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Is extracorporeal shock wave therapy effective in treating shoulder tendonitis?

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ABSTRACT

OBJECTIVE: The objective of this selective EBM review is to determine whether or not extracorporeal shock wave therapy is effective in treating shoulder tendonitis.

STUDY DESIGN: This review paper analyzes two, double-blind, randomized control trials (RCTs) and one retrospective cohort study. The population included adults with calcified or non-calcified shoulder tendinitis. The intervention was extracorporeal shock wave therapy (ESWT). The groups receiving ESWT in the RCTs were compared to those receiving placebo probes.

DATA SOURCE: Each article was a primary research design published in English after 2015 in peer-review journals.

OUTCOMES: The outcomes measured were patient-oriented evidence that matters, including pain and disability. The outcomes were measured by questionnaires and surveys including NRS, CMS, SPADI, and VAS. The summary of statistics was reported using mean change from baseline, 95% confidence intervals, standard deviations, and p-values.

RESULTS: Lie et al. RCT studied those with non-calcified CRTC tendonitis. There was a statistically significant decrease in mean NRS and CMS score in the group receiving ESWT compared to the control group receiving the placebo probe ($p < 0.001$; *Medicine*. 2017;96(35):1-4. doi:10.1097/MD.0000000000007940). Kvalaag et al. RCT studied those with non-calcified and calcified RTC tendonitis. There was no statistically significant difference in the group receiving ESWT with supervised exercises compared to the group receiving sham ESWT with supervised exercises ($p = .76$); however, both groups had a decrease in mean SPADI score (*Am J Sports Med*. 2017;45(11):2547-2554. doi: 10.1177/0363546517707505 [doi]). Malliaropoulos et al. retrospective cohort study showed a statistically significant improvement in shoulder pain, remission rate, and recurrence rate in those with calcified shoulder tendinopathy (*Musculoskelet Disord*. 2017;18(1):x. doi: 10.1186/s12891-017-1873-x [doi]).

CONCLUSION: It is inconclusive as to whether or not ESWT is effective in treating shoulder tendonitis. Two studies showed statistically significant improvements in shoulder pain and function after ESWT, while one study did not. Further studies are needed to determine which specific type of shoulder tendonitis would benefit most from ESWT.

KEY WORDS: extracorporeal shock wave therapy, shoulder tendonitis, tendinopathy, shoulder pain

INTRODUCTION

Shoulder tendonitis is an acute, subacute, or chronic inflammatory condition that is largely due to trauma and overuse of the rotator cuff tendons. Shoulder tendonitis is a common condition that medical professionals may encounter in primary care or orthopedic/sports medicine settings. Extracorporeal shock wave therapy (ESWT) is an emerging treatment for many common musculoskeletal complaints, including plantar fasciitis, epicondylitis and rotator cuff tendonitis.[1] Medical professionals need to be educated on ESWT in order to determine good candidates for the procedure.

Shoulder tendinopathy is the third most common orthopedic complaint in the United States, and it accounts for 4.5 billion healthcare visits.[4] The prevalence of shoulder tendonitis increases with age but can be seen in a younger population as well, commonly in athletes. Many shoulder complaints are due to rotator cuff (RTC) etiologies. The RTC includes four main tendons: supraspinatus, infraspinatus, subscapularis and teres minor. When there is damage to these tendons the body elicits an inflammatory response. As inflammation ensues during the acute phase, lasting anywhere from 3 weeks to 6 months[5], patients will complain of pain and decreased mobility.

This condition can be self-limiting, but other times scar tissue and calcifications can form causing chronic RTC (CRTC) tendonitis. In calcified RTC tendonitis, calcium hydroxyapatite crystals form along the tendons, most commonly the supraspinatus tendon, and it can impede mobility and blood flow to the muscles creating muscle hypoxia.[5] Patients may also have decreased range of motion (specifically with abduction), crepitus, impingement sign, and point tenderness.[5]

Typically, conservative measures are first employed to treat shoulder tendonitis. These include NSAIDs, physical therapy, corticosteroid injections, and transcutaneous nerve stimulation.[1,5] When these measures fail, arthroscopic surgery can be performed.

ESWT is proposed as a treatment for shoulder tendonitis because it is a non-invasive, cost-effective procedure that has minimal complications and minimal recovery time. In 2015, it was reported in the *International Journal of Surgery* that patients saved $2,000 when they choose ESWT compared to surgery.[2] In Europe, surgery cost 5-7x higher than ESWT and were associated with a longer time off work[2]. The cost of ESWT was €2700-€4300, which estimates to US$2,974-$4,736.[2,3] Additionally, ESWT is effective because it breaks down fibrous tissue, restores blood flow, stimulates formation of collagen, and improves sensation of pain.[1,5]

OBJECTIVE

The objective of this selective EBM review is to determine whether or not extracorporeal shock wave therapy is effective in treating shoulder tendonitis.

METHODS

In searching for data sources, the keywords that were used were extracorporeal shock wave therapy, shoulder tendonitis, tendinopathy, and shoulder pain. Articles were researched through PubMed and Alt Health Watch. Articles were chosen that aimed to answer the question in the objective and that had outcomes that were patient oriented evidence that matters (POEMs). The search's inclusion criteria were primary research design and studies published after 2015. The search's exclusion criteria were studies published before 2015. The summary of statistics was reported as mean change from baseline, 95% confidence intervals (CIs), standard deviations (SDs) and p-values.

The three studies selected included two randomized, double-blind, placebo-controlled trials; and one uncontrolled, retrospective, single-center cohort analysis. Each article was published in English. They were published in peer-review journals in 2017, including *The BioMed Central Journal of Musculoskeletal Disorders, Medicine, and The American Journal of Sports Medicine.*

In this review paper, the population studied was adults with calcified or non-calcified shoulder tendinitis. The intervention studied was extracorporeal shock wave therapy. The comparison group was those receiving placebo probes. The outcomes studied were shoulder pain and disability.

OUTCOMES

The outcomes measured were shoulder pain and disability. This was achieved through self-reported surveys and questionnaires including: Numeric Rating Scale (NRS), Constant Murley Score (CMS), Shoulder Pain and Disability Index (SPADI) and Visual Analog Score (VAS).

The SPADI measured shoulder pain and function. It consists of 13 questions, 5 of which assess pain and 8 that assess disability. Each question is scored using a visual analog scale of 0-11. The total SPADI score ranges from 0-100, with a higher score indicating higher pain and disability.[1] The VAS assessed pain on a scale of 0-10 with associated pictures depicting the levels of pain.[5] The NRS also assessed pain on a scale of 0-10, with 10 being the worst possible pain[6]. The CMS measured shoulder functionality on a 0-100 scale, with a higher score indicating better function of the shoulder.[6]

Table 1. Demographics and characteristics of included studies

Study	Type	# Pts	Age (yrs)	Inclusion Criteria	Exclusion Criteria	# W/ D	Interventions
Li et al. (2017)[6]	RCT	84	18-65	Dx of CRTC tendonitis w/o calcification, h/o clinical signs of chronic tendonitis for > 6 mo, no alternative therapy (including ESWT) w/i 1 mo of study	Pregnant, breastfeeding, coagulopathy, h/o surgery, h/o or current neoplasms, pacemaker, adhesive capsulitis, systemic ds, skin ds, severe mental ds	15	ESWT: 3,000 pulses of 0.11 mJ/mm^2 at 15Hz x 5 sessions with 3-day intervals
Kvalvaag et al. (2017)[1]	RCT	143	25-70	Sx of subacromial shoulder pain w/ and w/o calcifications for > 3 mo Pain with either abduction of arm in 45 degrees and/or external rotation of arm at side, Hawkins Impingement sign, normal passive glenohumeral ROM	H/o previous surgery or ESWT, corticosteroid injection in last 6 wks, SPADI score <20, instability of shoulder, RA, full thickness RTC tear, cervical radiculopathy, infections, coagulopathy, epilepsy, pregnancy, pacemaker	8	ESWT: 2,000 pulses of 0.14-0.33 mJ/mm^2 once/wk x 4 wks Supervised exercises: once/wk x 4 wks (in combo with ESWT), then twice/wk x 4 wks (w/o ESWT)
Malliaropoulos et al. (2017)[5]	Retrospective Cohort	67	26-63	Dx of calcified shoulder tendinopathy, pain > 3 mo, greater than 18yo, sessions performed under US guidance	Acute/severe painful calcified shoulder tendinopathy, RTC rupture; H/o surgery, ESWT, corticosteroid injection in past 6 wks, or malignancy	0	ESWT: Mean of 2,175 pulses of 1.7 mJ/mm^2 at 5Hz for a mean of 7 sessions once/wk

RESULTS

A randomized, double-blinded control trial, conducted by Li et al., studied the efficacy of ESWT in 84 patients with non-calcified CRTC tendonitis, compared to a placebo probe. Participants were randomly assigned to the intervention group or control group. The intervention group received ESWT at 3,000 pulses of 0.11 mJ/mm^2 at 15Hz for 5 sessions with 3-day intervals in between.[6] The control group received the placebo probe for 5 sessions with 3-day intervals in between.[6] In this study, three participants withdrew for consent withdrawal, and twelve were lost to follow-up. There were 35 participants that completed treatment in the interventional group and 34 participants that completed treatment in the control group. All patients were analyzed with intention-to-treat (ITT). The outcomes, pain and disability, were measured by the NRS and CMS and evaluated using mean change from baseline after 8 weeks of treatment, a 95% confidence interval and a p-value that was statistically significant when $p < 0.05$ (Table 2). After 8 weeks of the study, there was a 4.5 decrease in NRS score and a 27.2 increase in CMS score.[6] The 95% CIs had a narrow range, and the results were statistically significant when compared to the control group, with a p-value < 0.01 (Table 2).[6]

Table 2. Outcome measurements after 8 weeks of treatment in Lie et al. study[6]

Outcomes	**Mean Change from Baseline (95% CI)**		**P value**
	ESWT	Placebo	
NRS	-4.5 (-7.2, -2.3)	-0.5 (-0.9, 0.6)	**< .01
CMS	27.2 (18.6, 38.3)	14.1 (8.8, 20.2)	**< .01

**statistically significant difference (p = <0.05)

Another randomized, double-blinded, control trial, conducted by Kvalvaag et al., studied the effectiveness of ESWT in combination with an appropriate exercise regimen to treat calcified and non-calcified RTC tendinopathy, compared to those receiving the sham ESWT. The study

included 143 participants that were randomly assigned to the interventional group or the control group. The interventional group received ESWT at 2,000 pulses of 0.14-0.33 mJ/mm2 once a week for 4 weeks on painful shoulder tendons that were determined with isometric testing.[1] Additionally, they underwent supervised exercises once a week for 4 weeks (with ESWT) and then twice a week for 4 weeks (with no ESWT). The control group received the same exercise regimen and a sham ESWT, which was identical in appearance but delivered no extracorporeal shock waves. In this study, three participants were lost to follow-up, and five participants discontinued intervention due to pain after sham ESWT, sudden onset of other disorder, development of adhesive capsulitis or synovial chondromatosis. There were 65 participants that completed treatment in the interventional group and 70 participants that completed treatment in the control group. All patients were analyzed with ITT.

The outcomes, pain and disability, were measured using the SPADI self-reported questionnaire and evaluated using mean change from baseline after 24 weeks of treatment, 95% CIs, and a p-value that was statistically significant if $p < 0.05$ (Table 3).[1] After 24 weeks of the study, there was a 23.6-point decrease in SPADI score for those receiving ESWT and a 24.4-point decrease in SPADI score in those receiving the sham ESWT[1]. The treatment affect was small with a wide-ranged CI and high SDs (Table 3). The p-value = 0.76, which was not statistically significant (Table 3).[1]

Table 3. Outcome measurements at baseline and 24 weeks of treatment in Kvalvaag et al. study[1]

Outcomes	**Mean Baseline (SD)**	**Mean 24 weeks (SD)**	**Mean Change from Baseline**		**Mean Treatment Effect (95% CI)**	**P value**
	ESWT	Sham	ESWT	Sham		
SPADI	51.9 (16.7)	51.8 (17.5)	-23.6	-24.4	0.7 (-6.9 to 8.3)	.76

A retrospective cohort analysis, conducted by Malliaropoulos et al., evaluated ESWT in patients with calcified shoulder tendinopathy. In this study, there were 67 patients that were evaluated who were diagnosed with calcified shoulder tendinopathy with pain that lasted for at least three months. Three patients discontinued their treatment due to financial reasons or time constraints. There were 64 patients that completed their treatment protocol, 39% men and 61% women.[5] The average duration of shoulder pain experienced by this group of patients prior to treatment was 12.5 months,, and the patients completed an average number of 7 ESWT sessions.[5]

In this study, Malliaropoulos et al., each patient had an individualized treatment protocol determined by their severity of pain, tolerance of ESWT, and response to treatment. The outcome of pain was measured by the self-reported VAS score, which was taken at baseline, immediately post-treatment, 1-month post treatment, 3-months post-treatment and 1-year post treatment. Successful treatment was defined as those that had a 60% decrease in their VAS score. VAS scores were evaluated by using mean change from baseline, standard deviations (SDs), and a p-value that was statistically significant if <0.001 (Table 4).[5] There was a 3.4 mean decrease in VAS score from baseline immediately post treatment (52% decrease), 4.1 decrease 2-months post treatment (62% decrease), 5.0 decrease 3-months post treatment (75% decrease), and 5.8 decrease 1-year post treatment (88% decrease). The SDs ranged from 0.8-1.1. The results were statistically significant with a p value = 0.000 (Table 4).[5]

DISCUSSION

ESWT is an affordable, non-invasive, emerging therapy for those with shoulder tendonitis. In the Li et al. RCT study, ESWT was found to be clinically important for patients with non-calcified CRTC tendonitis. There was a statistically significantly improvement in the participants pain and shoulder function after receiving ESWT for four weeks, compared to those receiving no

ESWT. Additionally, there were no adverse events reported.[6] A limitation in this study was that the sample size was small and was only conducted at a single center with patients of Chinse Han ethnicity.[6]

Table 4. Outcome measurements at various follow-ups in Malliaropoulos et al. study[5]

Follow up	**Mean VAS**	**SD**	**Mean VAS reduction from baseline**	**% Mean VAS reduction from baseline**	**P-value**
Baseline	6.7	1.1			
Immediately post-treatment	3.2	0.8	3.4	52%	**0.000
1-month	2.6	0.9	4.1	62%	**0.000
3-month	1.7	1.0	5.0	75%	**0.000
1-year	0.8	1.0	5.8	88%	**0.000

**statistically significant difference (p = <0.001)

In the Kvalaag et al. study, there was no statistically significant improvement in pain for those who received ESWT and supervised exercises, compared to those that received sham ESWT and supervised exercises. Both the control group and the interventional group reported improvements in pain, but there was no statistically significant difference between both groups. A limitation to this study is that while patients met the common clinical criteria, they had different findings on their ultrasound.[1] Furthermore, the physical therapists who were solely in charge of administering the ESWT or sham ESWT were not blinded.[1]

In the Malliaropoulos et al. study, patients receiving an individualized protocol for ESWT to treat calcified shoulder tendonitis saw statistically significant reduction in pain post-treatment and up to 1-year after.[5] A limitation to this study is that there was no randomization or control group.

CONCLUSION

Based off of the studies analyzed, it has been determined that the evidence is inconclusive in determining if ESWT is effective in treating shoulder tendinitis, as the studies have opposing results. In the study conducted by Li et al, it was concluded that ESWT was safe and effective in treating non-calcified CRTC tendonitis. In the study conducted by Kvalvaag et al., it was concluded that ESWT provided no additional improvement in pain and level of disability in those with shoulder tendonitis (calcified and non-calcified). The improvement in both the interventional and control group may have been due to the supervised exercises, the common denominator in both groups. In the study conducted by Malliaropoulos et al., it was concluded that ESWT improved pain in those with calcified shoulder tendinopathy, and it was associated with a lower recurrence rate and higher remission rate up to 1-year post-treatment.

Further studies are necessary to determine the type of shoulder tendinopathy that would most benefit from ESWT. The Kvalvaag et al. study did not separate their study population into calcified vs non-calcified RTC tendonitis. Although this made the study more generalizable, it skewed the results because the population was not specific. The study also included supervised exercises into the treatment protocol making it difficult to draw conclusions specifically about ESWT, since it was not an isolated intervention. Furthermore, there needs to be a larger study of design that is conducted for a longer duration of time, as shoulder tendonitis can take up to a year to heal post treatment.

In the two studies that showed ESWT effective in treating RTC tendonitis, both studies included participants with chronic symptoms; Lei et al included those with pain lasting > 6 mo, and Malliaropoulos et al included those with a mean duration of pain of 12.5 months.[6,5] Therefore, future studies need to focus on a population that has CRTC tendonitis. Then, the study

can be further specified into calcified and noncalcified CRTC tendonitis. In conclusion, the studies on the effectiveness of ESWT in treating shoulder tendonitis were conflicting, and more specific studies need to be done before definitive conclusions can be made.

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