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ORIGINAL STUDY

High- versus low-energy extracorporeal shock wave therapy of rotator cuff tendinopathy : A prospective, randomised, controlled study

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A prospective, controlled, randomised trial was performed to compare the effect of high-energy extracorporeal shock wave therapy (ESWT) versus low-energy ESWT in treatment of rotator cuff tendinopathy. Forty adult patients were included in the study. Patients in the intervention group received 6000 impulses of high-energy (ED_+ 0.78 mJ/mm²) in 3 sessions under local anaesthesia. Patients in the control group received 6000 impulses of a low-energy ESWT (ED_+ 0.33 mJ/mm²) under local anaesthesia. Follow-up examinations were performed 12 weeks and one year after treatment by an independent observer. An increase in function and a reduction of pain were found in both groups ($p < 0.001$). Although the improvement in Constant score was greater in the high-energy group compared to the low-energy group, statistical analyses showed no significant difference between the groups with respect to all parameters studied (Constant score / pain / subjective improvement) after 12 weeks and one year follow-up. No statistically significant differences were found between the results of high-energy and low-energy ESWT of rotator cuff tendinopathy.

Keywords : shoulder ; shock wave therapy ; ESWT ; rotator cuff ; tendinopathy.

INTRODUCTION

Rotator cuff tendinopathy is a common cause of shoulder pain. Following recommendations by some authors, based on uncontrolled retrospective reports, a high number of low-energy extracorporeal shock wave therapy (ESWT) treatments for non calcifying tendinopathy of the rotator cuff are currently performed in Germany (*2,7,11,12*). To date, only two randomised, controlled studies exist to analyse the efficacy of such treatment. Schmitt *et al* (*18,19*) found no difference in shoulder function and pain in a placebo-controlled randomised study with low-energy ESWT. In a similar trial by Speed *et al* (*20*) with 78 patients, no difference could be found in shoulder pain and disability index between a low-energy ESWT and placebo treatment.

Several studies have showed that high-energy ESWT is significantly more effective than low-energy ESWT in the treatment of calcifying

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tendonitis of the shoulder. In 1998, Rompe *et al* (*15*) found a significant difference between high and low-energy ESWT 24 weeks after treatment of calcific tendonitis, with respect to Constant score and resorption rate. Loew *et al* (*13*) reported significant pain reduction in patients with calcific tendinopathy after high-energy ESWT, but not after low-energy or placebo ESWT. Albert *et al* (*1*) showed in a randomised trial that high-energy ESWT significantly improved symptoms in refractory calcifying tendonitis of the shoulder. In contrast they did not observe a significant clinical improvement after low-energy ESWT.

To date no controlled studies with high-energy ESWT for treatment of non calcifying tendinopathy of the shoulder have been reported. A study was therefore carried out comparing high-energy vs. low-energy ESWT to examine if high-energy ESWT has a higher effect on pain and shoulder function in non calcifying shoulder tendinopathy than low-energy ESWT.

MATERIAL AND METHODS

Participants

Only patients with failed conservative treatment of chronic rotator cuff tendinopathy were included. The minimum conservative treatment was 10 sessions of physiotherapy, two subacromial injections with steroids and intake of nonsteroidal antiinflammatory drugs. Inclusion and exclusion criteria were defined as shown in table I. Rupture of the rotator cuff was excluded by either ultrasound or MRI. The pre treatment examinations included standardised conventional X-ray investigations of the shoulder to exclude osteoarthritis of the glenohumeral and acromioclavicular joints. There was no difference in diagnostic workup between the two groups. The clinician checked the inclusion and exclusion criteria and obtained a signed informed consent by the patient before randomisation. Before consenting the patient was informed orally and also received an information sheet. The study design was approved by the local ethics commission (no. : 116/00).

Interventions

Every patient in the intervention group was treated with extracorporeal shockwave in 3 sessions, at one week intervals, with the Minilith SL 1 shock-wave generator (Storz Medical, Switzerland), applying 2000 high-energy ESWT (energy level setting 7) impulses at 120 impulses per minute with ultrasound localisation to the origin of the supraspinatus tendon (also the point of maximum pain). Patients in the control group were treated with a low-energy ESWT (energy level setting 4) under the same conditions as in the intervention group. Shock wave parameters for both energy settings can be found in table II. A subacromial local anaesthesia was given using 10 ml mepivacaine 1% before the treatment.

Objectives

This study is a prospective, single-blind trial with a randomised two-sample parallel-group design (high-energy ESWT vs. low-energy ESWT) to assess the difference in shoulder function (Constant score) and shoulder pain (visual analog scale) twelve weeks and one year after high- vs. low-energy ESWT for rotator cuff tendinopathy.

Outcomes

All patients were evaluated prior to randomisation using a questionnaire including the Constant score, subjective pain rated on a visual analog scale (VAS) from 0 points (no pain) to 10 points (maximum pain) for pain during activity and pain at rest. Twelve weeks and one year after the third treatment, patients were re-evaluated by an independent observer with the same questionnaire. The primary outcome measure of the study was the improvement of the age-corrected Constant score 12 weeks and one year after the last treatment (*4,5*).

Sample size

As this is the first trial to compare high- vs. low-energy ESWT in rotator cuff tendinopathy, no historical data were available on effect sizes. Therefore a sample size for this study was set to 20 patients in each group. No interim analysis was planned.

Randomisation

After the patients entered the study, they were randomised externally using random permuted blocks. The treatment-group assigned to the patient was written down on the treatment protocol that was separated from the evaluation protocol used by the independent observer. The observer was at no time involved in the treatment of

Table I. — List of inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
Clinical diagnosis of chronic rotator cuff tendinopathy	Glenohumeral or acromioclavicular joint arthrosis
Absence of calcifications	Rotator cuff tears
At least 6 months duration of symptoms	Allergic reaction to mepivacaine
Failed conservative treatment	Former operations to the treated shoulder
No treatment in the past 4 weeks	Local tumours or infections
Free range of movement or at least 90° abduction and free rotation	Age of patient below 18 years
	Pregnancy
	Neurologic disorders
	Acute bursitis of the shoulder

Table II. – Shock-wave parameters of the Storz Minilith SL1 shock-wave Generator

Parameter	High-energy group	Low-energy group
Energy level setting	7	4
Peak positive pressure (P_+)	62.5 MPa	26.0 MPa
Positive energy flux density (ED_+)	0.78 mJ/mm²	0.33 mJ/mm²
Total energy flux density (ED)	1.05 mJ/mm²	0.44 mJ/mm²
Positive Energy of 5 MPa Focus ($E_{+(5Mpa)}$)	62 mJ	30 mJ

the patient nor did he know to which group the patient was assigned.

Blinding

The primary endpoint (age-corrected Constant score after 12 weeks follow-up) was assessed by blinded independent observers. As there was the possibility of higher pain during application of high-energy ESWT, with a risk of unblinding, this was eliminated by treating patients from both groups with subacromial local anaesthesia with 10 ml mepivacaine. The treatment setup in both groups was identical. Only the physician doing the intervention was aware of the treatment group. The patients were not unblinded at any time.

Statistical analysis / Power analysis

SPSS 11.5 (SPPS Inc, Chicago, Illinois) was used for statistical analysis. The t-test for non-paired samples was used to analyse the differences between the high-energy and the low-energy group. Before applying the t-test, a test for normal distribution of the data and equal variances was performed. The 95% confidence intervals (CI) were calculated for the differences between both groups. Additionally a t-test for paired samples was used to analyse the effect of the treatment in both groups. A post-hoc power analysis for the main criterion was performed using the program G*Power (*6*).

RESULTS

Participant flow

A flow diagram showing the progress of patients throughout the trial is shown in fig 1. All patients were randomly allocated to the two groups.

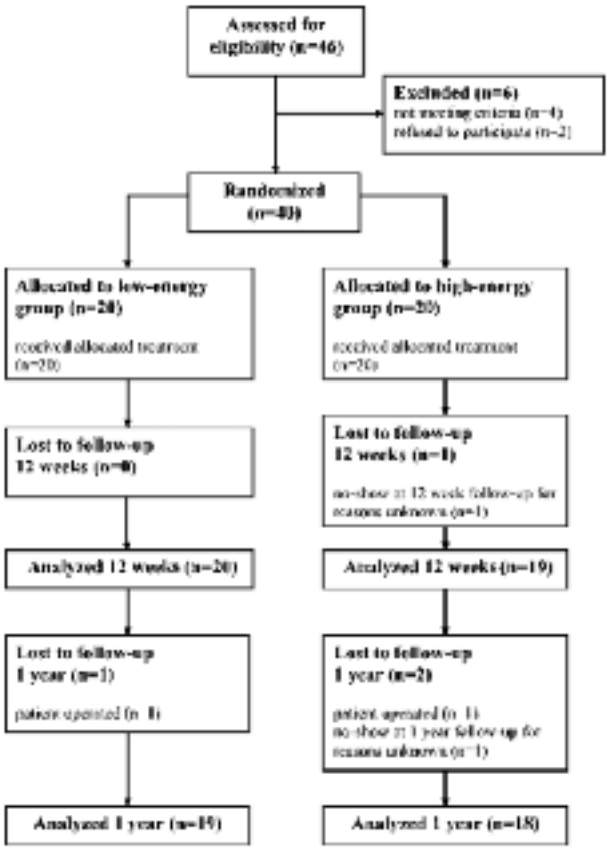

Fig. 1. — This flow diagram shows the progress of patients throughout the trial.

Recruitment

Forty patients who were referred to our outpatient clinic were included in the study. Twenty patients were randomised into the high-energy group and 20 patients in the low-energy group. A follow-up examination was performed after 12 weeks and one year.

Baseline data

Twenty-one patients were female, 19 were male. The right shoulder was affected in 21 cases, the left shoulder in 19. The mean age at time of randomisation was 53 years (range, 28 to 71 years). The mean age-corrected Constant score prior to treatment was 48 with a standard deviation of 21.1. Pain at rest on the VAS ranged from 1 to 10 points with an average of 4.6 (SD : 2.7). Pain during activity ranged from 1 to 10 points with an average of 7.3 (SD : 2.2).

Prior to treatment there was no significant difference in the primary outcome parameter. In one of the secondary outcome measurements (pain at rest) there was a statistically significant difference of 2 points on the VAS.

Numbers analysed

All 40 patients received the randomised treatment. One patient in the high-energy group did not show up for the twelve-week evaluation and one patient in the low-energy group did not appear for the one year assessment for unknown reasons. One patient in each group underwent subacromial decompression between the 12 week and 1 year evaluation and was excluded from the 1 year analysis. No other deviations from the study protocol occurred.

Outcomes and estimations

Table III illustrates the VAS pain results of the study. Fig 2 shows a plot of the 95% confidence interval of the 12 week and 1 year Constant score results for both groups. No statistically significant differences could be found between the treatment groups. There was a significant improvement from the preoperative values in Constant score, pain at rest and during activity (table IV).

Ancillary analyses

No subgroup analyses or adjusted analyses were performed. Using post-hoc power analysis we found a power (1-ß) of 46% to detect a medium effect (effect size d = 0.5). A priori-analysis using G*Power to find the sample size for a larger confirmatory study gave a total sample size of 156 patients for the 12 week Constant score (effect size d = 0.384 / α = 0.05 / power (1-ß) = 0.80) and a total sample size of 94 patients for the 1 year Constant score (effect size d = 0.518 / α = 0.05 / power (1-ß) = 0.80) to prove the observed group difference.

Table III. — Mean values (+/- standard deviation) of all outcome parameters before, 12 weeks and one year after intervention

Parameter	High-Energy Group	Low-Energy Group	t-Test p-value	95% CI
Constant score				
pre-intervention	46.37 +/- 22.47 (n = 20)	49.06 +/- 20.52 (n = 20)	0.691	–16.36 to 10.97
12 weeks	79.77 +/- 35.47 (n = 19)	67.89 +/- 32.94 (n = 20)	0.285	–10.31 to 34.07
1 year	88.45 +/- 31.97 (n = 19)	75.45 +/- 33.87 (n = 18)	0.237	– 8.95 to 35.00
Improvement (%)				
12 weeks	44.74 +/- 38.60 (n = 19)	46.50 +/- 32.65 (n = 20)	0.878	-24.92 to 21.39
1 year	63.42 +/- 37.46 (n = 19)	63.44 +/- 33.90 (n = 18)	0.998	-23.91 to 23.86
Pain at rest (VAS)				
pre-intervention	5.65 +/- 2.52 (n = 20)	3.45 +/- 2.44 (n = 20)	0.006	0.68 to 3.82
12 weeks	3.47 +/- 3.29 (n = 19)	2.30 +/- 2.56 (n = 20)	0.220	-0.73 to 3.08
1 year	2.11 +/- 2.71 (n = 19)	2.00 +/- 2.25 (n = 18)	0.899	-1.66 to 1.77
Pain during activity (VAS)				
pre-intervention	7.10 +/- 2.47 (n = 20)	7.40 +/- 1.88 (n = 20)	0.668	-1.70 to 1.10
12 weeks	4.58 +/- 3.60 (n = 19)	4.20 +/- 2.93 (n = 20)	0.720	-1.74 to 2.50
1 year	3.53 +/- 3.44 (n = 19)	3.56 +/- 3.29 (n = 18)	0.979	-2.26 to 2.22

VAS = visual analog scale from 0 points (no pain) to 10 points (maximum pain)
95% CI = 95% confidence interval of the group difference.

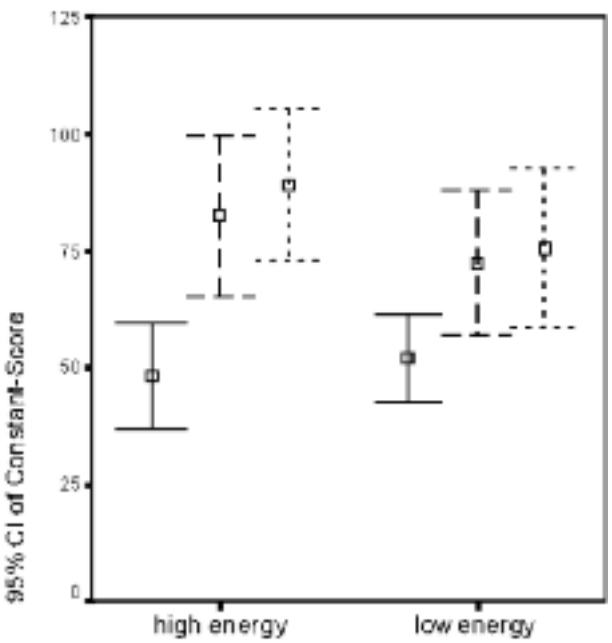

Fig. 2. — This plot shows the 95% confidence interval (CI) of the Constant score. The full lines stand for the initial Constant scores in both groups. The dashed lines show the Constant scores 12 weeks after intervention. The dotted lines illustrate the Constant score after 1 year.

Adverse events

No significant side-effects to the treatment were seen during the treatment. One patient in the low-energy group reported increased shoulder pain 10 days after the third treatment.

DISCUSSION

The primary aim of the study was to evaluate possible differences between two protocols of ESWT in treatment of rotator cuff tendinopathy. Former controlled studies showed no effectiveness of low-energy ESWT on that disorder (*8,18-20*). On the other hand some studies indicate a positive effect of high-energy ESWT on calcifying shoulder tendinopathy (*1,10,16,17*). The results of our study showed a statistically significant improvement from the pre-treatment status in both treatment groups with respect to Constant score, pain scale and subjective improvement. No statistically significant difference was noted for these parameters between the high-energy and low-energy group at the 12 week and 1 year evaluation.

Table IV. — Mean values (+/- standard deviation SD), 95% confidence interval (CI) and p-values of the difference between the Constant score and the pain at rest and during activity (VAS) before and after treatment, based on all patients at 12 week (n = 39) and 1 year follow-up (n = 37)

Results pre vs. post intervention	High-energy	Low-energy
Constant score 12 weeks	N = 19	N = 20
difference (+/- SD)	32.25 +/- 35.39	18.81 +/- 27.28
p-value	0.001	0.006
95% CI (difference)	15.19 to 49.31	6.04 to 31.58
Constant score 52 weeks	N = 19	N = 18
difference (+/- SD)	41.69 +/- 35.24	23.55 +/- 31.49
p-value	< 0.001	0.006
95% CI (difference)	24.71 to 58.67	7.89 to 39.21
Pain at rest (VAS) 12 weeks	N = 19	N = 20
difference (+/- SD)	-2.05 +/- 3.24	-1.15 +/- 3.15
p-value	0.013	0.119
95% CI (difference)	-0.49 to –3.61	0.32 to –2.62
Pain at rest (VAS) 52 weeks	N = 19	N = 18
difference (+/- SD)	-3,37 +/- 3.67	-1.17 +/- 2.98
p-value	0.001	0.115
95% CI (difference)	-1.60 to –5.14	0.31 to 2.65
Pain during activity (VAS) 12 weeks	N = 19	N = 20
difference (+/- SD)	-2.37 +/- 3.50	-3.2 +/- 2.51
p-value	0.009	< 0.001
95% CI (difference)	-0.68 to –4.06	-2.03 to –4.37
Pain during activity (VAS) 52 weeks	N = 19	N = 18
difference (+/- SD)	-3.47 +/- 3.99	-3.72 +/- 3.41
p-value	0.001	< 0.001
95% CI (difference)	-1.55 to –5.40	-2.03 to 5.42

VAS = visual analog scale, from 0 points (no pain) to 10 points (maximum pain).

The improvement in both groups underlines the importance of a control group for studies aiming to assess the effectiveness of treatment methods such as ESWT. The overall improvement in both study groups can be related with the natural history of the disease, the injection of local anaesthetic or a placebo effect. With all patients having already undergone various injections and physiotherapy treatments prior to the randomisation, the improvement is not likely to be caused by the mepivacaine injection. This is supported by Speed *et al* (*20*) who found no difference between ESWT and Placebo-ESWT in rotator cuff tendinopathy in a study in which no local anaesthetic was used.

The patients included in our study are typical for rotator cuff tendinopathy (*14*). The results are only valid for patients with a chronic rotator cuff tendinopathy with a history of at least 6 months and failed conservative treatment. Other pathologies such as biceps tendinopathy or acute impingement syndrome can have different outcomes.

In a review study Green *et al* (*9*) came to the conclusion that there is little evidence for the efficacy of common interventions for shoulder pain and that further clinical trials are necessary to determine the optimal treatment for shoulder pain. Chard *et al* (*3*) reviewed the long-term outcome of rotator cuff tendinopathy and concluded that it is not a rapidly self-limiting condition. Schmitt *et al* (*18,19*) tested placebo ESWT versus low-energy ESWT (both under local anaesthesia) in patients with supraspinatus tendinopathy. There was no difference in the Constant score or the pain scales between both groups 12 weeks or 1 year after intervention. Speed *et al* (*20*) tested low-energy ESWT vs. Placebo ESWT without the use of local anaesthetic and also

found no effect of ESWT on rotator cuff tendinopathy. In the current study an improvement in shoulder function could be seen in both groups. The degree of improvement was comparable to that found in the placebo-group of the former study (*18,19*). A placebo controlled study with higher number of patients is necessary to reinforce our findings.

Although we did not find a statistically significant difference between both groups, there was a trend towards a better Constant score after 12 weeks and 1 year in the high-energy group. Based on this study we do not recommend high-energy ESWT for the treatment of non calcifying rotator cuff tendinopathy other than in controlled clinical trials.

In summary no statistically significant differences were found between the outcome of high-energy and low-energy ESWT treatment of rotator cuff tendinopathy. Pain reduction and improvement in the Constant score was noted in both groups between pre-treatment and follow-up examinations.

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