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SHOULDER

Extracorporeal shockwave therapy in calcifying tendinitis of the shoulder

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Abstract
Purpose Strategies for extracorporeal shockwave therapy in calcifying tendinitis of the rotator cuff vary concerning quantity of sessions and doses. The purpose of this prospective pilot study was to determine the difference between the outcome of a single high-dosage extracorporeal shockwave therapy and two sessions of low-dosage extracorporeal shockwave therapy.
Methods This study compared a single high-level middle-energetic extracorporeal shockwave therapy (0.3 mJ/mm^2) with a low-level middle-energetic extracorporeal shockwave therapy applied twice in a weekly interval (0.2 mJ/mm^2). Thirty patients that suffered from calcifying tendinitis for at least 6 months received navigated, fluoroscopy-guided extracorporeal shockwave therapy. The gain of Constant Murley Score, Visual Analogue Scale during state of rest and weight-bearing situations ("stress") and radiographic progress was documented 6 and 12 weeks after therapy.
Results In both groups, a significant reduction in pain during stress and improvement of function was observed. In contrast, no significant reduction in pain during rest was observed. No significant difference between both groups concerning reduction in the calcific deposit after 6 weeks was detected. Group B showed minor advantages in radiographical improvement after 12 weeks. In 36% of the patients, the calcific deposit completely dissoluted after 12 weeks.
Conclusions This pilot study indicates that a single high-level extracorporeal shockwave therapy may be as effective as two applications of a lower-dosed extracorporeal shockwave therapy for calcifying tendinitis. An effective single-session strategy could reduce treatment time, material costs and healthcare expenses and ionizing radiation in case of fluoroscopy guidance.
Level of evidence II.

Keywords Extracorporeal shockwave therapy · Calcifying tendinitis · Rotator cuff · Time-saving factor · Economical benefit

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Introduction

In the last two decades, several studies demonstrated the effectiveness of extracorporeal shockwave therapy (ESWT) in treatment of calcifying tendinitis of the rotator cuff [3–5, 9, 12, 13, 16, 19, 24, 25]. There is clear evidence that ESWT should be initiated as safe second-line therapy [16, 23] after failure of other conservative treatments such as local infiltrations, physiotherapy or iontophoresis. One study even stated that ESWT should be preferred to

arthroscopy due to its non-invasiveness at equivalent outcome [18]. Even the administration of higher energy levels (>0.4 mJ/mm^2) showed no significant side effects [16]. Studies by Haacke et al. [6] and Sabeti et al. [22] revealed that navigation to the calcium deposit with a 3-D, fluoroscopy-guided device (e.g. Lithotrack, Storz Medical, Kreuzlingen) resulted in a significantly better outcome than ESWT treatment after the localisation of the point of maximum tenderness through a cooperative way ("biofeedback"). Concerning different treatment strategies with either low- or middle-energetic ESWT, Sabeti et al. [21] reported better results of the middle-energetic group in comparison with the low-energetic group. Other studies revealed no statistically significant difference comparing high-energetic to low-energetic ESWT treatment groups [23], whereas Albert et al. did find a significant difference in a larger cohort of 80 patients [1].

There is no clear evidence in the literature about the exact dosage, number and frequency of ESWT sessions to achieve the best clinical outcome. In most studies, diverging and inconsistent energy flux densities were applied as summarized by Mouzopoulos et al. in their review [14]. Due to incomparable parameters of the current literature, the review by Lee et al. finally could not contribute to a clear guidance of the particular dose–effect of midterm effectiveness [9]. Therefore, the authors requested studies following standardized treatment protocols. Procedures with repetitive treatments in short-term intervals (2–3 sessions) are difficult to handle for hospitals with large amounts of ambulant patients. Similar clinical improvement and reduction in pain in the single-therapy group could be a decisive time-saving factor for both patients and physicians. For economical reasons, a single-session strategy could reduce treatment expenses and material costs to an essential level.

The purpose of this prospective pilot study was to determine the difference between the outcome of a single high-level ESWT treatment and low-level ESWT applied twice in a weekly interval.

Materials and methods

Thirty patients (16 men, 14 women) were included in a prospective, randomised and observer-blinded study after the ethics committee approved the research protocol. A total of 27 patients completed all follow-up examinations (Fig. 1). All participating patients fulfilling the inclusion and exclusion criteria were recruited at the orthopaedic department's outpatient clinic. Inclusion criteria were as follows: radiologically verified calcifying tendinitis (Gärtner grade I, II or III), persisting pain for at least 6 months, minimum of two failed long-term (>6 months) conservative treatments (e.g. repetitive subacromial infiltrations, NSAIDs, physiotherapy, iontophoresis/ultrasound/deep friction). All persons that participated in this study gave their informed consent prior to their inclusion in the study.

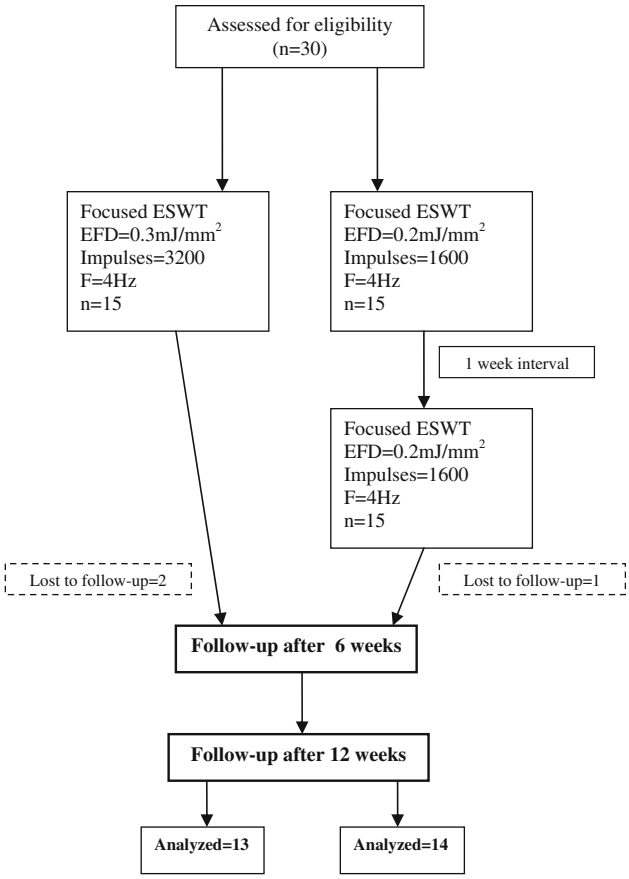

Fig. 1 Flow chart of study procedure

All patients were radiographically examined before shockwave therapy revealing calcifying tendinitis rated Gärtner grade I in 8, grade II in 15 and grade III in 7 cases. Compared to standard radiographs and sonography, MRI is not the first choice in diagnostics of calcifying tendinitis. Because of the obvious radiological findings according to the Gärtner classification and the clinical aspect, no MRI examination was accomplished in this study. The patients were split into two groups of equal numbers according to randomisation performed by the Institute of Medical Statistics. Each patient underwent detailed clinical examination to determine current pain during state of rest ("rest", e.g., sleeping, sitting) or weight-bearing situations ("stress", e.g., carrying a 5-kg bag) using the Visual Analogue Scale (VAS, reference 0–10). Current functional limitations were assessed by the Constant Murley Score (CMS, reference 0–100). Prior to intervention, all patients received one single subacromial infiltration with local anaesthetic (5 ml of Xylocain). Infiltration showed sudden

relief of pain in all patients. In both groups, a Storz Modulith SLK lithotripter (Storz Medical Products Kreuzlingen, Switzerland) in combination with a fluoroscopy-guided, 3-D computer-assisted navigation device (Storz Lithotrack; Storz Medical Products Kreuzlingen, Switzerland) was used. The calcific deposit was first located in the centre of a crosshair by fluoroscopy in two layers. The computer calculated angle and distance for maximum precision. The distance of the shockwave focus to the calcific deposit was stated in millimetres on the monitor of the navigation device. To achieve maximum precision, the navigation device was centred to the calcific deposit within 1–2 mm in all cases.

Patients of cohort A received one single application of middle-energetic extracorporeal shockwave therapy (frequency 4 Hz, 3,200 impulses, 0.3 mJ/mm^2). Patients of cohort B received two applications of a lower-dosed middle-energetic extracorporeal shockwave therapy in a weekly interval (frequency 4 Hz, 1,600 impulses, 0.2 mJ/mm^2). After 6 and 12 weeks, all patients were clinically re-examined to record therapeutic progress. Both CMS and VAS for rest and stress were documented (Table 1). Additionally, radiographs (a. p./axial) of all patients were taken after 6 and 12 weeks. Radiological difference of the calcific deposit was rated as "improvement", "unchanged" or "worsening" (Table 2). A 24-h emergency number was installed to guarantee medical help in case of side effects. None of the patients received any additional treatment (e.g. infiltrations) during the period of the study. For minor pain symptoms, NSAIDs in standard dosage were recommended (mefenamic acid, 500 mg maximum 3×/d). Undeclared usage of other drugs in some cases cannot be completely precluded.

Table 1 Demographics and time course of CMS and VAS

Treatment group	Time (weeks)	Variable	*N*	Mean	SD
A (1 ESWT)	–	Age (years)	15	49.7	9.0
		Weight (kg)	15	79.3	14.0
	0	CMS	15	67.7	14.7
		VAS (rest)	15	3.2	1.7
		VAS (stress)	15	5.9	2.0
	6	CMS	13	71.7	24.1
		VAS (rest)	13	3.0	3.1
		VAS (stress)	13	3.8	2.8
	12	CMS	13	79.9	19.3
		VAS (rest)	13	3.0	3.5
		VAS (stress)	13	3.9	3.2
B (2 ESWT)	–	Age (years)	15	48.6	7.3
		Weight (kg)	15	75.1	11.7
	0	CMS	15	60.2	15.6
		VAS (rest)	15	4.4	2.5
		VAS (stress)	15	6.0	2.7
	6	CMS	14	72.9	12.7
		VAS (rest)	14	4.7	2.5
		VAS (stress)	14	4.6	2.2
	12	CMS	14	80.3	18.5
		VAS (rest)	14	3.3	3.0
		VAS (stress)	14	4.2	3.5

Statistic analysis

Descriptive statistics were performed to overview data. To investigate the influence of the treatment on the time course of CMS, VAS (rest) and VAS (stress), for each target variable a repeated measurement ANOVA with fixed factors treatment group, co-variables time, sex, age and weight, the interaction between time and group and random factor patient was performed. To investigate the influence of the treatment group on radiographs 6 weeks after treatment, an ordinal logistic regression (for "worsening", "unchanged" and "improvement") was performed again with co-variables sex, age and weight. The same analysis was performed for radiographs 12 weeks after treatment.

Since this study was planned as a pilot study, no sample size calculation was done beforehand. However, using the given results for a future study, more than 1,000 patients per group are needed to detect the given differences in the reduction in VAS(stress) from time point 0–12 between the two groups using a two-sided two-sample *t* test at a significance level of 0.05 with 80% power. For VAS(rest) and CMS, approximately 200 patients per group would be required to detect the given differences between groups (again using two-sided two-sample *t* tests).

Results

No significant difference between the two treatment groups in age, sex, weight as well as VAS (rest), VAS (stress) and CMS at baseline (time point 0) was found (n. s.). For CMS, a significant increase ($P < 0.0001$) and for VAS (stress), a significant decrease ($P < 0.03$) overtime was found. Overall, for VAS (rest), no significant decrease or decrease overtime was found (n. s.). No difference in time course and no influence of age, sex or weight between the two treatment groups were found for both VAS(rest + stress) and CMS (n. s.) (Table 1).

Radiographical results

Sixty-two percent of the patients in both groups showed obvious reduction in the calcific deposit after 6 weeks. No increase in the deposit size was found at that time. After

Table 2 Radiographical results 6 and 12 weeks after therapy

Radiograph	6 weeks			12 weeks		
	Treatment group			Treatment group		
	A (1 ESWT)	B (2 ESWT)	Total	A (1 ESWT)	B (2 ESWT)	Total
Worsening	0 (0%)	0 (0%)	0 (0%)	1 (8%)	2 (15%)	3 (12%)
Unchanged	5 (38%)	5 (38%)	10 (38%)	4 (34%)	2 (16%)	6 (24%)
Improvement	8 (62%)	8 (62%)	16 (62%)	7 (58%)	9 (69%)	16 (64%)

12 weeks, the results improved in 58% (A) and 69% (B). In total, 12% showed worsened radiographic results (Table 2). Overall, in 36% of the patients, the calcific deposit completely dissoluted after 12 weeks. This effect appeared almost equally in the two groups (5 in group A, 4 in group B). No influence of group, age, sex and weight was found on the radiographic results (n. s.). No significant difference between patients with reduced calcifications ("improvement") and the remaining patients in VAS (rest), VAS (stress) and CMS was found 6 weeks and 12 weeks after treatment (n. s.). No complications were recorded during treatment or at any time of follow-up.

Discussion

The most important finding of the present study was that the treatment with middle-energetic ESWT in a single session and treatment with two lower-energetic dosages showed no significantly different clinical and radiographic outcomes. Both cohorts revealed significant improvement of shoulder joint function. These findings match the results by Pleiner et al. [17]. Improvement was even higher than in another prospective study with a comparable cohort [7]. Pain reduction appeared in both groups within 6 weeks after therapy except for VAS (rest) in group B. In addition, no significant difference between both groups concerning reduction in the calcific deposit after 6 weeks was detected. Group B showed minor advantages in radiographical improvement after 12 weeks. These radiological findings correlate with those of other studies that presented partial and total deposit elimination in 57% [8] and 62% [2]. Major progress of the calcific resorption was made within the first 6 weeks after therapy. Only 5 patients (2 in group A, 3 in group B) showed further radiographic progress between the 6th and 12th week.

The purpose of this pilot study was the comparison between one therapy session with a higher dosage of ESWT and a double session ESWT with lower dose. This study was not designed to determine whether the use of ESWT was more effective than no treatment, which would have made a third, placebo-controlled group necessary. Other studies have already shown its effectiveness in comparison with placebo [10].

Limitations of this study are the small sample size of 30 patients and the short follow-up period. Lack of superiority of one cohort might not be an indication of equivalence of both groups. Future research with a much larger sample size, as calculated in the material and methods section, is needed to find any statistically and clinically significant difference between these groups. Furthermore, the significant time interaction in this study could have been a factor of spontaneous recovery. As this disease can be self-limiting and shows continuity between its different stages [20], it is unclear at which stage the ESWT was applied. Relief of pain, as well as total resorption of the calcific deposit in 9 patients, can be a result of either the treatment applied or to an unknown amount of self-limitation. Even though, all well-established conservative and operative therapeutic strategies that are approved for calcifying tendinitis do not consider the fact of self-limitation. One exception is calcifying tendinitis of grade III, which is not suitable to be treated by operative removal as indicated, e.g., by radiographical results of Lorbach et al. [11]. According to Ogon et al., grade III is a positive prognostic factor for non-operative treatment [15]. Patients with grade III were included in this study because they did not experience any difference in functional limitation and pain course compared with those rated as more stable type I and II at the time of inclusion into this study. These study results of patients with grade III cannot confirm the general hypothesis of grade III being a stage of calcific resorption because three of them did not show radiographical improvement at all. A follow-up period of at least 6–12 months could give more precise information about time course of pain and functional limitations as well as dissolution of the calcific deposit for patients of all grades.

Extracorporeal shockwave therapy algorithms for calcifying tendinitis of the rotator cuff, that are based on randomized-controlled trials, are heterogeneous and often lead to multiple time-consuming and expensive therapies. The findings of this study may help to establish a more efficient and time-saving strategy to treat this very common disease in clinical day-to-day work. An effective

single-session strategy could reduce treatment time, material costs and healthcare expenses and ionizing radiation in case of fluoroscopy guidance.

Conclusion

A single high-level middle-energetic ESWT may be as effective as two applications of a lower-dosed middle-energetic ESWT for calcifying tendinitis of the rotator cuff after failure of other conservative treatment options. One single therapy may lead to a sufficient and significant improvement of clinical restrictions and pain.

Conflict of interest The authors declare that they have no conflict of interest.

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