



Comparison of Extracorporeal Shock Wave Therapy and Ultrasound-Guided Shoulder Injection Therapy in Patients with Supraspinatus Tendinitis

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Background: The present study compared the clinical effect of extracorporeal shock wave therapy (ESWT) with that of ultrasound (US)-guided shoulder steroid injection therapy in patients with supraspinatus tendinitis. We hypothesized that the two treatments would show comparable results.

Methods: The inclusion criteria were age over 20 years and diagnosis of supraspinatus tendinitis using US. Ultimately, 26 patients were assigned using blocked randomization: 13 in the US-guided shoulder injection group and 13 in the ESWT group. Treatment outcomes were evaluated using the pain visual analog scale (pVAS), the American Shoulder and Elbow Society (ASES) score, and the Constant score at baseline and at 1 and 3 months after the procedure.

Results: At 1 month after the intervention, pVAS, ASES, and constant score were significantly higher in the US-guided shoulder injection group than in the ESWT group, but not at 3 months after the intervention. Both groups showed clinically significant treatment effects at 3 months after the intervention compared to baseline. No significance was shown using equivalence testing.

Conclusions: US-guided shoulder injection therapy was not superior to ESWT therapy. Considering the complications and rebound phenomenon of steroid injections, interventions using ESWT may be a good alternative to treat patients with supraspinatus tendinitis.

Keywords: *Supraspinatus tendinitis, Extracorporeal shock wave therapy, Injection, Random allocation*

A number of literature reviews have revealed that the incidence of rotator cuff disorders is approximately 10% in individuals aged < 20 years and 60% in those aged ≥ 80 years, while the incidence of rotator cuff tendinitis is

approximately 5%–6%.^{1,2)} Despite the common occurrence, the exact pathophysiology of rotator cuff tendinitis remains unclear. In most cases, the disease is self-limiting, but chronic tendinitis symptoms can develop in rare cases. The general conservative treatments include rest, nonsteroidal anti-inflammatory drugs, physiotherapy, and steroid injections, although the therapeutic effects of these treatments have not yet been established.³⁾ Various studies have evaluated the efficacy of steroid injections in the shoulder and found that such treatment improves range of motion by reducing pain and inflammation.^{4,5)} However, the long-term effects remain controversial.

As an alternative treatment, extracorporeal shock

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wave therapy (ESWT) has proven effective in various musculoskeletal disorders.⁶⁾ In particular, ESWT shows remarkable treatment effects in enthesopathy including epicondylitis, Achilles tendinitis, patella tendinitis, and plantar fasciitis.⁷⁻⁹⁾ The precise therapeutic mechanism of ESWT is yet to be elucidated, but the treatment has a positive influence on neovascularization and growth factor release.¹⁰⁾ ESWT has proven effective in treating calcific shoulder tendinitis, while the benefits remain controversial in non-calcific shoulder tendinitis.¹¹⁾

Having reviewed the literature thoroughly, we found that few studies have compared the effects of ESWT with those of steroid injections in the treatment of patients with supraspinatus tendinitis—a subtype of non-calcific shoulder tendinitis. When designing the present study, we hypothesized that the treatment effects of ESWT would have an equivalent outcome to those of steroid injections in patients with supraspinatus tendinitis. The study also compared the clinical results of each patient group after ESWT or an ultrasound (US)-guided shoulder steroid injection to treat supraspinatus tendinitis.

METHODS

Ethical Statement and Study Design

Among patients scheduled for treatment of supraspinatus tendinitis between May 2017 and April 2018, those who conformed to the inclusion/exclusion criteria were recruited to the present study. Prior to participation, the principal investigator (GWL) explained the purpose and methods of the study in detail to the patients, who then signed a consent form to enroll in the study. The research protocol was approved by the Institutional Review Board of Hallym University Kangnam Sacred Heart Hospital (No. 2017-03-015), and the study was carried out in accordance with the Declaration of Helsinki.

To ensure scientific validity and prevent subjective judgment, the participants were assigned in a 1 to 1 ratio to one of the two following intervention groups using a method of random allocation based on probabilistic theo-

ry: (1) independent treatment using ESWT and (2) independent treatment using an US-guided shoulder injection. The codes were generated using blocked randomization in a computer program, and the allocation envelope was opened on the first day of the intervention. A three-digit random allocation number (R01 or R02) was assigned to each participant, and each participant received the treatment corresponding to that number.

Patient Enrollment

In the G-Power 3.1.5 software, the sample size was estimated based on an effect size of 0.45, a significance level of 0.05, and a power of 0.80, yielding a sample size of 12 subjects per group—24 subjects in total. Taking into account a $\geq 10\%$ dropout rate, a total of 26 patients (13 in each group) were recruited.¹²⁾ The study participants were outpatients visiting the hospital. When the predetermined number of subjects assigned to a group reached 100%, enrollment in this group was ended, while enrollment in the other group continued.

The inclusion criteria were as follows: (1) age ≥ 20 years, (2) diagnosis of supraspinatus tendinitis by US, and (3) written consent to participate in the study. US examinations were performed and read according to standardized procedures by a musculoskeletal radiologist with over 20 years of experience (IY). This result was confirmed secondary by a senior clinician (KCN). If a local hypoechoic lesion was seen or fibrillar disruption was less than 25% of the tendon height, it was classified as tendinitis, and if it was more than 25%, it was classified as partial thickness and excluded from the study (Fig. 1).

The exclusion criteria were as follows: (1) rotator cuff surgery on the corresponding side, (2) superior labral reconstruction on the corresponding side, (3) rupture in the supraspinatus or complete rupture in other rotator cuff tendons, (4) any steroid intervention (oral or injected) within the previous 3 months, (5) history of allergy to lidocaine or US gel, (6) inflammatory or autoimmune disease, (7) fever or infectious disease within the previous 2 weeks, (8) diabetes mellitus, (9) blood disorders such as

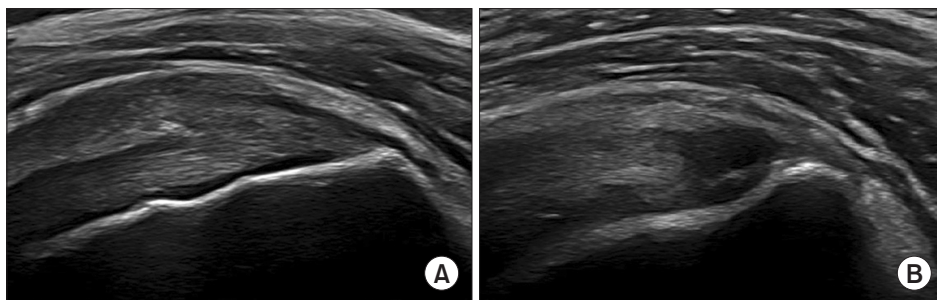


Fig. 1. Ultrasound images of a patient with tendinitis (A) and a patient with a partial thickness rotator cuff tear (B).

platelet dysfunction syndrome that prevented treatment using an injection, (10) increased hemorrhagic risk caused by an antiplatelet drug, (11) pregnancy or lactation, (12) individuals who failed to satisfy the requirements of the clinical study, as determined by the principal investigator (GWL) (Fig. 2).

Outcome Measures

To ensure that the study was valid, all participants underwent a clinical evaluation (pain visual analog scale [pVAS], American Shoulder and Elbow Society [ASES] score, and Constant score) prior to the intervention and at 1 month and 3 months after the intervention. Pain was measured using the pVAS, which visualizes the level of subjective pain on a scale of 0–100: 0 indicated no pain and 100 the worst imaginable pain. The ASES score assesses shoulder joint functions based on the patient's subjective pain and most frequently performed daily activities. The Constant score allows both subjective and objective functional assessments as it includes scores for range of motion (40 points) and muscular strength (25 points), measured using physical tests performed by an investigator, as well as scores for the level of subjective pain (15 point) and the level of patient satisfaction regarding sleep, work, exercise, and leisure (20 points).

Interventions

US-guided shoulder injection

To accurately detect the lesion area, the injection was performed under US guidance. A posterior approach was used because it allowed the marker to be easily identified and because the space between the humeral head and the

acromion was usually larger in that region. Firstly, the posterolateral edge of the acromion was sensed with the thumb and forefinger. After wiping the skin with an alcohol swab, the patient's upper arm was placed on the thigh to relax the deltoid. As the anterior acromion was sensed with one finger, a 25-G injection needle was pointed in the direction of the finger. When resistance was felt during the injection, the needle was determined to be in the tendon; the needle was then slowly pulled back until the resistance faded, and 2 mL of 2% lidocaine was rapidly injected. For 2 minutes, the clinicians monitored whether the anesthetic was working. The syringe containing the anesthetic was then replaced with a syringe containing a steroid (triamcinolone acetonide; 40 mg/m/V) in the same position. All injection treatments were administered once.

ESWT

Prior to the intervention, the patients were given detailed explanations of the possible side effects and intervention time. They were also told that the treatment effects of ESWT could fail if they moved. Next, the shock wave frequency and energy were selected (mode: linear focused, counter: 2000, energy level setting 5 = positive Energy Flux Density of 0.142 mJ/mm²), and the head of the ESWT device (PiezoWave² MULTIUSE60; WOLF) was covered evenly with US gel.¹³ ESWT was then applied once to the lesion area.

Statistical Analysis

To analyze the mean and frequency, the demographic data and the results of the questionnaire were evaluated. For categorical data, Pearson's chi-square and Fisher's exact tests were used. For continuous data from the pVAS, ASES, and constant score, the Student's *t*-test and Wilcoxon rank-sum test were used. For comparative analysis of time-dependent data (baseline, 1 month, and 3 months) from the two intervention groups, repeated-measures analysis of variance and the linear mixed model were used. A *post hoc* Bonferroni test was used to compare the means of baseline scores between the groups. To determine equivalence between the groups, equivalence testing was carried out. In all statistical analyses, IBM SPSS ver. 24.0 (IBM Inc., Armonk, NY, USA) was used, while statistical significance was set at a *p*-value of < 0.05.

RESULTS

The present study was conducted in a total of 26 patients: 13 in each group. In the US-guided shoulder injection group, 1 patient was lost to follow-up, while no one

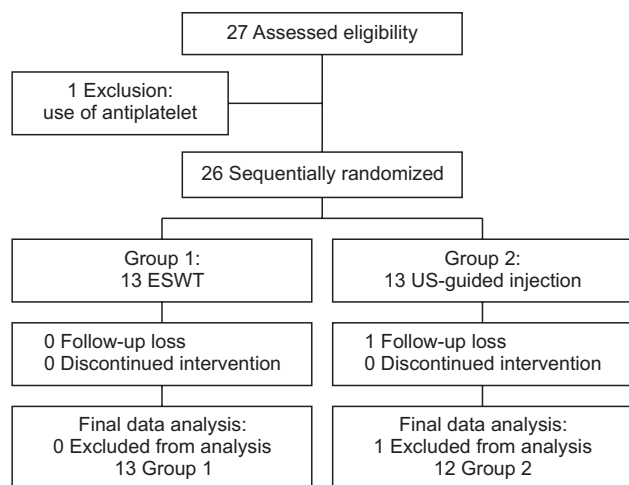


Fig. 2. Flowchart of patient selection in the study. ESWT: extracorporeal shock wave therapy, US: ultrasound.

dropped out of the ESWT intervention group. The two groups showed no significant difference in sex, age, or involved site (Table 1). Regarding the clinical treatment effects in each intervention group, the US-guided shoulder injection group showed treatment effects in the pVAS, ASES score, and Constant score at both 1 and 3 months after the intervention compared to baseline. However, the effects at 3 months after the intervention were significantly lower than those at 1 month after the intervention. The ESWT group showed significant treatment effects in the pVAS, ASES score, and Constant score at 3 months after the intervention compared to baseline, but not at 1 month after the intervention (Fig. 3).

When the two groups were compared, the pVAS, ASES score, and Constant score measured before intervention showed no significant difference between the US-guided shoulder injection group and the ESWT group. At 1 month after the intervention, the pVAS, ASES score, and Constant score indicated that the treatment effects were

significantly better in the US-guided shoulder injection group than in the ESWT group. However, at 3 months after the intervention, the 3 measures showed no significant intergroup difference in treatment effects (Table 2). Based on these findings, equivalence testing was carried out to verify the equivalence of post-intervention clinical outcome between the US-guided shoulder injection group and ESWT group, but the results showed no statistical significance (Table 3).

DISCUSSION

By comparing clinical outcome in the US-guided shoulder injection and ESWT groups, the present study showed that the latter can be considered an adequate alternative treatment for supraspinatus tendinitis. Although the ESWT group showed no significant treatment effects 1 month after the intervention, significant treatment effects were obtained in 3 months. The clinical treatment effects 1 month

Table 1. Demographic Data of ESWT and US-Guided Injection Groups at Baseline

Variable	Group 1: ESWT (n = 13)	Group 2: US-guided Injection (n = 12)	p-value
Sex			0.673
Male	5 (38.46)	3 (25.00)	
Female	8 (61.54)	9 (75.00)	
Age (yr)	52.31 ± 7.25	53.00 ± 9.52	0.921
Involved site			1.000
Right	7	6	
Left	6	6	

Values are presented as number (%) or mean ± standard deviation. ESWT: extracorporeal shock wave therapy, US: ultrasound.

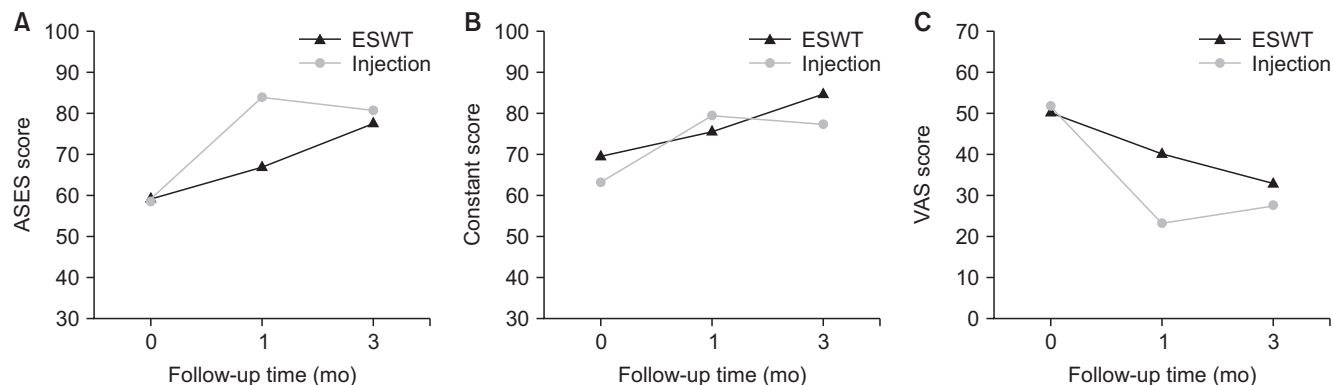


Fig. 3. Changes in the American Shoulder and Elbow Society (ASES) score (A), Constant score (B), and visual analog scale (VAS) score (C) over time. ESWT: extracorporeal shock wave therapy.

Table 2. Comparison of Clinical Score Difference between ESWT and Injection Groups

Variable	ESWT group	Injection group	p-value
ASES score			
Δ ASES _{1 month}	6.42 ± 9.31	25.08 ± 17.45	0.005*
Δ ASES _{3 months}	15.68 ± 13.03	22.22 ± 19.33	0.375
Constant score			
Δ Constant _{1 month}	6.17 ± 4.76	16.25 ± 14.98	0.044*
Δ Constant _{3 months}	12.30 ± 8.69	14.42 ± 17.80	0.870
VAS score			
Δ VAS _{1 month}	-8.42 ± 15.93	-28.50 ± 20.93	0.015*
Δ VAS _{3 months}	-18.00 ± 18.15	-24.17 ± 20.97	0.474

Values are presented as mean ± standard deviation.

ESWT: extracorporeal shock wave therapy, ASES: American Shoulder and Elbow Society, Δ ASES_{months}: ASES_{months} - ASES_{baseline}, Δ Constant_{months}: Constant_{months} - Constant_{baseline}, VAS: visual analog scale, Δ VAS_{months}: VAS_{months} - VAS_{baseline}.

*Indicates statistical significance ($p < 0.05$).

Table 3. Equivalence Testing of Clinical Score between ESWT and Injection Groups at 3 Months

Variable	ESWT group	Injection group	p-value
ASES score	77.82 ± 12.25	80.66 ± 17.76	0.299
Constant score	85.10 ± 12.13	77.42 ± 10.65	0.129
VAS score	33.00 ± 15.85	27.50 ± 24.63	0.688

Values are presented as mean ± standard deviation.

ESWT: extracorporeal shock wave therapy, ASES: American Shoulder and Elbow Society, VAS: visual analog scale.

after intervention were significantly higher in the US-guided shoulder injection group. However, 3 months after intervention, the treatment effects showed no significant intergroup difference. While the effects of independent ESWT treatment consistently increased over time, those of the US-guided shoulder steroid injection did not, presumably because the rebound phenomenon diminished the effects of the steroid treatment. In the present study, equivalence testing was carried out to verify equivalence in the treatment effects between the groups, but the results could not confirm any equivalence, probably because the patient groups were too small for the statistical analyses.

Most previous studies on patients with shoulder complaints have compared ESWT with a placebo,^{14,15} determined the independent effects of ESWT,¹⁶ or compared ESWT with physical therapy,¹⁷ kinesio taping,¹⁸ or acromion type.¹⁹ The short-term and long-term effects of ESWT to treat non-calcific tendinopathy of the rotator cuff remain controversial. Previous studies comparing the

treatment effect between placebo or control groups and an ESWT group have reported that the pain and constant scores indicated a significant treatment effect in the short term, but that the long-term effects were not different from those of a placebo.^{14,15,20} The present study showed that independent ESWT treatment had marked effects compared to the steroid injection during the 3-month follow-up period. These results are of great significance because they showed that ESWT has positive treatment effects on supraspinatus tendinitis in a prospective comparison of clinical results between independent ESWT treatment and the US-guided shoulder injection.

The therapeutic mechanism of ESWT in tendinitis has not been precisely defined, although there are various theories. In the case of non-calcific shoulder tendinitis, the neovascularization and blood supply effects of ESWT exert an influence on pain and functional improvement, while a decompressive effect occurs in patients with calcific tendinitis.^{10,21} ESWT is also thought to inhibit per-

sistent inflammatory reactions in soft tissues by inducing the repair of inflamed tissues and stimulating nitric oxide synthase.²²⁾ In this study, we used an energy level of about 0.15 mJ/mm². Although the consensus on the criteria for dividing energy level is not clear, it can be classified as low or medium. Similar to this study, there was a study showing that ESWT of medium energy (0.11 mJ/mm²) was effective in the treatment of calcific tendinitis.²³⁾ Although opinions are divided on non-calcifying rotator cuff tendinitis, effective results of low-energy ESWT have been reported, which are consistent with the good results of this study.^{15,24)}

In some studies, steroid injection has been more effective and cost-efficient than ESWT.²⁵⁾ *In vitro* studies have shown that in addition to anti-inflammatory effects, corticosteroids provide a therapeutic effect by inhibiting the production of collagen, extracellular matrix molecules, and granulation tissue.²⁶⁾ In addition, it is reported that corticosteroid injections are effective in pain relief and functional improvement in a short period of time (3 to 6 weeks).^{27,28)} However, there are potential complications of steroid injections, including subcutaneous atrophy, transient hyperglycemia, infection, skin pigmentation, ruptured tendon, and risk of allergic reaction to local anesthetics. Topical administration of glucocorticoids has been reported to have significant negative effects on tendon cells *in vitro* through reduced cell survival, cell proliferation, and collagen synthesis.²⁹⁾ It was also reported that the mid-term and long-term effects after corticosteroid injections were not significant, and the results were similar to those of our study.³⁰⁾ Considering these disadvantages of corticosteroid injections, ESWT could be recommended as an alternative treatment because it can induce neovascularization and tissue regeneration.

The present study has several limitations. Firstly, the sample size was small. Although the G-power was used to compute the number of patients, a larger sample size would have led to more significant results in the equivalence testing. In the future, by designing a study with a larger sample size, we could compare and analyze a placebo group, a simultaneous injection group, and ESWT group, which was not possible in the present study.

Secondly, the follow-up period was relatively short. While previous studies have also relied on an 8-week or 3-month follow-up, a year or more of long-term follow-up would have led to more reliable results. However, this would increase the possibility of increased patient dropout due to the rebound phenomenon of steroid injections. Lastly, the ESWT intervention was given only once. Had sequential intervention been carried out, superior results may have been obtained.

In conclusion, ESWT can be a safe and effective treatment for shoulder tendinitis. Furthermore, US-guided shoulder injections did not produce superior effects than independent ESWT treatment. Considering the complications and rebound phenomenon of steroid injections, ESWT treatment may be a good alternative in patients with supraspinatus tendinitis.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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