) Calcification size. 4) Characteristics of the tendon, divided into: regular; degenerated (tendinosic), in the presence of loss of integrity and continuity of the fibrillar texture, tendon echogenicity, tendon thickening; injured, in the presence of partial or complete lesions. 5) The presence of subacromial impingement, as assessed through dynamic test in abduction of the arm [12].

In the analysis of tendon characteristics and of the presence/absence of subacromial impingement, the US was integrated with any available MR or X-ray images.

US-guided treatment procedure

All US-guided percutaneous procedures were performed by a radiologist (or blinded) with several years of experience (at least 8 years) in the treatment of shoulder calcifications. A second operator was also present to assist in US guidance. Type I, type II, and >15-mm sized calcifications were treated with a two-needle technique, with a procedure similar to the

Table 1 Constant Shoulder Score

Parameters	Points
Pain	
None	15
Mild	10
Moderate	5
Severe	0
Activities of daily living	
Activity level	
Full work	4
Full recreation/sport	4
Unaffected sleep	2
Positioning	
Up to waist	2
Up to xiphoid	4
Up to neck	6
Up to top of head	8
Above head	10
Total	20
Range of motion	40
Power (1 point per pound of weight held in abduction by arm at 90°	25
Total	100

one described in detail in previous articles [5, 13], while all type III calcifications and those <15 mm were treated with a single-needle technique (16 or 18 gauge) (Fig. 2). In all cases, at the end of procedure, 40 mg of methylprednisolone acetate (40 mg/mL DepoMedrol; Pfizer Manufacturing Belgium, Puurs, Belgium) was injected directly into the SADB diluted in 4 mL of saline. Before the cortisone injection, the bursa was distended with a variable amount of saline, depending on the grade of adhesion, in order to obtain uniform distribution of the drug.

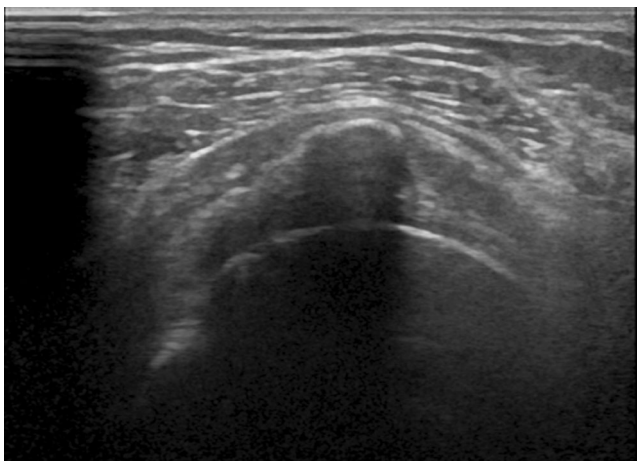

Fig. 1 Type 1 calcification based on Bianchi-Martinoli's classification. An elongated hyperechoic mass is shown with a well defined acoustic shadow inside the supraspinatus tendon, also with thickening of the overlying subdeltoid bursa. The calcification is located just below the subacromial-subdeltoid bursa (sub-bursal position). Another example is shown in Video 1

During the procedure, SADB were divided into two groups according to the response to distension: elastic bursae, with normal relaxation following liquid injection and with no evidence of significant fibrous strands or laciniae inside them (Video 2); fibro-adhesive bursae, with reduced distension following liquid injection and evidence of fibrous strands and laciniae inside them (Videos 3–4).

As indicated by literature, at the end of treatment, patients were advised to [5, 14]: rest and refrain from lifting weights for at least 1 week, in addition to applying ice locally; Take medications such as analgesics and NSAIDs (unless contraindicated) to soothe post-procedural pain if present.

Physiotherapy treatment was recommended to all treated patients. No precise information about the type of physiotherapy to be carried out was given, as there are no definitive studies on the effectiveness of different treatments. In general, we only suggested the need for rehabilitation physiotherapy, based on what Fusaro et al. describe in their work [4]. Patients were instructed to ask for a written report with details of the treatment that had been carried out.

Post-treatment follow-up

The follow-up of treated patients included both clinical and US assessments. All patients participating in this study completed CSS 12 months (T12) after treatment. Thirty of them also responded to a similar control at 3 months (T3). Those who did not respond at T3 for various personal reasons, but who had completed the T12 follow-up were enrolled in the study anyway.

As a minimum satisfaction index in treatment evaluation, an increase of 30 points between Constant Shoulder Score at T0 and T12 was chosen. Thirty was an arbitrarily chosen threshold, as we found that it meant significant improvement in the patient's symptoms. At this time, we wanted to be sure to include only patients with a real and incontestable benefit from the procedure, despite the risk of being excessively strict in the evaluation of the outcomes.

It is common practice that all patients with resumed pain a few weeks (3–8 weeks) after treatment are offered a second intrabursal steroid infiltration (40 mg triamcinolone acetate). Indeed, currently this is the only treatment with proven efficacy, at least in the short term for pain caused by SADB bursitis [15]. However, for the purpose of our study, we only analysed patients who did not accept the second treatment or those who could not undergo it for personal reasons, so as not to add an additional parameter that would complicate things further.

Data on post-procedural physiotherapy rehabilitation treatments were collected according to three different groups: no-

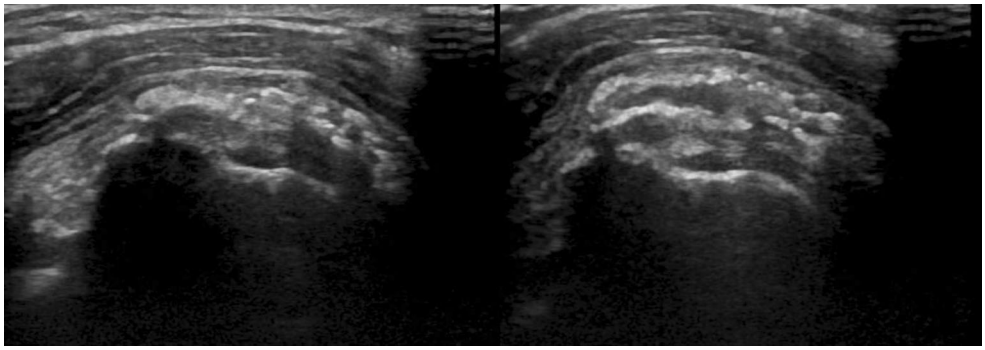

Fig. 2 a) Large type 3 calcification, with only a small nucleus showing posterior acoustic shadow at the periphery. The calcification was in a phase of active reabsorption and was treated with a single-needle technique obtaining prompt remission of symptoms. b) The calcification at the end of the lavage is completely destructurated and opens up easily during saline injection.

treatment; rehabilitation treatment, i.e. at least one rehabilitation cycle working on both active and passive motility and on muscle reconditioning, without resorting to instrumental physiotherapy; combined treatment, i.e. at least one motor rehabilitation cycle (10 sessions), and at least one instrumental physiotherapy cycle (10 sessions) [transcutaneous electrical nerve stimulation (TENS), laser therapy, etc.].

To sum up, the following inclusion parameters were used in the study: calcific tendonitis of the shoulder; no injuries detectable at US to the tendons of the rotator cuff; no other pre-procedural treatments; no post-procedural steroid infiltration in SADB; Constant Shoulder Score (CSS) completed at T0 and at T12.

A total of 47 patients were included (26 women, 21 men; age range 31–74 years; average age 49.4 years). Of these, 30 also joined the control at T3.

Statistical analysis

Data were appropriately checked for normal distribution and analysed using chi-squared test, t-test, and linear regression analysis as appropriate. Stepwise multiple regression analysis was carried out for each parameter to determine which characteristics were independently associated with a cut-off≥30 at 12 months (p-value set at 0.05). Analyses were performed with the Statistical Package for the Social Sciences. The Constant score was corrected as described by Tavakkolizadeh et al [16].

Results

Table 2 summarizes the patients' data at T12. Table 3 summarizes the patients' data at T3. Considering all patients as a whole, the shoulder percutaneous treatment showed an improved mean CSS score from 63.6±12.5 at 3 months to 75.3±15.2 at 12 months (p<0.001). With a satisfaction cut-off point arbitrarily established at 30 points, 46.7 % of patients exceeded the cut-off point at T3, and 59.6 % at T12.

Post-treatment physiotherapy did not show a significant association with better outcome. CSS at T12 was 78.4 in those who underwent physiotherapy and 71.1 in those who did not, with an average CSS at T0 of 38.53 for the former and 44.6 for the latter. At T3, the CSS was 64.6 and 62.4, respectively.

By analyzing the changes in CSS between T0 and T12 with respect to age variable, a linear relation between improvement and age of the patient was noticed, even though it was significant only among the female subjects (R^2=0.067, p=0.023) (Fig. 3).

By analyzing the US parameters registered before procedure, none of these showed a statistically significant influence on CSS at T12 (Table 4).

Discussion

The study confirms the efficacy of US-guided percutaneous treatment for calcific tendonitis of the shoulder, with long-term reduction of symptoms proven both by an increase in the average absolute value of CSS tests and by a>30-point improvement between pre- and post-treatment in most patients.

As for the patients who also underwent control at T3, the results were less positive than at T12, as about 53 % of the controls did not reach the satisfaction cut-off point (Δ CSS> 30). This element seems to match what Del Cura et al [17] found in a study in which nearly half of the patients presented with pain recurrence within about 15 weeks of treatment, with usually temporary relapse (lasting an average of about 6 weeks) and with an intensity lower than the disease peak of pain. The etiopathogenic explanation for pain recurrence seems to be linked to the development of a secondary bursitis [5]. It does not show entirely clear pathogenetic mechanisms and does not seem to result automatically in the development of a subacute/chronic bursitis: this explains why, despite the fact that

Table 2 Distribution of the patients with regard to the pre-, intra-, and post-procedural variables analyzed. Patients are divided into two groups on the basis of being above or below the 30-point cut-off of CSS improvement at T12, with relative percentages

			CSS	Cut-off 30				P
			Mean±SD	Below		Above		
				n	%	n	%	
Subjects		47		19		28		
Rehabilitative therapy	No	16	72.1 (±12.6)	9	−56.3	7	−43.8	
	Functional rehabilitation	13	82.6 (±8.5)	3	−23.1	10	−76.9	0.07
	Combined therapy	18	73.3 (±13.5)	7	−38.9	11	−61.1	0.31
Rehabilitative therapy	No	16	72.1 (±12.6)	9	−56.3	7	−43.8	
	Yes	31	77.2 (±12.4)	10	−32.3	21	−67.7	0.112
Calcification site	Intratendineal	35	75.3 (±12.8)	14	−40	21	−60	
	Sub-bursal	12	65.2 (±12.5)	5	−41.7	7	−58.3	0.91
Calcification type	I	18	72.3 (±14.1)	8	−44.4	10	−55.6	
	II	19	75.8 (±12.3)	8	−42.1	11	−57.9	0.89
	III	10	75.8 (±10.9)	3	−30	7	−70	0.45
Bursal distention	Elastic	30	75.8 (±12.9)	13	−43.3	17	−56.7	
	Fibro-adhesive	17	75.8 (±12.2)	6	−35.3	11	−64.7	0.59
Tendon	Normal	26	75.8 (±9.7)	10	−38.5	16	−61.5	
	Tendinopathy	21	75.8 (±14.5)	9	−42.9	12	−57.1	0.76
Impingement	No	30	75.8 (±11.2)	11	−36.7	19	−63.3	
	Yes	17	75.8 (±13.7)	8	−47.1	9	−52.9	0.485

Table 3 Distribution of the patients with regard to the pre-, intra-, and post-procedural variables analyzed. Patients are divided in two groups on the basis of being above or below the 30-point cut-off of CSS improvement at T3, with relative percentages

			CSS	Cut-off 30				P
			Mean±SD	Below		Above		
				N	%	n	%	
Subjects		30		16		14		
Rehabilitative therapy	No	8	61.6 (±14.4)	6	−75	2	−25	
	Functional rehabilitation	8	70 (±13.3)	2	−25	6	−75	0.05
	Combined therapy	14	61.5 (±16.5)	8	−57.1	6	−42.9	0.4
Rehabilitative therapy	No	8	61.6 (±14.4)	6	−75	2	−25	
	Yes	22	64.6 (±15.7)	10	−45.5	12	−54.5	0.15
Calcification site	Intratendineal	23	65 (±14.9)	12	−52.2	11	−47.8	
	Sub-bursal	7	59.8 (±16.4)	4	−57.1	3	−42.9	0.81
Calcification type	A	12	64.2 (±18.2)	7	−58.3	5	−41.7	
	B	12	62.6 (±14.1)	6	−50	6	−50	0.68
	C	6	65.5 (±12.4)	3	−50	3	−50	0.74
Bursal distention	Elastic	18	63.6 (±16.3)	10	−55.6	8	−44.4	
	Fibro-adhesive	11	64.2 (±13.7)	5	−45.5	6	−54.5	0.6
Tendon	Normal	20	67.9 (±12.3)	9	−45	11	−55	
	Tendinopathy	10	55.7 (±17.6)	7	−70	3	−30	0.2
Impingement	No	21	67.1 (±14.1)	9	−42.9	12	−57.1	
	Yes	9	56.1 (±15.5)	7	−77.8	2	−22.2	0.07

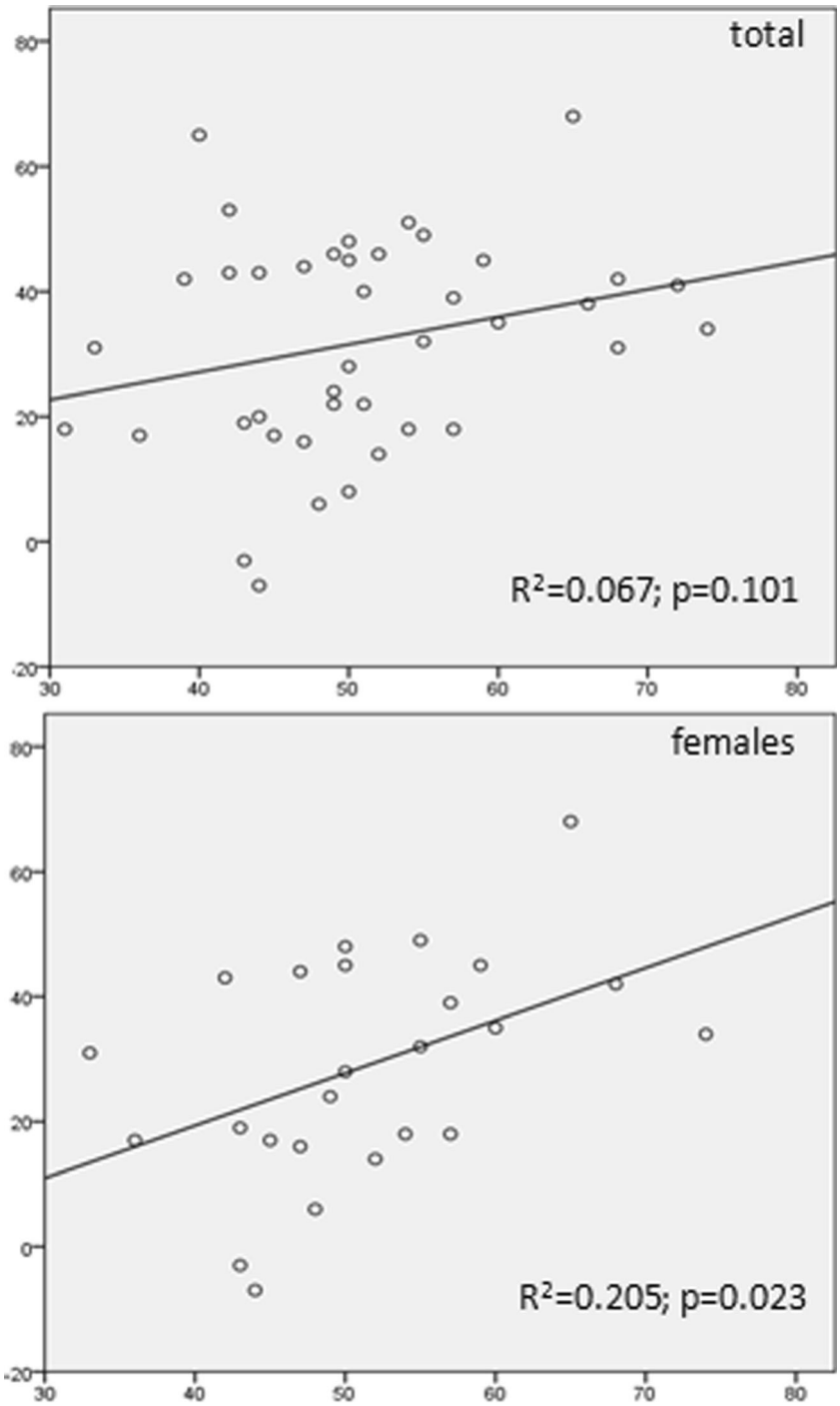

Fig. 3 Distribution of change in Constant Shoulder Score, obtained between CSS at T0 and at T12. Age was the independent variable. A statistically significant correlation resulted between outcome at T12 and age, in female subjects

patients in this study had not received a second intrabursal steroid infiltration, there was still a significant CSS improvement at T12. However, as a rule, our centre recommends a second bursal infiltration to all patients with pain recurrence within 3–8 weeks after treatment, as it allows acting on the symptoms more quickly and very effectively.

The persistence in time of a subacute/chronic bursitis is of great importance. Because it causes persistent pain and functional limitation, it seems, therefore, to be the most frequent cause of long- term patient dissatisfaction besides being difficult to treat. This condition is often maintained by concurrent conditions (for example, arthrosis, impingement) and includes many different conservative options in the post-treatment phase (physiotherapy or infiltrative). However, patients' daily activities and lifestyle also play an essential role. In the light of the last consideration, the statistically significant relation between outcome at T12 and age may be explained, particularly in female subjects, since elderly subjects have a reduced daily

Table 4 Multiple regression analysis carried out for each pre-, intra-, and post-procedural parameter to determine whether there was any characteristic independently associated with a cut-off≥30 at T12 (p=0.05). The dependent variable is a cut-off ≥30 at 12 months. None of these parameters showed a statistically significant influence on CSS at T12

	P	Adjusted OR	Adjusted OR 95 % CI	
			Lower	upper
Age	0.021	1.116	1.017	1.225
Gender (female vs. male)	0.354	0.464	0.091	2.355
Type of calcification				
Type I	0.463			
Type II	0.588	0.594	0.09	3.912
Type III	0.401	2.658	0.271	26.083
Tendon degeneration (yes vs. no)	0.984	1.018	0.178	5.814
Impingement (yes vs. no)	0.465	0.526	0.094	2.947
Bursal characteristics (fibro-adhesive vs. normal)	0.187	3.393	0.554	20.786
Site of calcification (intratendineal vs. sub-bursal)	0.742	1.370	0.211	8.905
Rehabilitation treatment (no vs. yes)	0.295	0.399	0.072	2.223

activity compared to younger ones, resulting in a lower tendency to bursitis recurrence in the short and medium term. An alternative explanation could be that older people are more prone to live with a little chronic pain, thus having a lower impact on CSS compared to younger patients.

The contribution of physiotherapy might play a role of great importance in the outcome of the patients treated. Fusaro et al [4] investigated the effectiveness of rehabilitation therapy after percutaneous treatment. By dividing their patients according to their clinical picture (pain, ROM, etc.) into two sub-groups who had undergone domiciliary or outpatient physiotherapy treatments, the authors proved that at 1 month, the CSS of patients treated with rehabilitation was higher than that of patients treated with high and low energy shock waves. Nevertheless, to date, Philadelphia Panel Evidence-Based Clinical Practice Guidelines [18] and recent systematic reviews [19–21] have pointed out the lack of clinical data able to prove definitively the effectiveness of rehabilitation interventions, also combined therapy, on shoulder joint pain.

As far as our analysis is concerned, the patients who did not undergo any post-procedural physiotherapy treatment showed a lower average CSS than the others, in relation to both at T3 and at T12 measurement, despite the fact that at T0 the average CSS was higher. In the group of patients undergoing physiotherapy, those who were treated with only rehabilitation therapy, that is, working on both active and passive motility and on muscle rehabilitation, showed results comparable to those treated with instrumental methods such as laser, TENS, magnet therapy, or with targeted shock waves. This trend was seen both at T3 and T12 controls, with a slight difference in the average CSS at T0 between the two groups (41.53 vs. 36.33). However, given the small size of the sample and the lack of selection and description of the rehabilitation procedures, these data did not reach statistical significance and might be biased.

No validated and standardized protocol for interventions on post-procedural treatment is available up to now. In our experience, instrumental methods were rather frequently combined with the simple functional rehabilitation therapy, with no clearly unified approaches. Though generally underestimated, this fact might actually have important implications: on the one hand, if not indicated, these treatments might be ineffective, or hypothetically they might even worsen the pain [18, 22, 23]. On the other hand, we should also take into consideration the socio-economic impact on the patient, both from a financial point of view and in terms of time required for therapies, which will inevitably affect the patient's overall satisfaction.

As for US parameters assessed before treatment and their impact on clinical outcome, none showed a statistically significant relation either positively or negatively. The location of calcification with respect to the tendon had been taken into account by assuming that a more severe chronic bursitis was more likely to occur if it was near SADB rather than in a more central position. The type of calcification had been evaluated to verify if a calcification undergoing active resorption (type III) or with previous partial resorption phases (type II) could cause the onset of a more severe or refractory pain to therapy, owing to crystals passing through the bursa (chronic bursitis). This assumption is based on the classification laid out by Uhthoff (also called "Uhthoff's cycle"), where type I calcifications are attributed to the "formative stage", while types II and III to the "resorptive phase" of hydroxyapatite crystals [1]. The affected tendon structural alteration did not appear to have a significant impact on the outcome either. Regarding subacromial impingement, its coexistence with calcific tendonitis of the shoulder was not uncommon among our group of patients (17 of 47), especially as age increased. However, we noticed that a high number of these patients showed a significant improvement in

post-treatment lasting 12 months, thus proving that the percutaneous treatment of calcification, the steroid injection in SADB, and rehabilitation physiotherapy have a rational and a positive clinical response in this particular subgroup too, especially when there are contraindications or refusals to undergo surgery.

Lastly, we also tried to find out if bursal distension, assessed by the operator during the procedure, led to a change in clinical outcome: some SADB appear to distend rather easily through a saline injection, while others show many laciniae, as well as a poor or very difficult distensibility. The latter were labelled as fibroadesive, and we tried to assess whether they were associated with a persistent subacute/chronic bursitis, thus leading to a worse outcome. Statistics did not support this hypothesis.

Our study has several critical limitations. First, the small population of recruited patients limited significantly the possibility to reach statistically supported conclusions. Then, defining easily reproducible and standardizable pre- and intra-procedural parameters to evaluate was also problematic. Finally, the lack of a standardized physiotherapeutic protocol and in general of a standardized post-treatment approach resulted in different treatment proposals to the patients. This occurred not only for the reluctance of the professional figures involved to actively cooperate (in our opinion mainly for economic reasons), but also for the intrinsic difficulty of such a standardization. Next goal for the future will be to standardize further the pre-, intra-, and post-procedural parameters that might affect the outcome of the procedure, and then test them on a wider cohort of patients.

Conclusion

The percutaneous treatment of intra-tendon calcifications of the shoulder is an effective and validated treatment option, whose long-term results seem affected by patients' needs in everyday life. Apart from that, up to now no proven pre- or intra-procedural parameters emerged that might help in predicting the outcome.

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