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Shock Wave Therapy for Calcific Tendinitis of the Shoulder

A Prospective Clinical Study with Two-Year Follow-up

Ching-Jen Wang,*† MD, Kuender D. Yang,‡ MD, PhD, Feng-Sheng Wang,‡ PhD, Han-Hsiang Chen,§ MD, and Jun-Wen Wang,* MD

*From the Departments of *Orthopedic Surgery, ‡Medical Research, and §Surgery, Chang Gung Memorial Hospital/Kaohsiung Medical Center, Kaohsiung, Taiwan*

Background: Shock wave therapy is a new modality that has shown efficacy in the treatment of various orthopaedic disorders.
Purpose: To determine the effectiveness, at 2- to 3-year follow-up, of shock wave therapy for calcific tendinitis of the shoulder.
Study Design: Prospective clinical study.
Methods: Thirty-seven patients (39 shoulders) with calcific shoulder tendinitis were treated with shock wave therapy (1000 impulses at 14 kV) and observed for 24 to 30 months. The control group, which underwent sham treatment with a dummy electrode, consisted of 6 patients (6 shoulders) with an average follow-up of 6 months. Evaluation included use of the 100-point Constant score system and shoulder radiographs.
Results: The overall results in the study group were 60.6% excellent (20 of 33 shoulders), 30.3% good (10), 3.0% fair (1), and 6.1% poor (2), and those of the control group were 16.7% fair (1 of 6 shoulders) and 83.3% poor (5). The symptom recurrence rate in the study group was 6.5%. Dissolution of calcium deposits was complete in 57.6% of the study group, partial in 15.1%, and unchanged in 27.3%. Fragmentation was seen in 16.7% of the control group patients; in 83.3% deposits were unchanged. No recurrence of calcium deposits was observed during the 2 years that the study group was followed.
Conclusions: Shock wave therapy is a safe and effective noninvasive treatment for patients with calcific tendinitis of the shoulder.

Many methods of treatment are available for patients with calcific tendinitis of the shoulder. These range from physical therapy, nonsteroidal antiinflammatory drugs, and corticosteroid injection to surgical intervention.[2] The effects of these different treatments have varied significantly, and no consistent and reliable long-term results have been shown. There are insufficient data to support one method of treatment over another.[5,17] In surgical treatment, the aim is to remove the calcium deposits and decompress the subacromion space.[2,5,6,13,17] However, many patients with calcific tendinitis may remain asymptomatic most of the time, depending on the position and size of the calcification, and yet sometimes experience impairment of mechanical function and severe pain. Furthermore, it is not uncommon for patients with calcific tendinitis to have long-term pain at rest and with movement.

Shock wave therapy is a new therapeutic modality that has shown efficacy in the treatment of various orthopaedic disorders, including nonunion of long-bone fractures, lateral epicondylitis of the elbow, calcific tendinitis of the shoulder, and chronic heel pain.[3,7–9,11–16,18–20] Our preliminary results of shock wave therapy for patients with calcific tendinitis of the shoulder showed 62% good or excellent outcomes at 3- to 6-month follow-up.[22] The purpose of this prospective clinical study was to further update the effectiveness, at a 2- to 3-year follow-up, of shock wave therapy for calcific tendinitis of the shoulder.

MATERIALS AND METHODS

This study was approved by the Institutional Review Board of Chang Gung Memorial Hospital. The inclusion criteria included patients with shoulder pain attributable to calcific tendinitis who had failed to respond to at least

† Address correspondence and reprint requests to Ching-Jen Wang, MD, Department of Orthopedic Surgery, Chang Gung Memorial Hospital, 123, Ta-Pei Road, Niao Sung Hsiang, Kaohsiung, Taiwan.
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6 months of nonoperative treatment either at our hospital or at other institutions and who, otherwise, might have considered surgery as an alternative. Nonoperative treatments included nonsteroidal antiinflammatory drugs, corticosteroid injection, physical therapy, an exercise program, and immobilization of the shoulder in a sling. Approximately two-thirds of the patients also received treatment with herbal medicine. Patients were excluded if they had a history of recent trauma or local infection, had used immunosuppressant drugs, had cardiac arrhythmia or a pacemaker, were pregnant, were skeletally immature, or if they had a rotator cuff tear or a diagnosis of arthritis of the shoulder.

Between May 1998 and May 1999, 43 patients (45 shoulders) were enrolled, 37 (39 shoulders) in the study group and 6 (6 shoulders) in the control group. Two patients in the study group were treated for bilateral shoulder involvement. Only those patients who agreed to participate as control subjects were selected for enrollment in the control group. Most patients were unwilling to participate in the study as control subjects, and this resulted in a disproportion in the number of patients in the two groups.

The study group consisted of 23 women and 14 men with an average age of 51 years (range, 36 to 66). The right shoulder was affected in 23 cases and the left in 16. The average duration of the condition was 8 months (range, 6 to 12) and the average length of follow-up was 24.7 months (range, 24 to 30). The control group consisted of six patients (three men and three women) with an average age of 53 years (range, 36 to 65). The average duration of the condition in the control group was 8.6 months (range, 6 to 24) and the average length of follow-up was 6 months (range, 5 to 8).

All patients discontinued the treatment they were currently receiving, including use of nonsteroidal antiinflammatory drugs, 2 weeks before shock wave treatment began. Informed consent was obtained and potential risks were explained to the patients, according to the study protocol. Shock wave therapy was performed with an OssaTron shock wave generator (High Medical Technology, Kreuzlingen, Switzerland). Treatment was performed on an outpatient basis. Patients received local anesthesia consisting of 2% xylocaine injected over the subacromion bursa. Patients were placed in a supine position and the shock wave tube was focused on the treatment area by using the machine's control guide. Each treatment consisted of application of 1000 impulses of shock waves at 14 kV (equivalent to 0.18 mJ/mm^2 energy flux density) to the affected shoulder. During treatment, vital signs and local pain were monitored. Approximately two-thirds of the patients experienced some discomfort at the treatment site. Repeated application at 30 to 60 days was provided to patients whose response to the initial treatment was inadequate. Overall, 27 patients (27 shoulders) received only one treatment, 8 patients (9 shoulders) received two treatments, and 2 patients (3 shoulders) received three treatments.

In the control group, sham treatment was performed by replacing the original electrode with a dummy electrode that prevented the shock wave machine from generating shock wave energy. Thus, these patients did not receive shock wave treatment, although the machine did deliver impulses in the usual manner.

Postoperatively, patients were checked for local reactions such as ecchymosis, swelling, and hematoma of the treated area. There were no systemic or local complications that required special treatment. Twelve patients had local reddening of the shoulder that resolved spontaneously after 48 hours. Patients were sent home with an ice pack and a non-narcotic analgesic (acetaminophen). Nonsteroidal antiinflammatory drugs were not prescribed. Patients were allowed to use the affected arm in the usual fashion. Follow-up examinations were scheduled at 2 and 4 weeks and 3, 6, and 12 months, and then once a year after shock wave treatment. All of the evaluations were conducted by orthopaedic staff blinded to whether patients were in the study or control groups.

The 100-point Constant score system[4] was used in the evaluation of patients. Fifteen points were included for pain, 20 points for activities of daily living, 40 points for shoulder motion, and 25 points for the power of the affected arm. The evaluation parameters included the intensity of pain, scores for pain during the day and at night, the power scores based on the percentage of power in the affected arm as compared with the opposite arm, activity scores relative to restriction of daily activities, and motion scores based on the range of shoulder motion. The intensity of pain was measured with a visual analog scale ranging from 0 to 10, with 10 points for no pain and 0 points for severe pain. The visual analog scales were reversed for the purpose of maintaining a consistent scoring system in the current study. This reversal did not alter or affect the statistical significance. The scores before and after treatment were compared statistically by using the Wilcoxon signed rank test, and the scores between the treatment group and the control group were compared by using the Mann-Whitney test. Values were considered to reach statistical significance at $P < 0.05$.

Anteroposterior radiographs of the shoulder with the arm in neutral rotation were taken at each follow-up examination (2 and 4 weeks, 3, 6, and 12 months, and once a year thereafter). All radiographs of the shoulder were performed in identical views by the same radiology technician. The radiographs were evaluated to compare the pre- and posttreatment scores and the presence and size of the calcium deposits after shock wave therapy.

RESULTS

In the study group, six patients (six shoulders) were excluded because of inadequate data and poor compliance. The remaining 31 patients (33 shoulders) were included in the analysis. Twenty-four of the 31 patients (24 shoulders) had undergone one treatment, 6 patients (7 shoulders) had two treatments, and 1 patient (2 shoulders) had three treatments. In the control group, all six patients were observed for 5 to 8 months, at which point they decided to seek alternative methods of treatment, including surgery, because of persistent or recurrent symptoms.

TABLE 1
Comparison of Shoulder Ratings before and after Shock Wave Therapy in the Study and the Control Groups[a]

Score	Study group	Control group	P value[b]
Intensity of pain			
Before treatment	3.17 ± 1.32	3.75 ± 1.04	0.316
After treatment	8.83 ± 1.82	3.92 ± 1.24	<0.001
P value[c]	<0.001	0.655	
Pain score			
Before treatment	2.98 ± 1.02	3.08 ± 0.66	0.952
After treatment	6.98 ± 0.98	3.25 ± 0.82	<0.001
P value[c]	<0.001	0.157	
Power			
Before treatment	7.06 ± 3.25	5.33 ± 1.63	0.196
After treatment	22.39 ± 4.66	5.83 ± 1.94	<0.001
P value[c]	<0.001	0.317	
Activity			
Before treatment	8.30 ± 4.11	6.50 ± 2.07	0.295
After treatment	18.58 ± 2.69	7.17 ± 2.48	<0.001
P value[c]	<0.001	0.295	
Motion			
Before treatment	23.79 ± 9.69	28.00 ± 10.88	0.211
After treatment	38.18 ± 3.48	28.00 ± 10.88	0.001
P value[c]	<0.001	1.000	
Constant			
Before treatment	46.09 ± 16.42	45.83 ± 14.69	0.861
After treatment	93.00 ± 11.65	47.50 ± 14.15	<0.001
P value[c]	<0.001	0.180	

[a] The study group included 31 patients (33 shoulders) with an average follow-up of 2 years and the control group included 6 patients (6 shoulders) with an average follow-up of 6 months.
[b] Comparison between treatment and control group both before and after treatment.
[c] Comparison between before and after treatment within each group.

Functional Assessments

The comparative results of pain, power, activity, motion, and total Constant scores before and after treatment between the study and the control groups are summarized in Table 1. Before treatment, no statistically significant differences were observed in the intensity of pain, pain scores, power scores, activity scores, and motion scores between the study and the control groups ($P > 0.05$). After treatment, however, statistically significant differences in these parameters were observed between the study and the control groups ($P < 0.001$). The improvement after treatment was statistically significant for the study group ($P < 0.001$) but not for the control group ($P > 0.05$).

The comparative results of one, two, and three treatments are summarized in Table 2. The improvement was statistically significant after one and two treatments ($P < 0.05$). Only one patient (two shoulders) received three treatments, and this patient's results showed considerable improvement even though statistical significance was not reached because of the small case number. It appeared that patients who did not respond adequately after the first treatment showed improvement after the second or third treatment.

In the study group patients, 20 shoulders (60.6%) were complaint-free, 10 (30.3%) were significantly better, 1 (3.0%) was slightly better, and 2 (6.1%) were unchanged. Two patients (two shoulders, 6.5%) in the study group developed recurrent pain of lesser intensity at 12 and 24 months, respectively, but neither of the two experienced worsening of these recurrent symptoms. In the control group, results showed that one patient (16.7%) was slightly better and five (83.3%) were unchanged. All six patients in the control group eventually received alternative treatments, including surgery. There were no device-related problems, and no systemic or local complications.

TABLE 2
Pain, Power, Activity, Motion, and Constant Scores after One, Two, and Three Treatments with Shock Wave Therapy[a]

Score	One treatment	Two treatments	Three treatments
Intensity of pain			
Before treatment	3.25 ± 1.19	3.21 ± 1.85	2.00 ± 0
After treatment	8.88 ± 1.87	8.86 ± 1.75	8.25 ± 2.47
P value	<0.001	0.018	0.180
Pain			
Before treatment	2.77 ± 1.05	3.50 ± 0.76	3.75 ± 0.35
After treatment	6.98 ± 1.03	6.86 ± 0.99	7.50 ± 0
P value	<0.001	0.017	0.180
Power			
Before treatment	6.42 ± 2.65	9.43 ± 4.50	6.52 ± 2.12
After treatment	22.67 ± 4.62	22.14 ± 4.85	20.00 ± 7.07
P value	<0.001	0.018	0.180
Activity			
Before treatment	7.08 ± 2.89	12.00 ± 5.97	10.00 ± 0
After treatment	18.50 ± 2.96	19.00 ± 1.83	18.00 ± 2.83
P value	<0.001	0.066	0.180
Motion			
Before treatment	22.46 ± 10.16	25.43 ± 7.81	34.00 ± 0
After treatment	38.25 ± 3.60	38.00 ± 3.65	38.00 ± 2.83
P value	<0.001	0.018	0.180
Constant			
Before treatment	41.96 ± 14.87	55.29 ± 17.85	63.50 ± 4.95
After treatment	93.21 ± 11.95	92.86 ± 12.17	91.00 ± 12.73
P value	<0.001	0.018	0.180

[a] One treatment, 24 patients (24 shoulders); two treatments, 6 patients (7 shoulders); three treatments, 1 patient (2 shoulders).

TABLE 3
Average Size of Calcium Deposits (in Millimeters) on Radiographic Examination[a]

Examination	Study group	Control group
Before treatment		
Mean ± SD	10.7 ± 6.4	12.8 ± 4.0
Range	2–30	8–18
After treatment		
Mean ± SD	3.2 ± 5.0	12.0 ± 4.0
Range	0–20	8–18
P value	<0.001	0.317

[a] The study group included 31 patients (33 shoulders) and the control group included 6 patients (6 shoulders).

Radiographic Assessments

The radiographic changes seen in calcium deposits are summarized in Table 3. A statistically significant reduction in the average size of calcium deposit after shock wave therapy was noted in the study group ($P < 0.001$). However, no changes were seen in the control group ($P = 0.317$). In the study group, the elimination of calcium deposits was complete in 19 cases (57.6%), partial in 5 (15.1%), and unchanged in 9 (27.3%) (Fig. 1). The length of time for the calcium deposits to be eliminated ranged from 2 weeks to 3 months. The status of the calcium deposits during the first 2 weeks after treatment was unknown because no radiographs were taken during this period. In three cases, the calcium deposits were observed to be eliminated as early as 2 weeks after shock wave therapy. None of the patients who obtained complete dissolution of calcium deposits showed any recurrence of calcium deposits at 2 years after shock wave therapy. For the control group, however, calcium deposits were observed to be fragmented in one patient (16.7%) and unchanged in five (83.3%). There was a correlation of functional improvement of the shoulder with the elimination of calcium deposits. Of the 19 patients (19 shoulders) who had complete elimination of calcium deposits, 17 were complaint-free and had normal Constant scores, whereas 2 patients who had mild pain had a Constant score of 82. Of the five patients (five shoulders) with partial elimination of calcium deposits, one was complaint-free, two had significant improvement, one was moderately symptomatic, and one had recurrent pain.

DISCUSSION

The causes and pathogenesis of calcific tendinitis of the shoulder remain unclear. Hypovascularization of the rotator cuff, degenerative changes, and metabolic disturbance have been suggested as possible causes.[5,6] Chondroid metaplasia may lead to calcification of tendon

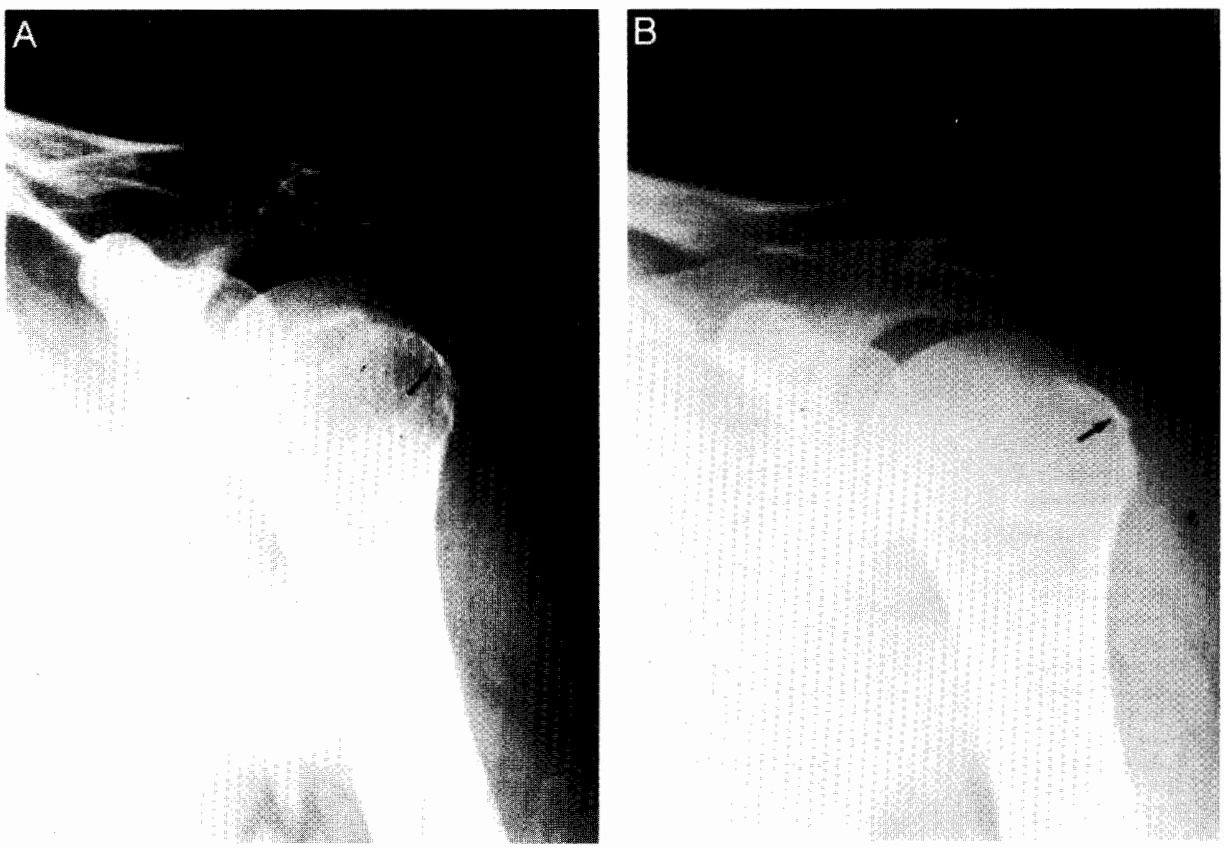

Figure 1. A, radiograph of the right shoulder of a 50-year-old woman shows a 12-mm calcium deposit. The patient had pain before shock wave treatment. B, radiograph of the same shoulder taken 6 weeks after treatment with 1000 impulses of shock waves at 14 kV, showing complete elimination of calcium deposit. The patient was pain-free.

tissue.[1] The relationship of calcium deposits to shoulder pain is unclear. The goals of treatment are to alleviate pain and restore function of the shoulder. Studies have shown that results of both nonoperative and surgical treatments for calcific tendinitis of the shoulder have been inconsistent and unpredictable.[2,17] Rompe et al.[13] found that the success rate of surgical treatment was comparable with that of shock wave therapy. Furthermore, surgery can still be done if shock wave therapy fails.

The mechanism by which shock wave therapy acts is not yet known. However, there have been several studies showing apparent improvement in patients with calcific tendinitis of the shoulder treated with shock wave therapy.[7,9,12,13,16,22] Spindler et al.[16] reported complete pain relief and full shoulder joint movement in three patients 2 years after shock wave therapy, and a fragmentation of calcification was achieved after 24 hours. Loew et al.[9] treated 20 patients with two sessions of 2000 impulses each of shock wave therapy and reported a marked reduction of symptoms, with an average 30% improvement in the Constant score at the 12-week follow-up. Radiographs showed complete elimination of the calcification in seven patients and partial elimination in five patients. Magnetic resonance imaging did not show any lasting damage to bone or soft tissue. Rompe et al.[12] reported significant improvement in subjective and objective criteria; 72.5% of their patients (29 of 40) had no or only occasional discomfort, and only 6 of 40 patients (15%) treated with 1500 shock waves reported no improvement. Complete or partial disintegration of the calcium deposits was observed in 62.5% of the patients. In another study, Rompe et al.[13] compared the results in 29 surgically treated patients with results in 50 patients treated with shock wave therapy. They noted comparable symptoms between the two groups after 1 year. However, at 2 years, significantly improved results were noted in the patients who had undergone shock wave therapy. When compared with surgery, shock wave therapy is safe, cost-effective, and without the risks and complications entailed by surgery.

The results of the current study showed 90.9% of patients in the study group obtained complete or nearly complete resolution of symptoms 2 years after shock wave therapy. These results are comparable to the results of other reported series.[7,9,12,13,16] Our preliminary results of shock wave therapy for calcific tendinitis of the shoulder were 62% good or excellent outcome at 3- to 6-month follow-up.[22] Our preliminary and current results lead us to observe that the effect of shock wave therapy for calcific tendinitis of the shoulder appears to be cumulative and time-dependent. Weaknesses of this study include the disproportional numbers of patients in the study and control groups and the lack of true randomization in patient selection. This was partly due to the fact that most patients were unwilling to participate as control subjects. Despite the disparity in the numbers of patients in each group, the differences in results of treatment were highly significant, favoring the shock wave therapy group.

The results of this study showed complete dissolution of calcium deposits in 57.6% of shoulders (19 of 33), and no recurrence of calcium deposits was observed at 2 years after shock wave therapy. Spindler et al.[16] noticed fragmentation of calcium deposits occurred as early as 24 hours after shock wave therapy. In our study, dissolution of calcium deposits was observed between 2 weeks and 3 months, with dissolution noted in three cases as early as 2 weeks after shock wave therapy. However, the actual time for dissolution of calcium deposits was unknown because no radiographs were taken before 2 weeks.

The mechanism of calcium deposit dissolution is unknown. We hypothesize that calcium deposits are eliminated through a molecular mechanism of absorption associated with improved circulation at the tendon-bone junction after shock wave therapy. In a report of 22 patients with femoral head necrosis, Ludwig et al.[10] reported pain relief and improved Harris hip score 1 year after shock wave therapy; they believed the success was due to improved circulation after shock wave therapy. Wang et al.[21] demonstrated that shock wave therapy enhanced neovascularization at the tendon-bone junction in a dog model. We speculate that shock wave therapy relieves the pain of insertional tendinitis of the shoulder by improving local circulation and tissue regeneration.

In conclusion, shock wave therapy has produced a high rate of success in pain relief and functional restoration with negligible complications in the treatment of patients with calcific tendinitis of the shoulder. In approximately 57.6% of cases, radiographs showed complete elimination of calcium deposits. Shock wave therapy is a new and noninvasive therapeutic modality that is safe and effective in the treatment of patients with calcific tendinitis of the shoulder.

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