

Extracorporeal shock-wave therapy for tendonitis of the rotator cuff

A DOUBLE-BLIND, RANDOMISED, CONTROLLED TRIAL

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We have performed a double-blind placebo-controlled trial of moderate doses of extracorporeal shock-wave therapy (ESWT) for non-calcific tendonitis of the rotator cuff. Adults (74) with chronic tendonitis of the rotator cuff were randomised to receive either active (1500 pulses ESWT at 0.12 mJ/mm²) or sham treatment, monthly for three months. All were assessed before each treatment, and at one and three months after the completion of treatment. The outcome was measured with regard to pain in the shoulder, including a visual analogue score for night pain, and a disability index. There were no significant differences between the two groups before treatment.

The mean duration of symptoms in both groups was 23.3 months. Both showed significant and sustained improvements from two months onwards. There was no significant difference between them with respect to change in the Shoulder Pain and Disability Index (SPADI) scores or night pain over the six-month period. A mean (\pm SD; range) change in SPADI of 16.1 \pm 27.2 (0 to 82) in the treatment group and 24.3 \pm 24.8 (-11 to 83) in the sham group was noted at three months. At six months the mean changes were 28.4 \pm 25.9 (-24 to 69) and 30.4 \pm 31.2 (-12 to 88), respectively. Similar results were noted for night pain.

We conclude that there is a significant and sustained placebo effect after moderate doses of ESWT in patients with non-calcific tendonitis of the rotator cuff, but there is no evidence of added benefit when compared with sham treatment.

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Extracorporeal shock-wave therapy (ESWT) by single-pressure pulses of microsecond duration can be guided by ultrasound to focus on a specific site. Having revolutionised the treatment of urolithiasis, ESWT has more recently been used in the treatment of a number of musculoskeletal conditions, including tendinopathies and enthesopathies, at doses of 10% to 20% of those used in lithotripsy for renal calculi.¹⁻⁵ The theoretical benefits are the stimulation of tissue healing and the breakdown of calcification.⁴⁻⁷ In spite of the increasing popularity of this method of treatment, there has been no randomised, controlled trial of its use in specific musculoskeletal conditions. Benefit from ESWT has been demonstrated in calcific tendonitis of the rotator cuff.⁴ We present our findings of a double-blind, randomised, controlled trial in non-calcific tendonitis of the rotator cuff.

Patients and Methods

We recruited adult patients with a clinical diagnosis of tendonitis of the rotator cuff. Informed consent was obtained. The patients were more than 18 years of age and had had pain in the shoulder for at least three months with clinical signs of a unilateral tendonitis of the rotator cuff. These included a painful arc and/or an impingement sign and pain, without weakness on resisted testing of one or more musculotendinous units of the rotator cuff. Exclusion criteria were demonstrable shoulder pathology including glenohumeral or acromioclavicular arthritis, instability, polyarthritis, neck pain, a local dermatological condition, neurological abnormalities, anticoagulant therapy, treatment to the affected shoulder within the previous six weeks, pregnancy, diabetes, connective tissue or infectious diseases, vasculitis or malignancy.

The patients were evaluated before treatment by a blinded observer. We used the Shoulder Pain and Disability Index (SPADI) which is a self-administered instrument developed to measure pain (five items) and disability (eight items) associated with shoulder complaints.^{8,9} In order to provide a frame of reference, the questions related to the preceding week. Patients assessed their status on an analogue scale in which a score of zero was given for 'no pain' and 100 for the 'worst pain imaginable' for the five pain items, and zero for 'no difficulty' and 100 for 'difficulty

requiring assistance' for the eight disability items. The total SPADI is scored by averaging the two subscales. The total SPADI and both the pain and disability scales have been shown to have high levels of consistency, a negative correlation with shoulder mobility and good repetition reliability.⁸ The index is sensitive to clinical changes in patients with pathology of the shoulder.⁹

The recommendations for conducting a randomised, controlled trial emphasise the importance of the use of patient-based outcome measures such as the SPADI in order to reflect clearly the patient's concerns.^{10,11} This contrasts with the Constant-Murley shoulder score,¹² which is not completely patient-based. It emphasises the measurement of ranges of movement, which are not necessarily a reflection of function.¹³ In addition, there is evidence that visual analogue scores, such as those used in the SPADI, are better than the Constant-Murley scoring system with respect to the degree of responsiveness and sensitivity to change.¹⁴ All patients also completed a percentage visual analogue score for night pain. All assessments were repeated before each treatment and at one and four months after completion of treatment. Plain radiographs and ultrasound revealed no evidence of calcification before treatment.

Patients were selected randomly to receive either ESWT (1500 pulses at 0.12 mJ/mm²) or sham treatment in which the treatment head was deflated, no coupling gel was applied and standard contact with the skin was avoided. The machine makes a noise as each shock wave is delivered and in order to enhance the sham design, minimal energy pulses (0.04 mJ/mm²) were generated.^{3,15,16} No local anaesthesia was used. All treatments were applied

using a Sonocur Plus Unit (Siemens, Munich, Germany) which generates mechanical shock waves from an electromagnetic generator.

After the recommendations by Russo et al,¹⁶ we used two parameters to focus the treatment on the target area in the ESWT group. The area was localised by ultrasound. The focus was then altered according to the site of maximal tenderness. All subjects received three treatments at monthly intervals. No other therapy was allowed during the period of study.

The primary endpoint was taken as one month after completion of treatment. Data were analysed on an intention-to-treat basis. A positive response was taken as an improvement of 50% at three months.

Results

The details of the 74 patients are described in Table I. There were no significant differences between the two groups at the start of treatment, although the sample size was slightly smaller in the treatment group (34 v 40). Nine subjects (four in the ESWT and five in the sham group) did not complete three treatment sessions. Two of the subjects withdrew after one treatment and two after two treatments because they could not tolerate the therapy (one) or for unknown reasons (three). In the sham group, three withdrew after one treatment and two after two treatments. The reason given in one was deteriorating symptoms; the other four offered no reason. No other adverse events were reported. Seven subjects in the ESWT group and eight in the sham group did not attend the final assessment.

Table I. Details of the 34 subjects who received treatment and the 40 given sham treatment

	Treatment	Placebo
Gender		
Male	13	18
Female	21	22
Mean age in years (range)	50.7 (26 to 72)	54.2 (25 to 75)
Mean (+ SD) duration of symptoms in months (range)	23 ± 31.0 (3 to 169)	23.3 ± 21.0 (3 to 104)
Dominant arm affected	21	24
Previous treatments		
Analgesics	18	16
NSAIDs*	22	22
Local corticosteroid injections	16	20
Physiotherapy	25	21

* non-steroidal anti-inflammatory drugs

Table II. The number and percentage of subjects with improvement of 50% from baseline at three months

	Group		p value	Odds ratio	95% confidence interval
	ESWT	Sham			
SPADI	12 (35.0)	18 (45.0)	0.479	1.176	0.809 to 0.711
Subscales					
Pain	15 (44.0)	13 (38.0)	0.8180	0.8726	0.3482 to 2.186
Disability	19 (47.5)	14 (35.0)	0.8122	1.150	0.4450 to 2.970
Night pain	14 (41.0)	15 (37.5)	0.814	0.941	0.650 to 1.362

Table III. Mean (\pm SD; range) SPADI and mean visual analogue scale for night pain for the ESWT and sham-treated patients throughout the study

	Baseline	1 month	2 months	3 months	6 months
SPADI					
ESWT	53.6 \pm 20.2 (13 to 89)	48.7 \pm 21.0 (7 to 83)	46.1 \pm 22.4 (9 to 88)*	34.7 \pm 26.6 (2 to 90)†	24.1 \pm 22.9 (0 to 82)‡
Sham	59.5 \pm 16.1 (16 to 90)	58.5 \pm 19.7 (13 to 93)	48.6 \pm 23.8 (3 to 90)‡	39.7 \pm 27.7 (5 to 96)‡	34.9 \pm 31.7 (0 to 95)‡
Night pain					
ESWT	60.9 \pm 24.6 (5 to 100)	47.8 \pm 28.0 (2 to 99)	48.3 \pm 28.1 (3 to 100)*	38.1 \pm 28.3 (0 to 95)†	27.3 \pm 26.9 (0 to 82)‡
Sham	67.7 \pm 25.7 (3 to 98)	57.7 \pm 28.9 (2 to 100)	46.4 \pm 27.0 (0 to 99)‡	39.3 \pm 31.8 (2 to 92)‡	33.3 \pm 32.3 (0 to 98)‡

* comparison with baseline value (non-parametric t-test); * $p < 0.05$; † $p < 0.01$; ‡ $p < 0.001$

At three months, 12 (35%) of the subjects in the ESWT group and 18 (45%) in the sham group showed a positive response (50% improvement in SPADI). A positive response in night pain occurred in 14 (41%) and 15 (37.5%) from the ESWT and sham groups, respectively (Table II).

Both groups showed significant and sustained improvements from two months onwards (Table III). There was no significant difference between the groups with respect to the degree of change in SPADI scores or night pain during the six-month period. The mean change in SPADI in the treatment group was 16.1 (SD; range 0 to 82) and in the sham group 24.3 (24.8; range -11 to 83) at three months. At six months the mean changes were 28.4 \pm 25.9 (-24 to 69) and 30.4 \pm 31.2 (-12 to 88), respectively. The changes in night pain were similar.

Discussion

Tendonitis of the rotator cuff is a common disabling condition, often chronic and recurring.^{17,18} A limited response to most conservative measures^{13,19} has led to a search for new forms of treatment. In Germany, where the therapy was developed, over 65 000 treatments using ESWT are given annually for musculoskeletal complaints.¹⁻⁵ The rationales proposed for the use of the technique in such conditions include the promotion of soft-tissue healing,⁷ reduction of calcification,⁴ inhibition of pain receptors⁶ or denervation to achieve relief from pain.⁵ In spite of the enthusiasm for its use in musculoskeletal conditions there has been no randomised, controlled trial to evaluate the effect of ESWT in specific conditions.^{2,19}

ESWT can be classified according to its energy levels. Low-energy shock waves have a focal energy flux density (EFD) of up to 0.08 mJ/mm², moderate energy an EFD between 0.09 and 0.28 mJ/mm² and high energy up to 0.6 mJ/mm².^{15,20} Others have suggested a simpler classification, with low energy ESWT having an EFD of less than 0.12 mJ/mm² and high energy an EFD between 0.12 and 0.38 mJ/mm².^{15,21} For soft-tissue lesions most of the reports relate to the use of low-energy (<0.12 mJ/mm²) shock waves. Loew et al⁴ reported relief from pain in a significant number of patients with calcific tendonitis after one or two high-energy (EFD 0.3 mJ/mm²) applications but not in low-dose and control groups, three months after treatment. Improvement in the Constant score was significant after high-dose treatment and correlated with

reduction in calcification. Treatments were preceded by the administration of local anaesthesia. No information regarding blinding of the study was given.

Our results suggest that there is a significant and sustained placebo effect after moderate-dose ESWT, but there is no evidence of added benefit from active, compared with sham treatment. The placebo effect may explain the significant improvements noted by others in uncontrolled studies of soft-tissue lesions.^{5,22-24} Pain is the feature which is most responsive to a placebo effect.²⁵

Other factors can lead to a false impression of the placebo effect, most importantly regression to the mean and two special forms of this, spontaneous improvement and fluctuation of symptoms.²⁶ The patients involved in our study had chronic symptoms. Regression to the mean is unlikely in such patients and has not been noted in other studies of similar populations^{4,18,27,28} but it cannot positively be excluded. Spontaneous improvement and significant fluctuation of symptoms would also be unusual in such patients.¹⁸

The form of sham treatment which we used was devised to ensure that no energy was delivered to the region under study. Elements used in the techniques of others were included,^{3,16} but with additional measures to ensure that this was a true sham. The combination of steps taken make it unlikely that any treatment was delivered to a patient in the sham group.¹⁵

There is no consensus on appropriate doses of ESWT and treatment parameters remain empirical. Emphasis was placed on the use of a feasible regime with minimal side-effects and thus a low-dose regime was chosen in order to avoid the need for local anaesthetic or significant rest after treatment. It is possible that different doses may be more effective and there is evidence, at least in calcific tendonitis, that effects are dose-related.⁴

In order to identify side-effects of treatment we used an interval between treatments which was usually one week. This was longer than that used by others.^{3,4} The technique is widely reported to be safe, but there is a potential for haemorrhage and local soft-tissue damage which are more likely with high doses.²⁹ No significant adverse effects were noted which is in agreement with the experience of others.^{3-5,24,26}

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