Which method is more effective in treatment of calcific tendinitis in the shoulder?  
Prospective randomized comparison between ultrasound-guided needling and extracorporeal shock wave therapy

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Hypothesis: Ultrasound (US)-guided needling with subacromial corticosteroid injection is more effective than extracorporeal shock wave therapy (ESWT) for function restoration and pain relief in patients with calcific tendinitis of the shoulder.

Methods: Fifty-four patients diagnosed with unilateral painful calcific tendinitis were randomly allocated to a US needling or ESWT group. The US needling group underwent US-guided needling and received a subacromial corticosteroid injection. The ESWT group received ESWT 3 times a week. All patients were prospectively evaluated; American Shoulder and Elbow Surgeons, Simple Shoulder Test, and visual analog scale for pain scores were recorded before the procedure and at 6 weeks, 12 weeks, 6 months, 12 months, and the last follow-up. The size and morphology of the deposits were evaluated by radiography.

Results: The average follow-up period was 23.0 months. At last follow-up, the mean size of the deposits was significantly different between the 2 groups ($P=.001$); it decreased to 0.5 mm from 14.8 mm in the US needling group and to 5.6 mm from 11.0 mm in the ESWT group. There were also significant improvements in clinical outcomes in both groups after treatment ($P<.05$). At 1-year follow-up, the US needling group had significantly better scores than the ESWT group with regard to the American Shoulder and Elbow Surgeons assessment (90.3 and 74.6, respectively; $P=.001$), Simple Shoulder Test (83.3 and 70.8, respectively; $P=.015$), and visual analog scale for pain (1.4 and 3.3, respectively; $P=.003$). The initial calcium deposit sizes and clinical outcomes were weakly correlated in both groups ($P>.05$).

Conclusion: Both treatment modalities for calcific tendinitis improved clinical outcomes and eliminated calcium deposits. US-guided needling treatment, however, was more effective in function restoration and pain relief in the short term.

The IRB of Seoul St. Mary’s Hospital, the Catholic University of Korea, approved this study (No. KC12RISI0829).

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Calcific tendinitis is a common disease associated with a painful shoulder and is estimated to affect 7% to 17% of those experiencing shoulder pain.\textsuperscript{14,15,27,29} It is occasionally characterized by intractable pain and morbidity. However, this disease is usually self-limited and can be treated by conservative treatment methods with good results.\textsuperscript{8,26,30} The most efficient treatment for this common disease is still under debate, and no standard treatment has been established yet. Several treatment options have been proposed, such as rest, physical therapy, medication with nonsteroidal anti-inflammatory drugs, calcium deposit needling, lavage with 1 or 2 needles, localized injection of anesthetics or corticosteroids, and extracorporeal shock wave therapy (ESWT).\textsuperscript{1,2,7,9,13,18,20,23,30,34,36} Nevertheless, failure of these nonoperative treatment methods may necessitate surgical treatment.\textsuperscript{3,19,32}

Currently, ultrasound (US) is being widely used as a diagnostic tool for calcific tendinitis in the outpatient setting. US is a relatively inexpensive and safe method of examination compared with other methods, such as computed tomography and magnetic resonance imaging. US can be used in needle decompression for calcium deposits with or without subacromial steroid injection in cases of calcific tendinitis.\textsuperscript{1,7,10,20,24,38}

Another alternative nonsurgical treatment option for calcific tendinitis is ESWT. ESWT has been recommended as a second-line therapy before surgery is performed.\textsuperscript{13,36} In the last 2 decades, several studies demonstrated the effectiveness of ESWT in treating this condition and proposed that it should be established as a safe second-line therapy.\textsuperscript{2,6,11,13,14,16,17,23,29,30,36} However, this procedure is extremely painful in hyperalgesic crisis.\textsuperscript{23} ESWT is not an invasive procedure and is relatively easy to perform in the outpatient setting. We wanted to compare the effectiveness of the 2 procedures.

Materials and methods

Sixty-two consecutive patients with painful calcific tendinitis of the shoulder were enrolled prospectively from November 2005 to March 2011 in this study. Patients diagnosed with unilateral calcium deposition at the supraspinatus tendon, confirmed on radiologic examination, and disease duration of more than 3 months were included in the study. Patients with other shoulder disease, such as rotator cuff tear, adhesive capsulitis, arthritis, fracture, infection, and history of treatment for the affected shoulder, were excluded from this study with initial examination (physical examination, radiography, and US). The randomization was conducted by an independent statistician who provided us with a computer-generated randomization list. All patients were divided into 2 groups and randomized to undergo either US-guided percutaneous needling or ESWT. Before undergoing the assigned procedure, all patients underwent diagnostic US and radiologic evaluation for identification of any associated pathologic conditions. During the assessment for eligibility, 11 patients were excluded; 6 patients did not meet the inclusion criteria, and 5 patients refused to participate in this study. At first, 62 patients were enrolled in this study; 8 patients were lost to follow-up because of noncompliance with the follow-up protocol after the procedure, and hence 54 patients were finally enrolled (Fig. 1).

US-guided needling and ESWT procedures

All US-guided needling procedures were performed by 1 orthopedic surgeon (Y.S.K.) with a single needle without lavage. The procedure was performed by sterile technique and surgical gloves. First, a diagnostic US examination was performed to evaluate the characteristics of calcium deposits at the affected shoulder in the sitting position. The skin was then cleaned with a 10% iodopovidone solution 3 times and antiseptically draped. After administration of local anesthesia (2% lidocaine), the patients in this group underwent multiple percutaneous punctures for each deposit with an 18-gauge needle under real-time monitoring with US (Fig. 2). The final step in the procedure was an injection of 1 mL (40 mg) of Depo-Medrol (Pharmacia & Upjohn, Kalamazoo, MI, USA; 40 mg/mL methylprednisolone acetate) into the subacromial space under US guidance.

In the ESWT group, all patients underwent US examination before shock wave therapy for the same reasons mentioned before. This procedure was also performed in the sitting position by 1 experienced technician. The procedure involved aiming at the maximum sore spot according to anatomic targeting. ESWT was administered for 3 sessions, 1 week apart (1000 impulses, 0.36 mJ/mm²).

For both groups, oral nonsteroidal anti-inflammatory drugs were prescribed at the end of the procedure for 7 days. The patients were permitted to perform daily normal activities to the extent possible, without any immobilizer brace.

Clinical and radiographic evaluations

For both the US-guided needling and ESWT groups, clinical and radiologic evaluations were performed before the procedure (initial) and at 6 weeks, 12 weeks, 6 months, 12 months, and the last follow-up visit. The average follow-up period was 23.0 months (range, 12.1-28.5 months) after treatment. Radiographic evaluations were performed by standard shoulder anteroposterior radiographs in neutral, internal, and external rotation together with axillary and supraspinatus outlet views to determine

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**Level of evidence:** Level II, Randomized Controlled Trial, Treatment Study.

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the size, morphology, and location of the calcific deposits. We determined the length of the calcium deposit in terms of the longest axis of the deposit in any direction. All radiographic measurements were made on the Picture Archiving and Communications System by use of a mouse cursor with automated distance calculation.

The size of the calcific deposit was measured on the radiographs obtained at each follow-up visit. Resorption of the calcific deposit was graded as none, partial, or complete by another physician who was blinded to the treatment status and grouping. American Shoulder and Elbow Surgeons (ASES), Simple Shoulder Test (SST), and visual analog scale (VAS) for pain scores were recorded at each visit.

**Statistical analysis**

The sample size was calculated to detect a significant difference (mean difference, 8 points; standard deviation, 12 points) in the ASES scores before conducting the study. We required 30 patients in each group for a power of 80%, at a type I error level of .05.

The statistical analyses were performed with SPSS version 11.0 (SPSS, Inc, Chicago, IL, USA). The level of statistical significance was set at \( P < .05 \) for all the tests. An independent \( t \) test was performed to evaluate the differences in the VAS pain scores between the 2 groups.

The following statistical analyses were performed to compare the results of the 2 groups. The Wilcoxon signed rank test was performed to compare functional scores and calcium deposit size at the initial stage and at 1-year follow-up. The Mann-Whitney test was used to compare functional scores between the groups at each time point. The Spearman test was used to evaluate the correlation between the size of the calcium deposit and clinical outcomes for both groups.

The procedures followed in the study were approved by the Institutional Review Board. All patients provided written informed consent before participating in the study.

**Results**

Among the 54 patients, 25 and 29 patients were allocated to the US-guided needling group and ESWT group, respectively (Fig. 1). The US-guided needling group consisted of 23 women and 2 men, with a mean age of 53.9 years (range, 45-76 years); the ESWT group consisted of 26 women and 3 men, with a mean age of 57.4 years (range, 47-78 years). At baseline, there was no significant difference in age, sex ratio, initial clinical score, and size of calcium deposit before treatment between the 2 groups. The
demographic characteristics of members of both groups are summarized in Table 1. The mean follow-up period was 25.2 months for the ESWT group and 21.1 months for the US-guided needling group.

**Radiologic evaluation**

The change in the size of calcium deposits after treatment is presented in Table II. The mean size of the calcium deposits before treatment was 14.8 mm (range, 6.6-31.0 mm; Gartner I/II 8/8 50%/50%) in the US-guided needling group and 11.0 mm (range, 4.9-19.3 mm; Gartner I/II 6/6 50%/50%) in the ESWT group. At the last follow-up visit, there was a significant difference in the size of calcium deposits between the 2 groups ($P < .001$); the mean size of the deposits decreased to 0.5 mm in the US needling group and to 5.6 mm in the ESWT group. Calcifications disappeared completely in 72.2% and partially in 11.1% of the patients in the US-guided needling group; the deposit disappeared completely in only 42.6% and partially in 16.7% of the patients in the ESWT group.

**Clinical evaluation**

The functional outcomes, measured by the ASES (Fig. 3) and SST (Fig. 4) scores, showed significant improvement in both groups after treatment ($P < .05$). In the US-guided needling group, the functional outcomes, measured by the ASES scores (from initial 41.5 to 91.1 at the last follow-up; $P = .001$) and SST scores (from initial 38.2% to 91.7% at the last follow-up; $P = .03$), significantly improved after treatment. There was a significant improvement in the functional scores of the ESWT group; ASES scores (from initial 49.9 to 78.3 at the last follow-up; $P = .026$) and SST scores (from initial 34.0% to 78.6% at the last follow-up; $P = .017$) significantly improved after treatment. With regard to the VAS for pain scores (Fig. 5), both groups showed significant improvement in the scores (US-guided needling group: from initial 6.8 to 1.1 at the last follow-up, $P = .006$; ESWT group: from initial 6.3 to 2.4 at the last follow-up, $P = .026$). However, compared with the US-guided needling group, the ESWT group showed slight worsening of pain at 12 months after treatment. The US needling group had significantly better scores than the ESWT group with regard to ASES (90.3 and 74.6, respectively; $P = .001$), SST (83.3 and 70.8, respectively; $P = .015$), and VAS (1.4 and 3.3, respectively; $P = .003$). There was no significant correlation between the initial size of the calcium deposit and clinical outcomes in both groups (Table III) ($P > .05$).

**Discussion**

This prospective randomized study is, to the best of our knowledge, the first trial comparing US-guided needling with subacromial corticosteroid injection and ESWT, the two nonsurgical treatment options for calcific tendinitis of the shoulder. Both methods showed improved outcomes without serious side effects. We hypothesized that US-guided needling with subacromial corticosteroid injection is a more effective treatment than ESWT in calcific tendinitis of the shoulder. The most important finding of this study is that US-guided needling was more effective than ESWT in function restoration and pain relief, at a relatively short-term observation. In addition, the calcium deposit was eradicated more effectively by the US-guided needling method than by ESWT.

Partial removal of calcium deposits with needling is known to enable decompression of calcium-containing cavities and to promote spontaneous resorption of calcium. We used this procedure with 1 needle without lavage because this procedure was simple, no special devices were required, and it was enough to gain the goal of decompression of calcium deposits. The rate of elimination of calcification ranges between 28% and 76% for needle aspiration and lavage,$^{10,12,24}$ and between 15% and 70% for ESWT.$^{22,27,29,33,37}$ In both groups of this study, functional and pain scores significantly improved after each session of the procedure, with relatively higher rates of symptom relief and elimination of calcium deposits achieved by US-guided needling and subacromial steroid injection than by ESWT. Although ESWT has a direct mechanical effect on the calcium deposits, direct mechanical needle decompression of calcium-containing cavities with anti-inflammatory steroids is found to be a more effective therapeutic method than ESWT for painful calcific tendinitis of the shoulder. We thought that the direct metal needle is a more reliable tool than ESWT in decompression of calcium deposits; this was followed by good clinical results.

Compared with the needleling technique, ESWT has been recently introduced as an alternative conservative treatment option for calcific tendinitis.$^{6,23}$ However, the exact underlying mechanism of the therapeutic effect of ESWT on calcific tendinitis is still uncertain. Nevertheless, several hypotheses have been proposed.$^{2,20,23}$ With regard to the direct mechanical effect, ESWT is thought to induce deposit fragmentation through a pressure increase inside the deposit. With regard to the molecular effect, phagocytosis of the deposit is induced through an inflammatory response, neovascularization, and leukocyte

<table>
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<td><strong>Variables</strong></td>
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<td>No. of patients</td>
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<tr>
<td>Age, mean (range), years</td>
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<td>Sex, male:female</td>
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<td>Mean follow-up period, months</td>
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ESWT, extracorporeal shock wave treatment; US needling, ultrasound-guided needling.
chemotaxis. On the basis of the clinical and radiologic examination results, the success rates for ESWT were reported to range between 78% and 91%.16,20,27,37 However, some aspects of ESWT are still under debate (e.g., the energy level, shock wave dosage, and number of sessions required for a therapeutic effect). Further studies are needed to identify the most beneficial protocol for treating calcific tendinitis of the shoulder. The purpose of needling or lavage is to reduce pressure and to remove the calcium deposits. Partial removal of deposits is known to enable decompression of calcium-containing cavities and to promote spontaneous resorption of calcium.4,7,10,35 After undergoing the needling procedure, patients experienced relief within 3 months, and deposit sizes were substantially decreased at 6 months.1,38

Imaging-guided procedures are also considered alternative, effective treatment options. Currently, US-guided procedures for calcific tendinitis are gaining popularity owing to several advantages of these procedures: no radiation exposure, 3-dimensional visualization for localization of the deposits, real-time monitoring during needle placement, confirmation of procedure success, and decreased risk of injury to the neighboring structures.55 In the present study, simple US-guided needling and subacromial steroid injection, without lavage, were found to be sufficient for clinical purposes and achieved excellent results.

| Table II | Radiologic examination results for the 2 groups after treatment |
|---------------------------------|------------------|------------------|------------------|
|                  | ESWT             | US needling      |                  |
|                  | Initial | Last follow-up | P value | Initial | Last follow-up | P value |
| Size (mm)        | 11.0 ± 1.0 | 5.6 ± 0.8 | <.05 | 14.8 ± 1.7 | 0.45 ± 0.3 | <.05 |
| CE (%)           | 42.6 | | | 72.2 | | |
| PE (%)           | 16.7 | | | 11.1 | | |
| NE (%)           | 41.7 | | | 16.7 | | |

ESWT, extracorporeal shock wave treatment; US needling, ultrasound-guided needling; CE, complete elimination; PE, partial elimination; NE, no elimination.

Figure 3  Comparison of the American Shoulder and Elbow Surgeons (ASES) scores between the extracorporeal shock wave treatment (ESWT) group and ultrasound-guided needling (needling) group before the procedures and at each follow-up visit. *P < .05.

Figure 4  Comparison of the Simple Shoulder Test scores between the extracorporeal shock wave treatment (ESWT) group and ultrasound-guided needling (needling) group before the procedures and at each follow-up visit. *P < .05.
In this study, there was no significant correlation between the initial size of the calcium deposit and clinical outcomes in both groups. It has previously been stated that the size of the calcium deposit does not always match the severity of the symptoms.\textsuperscript{8,21} Cho et al\textsuperscript{5} reported that the location and initial type and size of the calcium deposits and the severity of initial symptoms did not affect the clinical results of patients receiving conservative treatment, and complete removal of calcium deposits with surgical or other procedures was correlated with good or excellent clinical results.\textsuperscript{25} In contrast, other studies have reported excellent results in function restoration and satisfaction even when complete removal was not achieved.\textsuperscript{3,19,31} However, there were several limitations to this study. First, there was no control group in this study. Because of the naturally self-limited nature of calcific tendinitis, were an untreated group of patients included in this study, the comparison of the therapeutic effect of the procedures would be more accurate than that currently presented. Second, the procedures were performed without taking into consideration the stage of calcific tendinitis. The stage was regarded as painful absorptive stage for all patients because patients experiencing pain for more than 3 months and with calcium deposits confirmed by US were enrolled in this study. The stage of calcium deposition did not vary greatly among patients. Third, the follow-up period after the procedure was too short; a longer follow-up period would have enabled us to draw highly precise conclusions. Finally, to determine ultimate effectiveness of the procedures and to evaluate for the presence of rotator cuff tear, other advanced imaging tools (in the least US, at most magnetic resonance imaging) may be more helpful. These tools will be helpful to identify the potential adverse effects of corticosteroid injection in tendons (like tissue necrosis) and needling (tendon injury or deleterious effects to the tendon integrity). Unfortunately, we did not use such advanced imaging tools. Measurements of calcium deposits before and after each procedure were made with plain radiographs. Plain radiography may be an inaccurate method of measuring the real size of calcium deposits reliably because it is impossible to ensure that the x-ray beam is perpendicular to the long axis of the lesion with few plain radiographs.

### Conclusion

Both treatment modalities for calcific tendinitis, US-guided needling and ESWT, were successful in improving the clinical outcomes and eradicating the calcium deposit. US-guided needling treatment, however, was found to be more effective in function restoration and pain relief at a short-term observation. Moreover, the calcium deposit was eliminated more effectively by US-guided needling than by ESWT.

### Disclaimer

The authors, their immediate families, and any research foundation with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.
References


