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Low-energy extracorporeal shock-wave treatment (ESWT) for tendinitis of the supraspinatus

A PROSPECTIVE, RANDOMISED STUDY

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We have performed a controlled, randomised study to analyse the effects of low-energy shock-wave therapy (ESWT) on function and pain in tendinitis of the supraspinatus without calcification. There were 20 patients in the treatment group and 20 in the control group. The former group received 6000 impulses (energy flux density, 0.11 mJ/mm^2) in three sessions after local anaesthesia. The control group had 6000 impulses of sham ESWT after local anaesthesia.

The patients were examined at six and 12 weeks after treatment by an independent observer who evaluated the Constant score and level of pain. We found an increase in function and a reduction of pain in both groups ($p \leq 0.001$). Statistical analysis showed no difference between the groups for the Constant score and for pain. We therefore do not recommend ESWT for the treatment of tendinitis of supraspinatus.

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Tendinitis of the supraspinatus is a common cause of pain in the shoulder.[1,2] The symptoms include tenderness at the insertion of the tendon of supraspinatus and pain on abduction and extension against resistance. A tear of the rotator cuff and osteoarthritis of the acromioclavicular joint must be excluded by clinical examination, radiography and ultrasound or MRI. In contrast to calcifying tendinitis radiographs of the shoulder show no abnormality. The condition is usually treated by physiotherapy, analgesics and subacromial injection of steroids and local anaesthetic.[2] In some cases acute tendinitis becomes chronic and is resistant to non-operative treatment. In such cases, acromioplasty may be performed as an open or arthroscopic procedure. As a therapeutic option for patients with chronic tendinitis of supraspinatus low-energy shock-wave treatment (ESWT) has been recommended;[3-11] 1000 to 2000 shock waves of an energy flux density (ED) from 0.01 to 0.4 mJ/mm^2 are usually applied two to three times at weekly intervals.[9] The analgesic effect of ESWT was first described by Dahmen et al.[10] It has given relief of pain in 50% to 80% of patients with improvement in function depending on the site of the lesion.[11,12] Despite the fact that there is as yet no definite proof of the effectiveness of ESWT the number of patients receiving treatment in Germany each year is estimated to be 60 000 to 100 000, which is more than the number of patients receiving lithotripsy for urological conditions. The electrophysiological pathways and molecular mechanisms of the antinociceptive effect of ESWT are still unknown[13] and a matter of speculation. Previously published studies of the use of ESWT in the treatment of tendinitis of the supraspinatus have methodological and statistical flaws, such as uncontrolled design, no inclusion/exclusion criteria and no record of previous treatments. As a result ESWT is no longer recognised for insurance reimbursement, although it has become a well-known alternative to operative techniques. We have therefore carried out a prospective, randomised placebo-controlled, single-blind study to examine the effect of ESWT, and compared it with placebo treatment to create a basis for the planning of a larger trial.

Patients and Methods

Inclusion and exclusion criteria were defined as shown in Table I. The clinician checked eligibility and obtained signed informed consent before the randomisation. Before consenting, the patient was informed orally and was given an information sheet. Between March 1999 and February 2000, 40 patients were included in the study and randomly assigned to each group. There were 20 men and 20 women with a mean age of 52 years (29 to 66). In 23 the right shoulder was affected, and in the other 17 the left. All patients in the treatment group received extracorporeal shock waves in three sessions at intervals of one week, using the shock-wave generator Storz Minilith SL 1 (Storz

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Table I. Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Clinical diagnosis of chronic tendinitis of supraspinatus	Glenohumeral or acromioclavicular arthritis
Absence of calcification	Tear of the rotator cuff
Duration of symptoms for at least six months	Allergy to mepivacaine
Failed conservative treatment	Former operations to the treated shoulder
Minimum of 10 sessions of physiotherapy	Local tumours or infections
At least two subacromial injections	
Intake of NSAIDs	Age below 18 years
No treatment in the last four weeks	
Free range of movement or at least abduction of 90° and free rotation	Neurological disorders
	Acute bursitis of the shoulder

Medical AG, Kreuzlingen, Switzerland) (Fig. 1a), applying 2000 impulses of an ED+ of 0.11 mJ/mm^2 measured by a PVDF-Hydrophone, equivalent to 0.33 mJ/mm^2 measured by a fibreoptic-hydrophone, at 120 impulses per minute with ultrasound localisation to the insertion of the supraspinatus tendon (Fig. 1b). Patients in the control group were treated by sham ESWT under the same conditions as the treatment group.

All patients were evaluated using a questionnaire before randomisation. This included the Constant and Murley[14] score, and assessment of pain on a visual analogue scale from 0 (no pain) to 10 (maximum pain) during activity and at rest. Rupture of the rotator cuff was diagnosed either by ultrasound or MRI. The patients were reassessed by an independent observer using the same questionnaire at 6 and 12 weeks after the treatment. The primary outcome of the study was the rate of success 12 weeks after the last treatment, with success being defined by the increase in the age-corrected Constant score of at least 30 points or an absolute score of 80% of the normal value. Such an outcome is considered to be clinically significant. Because of the lack of previous data, no other important differences could be defined. The target sample size was projected by an estimated duration of the treatment phase of one year. Comparative analyses were completed on an intention-to-treat basis. No prospective cessation rules were defined.

Assignment. After each patient entered the study, a hotline (Institut für Medizinische Biometrie und Epidemiologie) was called and the patient was assigned to a treatment group using random permutated blocks. The group allocated to the patient was written on the treatment protocol which was separated from the evaluation sheet used by the independent observer, who was neither involved in the treatment nor knew to which group the patient had been assigned.

Masking. As the shock waves may cause pain, patients in both groups were given 10 ml of mepivacaine as subacromial local anaesthesia. In the placebo group a foil was placed between the patients and the water cushion to prevent the shock wave from reaching them. The typical sound created by the ESWT machine was present for both. Only the physicians operating the machinery knew the group to which each patient belonged, and they were not involved in further stages of the study.

Results

The mean Constant score before treatment was 34 (17 to 63). The mean score for pain at rest was 5 (1 to 10) and for that during activity 8 (4 to 10). One patient in the control

Fig. 1a

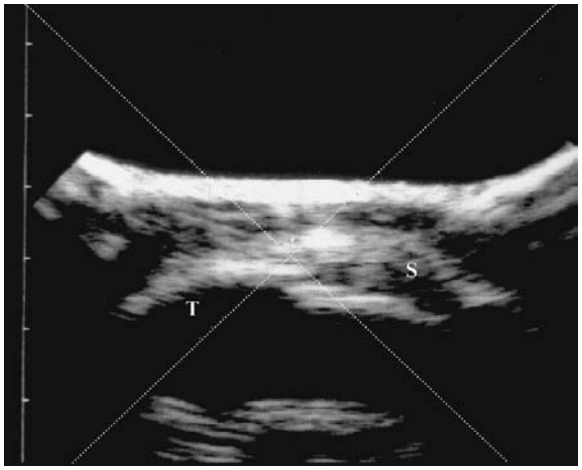

Fig. 1b

Figure 1a – Photograph showing the positioning of the patient and ESWT applicator. Figure 1b – Ultrasonogram to target the shock wave. The cross-hair indicates the focus of the acoustic lens aimed at the insertion of the tendon of supraspinatus (S) into the greater tuberosity (T).

Table II. Mean (± SD) values for parameters before and at six and 12 weeks after treatment comparing the control and treatment groups. In all parameters the differences between both groups are not significant ($p > 0.05$)

Group/parameter	Control group	Treatment group	95% CI (group difference)
Constant score (age-corrected)			
Pretreatment	42.20 ± 13.04 (n = 20)	40.70 ± 13.29 (n = 20)	-6.93 to 9.93
At 6 weeks	64.17 ± 25.17 (n = 18)	60.95 ± 29.62 (n = 19)	-15.17 to 21.61
At 12 weeks	64.39 ± 32.68 (n = 18)	66.50 ± 37.92 (n = 20)	-25.53 to 21.31
Number of successful treatments	8 (n = 18)	10 (n = 20)	N/A
Subjective improvement (%)			
At 6 weeks	*26.32 ± 28.67* (n = 19)	*28.42 ± 32.02* (n = 19)	*-22.10* to *17.89*
At 12 weeks	*31.05 ± 31.43* (n = 19)	*40.00 ± 38.35* (n = 20)	*31.77* to *13.87*
Pain during rest (VAS 0 to 10)			
Pretreatment	*5.40 ± 3.00* (n = 20)	*5.35 ± 2.54* (n = 20)	*-1.73* to *1.83*
At 6 weeks	*2.78 ± 2.71* (n = 18)	*2.74 ± 3.03* (n = 19)	*-1.88* to *1.97*
At 12 weeks	*3.22 ± 2.82* (n = 18)	*2.30 ± 3.03* (n = 20)	*-1.01* to *2.85*
Pain during activity (VAS 0 to 10)			
Pretreatment	7.95 ± 1.96 (n = 20)	7.75 ± 1.48 (n = 20)	-0.91 to 1.31
At 6 weeks	5.72 ± 2.80 (n = 18)	5.74 ± 2.51 (n = 19)	-1.79 to 1.76
At 12 weeks	6.11 ± 3.23 (n = 18)	4.85 ± 3.07 (n = 20)	-0.81 to 3.33

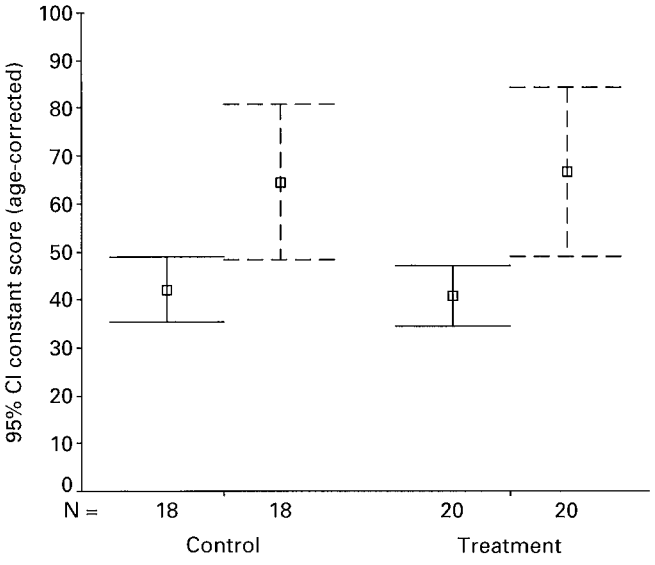

Fig. 2

Graph showing the 95% confidence interval (CT) of the 12-week age-adjusted Constant score showing the small difference between the control and the treatment group. The solid lines are the initial scores in both groups. The dashed lines show the 12-week scores.

Table III. Mean (± SD) and 95% confidence interval (CI) of the difference between the Constant score and the pain (VAS) during rest and during activity, before and after treatment, based on all patients at follow-up at 12 weeks (n = 38). All differences are highly significant ($p \leq 0.001$)

Parameter (n = 38)	Difference pre- *v* post-treatment	95% CI (difference
Constant score (age-corrected)		
12 weeks – pretreatment	17.61 ± 27.17	26.54 to 8.67
Pain during rest (VAS 0 to 10)		
12 weeks – pretreatment	-2.42 ± 3.58	-1.24 to -3.60
Pain during activity (VAS 0 to 10)		
12 weeks – pretreatment	-2.39 ± 3.54	-1.23 to -3.56

group did not return after the initial visit. The other 39 received the treatment as randomised.

No significant side-effects were seen during or after treatment. At follow-up at six and 12 weeks, 19 of the treatment group and 18 of the control group returned for examination. Sixteen patients were not satisfied with the results of their treatment. They were demasked and informed as to which group they belonged. The patients in the control group were offered the real ESWT treatment while those in the treatment group were informed about further options. There were no deviations from the study protocol.

We used SPSS 9.0 (SPSS Inc, Chicago, Illinois) for the statistical analysis of the results. For differences between the treatment and the control groups we used the *t*-test for non-paired samples ($p \leq 0.05$). Before using the *t*-test, a test for the normal distribution of the data and equal variances was performed and 95% confidence intervals were calculated for the differences between both groups. No significant differences were found between the controls and those treated (Table II). Figure 2 shows a plot of the 95% confidence interval of the 12-week Constant scores for both groups. In addition, a *t*-test for paired samples was used to analyse the effect of the treatment as a whole regardless of the group ($p \leq 0.001$). There was a highly significant improvement in the Constant score (age-corrected) and pain at rest and during activity (Table III). A power analysis was performed for the 12-week Constant score (age-corrected) using the program Gpower.[15] The *post-hoc* analysis gave a power of 5.37% to detect the effect of ESWT with subacromial injection of mepivacaine as against injection only. An *a priori* analysis gave a total sample size of 16 818 patients for a given power of 95% needed to prove the effect.

Discussion

Our aim was to examine critically the effect of ESWT in the treatment of tendinitis of the supraspinatus. Previous uncontrolled studies[7,10] have suggested that this treatment is effective. Our findings show a statistically significant improvement ($p < 0.001$) in both the treatment and the control groups as determined by the Constant score and a pain scale. No statistically significant differences between the groups were found at follow-up at six and 12 weeks.

Our study is the first controlled study of ESWT for this condition. Dahmen et al[10] reported six patients treated by ESWT, two with and four without calcification. They described improved function and less pain after the treatment in all the patients but the design was retrospective with no control group. Haist[7] found good results in 70 of 113 patients with different types of non-calcifying tendinitis. In his retrospective study neither the applied dose nor the number of treatments was standardised. The method of assessment was not uniform, nor was there a control group. Brunner et al[4] reported a success rate of 59.7% for ESWT in 266 patients with non-calcifying conditions of the shoulder. Again the study included no control group and the treatment was not standardised. They reported a reduction of pain after three months from 7.2 to 3.9, on a scale from 0 to 10. This is similar to the reduction of pain which we found in both our groups of patients. The function of the shoulder was not analysed. Despite the lack of prospective randomised studies these authors[4,7,10] recommend ESWT for the treatment of non-calcified tendinitis of the shoulder.

The improvement in both groups underlines the importance of a control group in studies attempting to prove the effectiveness of new methods of treatment such as ESWT. The overall progress in both study groups can be explained by the natural course of the disease, the injection of local anaesthetic or a placebo effect. While all patients had undergone various injections and methods of physiotherapy before randomisation for the present study, the improvement is not likely to have been caused by the injection of local anaesthetic.

The estimated number of 8400 patients per group needed to prove the very small possible effect of ESWT which we found in our study cannot realistically be achieved, even with multicentre trials. Indeed, such a study would not seem to be worthwhile. Based on our results, the use of low-energy ESWT in the treatment of tendinitis of the supraspinatus is time-consuming, expensive and probably ineffective compared with subacromial injections.

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No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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