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Extracorporeal shock wave therapy for non-calcific supraspinatus tendinitis – 10-year follow-up of a randomized placebo-controlled trial

Abstract: Evidence for the efficacy of extracorporeal shock wave therapy (ESWT) in supraspinatus tendinopathy without calcification is sparse, and therefore this treatment option is often controversial. Patients of a randomized placebo-controlled study to analyze the effects of ESWT on function and pain were revisited 10 years after the initial consultation. The former verum group received 6000 impulses (energy flux density, 0.11 mJ/mm²) in three sessions after local anesthesia between 1999 and 2000. The placebo group had 6000 impulses of a sham ESWT after local anesthesia in the same period. Re-evaluation of the patients included a relative Constant score as well as pain measurements (visual analogue scale) during activity and at rest. No significant changes ($p>0.05$) in relative Constant scores, pain at rest, or pain during activity could be found after a 10-year follow-up between the placebo and verum groups after ESWT. The treatment of non-calcific supraspinatus tendinopathy with ESWT does not seem to have an effect on function or pain improvement in the long run. The results of the present study cannot advise the use of ESWT in cases of non-calcific supraspinatus tendinopathy.

Keywords: non-operative treatment; physical treatment; rotator cuff; shoulder.

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Introduction

Tendinopathy of the supraspinatus is a common cause of pain in the shoulder [24]. Regardless of its clinical aspects, there is a distinction between calcific and non-calcific tendinopathies in radiologic imaging at first [3, 19]. Symptoms of both diseases include tenderness at the insertion of the supraspinatus tendon, and pain on abduction and extension against resistance. As there is a high prevalence of concomitant shoulder diseases, rotator cuff tears and osteoarthritis of the acromioclavicular joint should be excluded by means of clinical examination, radiography and ultrasound, or magnetic resonance imaging (MRI) scans in both cases before any form of therapy. Conservative treatment options combine physiotherapy, oral analgesics, and series of subacromial injections of local anesthetics and steroids [3, 16]. Tendinopathy of the supraspinatus may become a chronic condition with a high resistance against conventional non-operative treatments as mentioned before [16]. Arthroscopic or open surgery (removal of calcification, acromioplasty, etc.) has to be regarded as an option in these cases [23].

Much effort has been made to find alternative ways of treatment during the last two decades. Among them, extracorporeal shock wave therapy (ESWT) has been recommended frequently as it is used to treat a wide range of enthesopathies or other ligamentous disorders [14, 19, 33]. Today, good evidence levels are available for the treatment of calcific supraspinatus tendinopathy with ESWT [14], while there are only a few studies examining the use of ESWT in non-calcific supraspinatus tendinopathy [7, 13, 27–30]. Most of these studies either have a moderate study design or a far too short follow-up interval. There are no long-term trials available in the present literature.

The usual treatment with ESWT consists of limited 2 to 3 weekly applications of 1000–2000 shock waves of an energy flux density (ED) from 0.01 to 0.4 mJ/mm² [26]. Shock waves are classified by their energy level, thus being divided into low energy (<0.11 mJ/mm²), medium energy (0.12–0.28 mJ/mm²), and high energy (>0.28 mJ/mm²) [1].

Today, high-energy ESWT is thought to be superior to other energy levels in the treatment of tendinopathies [19]. However, some studies revealed that there is no significant difference between two energy levels with regard to their therapeutic outcome [29]. An analgesic effect has been proven already in previous studies where 50–80% of patients with a tennis elbow or golfers' elbow reached a substantial pain reduction together with functional improvements of the joint [20]. Although no proof of efficacy of ESWT in non-calcific conditions has been supplied until today, the number of patients receiving this treatment is still very high – not least owing to a good accessibility for outpatient care. The molecular mechanisms of ESWT-induced tissue remodeling and promotion of its analgesic effect remain unclear, although there are newer studies suggesting a revitalization and repair of tenocytes [21]. The long-term results presented in this prospective, randomized placebo-controlled, single-blinded study should add to a better understanding of the clinical value of ESWT and its limitations in the treatment of non-calcific tendinopathies of the supraspinatus.

The present study reports about the 10-year follow-up of a randomized controlled clinical trial of ESWT in the treatment of non-calcific supraspinatus tendinitis in comparison with placebo. It was hypothesized that there were no significant differences between the treatment and placebo groups after a course of 10 years, being in accordance to results published earlier.

Materials and methods

The inclusion and exclusion criteria of the initial study were defined as shown in Tables 1 and 2. Eligibility for the study was checked by a clinician before patients' consent was obtained. Within the same consultation, patients were informed orally and given an information sheet about the study. The study has a single-center design, and all investigations were conducted at the Department of Orthopedics and Rheumatology at the University Hospital Marburg, Germany. Patients were recruited initially between March 1999 and February 2000, and revisited for the present follow-up between May 2009 and April 2010. Randomization was performed externally by a telephone call at the Institute for Medical Biometry and Epidemiology by using random permutated blocks. All research procedures were consistent with the Declaration of Helsinki. Approval for this study was obtained from the institutional review board of the University Hospital Marburg (No. 02/99).

Table 1 Inclusion criteria [27].

Clinical diagnosis of chronic tendinitis of the supraspinatus without calcification
Duration of symptoms for at least 6 months
Failure of conservative treatment
– At least 10 sessions of physiotherapy
– At least two subacromial injections
– Intake of at least one NSAID per day
Free range of motion or at least 90° of abduction and free rotation
No therapy during the last 4 weeks

Table 2 Exclusion criteria [27].

Allergy against local anesthetics (e.g., mepivacaine)
Glenohumeral or acromioclavicular arthritis
Rotator cuff tears
Neurological diseases
Previous surgery to the treated shoulder
Local infection or tumor
Patient age <18 years

A total of 40 patients were included and randomly assigned to either the control or treatment group. The patient population included 20 men and 20 women with a mean age of 52 years (range 29–66 years), of whom 23 presented with pain on the right side and 17 with pain on the left side. Patients assigned to the treatment group received ESWT in three sessions with weekly intervals, using the shock-wave generator Storz Minilith SL 1 (Storz Medical AG, Kreuzlingen, Switzerland) (Figure 1A), applying 2000 shock waves of an ED of 0.11 mJ/mm² measured by a polyvinyldenfluoride-hydrophone, which is equivalent to 0.33 mJ/mm² measured by a fiber optic-hydrophone, at 120 impulses per minute with a prior ultrasound detection of the insertion point of the supraspinatus (Figure 1B). Patients assigned to the control group received a sham ESWT in the same setting as described above. Masking was achieved with subacromial injections of 10 ml mepivacaine for the course of the treatment. In the sham group, a special absorber foil between patients and water cushion was used to prevent the shock waves from reaching the treatment site. Therefore, all patients heard the typical sound of the ESWT machine. Operators of the machines were not blinded to the treatment groups and did not play any role in the further study. Constant and Murley [5] scores were evaluated in a patient form before inclusion in the study. Pain was measured on a visual analogue scale (VAS) ranging from 0 to 10 during activity and at rest.

Results of prior early investigations have already been published [27, 28]. In the present study, a 10-year follow-up of the original patient population was performed.

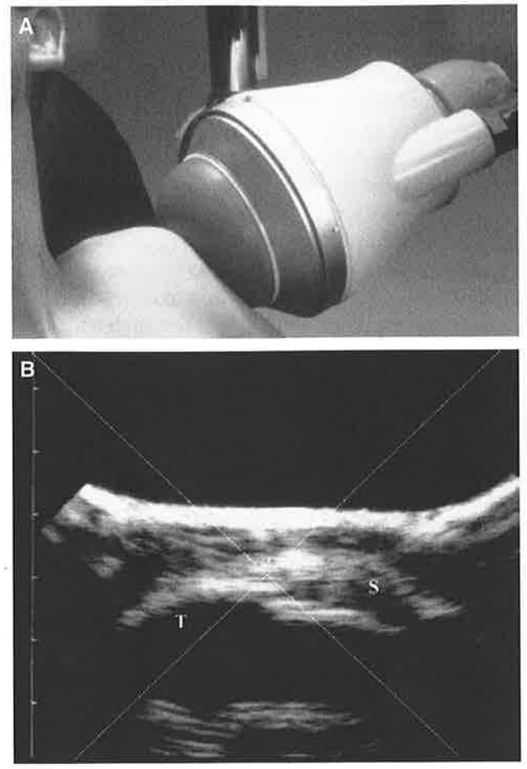

Figure 1 (A) Patient setup for ESWT application using the Storz Minilith SL 1 [27]. (B) Sonogram used in targeting the insertion of the supraspinatus for ESWT – supraspinatus tendon (S), greater tuberosity (T) [27].

Thirty-three of the initial 40 patients could be included into the 10-year follow-up after collection of actual contact details. Five patients could not be contacted because of unknown addresses, and two patients had already refused to participate during the course of the previous investigation. Twenty-five patients could be reassessed clinically, while eight patients refused a clinical examination. Five of eight patients could be recruited to at least fill out postal interviews, one could not be contacted despite a correct address/phone number, one did not consent to a clinical examination, and one only consented to a phone interview and did not want any further contact. The postal interviews included a cover letter, a Constant score, and DASH score self-assessment form as well as a manual for correct completion of the forms. Four of five patients returned their forms; one did not answer our request. It was also investigated if any of the patients received open surgical or arthroscopic therapy for the site treated with ESWT during the course of the 10-year trial period. The relative Constant score, meaning the percentage of age- and sex-corrected reference values in relation to the classic Constant score, was set as the primary outcome variable [12]. Success of the treatment was therefore indicated by changes of the relative Constant score over the trial period with an *a priori* power of 54% (α=0.05 and effect size d=0.68).

Statistical analysis

For statistical analysis, the software package SPSS 9.0 (SPSS Inc., Chicago, IL, USA) was used. Sample size calculations and power analyses were done using the software tool G*Power [11]. A two-factorial ANCOVA was used to compare data and reveal possible significant changes. Significance levels were set at $p \leq 0.05$. A non-parametric two-factorial ANOVA was used as a sensitivity analysis for the ANCOVA. Comparative analyses on an intention-to-treat basis as well as sample size calculations were completed earlier for the initial study and can be reviewed within an earlier publication [27].

Results

For the 10-year follow-up, a total of 29 patients (14 placebo, 15 verum) could be recruited. On the basis of this follow-up population, a *post hoc* power of 8.7% (α=0.05 and effect size d=0.22) was left together with a small effect. The mean relative Constant score at that time point was 102 (range 10–129) for all patients, with a mean score of 99±31 in the placebo group and 105±24 in the verum group. Differences between baseline and 10-year follow-up data were significant (p=0.02) (Figure 2). The mean score for pain at rest was 2 (range 1–10), whereas the mean score for pain during activity was 3 (range 1–10) for all patients. Mean pain at rest was 2.3±2.7 in the placebo group and 2.2±2.3 in the verum group. Differences between baseline and 10-year follow-up data were also slightly significant here (p=0.04) (Figure 3). Mean pain during activity was 3.0±2.9 in the placebo group and 3.6±3.5 in the verum group. There were no significant differences between baseline and 10-year follow-up data (p=0.28) (Figure 4). DASH scores were 39.8±17.1 (range 24.1–70) in the verum group and 38.8±14.1 (range 24.2–69.2) in the placebo group, with no significant differences (p=0.64) between both groups. Eight patients underwent arthroscopic subacromial decompression between 1- and 10-year follow-ups. Among these, six

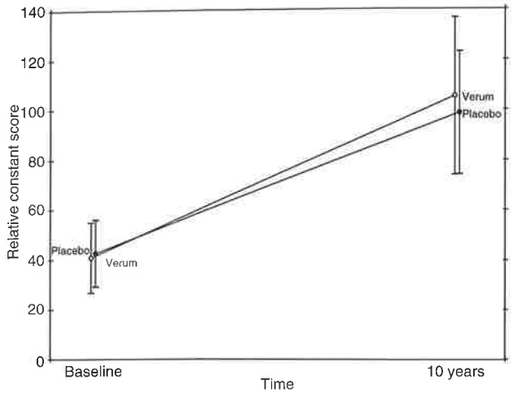

Figure 2 Relative Constant score at the beginning of the trial and after 10-year follow-up±standard deviations. There were significant differences between time points (p=0.02) but not between treatment groups.

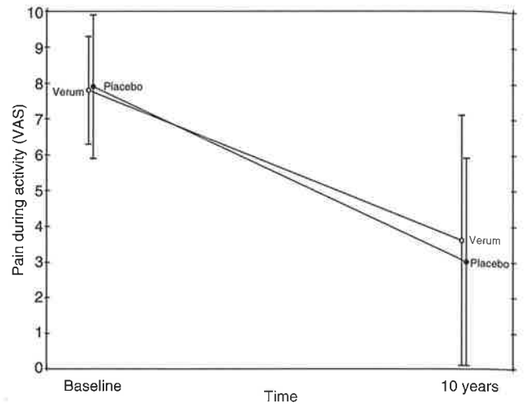

Figure 4 Pain during activity (VAS) at the beginning of the trial and after 10-year follow-up±standard deviations. There were no significant differences between time points or treatment groups.

were unblinded to their previous treatment group while two were still blinded. Four patients received verum and four patients received placebo before surgery, which was performed at an average of 2 years after placebo/verum intervention. This bias may thus be regarded as equally distributed between both groups. A two-factorial ANCOVA to compare relative Constant scores (p=0.49), pain at rest (p=0.92), and pain during activity (p=0.63) did not reveal significant differences between either the verum or placebo group after 10 years. A significant difference between blinded and unblinded participants could also not be detected for Constant scores (p=0.30), pain at rest (p=0.54), or pain during activity (p=0.65). However, 24 of 29 patients were satisfied with the results of the ESWT treatment and would possibly do it again in the future. The sensitivity analysis (non-parametric two-factorial ANOVA) showed no significant differences indicating a high sensitivity of the two-factorial ANCOVA.

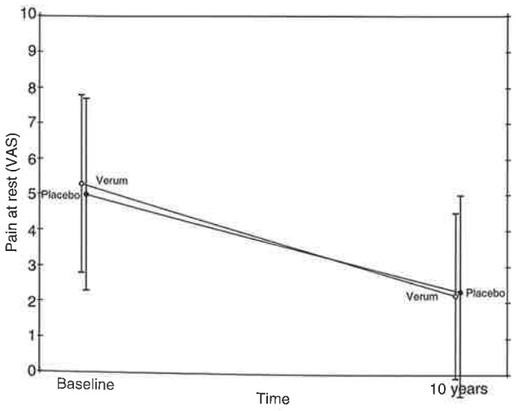

Figure 3 Pain at rest (VAS) at the beginning of the trial and after 10-year follow-up±standard deviations. There were slightly significant differences between time points (p=0.04) but not between treatment groups.

Discussion

The most important finding of the present study was that treatment of non-calcific supraspinatus tendinopathy with ESWT does not seem to have an effect on function or pain improvement in the long run.

ESWT is very common in the conservative treatment of non-calcific supraspinatus tendinitis especially in outpatient medical practice in European countries [29]. However, there is no good clinical evidence of its efficacy until today [19]. In fact, indications for ESWT treatment of the non-calcified rotator cuff are derived from other positive trials comprising, e.g., plantar fasciitis, tennis elbow, and other enthesopathies [31, 32].

The aim of the present study was to critically review our 10-year results after ESWT for supraspinatus tendinopathy with regard to the 1-year follow-up published earlier [28]. As for the 1-year results, no statistically significant differences could be found between verum and placebo ESWT. These findings are in accordance with other publications with shorter follow-ups, summed up in a recent review by Huisstede et al. [19]; however, there

are several factors that may influence the outcome in a 10-year period: (a) other treatment interventions, in particular physiotherapy with or without focus on scapular kinematics; (b) change in occupation and work load; (c) changes in lifestyle; and (d) changes in sports activity. However, long-term follow-up studies are of interest, as we would like to know the effect of the treatments we address to patients. Furthermore, it may be important to the selection of pathologies for ESWT treatment in the future, or for the development of other applications of ESWT treatment.

To the best of our knowledge, the present study is the first randomized, placebo-controlled study presenting a long-term follow-up with clinical data in this field. Galasso et al. [13] recently published short-term outcomes of a double-blind, randomized, placebo-controlled study of 20 patients receiving a low-energy (0.068 mJ/mm^2) ESWT for non-calcific supraspinatus tendinopathy. The mean relative improvements of the ESWT group were significantly higher than those of the control group after 3 months. All patients were satisfied with the treatment after 9 years, and none was lost due to surgery as determined by a simple telephone recall. It was argued within that publication that our workgroup may have achieved an equal therapeutic effect within the verum and placebo ESWT groups by its blinding method through a 10 ml bolus subacromial injection of mepivacaine [27, 28]. Considering pain only, there may be a certain therapeutic effect indeed; however, it will surely not exceed 3 months or 1 year because of the half-life of the drug administered [8]. Therefore, effects seen in the verum and placebo groups have to be regarded as equal, especially in the long-term follow-up. Furthermore, this present method of masking seems to be more adequate than that done by Speed et al. [30] in their study comprising 74 adults receiving a medium-energy (0.12 mJ/mm^2) ESWT and no local anesthesia in the sham group as well as a different treatment setting. A certain bias can also be found in the study by Galasso et al. [13] itself, considering their sham setup with a compact disc player imitating the sound of the original ESWT impulses and delivering them through speaker.

While most of the patients receiving therapy for chronic supraspinatus pain have a basic medication with NSAIDs or similar drugs, some even end up in diagnostic exploratory arthroscopies, for example, for the chance of becoming free of pain [18]. Furthermore, other available conservative treatment options comprising physical therapy or repeated corticosteroid injections have proven to be more sufficient than ESWT in terms of pain reduction and improvement in the Constant score [2, 9, 15]. Although there is relatively strong evidence for the harmful effect of corticosteroids on the viability and strength of human tendons today, repeated injections are still widely used to treat tendinopathies of all kinds [6].

Exact application and focusing of the extracorporeal shock waves is difficult and highly argued. Studies dealing with calcific tendinitis suggest to focus on the major calcified part of the tendon [10, 17]. For non-calcific tendinitis, this is problematic, of course, because there is no region to focus on that could be identified by MRI or ultrasound. Some studies suggest to focus on the insertion points of the supraspinatus, while others postulate the effect of ESWT would be most beneficial in the avascular region proximal to the insertion [22]. This approach is thought to lead to a better microvascularization and thus regeneration of the affected tendon; however, the whole mechanism is still not fully understood [34]. Newer studies also suggest that shock waves might have a totally different effect and could possibly inhibit vascular formation in less vascularized areas of the tendon [25].

In the present study, some limitations need to be addressed. First is its low number of cases and its limited patient retrieval for follow-up. A challenge in long-term studies is loss to follow-up. Therefore, a type II error is possible as no difference was found between the two groups in the 10-year follow-up. Yet, other studies rarely have higher case numbers owing to accessibility and practicability [19]. On the basis of this long-term study, the authors strongly question the major outcome variable of a pain relief of >30% as postulated by Buchbinder et al. [4] in their Cochrane Review protocol. This cannot be achieved realistically by means of randomized placebo-controlled trials mostly owing to accessibility but also because of certain ethical issues as mentioned before in a previous publication [27]. Furthermore, retrieval rates between 50% and 80% are common for long-term therapy studies in this field. This may be due to a general competition between surgical and conservative treatment options in musculoskeletal medicine. If patients experiencing painful disorders have the choice for either a long-lasting conservative treatment or a surgical approach, some of them might get lost to follow-up over such a long period.

Although improvements in relative Constant scores and pain at rest could be noted between baseline data and the 10-year follow-up in this study, there are no significant differences between the verum and placebo groups after that time. Therefore, the use of ESWT may not be better than a placebo treatment alone. Generally, it has to be argued also if the self-limiting course of supraspinatus tendinopathy may justify treatment with ESWT for achievement long-term results. This may be a cause for the absence of this form of treatment in the Anglo-American practice.

Altogether, the present long-term study suggests that the use of ESWT does not lead to a significant improvement of pain or movement over time and thus should be disregarded in future conservative treatment of non-calcific tendinopathies of the shoulder.

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