Extracorporeal Shock Wave Therapy for Chronic Calcific Tendinitis of the Shoulders: A Functional and Sonographic Study

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ABSTRACT. Pan P-J, Chou C-L, Chiou H-J, Ma H-L, Lee H-C, Chan R-C. Extracorporeal shock wave therapy for chronic calcific tendinitis of the shoulders: a functional and sonographic study. Arch Phys Med Rehabil 2003;84:988-93.

Objectives: To evaluate the therapeutic effect of extracorporeal shock wave therapy (ESWT) in shoulders with chronic calcific tendinitis, to compare the functional outcomes of ESWT and transcutaneous electric nerve stimulation (TENS) therapy, and to investigate which types of calcium deposit effectively respond to ESWT.

Design: Randomized controlled trial.

Setting: Outpatient clinics of the departments of physical medicine and rehabilitation and of orthopedics and traumatology of a veterans hospital in Taiwan.

Participants: Sixty patients with continuous shoulder pain for 6 months or more and with radiographically and sonographically verified calcific tendinitis. Patients were randomly allocated to receive ESWT (33 shoulders) or TENS treatment (30 shoulders).

Interventions: ESWT was performed with 2000 shock waves at 2Hz and energy level between .26 and .32mJ/mm^2 per session. Treatment was given in 2 sessions, 14 days apart. TENS therapy was given 3 times a week for 4 weeks.

Main Outcome Measures: Mean Constant score, visual analog scale (VAS), manual muscle test, and changes of sonographic size and shape of calcium deposits were calculated for 4 time points: at baseline, 2 weeks, 4 weeks, 12 weeks post-therapy.

Results: In both groups, Constant score and VAS improved significantly at 2-, 4-, and 12-week follow-ups ($P<.05$), and the size of calcium deposits decreased significantly at the 4- and 12-week follow-ups. Moreover, the arc-shaped calcific plaques of the rotator cuff were markedly meliorated with ESWT.

Conclusions: ESWT is more effective in the treatment of chronic calcific tendinitis of the shoulder than is TENS therapy, especially for arc-type calcific plaque.

Key Words: Lithotripsy; Rotator cuff; Rehabilitation; Tendinitis; Ultrasonography.

CALCIFIC TENDINITIS of the shoulder is characterized by a reactive calcification that affects the rotator cuff tendons.[1,2] Approximately 50% of patients with calcific tendinitis have shoulder pain, particularly nocturnal discomfort.[3,4] Most patients with calcific tendinitis develop a chronic syndrome that may cyclically precipitate subacute or acute symptoms when there is excessive use of the arm or an acute strain.[1,2] Acute or chronic painful restriction of the range of motion (ROM) of the shoulders limits patients' activities of daily living (ADLs). Many methods have been applied in the treatment of calcific tendinitis of the shoulder, including the use of nonsteriodal anti-inflammatory drugs, local injection with steroid, percutaneous needle aspiration,[5] physical modalities with therapeutic ultrasound,[6-8] or transcutaneous electric nerve stimulation[9] (TENS), and other conservative management methods such as therapeutic exercises.[10]

In 1980, the first clinical extracorporeal shock wave lithotripsy (ESWL) for renal stones was performed,[11] and ESWL treatment for stones in other organs such as the gallbladder, bile duct, pancreases, or salivary glands soon followed.[12] Currently, extracorporeal shock wave therapy (ESWT) in Peyronie's disease is also being studied.[13] Use of ESWT in pseudoarthrosis, tendinopathy, and other orthopedic diseases has recently been reported.[12,14] One promising clinical application of ESWT is the treatment of chronic calcific tendinitis of the shoulder. In previous studies, shock wave therapy reportedly disintegrated calcium deposits partially or completely in about two thirds of the patients, and three quarters showed clinical improvement.[15-18] However, the characteristics of patients who are likely to respond to ESWT remain unidentified.

The purpose of our study was (1) to evaluate the therapeutic effect of ESWT on function and sonographic morphology of calcified plaques in shoulders treated for chronic calcific tendinitis, comparing ESWT with TENS therapy, and (2) to investigate which types of calcium deposit effectively respond to ESWT, thus providing physicians with alternatives before selecting this therapy.

METHODS

Participants

From January 2001 to January 2002, patients with radiographically and sonographically verified calcific tendinitis attending outpatient clinics at the Taipei Veterans General Hospital were recruited. Inclusion criteria required that the patients had either moderate pain (visual analog scale[19] [VAS] score $\geq$4; range, 0–10) or a minimum period of continuous pain for 6 months. Patients were excluded if they had systemic diseases such as rheumatic disease and coagulation disorder; a cardiac pacemaker or other implanted devices; neuropathic, malignant, or infectious causes of pain; rotator cuff tear; previous surgery

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Fig 1. Treatment position: patients sit with their shoulder in the internal rotation position so that the shock wave contact head can approach the lesion site.

for calcification, percutaneous needle aspiration, or glucocorticosteroid injection in the shoulder within 3 months; or were pregnant. Procedural risks were explained and all patients provided written, informed consent. The protocol was approved by the institutional review board of Taipei Veterans General Hospital.

All patients were randomly assigned to ESWT or TENS groups by draw, and they were asked to stop analgesic medication and physiotherapy 2 weeks before the baseline assessment. Functional outcome measurements were performed by the same physician, and patients were treated by the same therapist throughout the study. The baseline and posttreatment sonographic assessments were performed by the same radiologist, who was blind to the assignment of the subjects.

Treatment Method

In the ESWT group, the Orthospec™,[a] was used to give patients shock wave therapy. The Orthospec is a spark gap generator in a mobile unit. The therapeutic zone is ellipsoid in shape, 95mm in height and 25mm in diameter. There is about .29mJ/mm^2 of energy density at the edge of therapeutic zone. The contact head was positioned at the marked painful area, which was defined by sonography before each treatment so that the acoustic shock wave could be transmitted effectively (fig 1). The ESWT was delivered at 2Hz with 2000 shock waves and the energy level ranged from .26mJ/mm^2 (level 5) to .32mJ/mm^2 (level 7), depending on the intensity, which was adjusted to the patient's tolerance.

In the TENS group, hydrocollator pack and TENS were applied to the affected shoulder 3 times a week for 4 weeks. The electrostimulator, Neurosan50,[b] delivered constant square-wave pulse stimulation current with a 0.5ms pulse width and a 10ms interval length to an active electrode secured firmly on the skin at the subacromion painful area. The stimulation frequency was set at 95Hz, and intensity was increased until local contraction of the adjacent muscles was obtained with a mild pain intensity that was acceptable to the patient.[9] The session lasted 20 minutes.

Method of Evaluation

The method of shoulder function assessment used by Constant and Murley[20] allows simple, repeated evaluation at various time intervals, and we did functional and pain assessment accordingly. The Constant score includes subjective parameters: pain (15 points); ADLs (work, recreation/sports, and unaffected sleep that together total 10 points; positioning, 10 points), and objective criteria: ROM (forward elevation, lateral elevation, internal rotation, external rotation, 10 points each; power, 25 points). A maximum of 100 points is attainable. In addition, a VAS (range, 0–10)[19] and a manual muscle test (MMT) were used to assess shoulder function.

Table 1: Baseline Characteristics of the 63 Shoulders Studied in 60 Patients

Characteristic	ESWT Group	TENS Group
Patients (n)	32	28
Age (y)	55.21±2.01	58.00±1.83
Duration (mo)	24.55±6.45	23.90±5.32
Male/female (n)	12/20	9/19
Dominant hand (right/left)	30/2	27/1
Shoulder (n)	33	30
Treatment side (right/left/bilateral)	18/13/1	14/12/2
Constant score (range, 0–100)	63.77±14.22	65.66±15.84
VAS (range, 0–10)	6.50±1.81	6.70±1.42
MMT (range, 0–5), n (%)		
2	1 (3.0)	1 (3.3)
3	6 (18.6)	12 (40.0)
4	19 (57.6)	15 (50.0)
5	6 (18.2)	2 (6.7)
Location of calcification, n (%)		
Supraspinatus	31 (70.5)	27 (69.2)
Infraspinatus	4 (9.1)	3 (7.7)
Subscapularis	8 (18.2)	9 (23.1)
Others (teres minor)	1 (2.3)	0
Maximal calcification size (mm)	9.22±4.08	9.17±5.45
Type of calcification,[21] n (%)		
Arc	19 (57.6)	12 (40)
Fragment/punctation	8 (24.2)	12 (40)
Nodule	6 (18.2)	4 (13.3)
Cyst	0	2 (6.7)

NOTE. Values are mean ± standard deviation (SD) unless otherwise noted.

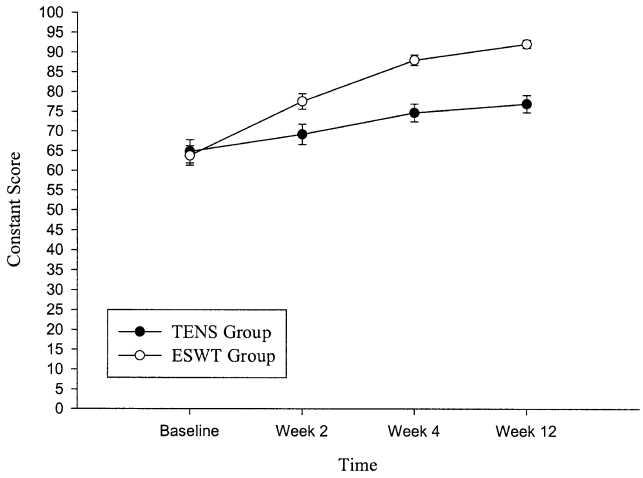

Fig 2. Development of function, as measured by Constant score (range, 0–100), at baseline, week 2, week 4, and week 12 evaluations. Values are mean ± standard error of the mean (SEM).

Table 2: Function, Severity of Pain, and Muscle Power Outcome After Treatment

Variable	Group	Mean of Difference Between Week 2 and Baseline Evaluation	*P* Value	Mean of Difference Between Week 4 and Baseline Evaluation	*P* Value	Mean of Difference Between Week 12 and Baseline Evaluation	*P* Value
Constant score (range, 0–100)	ESWT	13.79±11.25 (−6.00, 44.25)	.000*	24.21±13.68 (−10.00, 48.50)	.000*	28.31±13.10 (4.00, 51.00)	.000*
	TENS	3.52±6.73 (−1.00, 24.00)	.009*	9.59±9.62 (−2.00, 40.00)	.000*	11.86±13.32 (−6.00, 54.00)	.000*
	P value	.000†		.000†		.000†	
VAS (range, 0–10)	ESWT	−1.85±1.90 (−6.00, 2.00)	.000‡	−3.00±2.41 (−6.50, 3.00)	.000‡	−4.08±2.59 (−8.00, 3.00)	.000‡
	TENS	−1.31±2.31 (−10.00, 0.50)	.001‡	−1.10±1.94 (−5.50, 2.00)	.010‡	−1.74±2.20 (−5.50, 2.00)	.001‡
	P value	.027‖		.001‖		.000§	
MMT (range, 0–5; no. of improved shoulders/ total no. of shoulders)	ESWT	13/33 (39.4%)	NS‖	21/33 (63.6%)	NS‖	23/33 (69.7%)	NS‖
	TENS	7/29 (24.1%)	NS‖	15/29 (51.7%)	NS‖	18/29 (62.1%)	NS‖
	P value	NS¶		NS¶		NS¶	

NOTE. Values are mean ± SD (minimum, maximum). Number of shoulders analyzed was 33 and 29, respectively, in the ESWT and TENS groups. *P* less than .05 was considered statistically significant.
Abbreviation: NS, not significant
* Paired *t* test.
† Two-sample *t* test.
‡ Wilcoxon signed-rank test.
§ Mann-Whitney *U* test.
‖ McNemar test.
¶ Pearson chi-square or Fisher exact tests.

High-resolution ultrasonography[c] (HRUS) with a Logiq 700 MR and a M12L linear transducer at the 13MHz setting was used for imaging measurements. The morphology of calcific plaque of the shoulder on HRUS was classified into 4 types: (1) arc-shaped (echogenic arc with clear shadowing), (2) fragmented (at least 2 separated echogenic plaques with or without shadowing) or punctuated (tiny calcific spots without shadowing), (3) nodular (echogenic nodule without shadowing), and (4) cystic types (bold echogenic wall with echo-free content).[21]

Before the first treatment session, baseline measurements were established. The second measurements were performed just before the second session. Therefore, patients were examined at the following stages: at baseline, 2 weeks, 4 weeks, and 12 weeks after the first treatment.

The therapeutic side effects were monitored throughout. The significance of the results was calculated with the SPSS, version 10.0, statistical package program[d] for Windows. Paired *t* tests or the Wilcoxon signed-rank test were used to compare the difference between baseline and posttreatment effects in the same group. Two-sample *t* tests or the Mann-Whitney *U* test were applied to compare the differences of baseline and posttreatment data between the ESWT and TENS groups. For nominal data, the Pearson chi-square analysis or Fisher exact test was used. Statistical significance was specified as *P* less than .05.

RESULTS

Baseline Characteristics

Sixty consecutive patients (63 shoulders: 33 in the ESWT group, 30 in the TENS group) were enrolled in this study. With the exception of 1 patient in the TENS group who dropped out

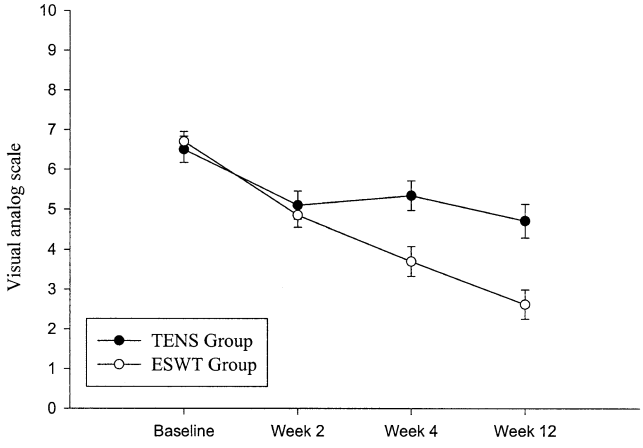

Fig 3. Development of pain according to VAS (range, 0–100) at baseline, week 2, week 4, and week 12 evaluations. Values are mean ± SEM.

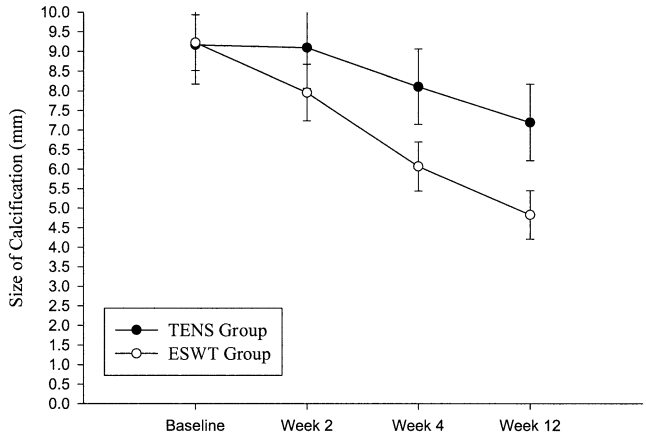

Fig 4. Development of size of maximal calcification diameter (mm) at baseline, week 2, week 4, and week 12 evaluations. Values are mean ± SEM.

Table 3: Sonographic Outcome After Treatment

Variable	Group	Mean of Difference Between Week 2 and Baseline Evaluation	*P* Value	Mean of Difference Between Week 4 and Baseline Evaluation	*P* Value	Mean of Difference Between Week 12 and Baseline Evaluation	*P* Value
Size of calcification (mm)*	ESWT	1.26±3.71 (−1.20, 0.58)	NS†	3.16±4.09 (−1.42, 0.48)	.000†	4.39±3.76 (−1.45, 0.17)	.000†
	TENS	0.25±1.97 (−0.40, 0.50)	NS†	0.75±1.70 (−0.45, 0.30)	.025†	1.65±2.83 (−0.90, 0.10)	.004†
	P value	NS‡		.003‡		.002‡	
Type of calcification (%) (no. of changed shoulders/total no. of shoulders)	ESWT	23/33 (69.7)		20/33 (60.6)		16/33 (48.5)	
	TENS	6/29 (20.7)		6/29 (20.7)		3/29 (10.3)	
	P value	.000§		.001§		.001§	

NOTE. Values are mean ± SD (minimum, maximum). Number of shoulders analyzed was 33 and 29, respectively, in the ESWT and TENS groups. *P* less than .05 was considered statistically significant.
* The greatest diameter of the calcific deposit.
† Paired *t* test.
‡ Two-sample *t* test.
§ Pearson chi-square or Fisher exact tests.

after the first session because of severe pain, all patients completed the scheduled treatments and follow-up. The characteristics of the patients in both groups were similar (table 1). The baseline data, including a Constant score, VAS, muscle power, and sonographic morphology of the calcification (locations, types, sizes), in the 2 groups were not significant ($P>.05$). There were twice as many women (n=39) as men (n=21) in the study. The locations of calcification were found (in the order of decreasing frequency) in the supraspinatus, subscapularis, infraspinatus, and teres minor. Calcium deposits in the shape of arcs were the most common type found, followed by fragmented or punctuated, and nodular types. There were only 2 cases of the cystic type.

Functional Outcome

After 1 session (ESWT once, TENS 6 times), 2 sessions (ESWT twice, TENS 12 times), and at 12-week follow-up, there were functional improvements in the Constant score and pain alleviation (VAS) in both groups ($P<.05$). Patients who had received ESWT had greater functional amelioration and pain reduction than did those who had TENS therapy at the 3 follow-up times ($P<.05$) (table 2; figs 2, 3). The average change in the Constant score (the difference between the 3 time points and the baseline) increased from 13.79 to 28.31 in the ESWT group. The TENS group had an increase from 3.52 to 11.86. In addition, 69% (23/33) of the shoulders in the ESWT group and 43% of the shoulders in the TENS group had a Constant score at or above 85. However, no significant difference was found for the MMT in either group ($P<.05$).

Sonographic Outcome

At the end of treatment, there was still calcific plaque in the shoulders of most patients, as shown by high-resolution ultrasonography (only 2 shoulders in ESWT group and 1 shoulder in the TENS group showed complete resorption of the plaque). Maximal diameters of calcific plaques showed a decrease after 2 treatment sessions and at 12-week follow-up, compared with baseline measurements in both groups ($P<.05$) (table 3, fig 4).

Table 4: Comparisons of the Therapeutic Efficiency in Patients With Different Types of Calcification

Type	Variable	Group	Mean of Difference Between Week 2 and Baseline Evaluation	Mean of Difference Between Week 4 and Baseline Evaluation	Mean of Difference Between Week 12 and Baseline Evaluation
Arc	Constant score (range, 0–100)	ESWT	11.38±10.15 (−2.00, 39.00)	23.91±12.52 (0.00, 48.00)	27.21±13.22 (4.00, 51.00)
		TENS	2.92±6.83 (−10.0, 24.00)	6.00±5.91 (−2.00, 17.00)	7.33±7.18 (−6.00, 19.00)
		P value†	.001	.000	.000
	VAS (range, 0-10)	ESWT	−2.24±2.08 (−6.00, 1.5)	−3.63±2.25 (−6.50, 1.50)	−4.39±2.63 (−8.00, 1.50)
		TENS	−1.58±2.90 (−10.00, 0.00)	−0.96±1.96 (−4.50, 2.00)	−1.50±2.02 (−4.00, 2.00)
		P value†	NS	.002	.003
	Size of calcification (mm)*	ESWT	−0.42±3.47 (−6.00, 5.80)	−2.56±3.78 (−11.00, 4.80)	−3.56±3.03 (−11.00, 1.70)
		TENS	−0.21±2.03 (−4.00, 3.00)	−0.07±1.59 (−3.00, 2.00)	−1.37±3.11 (−9.00, 1.00)
		P value†	NS	.035	.020
Fragment/ punctation	Constant score (range, 0–100)	ESWT	14.78±15.87 (−6.00, 44.25)	21.22±19.65 (−10.00, 47.50)	26.50±14.45 (8.00, 48.25)
		TENS	1.00±1.09 (0.00, 3.00)	8.50±6.42 (1.00, 22.00)	12.83±14.87 (−3.00, 54.00)
		P value†	NS	NS	.016
	VAS (range, 0–10)	ESWT	−1.69±1.41 (−4.00, 0.00)	−2.38±1.96 (−5.00, 0.50)	−3.94±1.64 (−5.50, −0.50)
		TENS	−0.36±0.55 (−1.50, 0.00)	−0.33±1.01 (−2.00, 2.00)	−1.33±2.03 (−5.50, 2.00)
		P value†	.016	.020	.012
	Size of calcification (mm)*	ESWT	−2.63±4.41 (−12.00, 1.00)	−4.55±4.99 (−14.20, 0.00)	−6.51±5.00 (−14.5, −1.20)
		TENS	−0.75±1.33 (−3.00, 2.00)	−0.80±1.45 (−3.00, 3.00)	−0.98±1.09 (−3.00, 0.00)
		P value†	NS	NS	.000

NOTE. Values are mean ± SD (minimum, maximum). Number of shoulders analyzed was 33 and 29, respectively, in the ESWT and TENS groups. *P* less than .05 was considered statistically significant.
* The greatest diameter of the calcific deposit.
† Mann-Whitney *U* test.

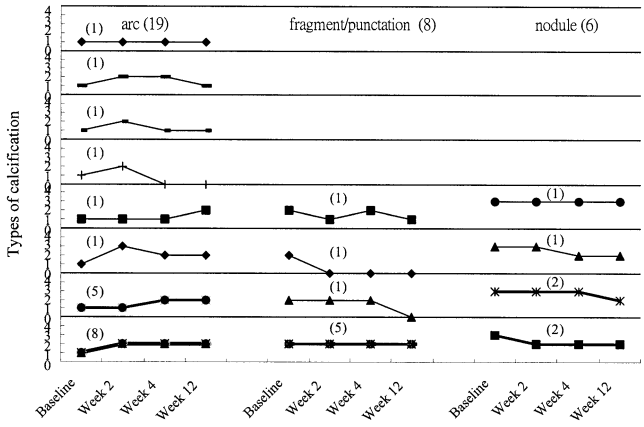

Fig 5. Change in types of calcification of all patients in the ESWT group at baseline, week 2, week 4, and week 12 evaluations. Types of calcification: 0, disappearance; 1, arc; 2, fragment/punctation; 3, nodule; and 4, cyst.

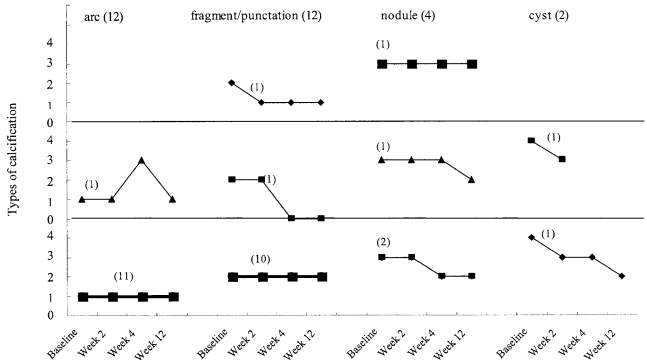

Fig 6. Change in types of calcification of all patients in the TENS group at baseline, week 2, week 4, and week 12 evaluations. Types of calcification: 0, disappearance; 1, arc; 2, fragment/punctation; 3, nodule; and 4, cyst.

The ESWT group also had greater average changes than the TENS group in the later 2 follow-up visits ($P<.05$). Sonography showed that the percentage change in calcification was greater in the ESWT group ($P<.05$) (table 3).

Therapeutic Outcome for Arc- and Fragmented-Types of Calcific Deposits

The therapeutic efficiency of ESWT and TENS, as measured by Constant score, VAS, and size of calcification, was compared for the treatment of arc and fragmented or punctuated types of calcific deposits. Patients with arc-type calcification improved faster in response to ESWT. For arc-type cases, functional performance improved to a greater degree and more quickly in the ESWT group, as compared with the TENS group after the first therapy. As such, for people with arc-type chronic calcific tendinitis of the shoulder, ESWT can provide a better therapeutic effect (table 4). The type of changes of all calcific deposits are shown in type-time profiles (figs 5, 6). For patients in the ESWT group, the majority of calcific plaques (fig 7) were transformed to fragmented or punctated type deposits (fig 8) by the end of treatment and at the 12-week follow-up visit. ESWT produced disintegration and provoked absorption of the calcific plaques.

Side-Effect Record

Five patients complained of soreness in the upper arm after ESWT, but this soreness had subsided before their next visit. One patient had cardiac palpitations during the first ESWT session as a result of anxiety, but was calm after taking a break. Otherwise, no specific side effect (eg, hematoma, paresthesia) occurred in either group.

DISCUSSION

The causes and pathogenesis of rotator cuff calcifications remains unclear.[1,3,22] Relative ischemia as a result of hypovascularization in the critical zone of the rotator cuff,[23] degenerative tendons,[24] and metabolic disturbances[22] have been mentioned. In our study, patients' occupations and living habits correlated highly with prolonged, constant shoulder positions that would exacerbate poor regional blood circulation of the rotator cuff and cause tissue hypoxia. Therefore, fibrocartilaginous transformation was triggered and calcium deposits of the tendon were formed.[1] Persons employed in occupations such as secretarial work and teaching were recruited in our study, and we educated them about the need for ROM and stretching exercise in daily living.

High-resolution sonography, rather than radiographic plain film,[15-18] was used to examine the shoulder calcium deposits. Sonography provides a noninvasive, radiation-free method of assessment that can be performed conveniently and repeatedly, and it can verify rotator cuff tears, peritendon effusion, and the morphology of calcium deposits.[21] The effects of ESWT and TENS on calcium deposits can be conveniently recorded, and differences in the response to each type of calcification can be detected.

Although the functional score and pain condition tests showed significant improvement in both groups, the MMT results remained unchanged. Regarding the underlying mechanism of pain relief by TENS, which might be explained by gate control theory, ESWT also has an analgesic effect. As treatment progressed, most patients were able to tolerate higher intensities of ESWT, and their pain decreased. It is assumed that the immediate effect is achieved through hyperstimulation analgesia, and the pain threshold is elevated. After the pain was relieved, shoulder joint ROM was increased and as a consequence so did ADLs. In addition, ESWT produces a "knocking" force on the tendon that may relieve the adhesion resulting from the chronic tendinitis. Perhaps it was for this reason that

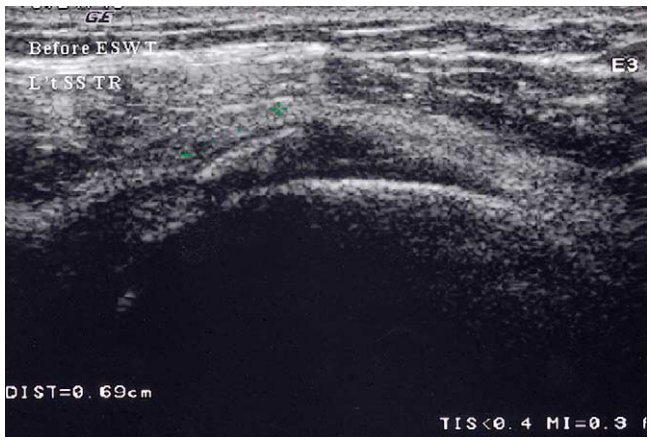

Fig 7. Transverse high-resolution ultrasonographic image of the left supraspinatus tendon showing arc-type calcific plaque before ESWT.

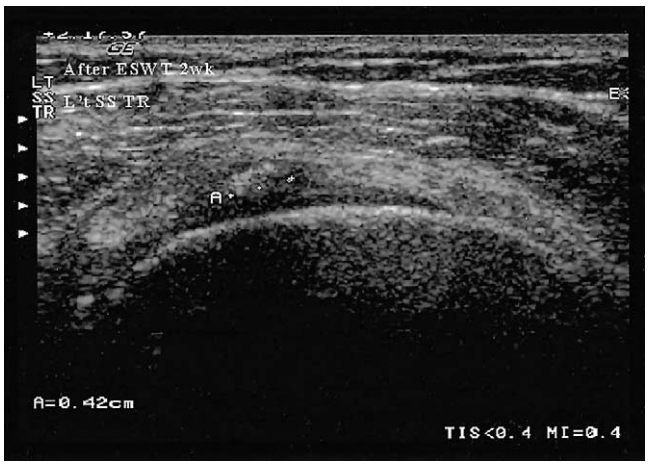

Fig 8. Transverse high-resolution ultrasonographic image of the left supraspinatus tendon showing fragmented-type calcific plaque after ESWT.

the ESWT group experienced better functional improvement than did the TENS group, especially after the 12-week follow-up. Moreover, in the TENS group, the functional improvements and increases in pain relief had diminished by the 12-week follow-up. Muscle power increased minimally, but that change was not significant. This may be explained by the fact that most patients with chronic tendinitis do not have muscle weakness, but rather suffer from pain and limited ROM.

Ultrasound diathermy, the alternative management method, has been reported to help resolve calcifications and reduce pain.[8] However, this therapy requires much longer treatment periods, resulting in increasing demands on staff time, while at times producing only short-term improvement.

Topical steroid injections have been used for symptomatic relief and are usually effective. However, frequent injections are harmful to tendon structure. Percutaneous needle aspiration with a large size needle (> no. 18 needle) alleviates symptoms in up to 60% of patients[25]; however, larger needle sizes may cause tendon injury and patients could have pain for up to 1 week after puncture because of acute inflammation. Surgery for shoulder calcification removal has a high rate of success, but carries risks of complications.[4] In this study, we found that (1) ESWT is easy to apply without the need for local anesthesia, (2) most patients can tolerate the whole procedure, and (3) patients could benefit from this intervention after just 2 therapy sessions.

An important limitation of our study was the lack of hymodynamic information, which could provide the vascularity of calcific tendonitis and phases of the calcification.[26] We will study this phenomenon in future research on hymodynamic changes and resorption of calcium deposits.

CONCLUSION

The use of ESWT is more effective than the use of TENS to achieve functional improvement and to alleviate pain in patients with chronic calcific tendinitis of the shoulder, especially of the rotator cuff with arc-type calcific plaque.

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