LETTER TO THE EDITOR

ELSEVIER

Journal of Orthopaedic Research 21 (2003) 958–959

Journal of Orthopaedic Research

www.elsevier.com/locate/orthres

Letter to the Editor

"Extracorporeal shock wave therapy for lateral epicondylitis—a double blind randomized controlled trial" by C.A. Speed et al., J Orthop Res 2002;20:895–8

Sir,

I read with interest the article in the Journal of Orthopaedic Research entitled "Extracorporeal shock wave therapy for lateral epicondylitis—a double blind randomized controlled trial" by Speed et al. [1].

I congratulate them for the well-conducted randomized controlled trial, the negative results of which confirm data of the German multi-center study [2]. However, some controversial issues should be addressed.

Seventy-five patients were in the study. Was it a pilot study? Was there any sample size calculation prior to starting the trial. If so, which data were the basis of this calculation?

In the abstract the authors report 1500 pulses of 0.12 mJ/mm^2 were administered, while in methods they report of 0.18 mJ/mm^2. Which energy flux density was applied in the study as a standard? The primary endpoint relied on assessment of elbow pain during the day. It remains unclear how patients rate a pain over a 12 h period. It would have been better to assess pain during a standardized provocation test.

On an intention to treat basis 14/40 patients and 12/35 patients achieved a >50% reduction of pain. The difference between groups was not significant. However, follow-up was only 4 weeks after the last intervention. In contrast to the studies of Rompe [3] and of Pettrone [4,5] the follow-up time was very short (one month after the last intervention), and the interval between the treatments was very long (one month). A more pronounced improvement in the active extracorporeal shock-wave therapy (ESWT) group could be expected until i.e. three months after the last of three intervention in weekly intervals, as had also been demonstrated by Crowther et al. [6]. In my opinion the follow-up in the study of Speed et al. is too short. The authors should provide data 12 weeks, 24 weeks and one year after the last intervention.

The experience of the feasibility study reported in the FDA approval for the Sonocur device [5] makes evident how important patient selection and treatment modalities are. In a small randomized, double-blinded, placebo-controlled pilot study to assess the feasibility of using the shock wave system, inclusion criteria were duration of symptoms for only three months, and failure of only one of three conservative treatment efforts (injection, occupational therapy, NSAIDs). Three times 1000 impulses were applied, all within 1 week. In 24 patients these modalities did not show any better results after active ESWT compared with placebo ESWT. Accordingly, inclusion criteria were tightened, the number of impulses was doubled, and three treatments were to be performed in weekly intervals.

I think that for repetitive low-energy ESWT for lateral epicondylitis, an interval of two days between the applications is too short [5], while an interval of 4 weeks [1] is too long for a successful outcome: In a recently completed study, we enrolled 58 were enrolled in a single-blind, randomized, placebo-controlled trial [7]. Entry criteria included age, recreational tennis player with tennis elbow, at least 12 months duration despite at least three efforts of conservative treatment, and an MRI-confirmed alteration at the origin of the extensor muscles at the lateral epicondyle. Repeating the treatment concept reported by Pettrone et al. [4,5] patients were randomly assigned to receive either active ESWT given weekly for 3 weeks or identical placebo ESWT. At three months after the last intervention, there was significant improvement in pain measured on a 0–10 visual analog scale during resisted wrist extension in both Groups I and II (mean [S.D.] improvement, 3.6 [1.6] points and 2.3 [2.0] points [$P = .0122$ for between-group difference of improvement]). In the treatment group 16/27 (59%) patients achieved at least a 50% reduction of pain, compared with 8/31 (26%) patients in the sham group (intention-to-treat; $P = .0158$ for between-group difference). The success rate in this trial was very similar to that reported by Pettrone et al. [4,5] and by Crowther et al. [6]. There was a placebo effect of low-energy ESWT, and there was added benefit of low-energy ESWT as applied when compared to sham therapy for tennis elbow.

As I read there was no statistically significant difference between both groups concerning the visual analog pain scores one month after treatment. What was the statistical power of the analysis? Maybe the power was too small to detect a clinically relevant difference between the groups?

It is clear that further randomized controlled studies with adequate concealment are required to assess more exactly the possible influence of duration of symptoms,

0736-0266/$ - see front matter
doi:10.1016/S0736-0266(03)00044-5

of number of impulses, and of local anesthesia on the efficacy of repetitive low-energy shock wave therapy. There is, no doubt, a substantial placebo effect of low-energy ESWT in patients with lateral epicondylitis. In my opinion, ESWT is not, and will not be, a first-line procedure for the treatment of tennis elbow in the near future. On the contrary, we recommend ESWT only when

- several conventional treatment concepts have failed over a considerable number of months, including corticoid injections;
- the diagnosis has been verified by MRI;
- the indication for surgery is given in the individual patient.

Sir, I would be grateful if you forwarded my remarks to the authors and asked them for a reply.

Yours sincerely,

Jan D. Rompe, MD

References

[1] Speed CA, Nichols D, Richards C, et al. Extracorporeal shock wave therapy for lateral epicondylitis—a double blind randomised controlled trial. J Orthop Res 2002;20:895–8.

[2] Haake M, König IR, Decker T, et al. Extracorporeal shockwave therapy in the treatment of lateral epicondylitis—a randomized multicenter trial. J Bone Jt Surg 2002;84A:1982–91.

[3] Rompe JD, Hopf C, Küllmer K, Heine J, Bürger R. Analgesic effect of extracorporeal shock-wave therapy on chronic tennis elbow. J Bone Jt Surg 1996;78B:233–7.

[4] Pettrone FA, Lefton CS, Romness DW, et al. Evaluation of extracorporeal shock wave therapy for chronic lateral epicondylitis. In: Paper 271, AAOS Annual Meeting 2002. Available from: http://www.aaos.org/wordhtml/anmt2002/sciprog/271.htm.

[5] US Food and Drug Administration. Siemens sonocur basic system. Summary of safety and effectiveness. Available from: http://www.fda.gov/cdrh/pdf/p010039.html. Accessibility verified September 22, 2002.

[6] Crowther MAA, Bannister GC, Huma H, Rooker GD. A prospective, randomised study to compare extracorporeal shock-wave therapy for and injections of steroid for the treatment of tennis elbow. J Bone Jt Surg 2002;84B:678–9.

[7] Rompe JD, Decking J, Schoellner C, Theis C, Herber S, Zoellner J. Repetitive low-energy shock wave therapy for chronic lateral epicondylalgia in tennis players. Personal communication.

Jan D. Rompe
Department of Orthopaedics
Johannes Gutenberg University School of Medicine
Langenbeckstr. 1, D-55131
Mainz, Germany
Tel.: +49-6131-177302; fax: +49-6131-176612
E-mail address: rompe@mail.uni-mainz.de
October 16, 2002

ELSEVIER

Journal of Orthopaedic Research 21 (2003) 960

Journal of Orthopaedic Research

www.elsevier.com/locate/orthres

Letter to the Editor

"Extracorporeal shock wave therapy for lateral epicondylitis—a double blind randomised controlled trial", by Speed CA, Nichols D, Richards C, Humphreys H, Wies JT, Burnet S, Hazleman BL [Journal of Orthopaedic Research 29 (2002) 895–898]

Although almost all studies of extracorporeal shock wave therapy (ESWT) for the treatment of lateral epicondylitis have shown it to be very effective, the authors in the above study failed to demonstrate any superiority of ESWT over a sham control. Confusingly, the abstract states that 1500 pulses of ESWT at 0.12 mJ/mm^2 were delivered but in the main text of the article a figure of 0.18 mJ/mm^2 is mentioned. This study claimed to use energy levels (0.18 mJ/mm^2) that in our experience, comprising over 5000 treatments, can be tolerated by only 1% of non-anaesthetized patients. In fact, with accurate clinical focusing, the majority of patients with lateral epicondylitis are unable to tolerate a level much greater than 0.06 mJ/mm^2. It is clear that the authors failed to correctly identify and target the site of pathology. The authors' statement that there is a significant placebo effect is valid and is seen with all treatments for painful conditions. The inclusion of patients with a short duration of symptoms, who have a high rate of spontaneous improvement, was inappropriate. The follow up period was also too short to reach the conclusions made.

In a better designed multi-center FDA directed study of low dose (Siemens Sonocur^{TM}) ESWT treatment for chronic refractory lateral epicondylitis, Pettrone et al. [1] described the outcomes in 111 patients who participated in a randomized double blind prospective study. There was a greater than 50% improvement in pain in 64% of the active treatment group, compared with only 31% in the controls. A corresponding improvement in function was also observed.

"Clinical focusing" in treating patients with ESWT is a concept that we have found to be extremely important. Several shock waves are applied to the point of maximal tenderness at the lowest energy setting. Through clinical focusing, with direct patient feedback, the exact site of pain and pathology is identified, and the intensity is slowly increased within the patient's level of tolerance. Anaesthesia is not only unnecessary, but undesirable. The patient is able to verify that the correct site has been targeted and the analgesic effect allows the energy level to be slowly increased. Focusing is checked every 200–400 shocks. If the pain is not reproduced by the shock wave, the condition is unlikely to respond and ESWT is not indicated. The use of ultrasound imaging may result in errors in localization of the pathology—one cannot image pain.

Reference

[1] Pettrone F, Lefton CS, Romness DW, McCall BR, Covall DJ, Boatright JR. Evaluation of extracorporeal shock wave therapy for chronic lateral epicondylitis: AAOS, Paper 271, 2002.

Brian Day
Department of Orthopaedics
University of British Columbia
Suite 204-888, West 8th Avenue
Vancouver, BC, Canada V5Z 3Y1
Tel.: +1-604-732-3033; fax: +1-604-874-1549
E-mail address: bday@telus.net

0736-0266/$ - see front matter
doi:10.1016/S0736-0266(03)00045-7

ELSEVIER

Journal of Orthopaedic Research 21 (2003) 961

Journal of Orthopaedic Research

www.elsevier.com/locate/orthres

Reply to Letter to the Editor

Extracorporeal shock wave therapy for lateral epicondylitis—a double blind randomised controlled trial

We thank Drs Day and Rompe for their comments on our paper *Extracorporeal shock wave therapy for lateral epicondylitis—a double blind randomised controlled trial* [1].

There continues to be a considerable debate relating to the use of shock wave therapy in soft tissue musculoskeletal complaints, and much of this is due to the plentiful anecdotal reports and uncontrolled trials of shock wave therapy in the literature. Randomised controlled trials are more limited in number.

It is clear that RCTs vary in their findings relating to efficacy of this treatment. This may be due to heterogeneous study populations, differences in treatment regimes and/or variations in outcome measures. We agree that our study involved a small sample size and relatively short (3 month) follow-up. However we noted similar findings to those made by Haake et al. in an RCT of 270 subjects with 12 months follow-up [2]. We note the findings of an FDA study of shock wave therapy that is quoted by Dr Day and look forward to its publication in the formal literature.

Accurate focussing of the shock wave therapy is increasingly recognised as an important aspect of shock wave administration [3] and manufacturers have worked to ensure that accurate focussing is possible. Most well designed studies of shock wave therapy have ensured that the treatment is focussed using fluoroscopy or ultrasound.

We fully agree with Dr Rompe that ESWT should be reserved for recalcitrant cases where the diagnosis is clear. We also support the view that optimal shock wave treatment regimes and dosing intervals have not yet been defined, but well designed RCTS will help to provide insight into this issue.

References

[1] Speed CA, Nichols D, Richards C, Humphreys H, Wies JT, Burnet S, et al. Extracorporeal shock wave therapy for lateral epicondylitis—a double blind randomised controlled trial. J Orthop Res 2002;20(5):895–8.

[2] Haake M, Konig IR, Decker T, Riedel C, et al. No effectiveness of Extracorporeal shock wave therapy in the treatment of tennis elbow—results from a prospective randomized placebo-controlled multicenter trial. J Bone Joint Surg Am 2002;84-A(11):1982–91.

[3] Haake M, Deike B, Thon A, Schmitt J. Exact focussing of Extracorporeal shock wave therapy for calcifying tendinopathy. Clinical Orthop Rel Res 2002;397:3230331.

C.A. Speed
Rheumatology Sports and Exercise Medicine
Addenbrooke's Hospital Box 204, Hills Road
Cambridge CB2 2QQ, UK
Tel.: +44-1223-586518; fax: +44-1223-216969
E-mail address: cas50@medschl.cam.ac.uk

0736-0266/$ - see front matter
doi:10.1016/S0736-0266(03)00046-9