Original Article

Ultrasound guided Needling vs Radial Shockwave Therapy in calcific tendinitis of the shoulder: A prospective randomized trial

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ABSTRACT

Purpose: Ultrasound Needling(UN) and Radial Shockwave(RSWT) aim to dissolve deposits in Shoulder Calcific tendinitis.

Methods: RCT in 25 patients to compare short term effectiveness. Outcome measures were pain and functional outcome at 6 weeks and 1 year and decrease of deposits after 6 weeks.

Results: UN decreased deposit more than RSWT($P=0.029$). After 6 weeks, Constant, NRS and Oxford improved more in UN. After 1 year, there was no significant difference in NRS($p=0.45$) or Oxford ($p=0.32$).

Conclusion: Compared to RSWT, UN resulted in lower pain and faster resorption of calcifications after 6 weeks. No significant differences were found after 1 year.

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1. Introduction

Calcific tendinitis of the shoulder is a self limiting but very painful condition, whereby (multiple) calcific deposits are located in one or more of the rotator cuff tendons¹. Beside severe pain mostly located on the anterolateral part of the shoulder and the upper arm, one of the main symptoms is loss of active function. A prevalence of 3–5% is described, and one third to one half of these people will actually have shoulder complaints².

It may take years before the natural process of resolving starts. Generally accepted treatment options consist of NSAID, physical therapy and/or cortisone injections in the subacromial bursa to control pain. If symptoms persist or return, further treatment options are, besides an arthroscopic debridement which requires general anesthesia, Ultrasound guided Needling (UN), which require only local anesthesia in the outpatient clinic, and Radial Shockwave Therapy (RSWT) which require no anesthesia and could be performed in an out-of-hospital environment. These treatments aim to stimulate the body to dissolve the calcific deposits^{3–5}.

UN is a single treatment procedure in which the calcium deposit is punctured under ultrasound guidance. UN shows good results in terms of reduction of pain and improvement of function and satisfaction within 36 weeks after treatment⁶. This improvement has also been seen in short term radiographic results⁷.

The mechanical RSWT pulses used for treatment of calcific tendinitis of the shoulder have a much lower focus and intensity than the wider used Extracorporeal Shockwave Therapy (ESWT). Therefore, RSWT was reported to be less painful than ESWT and is acceptable without anesthesia for most patients in terms of pain. Short-term effects of RSWT therapy show significant improvement of shoulder joint function and good effectiveness on reducing pain with minimal side effects^{4,8,9}. This was also confirmed in radiographic results^{3,10}. ESWT was compared to UN before, reporting UN to be more effective^{11,12}. Although the effectiveness of the RSWT and UN treatment has been investigated, to our knowledge no studies have been performed where the two treatments are compared directly. In our randomized controlled trial we compared the short-term effectiveness of UN against RSWT. We studied the decrease of the calcific deposits on x-ray and differences in pain and function at 6 weeks and after one year.

We hypothesized that UN would result in a greater reduction of the calcific deposit size and improved clinical outcome compared to RSWT.

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2. Methods

2.1. Participants

All patients seen on the outpatient clinic of our hospital between May 2010 and March 2011 were eligible for inclusion if they met the following inclusion criteria: shoulder pain persisting more than 6 months, calcification in the rotator cuff region type I or II according to Gärtner¹ on a standard shoulder radiograph. Furthermore, the Numeric Rating Scale (NRS) for pain had to be ≥ 4 at the time of inclusion and previous conservative therapy (physiotherapy, Non-steroidal Anti-Inflammatory Drugs (NSAIDs), cortisone infiltration) should have failed. We excluded patients on the following criteria: insufficient knowledge of Dutch language, age under 18, inability to receive informed consent, participation in other study, other pathology which could cause shoulder- or upper limb pain (eg. rotator cuff tears, acromioclavicular arthropathy, frozen shoulder, cervical disc hernia). Patients who suffered from inflammatory-, malignant- or clotting disease were excluded, as well as pregnant woman. If patients agreed to participate, informed consent was obtained and patients were randomized. This study was approved by the local medical ethical committee (NL24917.098.08). In the initial power calculation of the medical ethical committee we needed 40 patients for inclusion (20 in each group). During the trial the Data Safety Monitoring Board decided to stop the inclusion prematurely due to the extremely high NRS score of the patients in the RSWT group. Before the study was terminated, 25 patients were included (Fig. 1). Thirteen patients were male and twelve female. After randomization, 11 patients were treated with UN (Mean age: 53 [95%CI 50–57], 5 female, 6 male) and 14 with RSWT (Mean age: 53 [95%CI 48–58], 7 female, 7 male).

2.2. UN

The UN protocol consisted of a single treatment procedure. Before the start of the treatment, 1 ml (40 mg) of corticosteroid (Depo-medrol 40 mg/ml, Pfizer Medical, New York City, NY, USA) was left inside the subacromial bursa without ultrasound guidance. Then a local anaesthetic (lidocaine 1%) was administered to the skin, bursa and tendon. The calcification was localized with ultrasound and pierced several times with 2 hollow 18 gauge needles. A saline solution was flushed through both needle portals in order to wash out the calcium. All procedures were done by the senior author (PH) who is a shoulder surgeon experienced in ultrasonography.

2.3. RSWT

The RSWT protocol consisted of 4 sessions of RSWT therapy, one week apart. Each session was similar: 500 pulses of 1.5 bar (150 kPa) with a frequency of 4.5 Hz, followed by 2000 pulses of 2.5 bar (250 kPa) with a frequency of 10 Hz; EFD (Energy Fluctuation Density) 0.10 mJ/mm. Duration of pulses was 2 ms. We used a Masterpuls MP 100 (Storz Medical, Tägerwil, Switzerland) in combination with a standard ultrasound transfer gel. RSWT was performed by a specialist physical therapist that initially treated 20 patients who were not included in the study, to pass the learning curve.

2.4. Variables

Scoring of calcification deposits was done by a nurse practitioner through the Gärtner classification¹. This classification

Fig. 1. inclusion table.

if defined by three categories (type I well demarcated, dense deposit; type II soft contour and dense deposit or sharp contour and transparent deposit; type III soft contour and transparent). We included a type IV when deposit was totally dissolved.

Pain was scored using the NRS, ranging from 0 to 10, in which only absolute numbers can be used. Score 0 equals no pain. When the patient could not choose between two numbers (eg. between a score of 3 and 4) we used the higher (4) score.

Clinical outcome was measured using the Oxford Shoulder Score¹³ and the Constant Murley Score¹⁴. The Oxford score is a 12-items questionnaire to assess the patient's functional ability (for each question 1 = worst, 5 = best). Therefore, the score of 12 was the worst score which patients could receive and the score of 60 the best score. The Constant Murley score is a combined score which measures the pain score, functional assessment, range of motion and strength. The maximum score is 100 and the minimum score 2.

2.5. Design and procedure

Randomization was done by allowing the patient to choose an unmarked envelope containing the treatment protocol for either UN or RSWT from a box. The envelopes were randomized in blocks (6 envelopes, 3 of each treatment). When a block was finished, the next block was started. Patients completed the Oxford Shoulder Score and NRS at home before the start of the intervention and at 6 weeks and 1 year after initial treatment. The Constant Murley Score was completed at the outpatient clinic pre-treatment and at 6 weeks. Routine shoulder x-rays (anteroposterior (AP) view in exo- and endorotation) were used to assess the calcification.

2.6. Statistics

All data was analyzed in SPSS Statistics version 17.0 (IBM, Armonk, NY, USA). A p-value less than 0.05 was considered statistically significant.

A mixed model with a fixed factor of group (UN vs RSWT) and time (pre vs 6 weeks), and interaction between group and time was used to assess improvement in Gärtner classification, NRS, Oxford Score and Constant Murley Score after 6 weeks. Because of the high crossover the results after 1 year were not included in this analysis. An Independent T-test was used to compare NRS and Oxford Score after 1 year between the groups.

3. Results

3.1. Radiological outcome after 6 weeks

The mixed models analysis showed an interaction effect which indicated that the Gärtnner classification after 6 weeks improved significantly better in the UN group compared to the RSWT group ($p=0.029$). 1 patient in the RSWT group had complete disappearance of deposit, versus 5 patients in the UN group.

3.2. Clinical outcome after 6 weeks

There were no significant time-by-group interactions of NRS ($p=0.15$) or Oxford Score ($p=0.53$) after 6 weeks between the UN group and the RSWT group. No significant interaction was shown for Constant Score, which indicated that the UN group ($p=0.020$) improved more than the RSWT group. See Table 1 for an overview of results.

3.3. Clinical outcome after 1 year

6 patients changed treatment in the period between 6 weeks and 1 year, and were therefore excluded from 1 year analysis. In Table 2, the 1 year follow-up results are presented. No significant differences were found between the groups in NRS ($p=0.45$) or Oxford score ($p=0.32$). The results show that around 40% of the patients are free of complaints in both groups. This did not differ between the two groups. However, whereas most patients in the UN group would choose the same treatment again, less than half of the patients would choose RSWT.

3.4. Complications

As mentioned before, 5 patients in the RSWT group changed to UN due to pain in the period between 6 weeks and 1 year. Because of higher pain in the RSWT group after 6 weeks, the Data Safety Monitoring Board decided to stop further enrollment in the study. One patient in the UN group eventually got a subacromial debridement and decompression because of unacceptable persistent pain (Fig. 1).

4. Discussion

The goal of this study was to compare two types of treatment (UN vs RSWT) for calcific tendinitis in the shoulder. The results showed a decrease in calcium deposits in both groups. The UN group showed a higher decrease compared to the RSWT group at 6 weeks. In addition to the decrease in calcium, the UN group showed a non-significantly higher improvement in the Constant Score and a significantly higher improvement in the Oxford Score pre- and post-treatment compared to the RSWT group. After one

Table 2
1 year results.

	UN [95% CI]	RSWT [95% CI]
NRS	1.9 [0.6–3.2]	2.1 [0.3–3.9]
Oxford Score	53.2 [47.1–59.3]	49.1 [39.2–59.0]
Choose same treatment again?	90%	44%
Free of complaints	40%	44%

year, there was no significant difference in NRS and Oxford Score between groups. It was remarkable to see that despite approximately 40% of the patients were free of complaints after one year in both groups, only 44% of the patients in the RSWT group would choose this treatment again, compared to almost every patient in the UN group. Since this study was terminated prematurely because of high NRS in the RSWT group, we could not advise the use of RSWT over UN.

As previously described there was a higher reduction of the calcium deposits 6 weeks after treatment in the UN group compared to the RSWT group. Even more evident are the results looking at total disappearance of the calcium deposits 6 weeks after treatment. The x-ray of only one patient in the RSWT group against five in the UN group showed that the calcium deposit had dissolved completely. The radiological short term results of both UN and RSWT are rarely described in literature⁹. Most studies compare the radiological results after at least one year^{3,5–7,10}. Nevertheless, one can argue whether dissolution of a calcium deposit after a longer period of time is caused by treatment or by spontaneous resorption. Gärtnner and Heyer showed a spontaneous resorption in 9% of the patients after 37 months ($n=235$)¹. Using RSWT, Farr et al. reported a resorption of 36% of the calcium deposits ($n=26$) after 12 weeks⁹ and Wang et al. described 28.6% resorption ($n=20$)⁴. Critics might argue that our protocol used in the RSWT group was not sufficient to reduce the calcium deposits, however a systematic review showed a comparable protocol with proper results¹⁵.

Parallel to the radiological difference there was a difference in the Constant Murley Score between both groups. The RSWT group did not appear to improve in 6 weeks time, in contrary to the UN group. In several studies we see a correlation in reduction of calcium deposits and improvement of functional scores^{4,5,9}.

Comparing results after 1 year between the UN and RSWT group, no differences on functional scores were found. In addition, a large group of patients was still experiencing pain and discomfort of the shoulder. However, compared to pre-treatment, pain was reduced and function improved after one year follow-up in both groups.

Our study had some weaknesses. It is important to note that the Data Safety Monitoring Board prematurely terminated inclusion because of the higher NRS in the RSWT group after 6 weeks. This

Table 1
Results after 6 weeks.

		Preoperative [95% CI]	6 weeks postoperative [95% CI]
Gärtnner classification [*]	RSWT	1.1 [0.7–1.5]	1.7 [1.3–2.1]
	UN	1.2 [0.7–1.6]	2.8 [2.4–3.3]
NRS	RSWT	7.9 [6.9–8.8]	6.2 [5.2–7.1]
	UN	7.5 [6.5–8.6]	4.6 [3.4–5.7]
Oxford Score	RSWT	38.5 [34.0–43.0]	45.1 [40.6–49.7]
	UN	38.5 [33.3–43.6]	47.4 [42.1–52.7]
Constant Score [*]	RSWT	57.5 [48.9–66.1]	61.1 [52.5–69.6]
	UN	55.7 [46.1–65.4]	72.8 [62.9–82.7]

^{*} $p < 0.05$.

was remarkable since RSWT was reported before to be less painful than the wider used ESWT⁸. In addition, a considerable group of patients changed treatment, caused by increase of symptoms, especially pain. In all cases, it was the patient's choice to change treatment. We mentioned earlier that 6 patients changed treatment between 6 weeks and 1 year after their initial treatment. It is remarkable to see that 5 patients in the RSWT group eventually changed to UN, only 1 patient in the UN group changed treatment. After UN all of the calcification deposit and the pain of these patients decreased. However, because of the crossover, those patients were excluded from analysis after 1 year. Therefore, the number of patients that could be analyzed was only small. However, short term radiological and functional results did show a significant improvement for the UN group in comparison to the RSWT group.

Second, patients in the UN group were infiltrated with corticosteroid in the subacromial space, in contrast to the patients in the RSWT group, since RSWT is a non-invasive therapy. This could possibly bias the results after 6 weeks, however not the results after 1 year. Third, our study lacked a placebo-control group. Further, no routine radiographic studies were performed at 1 year follow-up.

Compared to Radial Shockwave Therapy, Ultrasound guided Needling resulted in significant improvement in Constant Score and faster dissolution of the calcifications 6 weeks after treatment. There was a non-significantly improvement in pain score and Oxford Score. However, there were no differences after 1 year. Since this study was prematurely terminated because of high NRS in the RSWT group, we could not advocate the use of RSWT. However, further research is necessary to indicate which treatment (or no treatment) is best on long term.

Conflict of interest

None.

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