of surgeons refusing to operate on high risk cases. For these reasons we believe that the registration of lobectomy data is an inadequate means of measuring surgical competence. Lung cancer is a rapidly fatal disease, and an informed patient might well choose to face a substantial surgical risk for the chance of cure.[7] A better indicator of quality would be cancer free survival at five years,[3] and this would reflect better the performance of the cancer multidisciplinary team, who are jointly responsible for patient selection.

The members of the UK Society of Cardiothoracic Surgeons voluntarily contribute their data. The content of this paper was presented to the UK Thoracic Forum on 9 February 2002, and the members present unanimously agreed to these data being presented. The interpretation and opinions are those of the authors.

Contributors: See bmj.com

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Extracorporeal shock wave therapy for plantar fasciitis: randomised controlled multicentre trial

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ELPS

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Abstract

Objective To determine the effectiveness of extracorporeal shock wave therapy compared with placebo in the treatment of chronic plantar fasciitis.
Design Randomised, blinded, multicentre trial with parallel group design.
Setting Nine hospitals and one outpatient clinic in Germany.
Participants 272 patients with chronic plantar fasciitis recalcitrant to conservative therapy for at least six months: 135 patients were allocated extracorporeal shock wave therapy and 137 were allocated placebo.
Main outcome measures Primary end point was the success rate 12 weeks after intervention based on the Roles and Maudsley score. Secondary end points encompassed subjective pain ratings and walking ability up to a year after the last intervention.
Results The primary end point could be assessed in 94% (n=257) of patients. The success rate 12 weeks after intervention was 34% (n=46) in the extracorporeal shock wave therapy group and 30% (n=41) in the placebo group (95% confidence interval −8.0% to 15.1%). No difference was found in the secondary end points. Few side effects were reported.
Conclusions Extracorporeal shock wave therapy is ineffective in the treatment of chronic plantar fasciitis.

Introduction

Plantar fasciitis is a common cause of heel pain, affecting 10% of the general population.[1] It may be due to injury at the origin of the plantar fascia or to biomechanical abnormalities of the foot.[2 3] Standard treatment for plantar fasciitis is conservative, but about 10% of patients fail to respond.[4] Surgery is recommended eventually, but is unsuccessful in 2% to 35% of patients.[5] Only limited evidence exists for a short term reduction of pain from local treatment with corticosteroids.[6]

Extracorporeal shock wave therapy was introduced in the early 1990s for the treatment of insertion tendinopathies, where it is thought to provide long lasting analgesia and stimulate the healing process.[7] It has been recommended as treatment for chronic plantar fasciitis in patients unresponsive to conservative treatment.[8–12] However a recent review found that the efficacy of extracorporeal shock wave therapy in plantar fasciitis could not be ascertained owing to poor methodology in previous studies.[13]

Materials and methods

Our study was a randomised, blinded, multicentre trial with a two sample parallel group design. Patients were recruited in seven university hospitals, two clinics, and one practice in Germany (see bmj.com for inclusion and exclusion criteria). They were randomised to receive either extracorporeal shock wave therapy (135 patients) or placebo (137 patients). Treatment was allocated only at the time of the first intervention.

Intervention

Extracorporeal shock wave therapy comprised 4000 impulses of a positive energy flux density (0.08 mJ/mm^2) under local anaesthesia with 2 ml mepivacaine 1%. Therapy was applied every two weeks plus or minus two days (3 × 4000 impulses). The total positive dose was 0.96 J/mm^2, the energy flux density was 0.22 mJ/mm^2, and the positive pressure was 13.7 MPa.

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Tables and criteria for inclusion or exclusion of patients appear on bmj.com

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Patients in the control group received the same regimen of placebo therapy under local anaesthesia. A polyethylene foil filled with air was fixed with ultrasound gel in front of the coupling cushion to reflect the shock waves. The set up in both groups was identical, and the sound created by the lithotripters was similar.

Blinding

Patients were blinded to their treatment, and only the caregiver performing the intervention knew the treatment. Study doctors were not informed of the primary end point until assessment. The caregiver was not involved in follow up and was not allowed to decide about further treatment.

The clinical outcome was assessed by observers blinded to treatment allocation. The extent to which patients' remained blinded was assessed after the last intervention. Unblinding was possible after the assessment of the primary end point and only if the patient required further therapy.

End points and side effects

Follow up examinations were carried out at six and 12 weeks and at one year after the last intervention. The primary end point was the success rate after 12 weeks; success was defined by a Roles and Maudsley score of 1 or 2 and if the patient received no additional treatment. Additional treatment was allowed after assessment of the primary end point. The modified Roles and Maudsley score is a patient administered scoring system (see table A on bmj.com).[14]

Secondary end points encompassed the Roles and Maudsley score and pain intensities on visual numeric rating scales, walking ability, and the need for additional treatments for one year after the last intervention. Side effects were noted.

Statistics

We carried out a two sided Fisher's exact test to compare the success rates at an overall significance level of 5%. Absolute differences were calculated for the success rates, odds ratios, and 95% confidence intervals. In addition we performed a stratified analysis by centre. The secondary end points were analysed descriptively. We required 272 patients to detect a difference of 20% in success rates (the minimal clinically relevant difference was supposed to be 35% for placebo and 55% for extracorporeal shock wave therapy) with a power of 80%, allowing for a dropout rate of 20%.

Results

Overall, 272 patients were randomised between March 1999 and February 2001. Personal characteristics were similar in both groups. The required number of pulses and energy level for treatment was reached in all cases (see bmj.com). Blinding of the patients was successful: 95 patients (74%) in the therapy group and 89 patients (69%) in the placebo group thought they had been treated with extracorporeal shock wave therapy, the difference being less than 6%.

End points

The primary end point could be assessed in 95% of the patients (table). The difference in success rates was 3.6% (−8.0% to 15.1%; P=0.5927) and the odds ratio was 1.18 (0.675 to 2.07). None of the observed differences reached the minimal clinically relevant difference of 20%. The odds ratio remained robust when data were stratified by centre (1.20, 0.674 to 2.13).

At the one year follow up, 91 of 113 (81%) patients in the therapy group and 87 of 115 (76%) in the placebo group had a Roles and Maudsley score of 1 or 2. No additional treatment was sought by 41 (36%) patients in the therapy group and 64 (56%) patients in the placebo group. The number of conservative treatments was comparable between the groups except for the use of extracorporeal shock wave therapy (13 (12%) patients in therapy group, 44 (38%) patients in placebo group). One in each group had undergone surgery (see table B on bmj.com).

Side effects

Few side effects occurred during and after the treatment and more were reported by the therapy group than by the placebo group (24 (18%) *v* 12 (9%)). Side effects were skin reddening, pain, and local swelling. Less often reported were haematoma, nausea, dizziness, hair loss, and sleep disturbance. These did not result in discontinuation of treatment. We expected a higher risk for side effects in the therapy group than in the placebo group (odds ratio 2.26, 1.02 to 5.18). We considered the case of deep vein thrombosis that developed in one patient in the placebo group as not related to the treatment.

Discussion

We found no meaningful improvement of clinical outcome in patients treated with extracorporeal shock wave therapy for chronic plantar fasciitis compared with placebo, unlike previous studies. Although the success rates in patients with excellent or good results

Success rate of treatment for chronic plantar fasciitis six and 12 weeks and one year after extracorporeal shock wave therapy or placebo. Values are numbers (percentages) of patients unless stated otherwise

Variable and group	Baseline	Difference (95% CI)	6 weeks	Difference (95% CI)	12 weeks	Difference (95% CI)	1 year	Difference (95% CI)
Success rate:								
Therapy	—	—	—		43/127 (34)	3.6 (–8.0 to 15.1)	—	
Placebo	—		—		39/129 (30)		—	
Roles and Maudsley* score 1 or 2:								
Therapy	0/135 (0)	Inclusion criterion†	28/129 (22)	3.3 (–13.7 to 7.1)	58/127 (46)	5.4 (–7.0 to 17.5)	91/113 (81)	4.9 (–6.0 to 16.0)
Placebo	0/136 (0)		33/132 (25)		52/129 (40)		87/115 (76)	

*Pain score according to Roles and Maudsley.[18]
†Only patients with score of 3 or 4 included, therefore no patient had 1 or 2 at baseline.

for the Roles and Maudsley score three months (45.7%) and one year (80.5%) after intervention were comparable to former trials, similar results could be achieved with placebo.[9 11 15]

About three quarters of the patients in both groups had a good outcome one year after intervention. Reasons for the observed improvement could have been a spontaneous remission of plantar fasciitis, additional conservative treatment, or a sustained placebo effect.

Most of the newly reported trials on extracorporeal shock wave therapy for plantar fasciitis not included in a former systematic review[13] show deficiencies in the quality of the methods (for example, lack of a control group,[16 17] small sample size,[16 18] unblinded design[15 18 19]). Therefore these trials only provide limited evidence of effectiveness.

We are aware of only three published randomised, blinded, placebo controlled trials. Two of them show benefits from extracorporeal shock wave therapy for plantar fasciitis.[11 12] However, the absolute difference of 17% in the first trial was not statistically significant and would not have met our definition of a clinically relevant result.[11] The authors did not report the method of randomisation, different types of anaesthesia were used, and problems in the analysis and presentation of the data of this study have been published.[20]

One study reported the alleviation of pain in the morning,[12] but according to the Roles and Maudsely score, the American Orthopaedic Foot and Ankle Society score, and pain scores, the findings were negative and comparable to our results. We do not believe that the only positive variable in that trial is a clinically relevant finding.

The negative findings of our study support the conclusion of the recently published third trial, although the treatment protocols of the studies differ slightly (mean total dose 1.4 J/mm^2).[21] In contrast to our study the authors applied a minimal shock wave dose without anaesthesia (3 × 100 impulses; 0.02 mJ/mm^2) instead of a sham therapy in the control group. This may have minimised a clinically relevant effect between both treatment groups.

Our results are only valid for the therapeutic variables applied, which reflect the true setting of extracorporeal shock wave therapy. The total energy of shock waves was higher in our trial than in most of the previous studies.[8 9 15] The use of different treatment variables might lead to different overall results. However, we cannot recommend that specific applications be tested in further clinical studies because all major trials, using different shockwave variables and types of lithotripters, showed negative results.

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Competing interests: None declared.

Ethical approval: The study protocol was approved by the local ethics committees of the principal investigator (approval No 83/98) and the participating centres.

What is already known on this topic

Observational trials recommend extracorporeal shock wave therapy as treatment for recalcitrant chronic plantar fasciitis

No evidence exists of its efficacy from well designed randomised clinical trials

What this study adds

Extracorporeal shock wave therapy is ineffective in the treatment of chronic plantar fasciitis

No clinically relevant difference was found in success rates between therapy and placebo after 12 weeks and a year

Three quarters of patients improved 12 months after intervention, irrespective of treatment

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