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ORIGINAL ARTICLE

Extracorporeal shockwaves *versus* ultrasound-guided percutaneous lavage for the treatment of rotator cuff calcific tendinopathy: a randomized controlled trial

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ABSTRACT

BACKGROUND: Extracorporeal shockwave treatment (ESWT) and ultrasound-guided percutaneous lavage (UGPL) are two effective ways of treating rotator cuff calcific tendinopathy (RCCT).
AIM: The aim of the present study was to compare the effectiveness of these techniques in the treatment of RCCT.
DESIGN: Prospective, randomized, controlled trial.
SETTING: Patients treated in our sports medicine and rehabilitation center (Centro Médico Deyre, Madrid. Spain) between January 2007 and December 2013.
METHODS: This randomized study compares the results achieved with these techniques over one year following their use to treat the above condition. Eighty patients received ESWT and 121 received UGPL. A visual analogue scale was used to measure pain, and ultrasound to determine the extent of calcification, at 3, 6, and 12 months after treatment.
RESULTS: Pain and the amount of calcification were significantly reduced by both techniques at 3, 6 and 12 months ($P<0.001$ for each), but significantly more so by UGPL ($P<0.001$).
CONCLUSION: Both techniques are valid for the treatment of RCCT, although UGPL is associated with a greater reduction of calcification and greater reduction in pain.
CLINICAL REHABILITATION IMPACT: The results obtained applying UGPL, the low cost and the lack of complications should therefore make the treatment of choice in centers that are appropriately equipped and staffed.

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Key words: Tendinopathy - High-energy shock waves - Ultrasonography - Therapeutic irrigation.

Rotator cuff calcific tendinopathy (RCCT) is the most common cause of shoulder pain, with an incidence of 5-39% in the general population.[1, 2]

The classic recommendation for the treatment of RCCT is conservative physiotherapy;[3] surgery is only considered if no clinical improvement is seen after six months.[4] Surgery provides better results than physiotherapy and reduces the risk of tendon rupture,[5, 6] but it is not the first treatment option for several reasons. If the calcification is large, resection may cause a tendon defect or even a breakage, which then requires repair.[7] Furthermore, surgical treatment usually requires hospitalization and a general anesthetic, making it a more costly and potentially less safe option.[8, 9] Finally, reha-

bilitation treatment is necessary after surgery, further inflating costs.[10] Two minimally invasive alternatives to surgery might, however, be considered: extracorporeal shockwave treatment (ESWT) and ultrasound-guided percutaneous lavage (UGPL). A number of studies have confirmed the effectiveness of the former,[11-17] and in recent years good results have been reported with the latter,[9, 18-23] but no study has yet compared them. The aim of the present study was to make this comparison.

Materials and methods

Study design and patients

The study was designed as a randomized, prospective, 12-month longitudinal comparison, to compare the effectiveness of ESWT and UGPL in the treatment of RCCT.

The study subjects were recruited from 294 patients who attended our medical center between January 2007 and December 2013. All had a clinical, radiological and ultrasound diagnosis of RCCT. To be included in the study, patients had to show a minimum calcification of 5 mm diameter, a minimum visual analogue scale (VAS) pain score of 6 (where 0 represents no pain, and 10 maximum pain), have no allergies to the medications used. They were excluded patients with any form of tendon rupture, total or partial. The number of patients eligible for inclusion was 243.

Using tables of randomized numbers (www. randomized.org), a collaborator who took no further part in the study randomly assigned patients to undergo either ESWT (N.=121) or UGPL (N.=122). The medical staff involved did not know to which arm the patients had been assigned before treatment began (Figure 1).

All interventions in both groups were performed by specialist medical staff (FCG, JJRA, GRF, and JGP). Clinical examination involving ultrasound scans and X-rays were performed at 3, 6 and 12 months post-treatment. The extent of calcification was determined by a specialist in radiodiagnosis (FCG) and it was always measured by ultrasound imaging.

In agreement with the Declaration of Helsinki regarding research on human subjects,[24] all patients were informed of the characteristics of the study and gave their informed consent to be included. The study was approved by the ethics committee of the Universidad Alfonso X el Sabio de Madrid (Madrid, Spain).

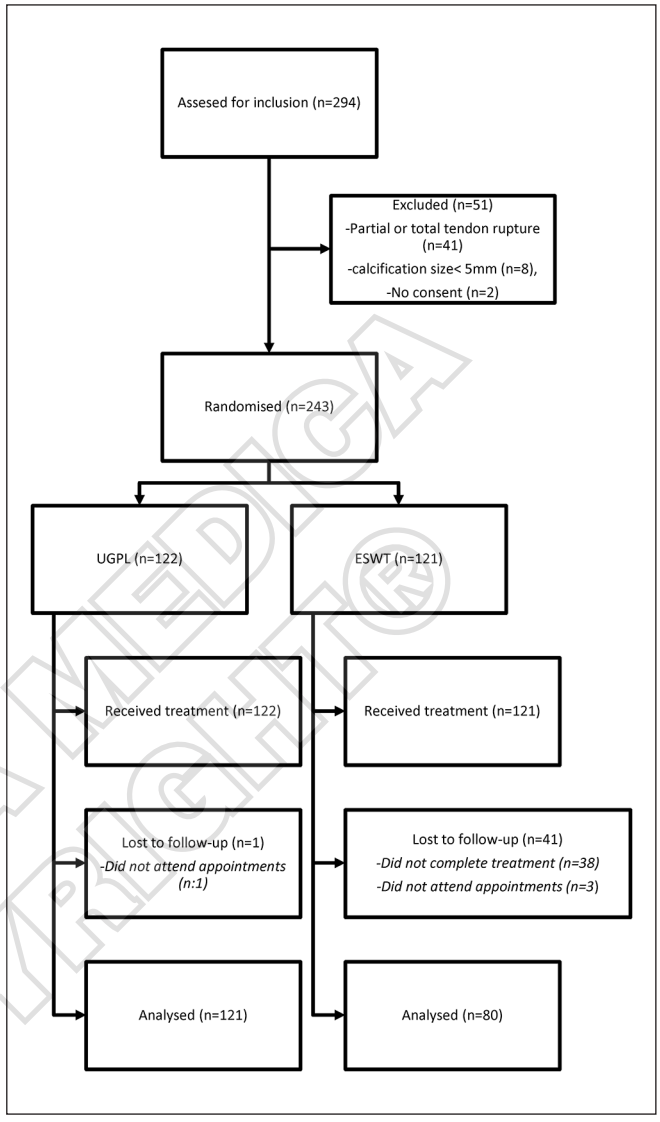

Figure 1.—Flow diagram showing how the study population was selected and treated.

Materials

Ultrasound diagnoses and the measurement of calcification size were performed using a TOSHIBA Xario SSA-660A equipped with a multifrequency probe (8-12 MHz). A portable I-Scan 4400 (FM.Control®) fluoroscope was used for radiological monitoring. UGPL was performed using 18-G and 20-G 10-mL syringes. ESWT was provided using the Swiss DolorClast® device.

Ultrasound-guided percutaneous lavage

This technique does not require patients refrain from eating or drinking prior to treatment, nor meet any other condition. Patients were provided an anxiolytic (bromazepam 1.5 mg) 30 minutes before the procedure to reduce the possibility of the appearance of vagal syndrome.

A prior ultrasound examination was used to determine the position of the shoulder that would leave the calcification most accessible from the cutaneous plane. The procedure was performed with the patient sat in a chair with armrests, facing the physician, with the shoulder rotated internally and the forearm placed on the back. This position increases the pressure within the tendon and facilitates the movement of the calcium into the syringe. All patients were told to hold this position during the entire procedure, which lasts about 30 minutes. The needle insertion point was marked on the skin. Asepsis was guaranteed by swabbing with iodated povidone.

Under aseptic conditions, a 10-mL syringe filled with 2% mepivacaine, a 5-mL syringe containing triamcinolone, several syringes containing sterile physiological saline, and 18-G and 20-G needles were laid out on a sterile gauze.

The procedure was begun by injecting the mepivacaine into the skin using a syringe with a 20G needle, and placing the ultrasound probe over the trajectory to cover (from the entry point to the calcification). The needle was gradually pushed towards the calcification, anesthetizing from the point of entry in the skin through to the subacromial bursa. The needle was then placed below the calcification, and the remaining anesthetic used to begin its fragmentation and lavage, working the plunger with a forward pumping movement only, *i.e.*, without aspiration (Figure 2). These impulses were kept up until the calcified material began to leave the calcification and enter the syringe. When the syringe body was full it was replaced by one containing physiological saline, but without removing the needle from its position. The same lavage and pumping action was then performed again. The procedure was repeated until no more calcified material could be withdrawn, until the calcification had been completely fragmented, or until the patient showed signs of discomfort. At this point the syringe body was switched (without withdrawing the needle) for that containing 2 mL triamcinolone. The needle was then gradually extracted as far as the bursa where the syringe contents were emptied, before being completely removed. The insertion point in the skin was then covered with a sterile gauze. In patients with a hard calcification, or in which the needle became blocked due to the entry of dense material, the latter was switched for an 18-G one.

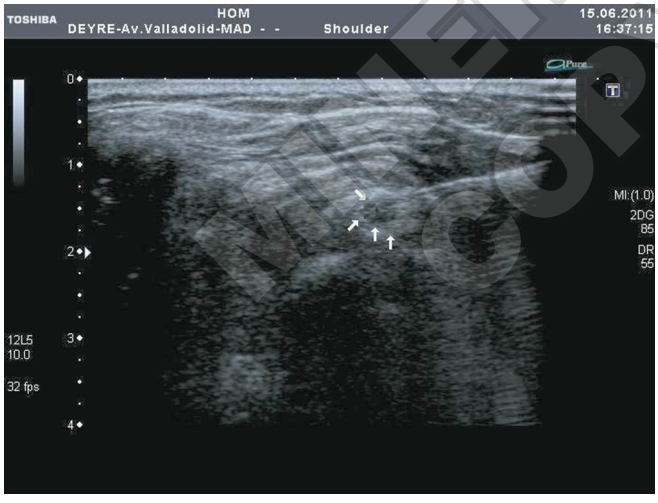

Figure 2.—In the UGPL technique, the insertion of liquid induces pressure on the calcification as the syringe plunger is pushed down (arrows). The calcified material flows back into the syringe as the plunger naturally recedes.

Extracorporeal shockwave treatment

This was performed with the patient sat in a chair with armrests and facing the physician. A conducting gel was placed on the area where the waves were to be transmitted. The calcification was localized by fluoroscopy, and the point on the skin where the shockwaves would be delivered identified (Figure 3). A total of 2000 impacts (two series of 1000 each) at a frequency of 8-10 Hz and an energy density of 0.20 J/mm^2 was then delivered with the shockwave emitter in direct contact with the skin. This was performed twice per week for four weeks. After each session the patient was monitored in the waiting room for a few minutes to make sure no complications had arisen before discharge. The procedure can be painful, especially at the start of therapy, but never requires local anesthetic.

All patients were told to continue their normal lives, but to avoid overloading the affected shoulder for one week. All were told to take the same oral non-steroidal

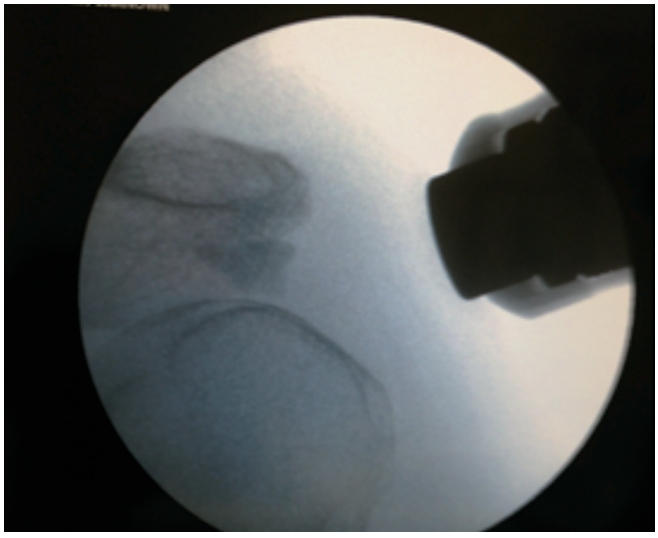

Figure 3.—Fluoroscopy-guided placement of the shockwave emitter over the calcification.

inflammatory drug (ibuprofen 600 mg/12 h) for three days if there was no contraindication.

Physical activity and relationship with RCCT

The patients were classified into one of four activity groups according to energy expenditure or profession-determined energy demand following the criteria of the National Institute of Health of Spain (INSS):[25] Grade 1, low expenditure or profession-determined energy demand; Grade 2, moderate expenditure or profession-determined energy demand; Grade 3, mid-high expenditure or profession-determined energy demand; Grade 4, very high expenditure or profession-determined energy demand.

Statistical analysis

Descriptive analysis was performed for all quantitative and qualitative data. The Kolmogorov-Smirnov test was used to confirm that the quantitative variables were normally distributed and the Student's *t*-test to analyze differences between the means. Pearson correlation coefficients were calculated to establish bivariate relationships. Contingency tables were used to explore the relationship between qualitative variables. The Fisher exact test or the χ^2 test was used to analyze the influence exerted by one qualitative variable on another, and ANOVA for repeated measures was used to study behavior over time. Significance was set at $P<0.05$. All calculations were performed using SPSS v.19.0 software for Windows.

Results

The analyzed patient sample included 137 women (68.16%) and 64 men (31.84%). The mean age of all patients (137 F, 64 M) was 49±7 [48; 56], without significant difference between both sex (P=0.32). One hundred and eighty one patients showed calcification of the supraspinatus tendon only, nine showed calcification of the subscapularis tendon only, five showed calcification of the supraspinatus and infraspinatus tendons, and six showed calcification of the supraspinatus and subscapularis tendons.

The mean calcification size before treatment was 12.07±4.8 mm, and the mean VAS pain score was 7.43±0.99. No significant differences is seen between the two procedure groups in terms of either variable (p=0.088 and P=0.798, respectively).

The pain score of both groups decreased over time (P<0.01) (Figure 4). Significant differences is seen between the techniques in terms of the reduction in pain at all-time points (3, 6 and 12 months) with the UGPL treatment the more effective (P<0.01). With the UGPL technique, pain was completely relieved in 89.26% of patients. The ESWT technique achieved freedom from pain in 65.0% of patients at 12 months

Both techniques led to significant reductions in the size of the calcification over time (P<0.01) (Figure 5). However, significant differences is seen between the techniques in terms of calcification size at all-time points (3, 6 and 12 months) with the UGPL treatment again the more effective (P<0.01). With the UGPL technique, complete removal of the calcification was achieved in 86.78% by 12 months. The ESWT technique achieved complete disappearance of calcification in 55.6% of patients.

A growing positive correlation was detected between the size of the calcification and the pain score over time after treatment in both groups; as the calcification between smaller, the pain became less intense (Table I).

Complications were minimal in both groups. In the UGPL group, 5% of patients suffered a vagal reaction

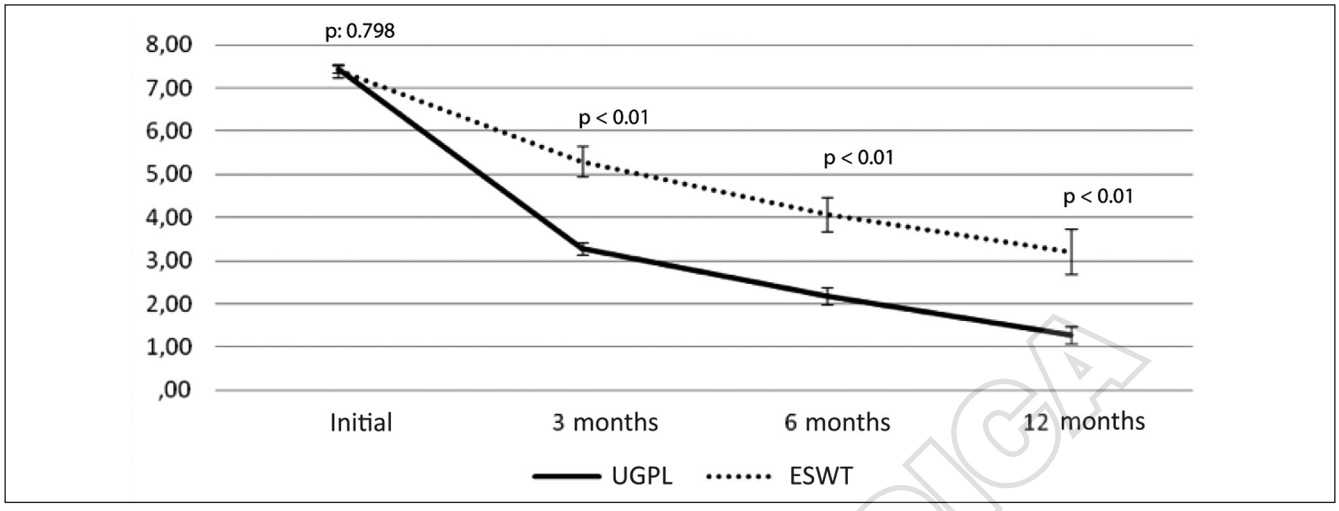

Figure 4.—Post-treatment change in sensation of pain (as measured on a visual analogue scale) over time.

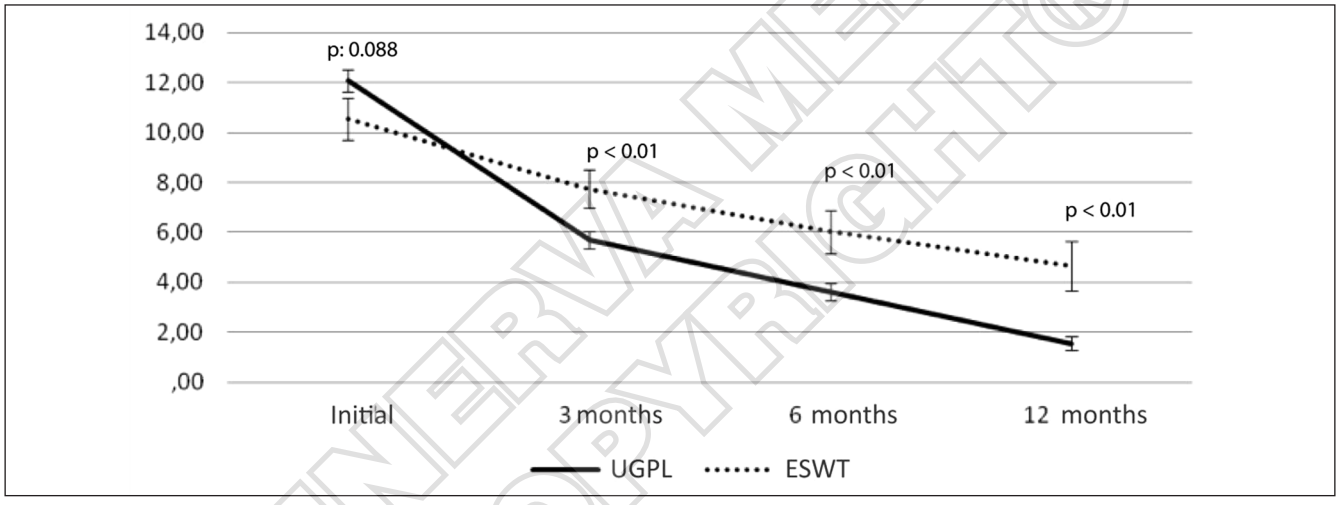

Figure 5.—Post-treatment change in size of calcification over time.

TABLE I.—*Pearson correlation (ρ) between calcification size and pain score over time. Significance was set at P<0.05.*

		Before	3 months	6 months	12 months
UGPL	ρ	0.181	0.492	0.820	0.784
	P	0.427	0.003	0.001	0.001
ESWT	ρ	0.572	0.329	0.496	0.719
	P	0.001	0.038	0.001	0.001

either during or immediately after the procedure. All resolved without the need to interrupt the procedure or administer any medication. No complication is seen with the ESWT technique, although all patients reported slight discomfort (not above a VAS score of 2). No other complications were reported at any time.

In the examination of the relationship between physical activity and the appearance of RCCT, 130 patients

(64.68%) fell into Groups 1 and 2 (low and moderate energy expenditure or profession-determined energy demand), and 71 (35.32%) into Groups 3 and 4 (mid-high and very high expenditure or profession-determined energy demand).

Discussion

Several UGPL techniques have been described. Some require the use of two needles,[9, 22] and some actually puncture the calcification and aspirate the content.[18] However, no differences in result are seen whether the calcification is aspirated or not;[23] some authors therefore discourage it since it could increase the risk of damaging the tendon and blocking the needle.[20, 23] When performing the technique, a 20-G needle is always preferred. If a smaller bore is used, the calcified material can causes blockages; if a larger bore is used, the risk of damaging the tendon is greater.[19] At our clinic, the calcification is not directly entered in order to break it up. Rather, the needle is introduced under the calcification and then pressure applied by injecting 2% mepivacaine and then physiological saline. The diluted calcium deposits enter the syringe as the plunger naturally recedes, without the need for forced aspiration. This minimizes the risks of damaging the tendon and obstructing the needle lumen.[19] Since a significant reduction was seen in the size of the calcification at all times post-intervention, aspiration is clearly not needed. Certainly, there is no need to introduce two needles (one to introduce the anesthetic and saline, the other to aspirate). The procedure can therefore be performed by a single person.[19] The present UPGL results are better than those reported by other authors using other techniques.[9, 20, 26, 27]

There is no consensus with regard to the number of sessions of ESWT required; between 1 and 6 are commonly suggested.[12, 27, 28] In the present work, two sessions per week for four weeks was chosen. Increasing the number of sessions beyond this seems to offer no better results. Neither is there any consensus regarding the energy setting that should be used. In the present work, an intensity of 0.2 mJ/mm^2 was chosen; several authors report better results at high energies such as this.[12, 13, 16, 28] Fluoroscopy was used to locate the shockwave delivery area; treatment is more effective if the shock waves are delivered at the optimum point.[29] Following this protocol, the results obtained were similar to those reported by other authors.[16, 30, 31]

UGPL has the further advantage that it requires only syringes, ultrasound and fluoroscopy (for diagnostic purposes) equipment, while ESWT requires these last two plus expensive shockwave delivery apparatus. In addition, patients have to attend several clinical sessions.[12, 32, 33] ESWT does offer the advantage that it requires less specialized personnel to perform it. However, UGPL is recommended as the treatment of choice in clinics with sufficiently trained personnel. When staffs are less well trained, ESWT provides a viable alternative.

In the present work, the UGPL technique was significantly more effective at reducing pain and calcification than the ESWT technique, although both provided significant improvements (the results cannot be compared to those of any other authors since no comparative study has previously been performed). The literature contains no studies on the change in size of the calcification, its morphology or clinical manifestation over the long term. In the present work, a strong correlation was seen at 12 months between the reduction in the size of the calcification and the pain experienced by the patients.

The study suffers from the limitation that, although the groups were randomly formed, some patients were excluded on the basis of a VAS pain score of <6 and a calcification of <5 mm diameter (these patients received physiotherapy). Further, the study has no control group. Finally, the sample was composed entirely of patients at our own center.

In conclusion, both techniques are valid for the treatment of RCCT, although those achieved with UGPL are better. UGPL is therefore recommended as the treatment of choice if centers have personnel with sufficient training to perform the procedure.

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