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Extracorporeal shock wave therapy in calcific tendinitis of the shoulder

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Abstract *Objective:* To investigate clinical (pain, mobility) and radiological (resolution of calcium deposits) efficacy of different energy levels of extracorporeal shock wave therapy (ESWT) in calcific tendinitis of the shoulder. *Design and patients:* There were 90 study subjects with radiographically verified calcific tendinitis of one shoulder, mean age 52 ± 6 years (range 29–65 years; females:males=55:35), all of whom had had symptoms for at least 6 months and substantial restriction of shoulder mobility and pain that required taking anti-inflammatory drugs. Calcium deposits were of type I or type II (clearly circumscribed and dense) and ranged from 1 cm to 3 cm in diameter. Subjects were divided into three groups to receive ESWT at one of two energy levels ($E_1=0.15 \text{ mJ/mm}^2$, $E_2=0.44 \text{ mJ/mm}^2$) or sham treatment. Treatment was given at 6 weekly intervals until

symptoms resolved, five treatments had been given or the subject dropped out of the programme. *Results:* All subjects in groups E_1 and E_2 completed the programme. Those in group E_1 had significantly less pain during treatment but more treatments than those in group E_2 , and at 6 month follow-up had residual calcification and recurrence of pain (87%). Subjects in group E_2 had no residual calcification or recurrence of pain. Sham treatment had no effect. There were no side effects except a small number of haematomas (2 in E_1 , 6 in E_2 ; maximum size 2 cm). *Conclusion:* ESWT in calcific tendinitis of the shoulder is very effective. It does not have significant side effects at an energy level of $E=0.44 \text{ mJ/mm}^2$, which can therefore be recommended.

Keywords Calcific tendinitis · ESWT · Orthotripsy

Introduction

Calcific tendinitis is characterized radiographically by calcification of rotator cuff tendons and is the most common abnormality of the shoulder [1]. It affects mainly individuals between 30 and 50 years of age. Most frequently it occurs in the supraspinatus tendon near its insertion followed by infraspinatus, teres minor and subscapularis tendon in descending order [2]. The disorder is painful in 50% of patients and frequently leads to considerable restriction of motion [3, 4].

Extracorporeal shock wave therapy (ESWT) has long been used successfully in lithotripsy for destruction of renal calculi and has been tested in the treatment of salivary gland calculi [5]. Since it had gained increasing acceptance in Europe for a number musculoskeletal problems clinical studies were initiated in the United States [6]. It was recently introduced as orthotripsy [6] for treatment of non-union fractures [7], plantar fasciitis [8, 9, 10, 11], tennis elbow [12, 13, 14] and calcific tendinitis of the shoulder [15, 16, 17]. In treatment of calcific tendinitis controversial results have been reported concerning its success [15, 16, 18, 19, 20], its dependence on the

energy used [14, 21, 22] and the need for local or regional anaesthesia [21, 23]. The controversial results might be explained by the different techniques that were used. Currently a third generation of ESWT machine is available that introduces the energy into the area of interest within a smaller focus of 5 mm [24, 25] using acoustic lenses. Thus, by minimizing the focus area the density of energy flux can be increased and side effects in other areas are minimized.

The purpose of our study was to investigate clinical (pain, mobility) and radiological (resolution of calcium deposits) efficacy of different energy levels of ESWT in calcific tendinitis of the shoulder.

Materials and methods

Patients

Ninety study subjects, with a mean age of 52±6 years (range 29–65 years; females:males=55:35), received ESWT or sham treatment. The study protocol was approved by our institutional review board. Written informed consent was obtained from each study subject prior to inclusion in the study. All patients had radiographically verified calcific tendinitis of one shoulder as shown on internal and external rotation views of the shoulder. The size of calcium deposits ranged from 1 cm to 3 cm in diameter as measured by two radiologists (J.P. and V.J.). Deposits smaller than 1 cm were not included because they are difficult to visualize sonographically. Only patients having type I (clearly circumscribed and dense) or type II (clearly circumscribed or dense) calcifications according to the classification of Gaertner and Heyer [26] were eligible for the study. Patients with type III calcifications (cloudy or translucent and not clearly circumscribed) were excluded because these have a tendency to resolve [3]. We also excluded patients with MRI-proven rotator cuff tears and degenerative changes of the acromioclavicular joint.

All study subjects had had shoulder pain for at least 6 months and had gone through a minimum of 10 sessions of physical therapy. They still had substantial restriction of shoulder mobility and pain that required taking anti-inflammatory drugs. Twenty-six of the 90 patients (29%) were limited in their everyday activities to the point where they were unable to work.

Demographic data of the groups were comparable with regard to age, size and type of calcification.

Methods

ESWT

ESWT was performed using the miniaturized shock wave source Minilith (15 cm diameter, 15 cm length) (Storz Medical, Switzerland) with an in-line ultrasound device. Equipment was handled by a technician, thus masking the evaluating physicians with regard to energy flux levels. Technicians had been trained by two of the authors (J.P. and V.J.) each of whom had more than 5 years' experience in joint ultrasound and one of whom (J.P.) had experience in lithotripsy of salivary gland stones. Shock waves were always focused on the calcified area, which was shown to be more effective than focusing on the insertion of the supraspinatus tendon [19]. Targeting of calcifications was achieved by using the in-line ultrasound transducer (7.5 MHz) of the Minilith. In order to assess the impact of the energy flux density (EFD) used, two different EFDs (E_1 , E_2) in the high-energy range (≥ 0.12 mJ/mm²) were employed.

Thirty patients received $E_1=0.15$ mJ/mm² and 31 patients received $E_2=0.44$ mJ/mm². The control group consisted of 29 patients who received an indistinguishable sham treatment (E_3). An on-off switch introduced into the circuit allowed shock wave as well as sham treatment. Total EFD is given as measured by the manufacturer with a fiberoptic hydrophone. The number of pulses per session ($n=1,500$) was kept constant in E_1 and E_2 groups. Anaesthesia was not used in any of the protocols. Patients in each group received treatments at intervals of 6 weeks until symptoms had resolved, until five treatments had been applied or until patients dropped out of the programme.

Randomization

In order to ensure a randomized double-masked study, patients were assigned to the different energy levels (E_1 , E_2 , E_3) by using a spreadsheet program that generated a list of random numbers. Thus both patients and physicians involved in ESWT and follow-up were unaware of the EFD used.

Analysis

Time requirement for treatment was documented.

Efficacy of the different energy flux densities in ESWT was compared in terms of:

- pain during the ESWT measured on a 10-point scale (Student's *t*-test), 10 points meaning no pain, 0 points severe pain;
- side effects (haematomas registered sonographically after the procedure by J.P. and V.J.);
- number of ESWT sessions needed to fully resolve pain and restore mobility (Mann-Whitney *U*-test);
- resolution of calcifications assessed by internal and external rotation radiographs of the shoulder and read separately by two radiologists (J.P., V.J.) 6 months after the last treatment;
- status of symptoms as assessed in the follow-up clinical examination 6 months after the last ESWT, subjective success of treatment being freedom from pain without any anti-inflammatory medication.

The number of patients who completed therapy was also recorded.

Results

All patients in the E_1 and E_2 groups completed treatment. Three patients in the E_3 group dropped out because the pain did not resolve or even improve after the third (1 patient) or fourth (2 patients) treatment.

A summary of the comparison of the two different energy levels and sham treatment is shown in Table 1.

Patients receiving the lower energy level treatment, E_1 , had significantly ($t=7.77$; $p<0.001$) less pain during ESWT (mean: 6.9 ± 1.6 , 10-point scale) than patients treated with the higher energy level E_2 (mean: 9.6 ± 1.0). Patients receiving sham treatment did not complain of pain caused by treatment. In patients treated with the lower energy level E_1 , two individuals presented with small haematomas of 1 cm and 1.5 cm in diameter respectively. In patients treated with the higher energy level E_2 , six haematomas were found at ultrasound ranging

Table 1 Efficacy of extracorporeal shock wave therapy (ESWT) in calcific tendinitis of the shoulder in relation to EFD (E_1, E_2)

		EFD in ESWT		
		E_1 (=0.15 mJ/mm ²) n=30	E_2 (=0.44 mJ/mm ²) n=31	E_3 (=0.00 mJ/mm ²) n=29
Pain during ESWT				
Scale	10-9 (no pain)	26 (87%)	–	29 (100%)
	8 (discomfort)	–	20 (65%)	–
	7 (moderate)	4 (13%)	–	–
	6 (moderate)	–	5 (16%)	–
	5 (moderate)	–	–	–
	4-0 (considerable) ^a	–	6 (19%)	–
Side effects (haematoma)		2 (6%)	6 (19%)	0
No. of treatments ^b				
	1	–	25 (81%)	–
	2	–	6 (19%)	–
	3	8 (27%)	–	11 (38%)
	4	10 (30%)	–	10 (35%)
	5	12 (43%)	–	8 (27%)
Follow-up (6 months after the last session)				
Residual calcifications		30 (100%)	–	28
No calcifications		0	31 (100%)	0
Recurrence of pain		26 (87%)	0	29 (100%)

^a Demanding a short interruption of application of shock waves

^b Required for total relief from pain and full restoration of mobility

from 1 to 2 cm in diameter. No haematomas were found in the E_3 group.

Patients receiving the lower energy protocol E_1 needed significantly ($p < 0.001$) more treatments (mean: 4.1 ± 0.8) than patients receiving the higher-energy protocol E_2 (mean: 1.2 ± 0.4). At the 6 month follow-up examination all patients receiving the lower energy E_1 showed residual calcifications (Fig. 1). None of the calcifications had transformed into group III, thus subsequent resolution was not to be expected. In 26 of 30 cases (87%) recurrence of pain was experienced. Patients receiving the higher energy level E_2 showed no residual calcification (Fig. 2) and pain did not reoccur. In none of the patients receiving sham treatment (E_3) was reduction, transformation or complete resolution of calcium deposits observed. Three individuals (8%) had experienced intermittent slight alleviation of pain but not to a degree that allowed reduction or elimination of anti-inflammatory medication and 26 of them (92%) had no relief at all.

None of the patients had other side effects than the few small haematomas that were observed. In particular reddening of the skin did not occur.

Discussion

Extracorporeal shock wave therapy, which now is used routinely for urolithiasis and has been tested in sialolithiasis, has gained increasing acceptance in Europe for a number musculoskeletal problems. This has led to the inception of clinical studies in the United States [6]. The primary advantage of extracorporeal shock wave therapy

is its non-invasive nature and seemingly minimal complications when applied to musculoskeletal tissues. However, absence of complications does not justify its use when the method has not proven to be effective. In this study we have shown that ESWT is effective, that its efficacy depends on the energy used and that even with high EFDs ($E_2 = 0.44$ mJ/mm²) local or regional anaesthesia is not required. In the control group there was spontaneous reduction of pain in three patients and no change in the calcium deposits at all.

Shock or sound waves used in medicine are single-impulse waves that may be produced in water by an electromagnetic cylinder source. The waves are focused by a parabolic reflector system inside the target tissue. Pressure levels between 10 and 80 megapascals (MPa) are generated in the focal point. The effective energy in the focal point is called the EFD. The fact that we could perform high-energy ESWT without local or regional anaesthesia possibly can be explained by the use of a third-generation ESWT machine which offers better focusing of energy on the spot of interest [24, 25] than the machines designed for disintegration of renal calculi.

Side effects of ESWT in treatment of insertion tendinopathies include transitory reddening of the skin (21%), pain (5%) and small haematomas (3%) when an EFD between 0.04 and 0.22 mJ/mm² is used [23]. An important aspect of using ESWT in soft tissue disorders is the fact that elimination of fragments does not cause the problems that it does in the treatment of renal calculi, where congestion of the ureter may occur. In soft tissue treatment fragments are eliminated at a cellular level by mechanisms that are not yet fully understood.

Fig. 1 A 55-year-old patient with extremely severe shoulder pain and restriction of mobility before (A, B) and after three sessions of ESWT (C, D) performed with the energy level $E_1=0.15 \text{ mJ/mm}^2$. External (A, C) and internal (B, D) rotation views showing considerable calcium deposit in the supraspinatus tendon (arrow). Follow-up examination 6 months after first treatment (C, D) shows residual calcifications (arrow). Pain is reduced but not completely eliminated and mobility is improved but not fully restored



The appearance of haematomas after treatment with shock waves is explained by capillary disruption and consecutive extravasation of erythrocytes [27]. In order to avoid this complication continuous-wave ultrasound [28] and low-energy ESWT [21] have been favoured for a long time. High-energy EFD ($>0.12 \text{ mJ/mm}^2$) ESWT has only been used with local anaesthesia. We observed that both pain and the occurrence of haematoma correlate with the energy introduced into the tissue (Table 1). With an increase of energy from 0.15 mJ/mm^2 (E_1) to 0.44 mJ/mm^2 (E_2) pain increased significantly. Patients treated with E_1 experienced no pain (10 to 9 points on a 10-point scale) or moderate pain (7 to 5 points) (87%/13%). Patients treated with E_2 complained of discomfort (8 points) up to considerable pain (4 and 2 points) (65%/16%/19%) (Table 1). None of the patients, however, asked for anaesthesia during the treatment, although it was offered as an option

before treatment was started. With a threefold increase in energy the occurrence of haematomas did not increase more than linearly from 7% to 19% (Table 1). Patients receiving sham treatment did not experience pain during the procedure.

The significantly better results of the higher-energy protocol, e.g. alleviation of symptoms after only one or two sessions (mean: 1.2 ± 0.4) and no recurrence, compared with the lower-energy protocol's requirement of three to five sessions (mean: 4.1 ± 0.8) and recurrence in 87% of patients (Table 1), seems to justify the higher level of pain and the slightly higher incidence of haematoma. This is particularly true when taking into account that, in contrast to the literature [23], high-energy treatments were performed without local or regional anaesthesia.

Fig. 2 A 29-year-old patient with severe shoulder pain and restriction of mobility before (A, B) and 6 months after ESWT (C, D) performed with the energy level $E_2=0.44$ mJ/mm². External (A, C) and internal (B, D) rotation views show large calcium deposits in the supraspinatus tendon (A). After ESWT (C, D) there is complete resolution of calcium deposits. The patient had no pain, mobility was fully restored and there was no relapse



In agreement with Seil et al. [21] we observed that the use of lower-energy protocols requires significantly more treatments. In contrast to Seil et al. [21], however, but in agreement with Loew et al. [22], who treated three groups of patients with 0.1 and 0.3 mJ/mm² (one session and two sessions) respectively, we found a significant relation between the EFD and radiological (calcium resolution) and clinical (pain, mobility) outcome (Table 1). Beyond the results of Loew et al. [22] we found a relation between EFD and the percentage of patients with relapse of symptoms (Table 1). In order to understand the reason for recurrence the aetiology of calcific tendinitis must be considered. Jakobeit et al. [29] found that complete resolution of calcium deposits led to alleviation symptoms. Thus, calcification can be assumed to be the cause or at least the radiological correlate for clinical symptoms. Calcification is a reactive process actively mediated by cells in a viable environment. The deposit undergoes an evolution (pre-calcific stage/calcific stage with formative phase, resting period and resorption/postcalcific stage), which ultimately remodels normal tendon tissue. The therapeutic approach depends on the evolution of the disease [17].

ESWT disintegrates calcium deposits and thus accelerates the process of calcium resorption. Therefore, besides the energy introduced into the focus (EFD), correct positioning of the focus [19] and susceptibility of the calcium formation to ESWT (amorphous calcareous deposits, mixed calcareous foci, homogeneous calcareous deposits) [29] determine the efficacy of ESWT. Exact focusing of energy on the area of calcification can be achieved by fluoroscopic guidance [19], or ultrasound guidance as was done in our study. Disintegration and thus the size of fragments are related to EFD. Smaller fragments can be cleared better than larger ones. Residual calcifications possibly lead to repeated apposition of calcium and thereby to recurrence of symptoms. EFD determines the extent of fragmentation and thus the probability of recurrence. Focusing of shock waves on calcium deposits with third-generation lithotripters breaks them up to an extent that leads to complete (100%) resolution of calcium in 81% of our patients after the first treatment. These results are superior to those obtained with continuous-wave ultrasound [28] (complete resolution: 19% after a 44 day treatment, 13% uncompleted therapies) or

other ESWT protocols (complete resolution: 44–77%, depending on the type of calcium formation [29], and 31% [30] where an energy density of 0.28 mJ/mm² was used) and are also better than those obtained by Pan et al. [31] who treated twice applying energy levels between 0.26 and 0.32 mJ/mm² per session as well as sham treatment.

We did not test the maximum EFD ($E_3=1.49$ mJ/mm²) available in our lithotripter, both because of the relationship between pain and energy introduced in ESWT and because the results using 0.44 mJ/mm² were highly satisfactory. Using the intermediate EFD, $E_2=0.44$ mJ/mm², in most cases (81%) only one session was necessary to resolve pain and fully restore mobility. Thus there is no need to apply higher EFD possibly increasing the risk for pain and/or haematoma.

We included only patients with calcium deposits larger than 1 cm in diameter because these can easily be located

sonographically. Thus, we cannot contribute results concerning patients with smaller calcifications.

However, treatment should be based on the knowledge of the natural course of the disease, which shows a strong tendency towards self-healing as in Gaertner and Heyer type III deposits (translucent or cloudy without clear borders) that frequently resolve spontaneously [17]. Thus, for those and calcium deposits smaller than 1 cm ESWT should only be considered if different conservative therapies have failed over a longer period of time.

In conclusion, ESWT in calcific tendinitis of the shoulder is very effective. It does not have significant side effects at an EFD of $E=0.44$ mJ/mm², which can therefore be recommended.

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