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ORIGINAL STUDY

Extracorporeal shock wave therapy in chronic calcific tendonitis of the shoulder – Is it effective ?

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Extracorporeal shock wave therapy has been claimed to be an effective non-invasive treatment for chronic calcific tendonitis of the supraspinatus tendon. However many trials have been criticised for not achieving necessary scientific standards. We report a prospective, single blinded, randomised control trial of 20 patients, which looked into effectiveness of the therapy. Subjectively, 45% of the treated patients were satisfied with the outcome and also had objectively increased their Constant score by 11% at 6 months. The control group experienced no subjective or objective improvement with p value < 0.03. This study confirms that extracorporeal shock wave therapy is effective in treating chronic calcific tendonitis when compared with a placebo group. However in our experience it is not as successful as previously claimed, with half the patients failing to achieve a satisfactory out come and requiring surgical excision. Patients found the procedure painful, which has not been previously alluded to.

Keywords : calcific tendonitis ; rotator cuff ; extracorporeal shock wave therapy.

INTRODUCTION

Calcifying tendonitis of the rotator cuff mainly affects the supraspinatus tendon in middle-aged women between 30 and 50 years of age, is painful in 50% of patients, and frequently leads to considerable restriction of motion (*3,29*). It is a common enthesopathy of the shoulder, and is characterised by inflammation around calcium hydroxyapetite crystal deposits, usually localised in the suprasipnatus tendon, near its insertion. The mechanisms underlying the aetiology of intratendinous deposits of carbonated apatite are not fully understood (*8*). The condition is usually treated by conservative methods like physiotherapy, analgesics, subacromial injection of local anaesthetic and steroids (*28*), the efficacy of which is poorly documented (*1*). Needle extraction and bursoscopic excision have also shown to be successful with variable efficacy (*10,19*). In chronic cases and in cases resistant to non-operative treatment, acromioplasty may be performed as an open or arthroscopic procedure (*28*).

Over the last 15 years extracorporeal shockwave therapy (ESWT) or lithotrypsy, has been used for

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the treatment of many conditions in orthopaedics. Much of the work has been in Europe where it has been used extensively in epicondylitis, chronic calcific tendonitis, plantar fasciitis and other applications including non-union of fractures. ESWT potentially offers a non-invasive method of treating these difficult chronic conditions including calcifying tendonitis of the rotator cuff (*1*). However there have been few prospective controlled trials to measure its efficacy and therefore the evidence remains largely anecdotal (*15*).

Although ESWT has become increasingly popular there is considerable debate as to its appropriate usage and efficacy. Schmitt *et al* report that despite the fact that there is no definitive proof of 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 receiving lithotripsy for urological conditions (*28*).

All the studies published in the last decade have shown a degree of efficacy, but the devices, treatment and end-points differ from one publication to another (*14*). Some studies compared efficacy of low-energy versus high-energy ESWT and some trials compared either high or low-energy ESWT with sham treatment or placebo. None of the studies reported the pain perspective of the therapy.

Hence we aimed to investigate the efficacy of ESWT as a treatment modality for calcific tendonitis of the supraspinatus tendon, and to assess the pain patients experienced during the treatment by a prospective, single blinded randomised placebo-controlled trial to create a basis for the planning of a larger trial.

Principles of ESW Therapy

ESWT works by non-invasive disruption of soft tissues. The shock waves are made up of sound. Sound is a series of compressions and depressions in the density of air or any medium through which it passes. The particles in the medium move as the compression and then depression of the sound wave passes, the amount of displacement of the particles being dependant on the amplitude of the sound. The shockwave generator used in ESWT focuses a loud sound onto a small area, using an acoustic lens. At the focus they are in phase and therefore constructive interference takes place. Because of this the amplitude of the compression and the following depression is multiplied many times in a small area, generating huge pressures and displacement, this is called cavitation. The *energy flux density* (EFD) is the energy dissipated within a given volume of tissue, this represents the work done by the movement of the tissue within a given time and volume of space, measured in mJ/mm^2, it is this measurement, which is used for comparison.

The effective total energy of a treatment is defined by the number, EFD of the single impulses and by the geometrical measurement of the focus. Although there is no universal agreement on the threshold values, low-energy extracorporeal shock waves have an energy flux density below 0.08 mJ/mm^2, medium energy shock waves from 0.08 mJ/mm^2 to 0.28 mJ/mm^2, and high-energy shock waves from 0.28 mJ/mm^2 to 0.60 mJ/mm^2 (*26*).

PATIENTS AND METHOD

An ethical committee approval was obtained prior to this prospective study. The patients were selected from 27 consecutive referrals to orthopaedic outpatients from general practice, who would classically be offered arthroscopic debridement and subacromial decompression surgery. Patients in either group were well matched for demographics, symptoms and type of deposits. The inclusion criteria were : Gartner type I or II calcific deposit on radiograph (*11*), complaining of shoulder pain secondary to supraspinatus tendonitis [diagnosed using magnetic resonance imaging (MRI) in 8 patients or ultra sound scan (USS) in 15 patients], a history of pain for a period greater than 12 months and a failure of conservative therapy. Patients with rotator cuff rupture, local arthritic changes or generalised polyarthropathies, neurogenic syndromes, pregnancy, infection or coagulation disorders were excluded from the trial. Hence seven patients were excluded from the study due to the criteria as mentioned. All the patients who consented to take part in the trial were evaluated by using a questionnaire i.e. Constant and Morley score and Visual analogue pain score, before randomisation. An independent assessor using the same questionnaire at the end of 1st week, 6 weeks and 6 months reassessed the patients. Randomisation was performed just before the first treatment session, using a centralised list in blocks to get two equal

groups. Patients were allocated into either group after opening the sealed opaque envelope.

The control group I (n = 9) received a sham treatment of only 20 shocks with a negligible energy flux density of 0.03 mJ/mm^2. Group II (n = 11) received 2000 shocks fixed at 0.28 mJ/mm^2 (high energy). Before treatment both groups had the exact location of the calcific deposit marked on their skin using high resolution USS by the radiographer. This area was then infiltrated with 20 mls 0.5% marcaine. The lithotripter was then placed on the shoulder and using the inline ultrasound imaging the ESWT was focused on the deposit, applying the appropriate dose depending on the group. The patients were blinded for the treatment they received.

All the patients were assessed pre-treatment and followed up at 6 months with a radiograph and USS. Subjective improvement was assessed by asking the patients, are you happy with the result ?' YES/NO. They were then asked to describe their outcome, categorised as worse, no change, slight improvement, satisfactory improvement and complete resolution. Objective improvement was measured using the Constant-Morley shoulder assessment score at the end of 6 months. Visual analogue score (VAS) for pain was used to assess level of discomfort before, during and after the procedure. Time to return to work was also noted at the last follow-up in either group.

RESULTS

All patients were happy to undergo the treatment, preferring it to the idea of having surgery. Table I shows how the patients responded to the question 'are you satisfied with the outcome of the treatment'. Using Fisher's exact test we can show that despite the small numbers in the study, the results are significant with 5/11 of patients having a satisfactory result at 6 months ($p < 0.038$).

Table I. — Subjective patient outcome

Response to question 'are you happy with result' ?	Yes	No	Total
Control group	0	9	9
Treatment group	5	6	11

Figure 1 shows how the patients described their symptoms at 6 months. The results of the control group show that 7/9 had no change in their symptoms, while the remainder classified their outcome as only a slight improvement or got worse ; therefore none in the control group had a good result. In the treated group, however, 5/11 of patients described their outcome as satisfactory improvement or complete resolution. The rest of the patients in the treatment group described a similar outcome to those in the control group (i.e. mainly no improvement but with a few experiencing slight improvement or worsening) this probably represents the natural history of the chronic condition.

Table II shows the scores of the objective testing using the Constant Morley shoulder assessment score. Using the Mann Whitney U test it can be demonstrated that there is no statistical difference

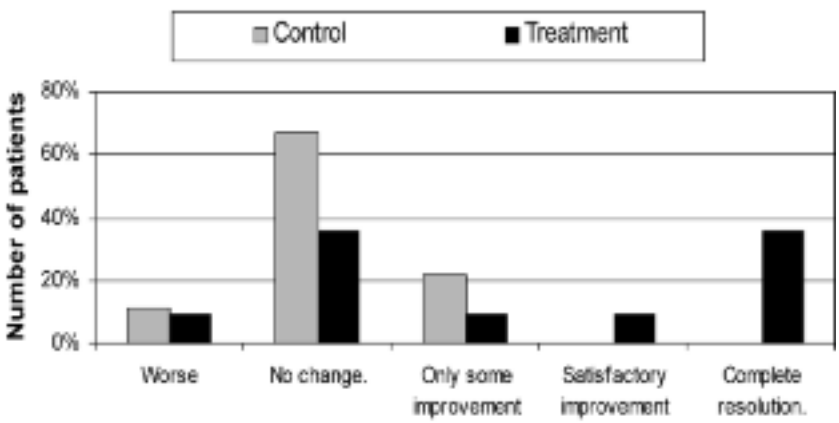

Fig. 1. — Patient description of outcome

Fig. 2. — Visual analogue pain score recorded before, during and after treatment with 2000 shocks of 0.28 mJ/mm^2 ESWT.

Table II. — Objective patient outcome

Average increase in Constant Morley score	
Control Group	0
Treatment Group	11

between the treatment and control group prior to treatment. However after treatment there is a significant difference between the groups. There is no improvement in the score of the control group but an increase of 11 in the treated group with a p value < 0.03.

ESWT is painful, with 9/11 of the patients complaining of pain after the treatment when the local anaesthetic had worn off. The treatment typically lasted 20 minutes, during which time the treated group had 2000 shock waves into the shoulder.

Figure 2 shows how the patients described their pain before, during and after treatment. The average visual analogue pain score for the treatment group is seen to rise sharply during treatment to 7 (severe). The graph shows that on average it took two days for the pain to settle to the pre treatment level and then a further week to reach a lower post therapy plateau. Those patients who were successfully treated were pain free within a week of ESWT, and account for the improved pain score for the group. All patients were able to drive home after treatment and return to work the next day, this represents an advantage over other treatments. Sixty-two percent developed bruising to the shoulder of between 2-10 cm^2, which resolved quickly without complication.

Of the 11 patients who received the ESWT, 6 had no evidence of the calcific deposit at follow-up. However this did not correlate with symptoms as two patients who had resorption continued to have pain. We were unable to demonstrate an association between the presence of the calcific deposit and symptoms.

None of the patients received another dose of ESWT. All the patients who did not get better with the treatment and patients in the placebo group were offered surgical treatment if still symptomatic at the end of six months.

DISCUSSION

Tendinitis of the shoulder is a common cause of pain in the shoulder (9). Needling has been shown in many studies (*6,12*) to be effective, with 60% of patients having complete resolution of pain and regaining full range of movement. Arthroscopic surgery has become increasingly popular as a minimally invasive day case procedure, but requires a general anaesthetic. Results demonstrate complete recovery in 72-93% (*2,16,20*). Open surgery is successful in 90% (*13,24*) of patients but recovery time can be long.

The mechanism of action of shock waves delivered at the energies used in clinical practice is uncertain (*21*), and despite some correlation between clinical and radiological outcome, the procedure appears to be associated with mid-term symptomatic effect that is independent of any lithotriptic action (*1*).

The ESWT machines used in lithotripsy all vary to some degree. There has recently been a drive to standardise and calibrate the machines so as to compare data. It is not clear what the optimum energy flux density should be ; the literature suggests that an energy level of 0.28 mJ/mm^2 is used for calcific tendonitis of the shoulder (*22,25*).

The results of this study are interesting, as they are in part different than those published by other authors who have shown a wide range of success with ESWT in calcific tendonitis. Initial papers published results with good or excellent outcomes in as many as 80% of patients (*30*). However a meta-analysis of the literature, advocating the use of ESWT in musculoskeletal applications, revealed that very few papers achieved adequate scientific standards (*2*) and therefore the evidence for its use remained largely anecdotal. Most papers fail to compare the results with a control group, this is particularly important, as calcific tendonitis is a self-limiting condition. Many of these papers recommend the use of ESWT as a preferred method of treatment. We were unable to attain the 80% success rate achieved by other studies. Our results are, however broadly in line with the largest study by Leow *et al* (195 patients) that recorded relief of pain in 58% of treated patients but only 5% of the control group (*17*). This paper was not a prospective randomised control trial.

Daecke *et al* (*7*) reported a clinical improvement and significant correlation between the dose of energy and radiological effectiveness after one or two sessions of high-energy shock waves. Loew *et al* (*17*) reported that only 58% patients gained effective relief from a high-energy ESWT.

In another trial by Albert *et al* (*1*) they reported pain relief measured by VAS was marked in the active treatment group but it was not statistically significant. They also found that the improvement in Constant and Morley score after three months was relatively smaller as compared to other studies. They also did not observe any significant improvement after low-energy ESWT.

Several studies showed high-energy ESWT was more effective than low-energy ESWT, but all of them failed to report the effect of such treatment at the end of six months (*7,17,18,27,30*) as compared to our study.

Bruner *et al* (*4*) reported a success rate of 57.9% for ESWT in 266 patients with non-calcifying conditions of the shoulder and this study was carried out without any control group. In a study similar to ours, Schmitt *et al* (*28*) found that there is no statistical significant difference in Constant score and VAS between either group at 6 and 12 week follow-up.

Our study is also important as it compared two well-matched cohorts of patients , it had a longer follow-up of all patients as compared to various studies with 12 weeks follow-up, and all cases were assessed by a single surgeon with a standard protocol and no cases were lost to follow-up.

The number within our trial is small, however we were able to demonstrate a statistical significance. While it demonstrates that ESWT does work, the main limitation of our study is the small group of patients in both groups and the fact that it was a single blinded study. However, Schmitt *et al* concluded that around 8400 patients per group are needed to prove the very small possible effect of ESWT, which cannot be realistically achieved, even with multicentre trials (*28*). In a systemic review by Harniman *et al* (*14*), there was moderate evidence that high-energy ESWT is effective in treating chronic calcific rotator cuff tendonitis when the shock waves are focused at the calcified deposit. They also found that there is only moderate evidence that low-energy ESWT is not effective for treating chronic noncalcific rotator cuff tendonitis, although this conclusion is based on only one high-quality study, which was underpowered. They concluded that high-quality randomised, controlled trials are needed with larger sample sizes, better randomisation, blinding, and better outcome measures.

Albert *et al* (*1*) and Peters *et al* (*23*) reported that high-energy shock waves were significantly more painful than low-energy waves. In our study even though we used 0.28 mJ/mm^2, we found significant pain in the treatment group, which is contrasting with several other studies.

We also observed that ESWT is non-invasive and is a simple 20-minute outpatient procedure. The patients were able to drive home after treatment and return to work the next day. We did not encounter any serious complications despite 62% developing bruising, which resolved in a few days.

CONCLUSION

This prospective, blinded randomised control trial confirms that ESWT can be effective in treat-

ing calcific tendonitis when compared with a placebo group. It is a safe outpatient procedure, which can be performed by a radiographer. However in our experience it is not as successful as previously claimed, with half of the patients failing to achieve a satisfactory outcome and requiring surgical excision. Patients found the procedure to be painful, which has not been previously alluded to. In our experience half of the patients treated had resolution of their chronic symptoms within a week. They required no hospitalisation and no time off work. There is however a cost implication in hiring a lithotripter, added to the high proportion of patients requiring further treatment. The small patient numbers limits this study and a multi-centre trial would be necessary to assess its long-term efficacy and complication rate, before ESWT is demonstrated as an effective treatment modality.

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