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ORIGINAL ARTICLE

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Low-energy extracorporeal shock wave therapy for painful heel: a prospective controlled single-blind study

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Abstract The aim of this prospective single-blind pilot study was to explore the pain-alleviating effect of low-energy extracorporeal shock wave therapy (ESWT) in painful heel associated with inferior calcaneal spurs. Thirty patients who suffered from persistent symptoms for more than 12 months qualified for low-energy ESWT and were assigned at random to two groups, real or simulated ESWT. Before beginning the treatment, any other therapy was stopped for a period of 6 weeks. The shock waves were applied by an experimental device allowing exact localization through an integrated fluoroscopy unit. Patients were treated three times at weekly intervals. Each time 1000 impulses of 0.06 mJ/mm^2 were given around the heel spur. Follow-ups were done after 3, 6, 12 and 24 weeks. Patients of the placebo group who did not improve at the 6-week follow-up were then offered ESWT therapy and were checked at 3, 6, 12 and 24 weeks after the last treatment. Whereas we noticed no significant differences between the groups before ESWT, there was a significant alleviation of pain and improvement of function at all follow-ups in the treatment group.

Introduction

Painful heel is a common orthopaedic syndrome among athletes and non-athletes [26], with evidence of a spur in about 50% [14, 20]. The cause of this clinical entity remains enigmatic and often frustrating to the physician as well as the patient [14]. It is known that the most dense, unyielding section of the plantar aponeurosis originates from the medial tubercle of the calcaneal tuberosity where the most common point of local tenderness is found [25]. This similarity with a tennis elbow made Woolnough [36] call this entity 'tennis heel'. Encouraged by the significant pain relief in persisting lateral epicondylitis achieved with low-energy extracorporeal shock wave therapy (Rompe et al. unpublished results), a prospective study was started to clarify the effectiveness of ESWT in chronic plantar fasciitis associated with inferior calcaneal spur. Primary results are presented.

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Patients and methods

Over a period of 2 years, 36 patients suffering from calcaneous spurs qualified for the study of the effectiveness of ESWT. Six patients originally introduced to the study dropped out during the follow-up without providing an explanation. Thus, 30 patients (11 female, 19 male; mean age 49 years; 24 right, 10 left) with a mean pain history of 18 months (range 12–38 months) completed the 6-month follow-up.

Inclusion criteria were pain over the radiologically proved calcaneal spur for more than 12 months and unsuccessful conservative or operative therapy during the 6 months before referral to our hospital. Three-phase technetium-99 bone scintigraphy findings had to be consistent with plantar fasciitis.

Exclusion criteria were: dysfunction in the knee or ankle, local arthritis, generalized polyarthritis, rheumatoid arthritis, ankylosing spondylitis, Reiter's syndrome, neurologic abnormalities, nerve entrapment syndrome, age under 18 years, pregnancy, infectious or tumorous disease.

All patients were informed of and consented to the treatment modalities. No other treatments or drugs were used during 6 weeks before the trials began or during the study period, with the exception of already worn shoe inserts. Patients were instructed to use the foot but to avoid painful stress.

Consecutive cases were randomly assigned to two groups. Group I received ESWT: 15 patients, 5 women and 10 men, with a mean age of 47 years (range 26–61 years) and a median duration of pain of 16 months (range 12–36 months). Group II was the placebo group: 15 patients, 6 women, 9 men, with a mean age of 51 years (range 31–58 years) and a median duration of pain of 22 months (range 12–38 months).

Treatment

ESWT was applied by an experimental device, the Siemens Osteostar, characterized by the integration of an electromagnetic shock wave generator in a mobile fluoroscopy unit. The shock waves are generated by passing a strong electric current through a flat coil. This induces a magnetic field, which induces another magnetic field in a metal membrane overlying the flat coil. Just as similar poles repel each other, so do the generated magnetic fields of the membrane and the coil. By means of an acoustic lens, the focus of the shock wave source is identical to the centre of the C-arch. The focal area of the shock waves is defined as the area in which 50% of the maximum energy is reached. It has a length of 50 mm, in the direction of the shock wave axis, and a radius of 3.5 mm, in the direction perpendicular to the shock wave axis. Once the tip of the calcaneal spur was situated in the centre of the C-arch, the shock wave unit was docked to the foot by means of a water-filled cylinder. As a contact medium between cylinder and skin, common ultrasound gel was used. In the placebo group, no ultrasound gel was used, and the cylinder was kept at a 1 cm distance from the skin to prevent transmission of the shock waves. Both groups were treated under the same conditions, and the patients were treated singly to avoid influencing one another. The energy density of the Osteostar can be varied from 0.06 mJ/mm^2 to 0.6 mJ/mm^2. This is represented by a power setting scale ranging from 0.1 to 9 in which the energy density has a nonlinear increase. Three times, in weekly intervals, 1000 impulses of 0.06 mJ/mm^2 were administered at the heel spur and at 3 points around this site at a radius of 1.5 cm to 2 cm. Follow-ups were done 3, 6, 12 and 24 weeks after the last application.

Evaluation

The extent of night pain, resting pain and pressure pain was specified with a Visual Analog Scale (VAS) ranging from 0, i.e. no pain, to 100, i.e. maximal pain.

In addition, by means of digital scales, painfree plantar pressure was measured on both sides. The weight applied to the scales was registered in Kilograms. The classification was as follows: 1 = equal weight-bearing on both sides; 2 = up to 25% reduction of weight-bearing compared with the unaffected side; 3 = up to 50% reduction; 4 = up to 75% reduction.

Walking abilities without a need for rest to relieve the painful heel were rated in six steps: 0 = less than 5 min; 1 = less than 15 min; 2 = less than 30 min; 3 = less than 45 min; 4 = less than 60 min; 5 = more than 60 min.

At the end of the follow-up, all patients were asked about their pain assessment compared with pretreatment conditions. The rating was: 1 = no pain; 2 = symptoms improved; 3 = symptoms identical; 4 = symptoms increased. Moreover, improvement could be rated from 0 to 100.

Statistics

Statistical analysis was done with SAS. Tests applied were the Mann-Whitney U-test for two independent samples, the Fisher Test for independent samples for two categorical data, the Wilcoxon Test for dependent samples and the McNemar Test.

Results

Subjective outcome

Night pain varied in group I from a mean 20.5 at the beginning of the study to 21.8 just before the start of ESWT, compared with 18.9 ($P > 0.05$) and 21.2 ($P > 0.05$) in group II, respectively. Thee weeks later there was a decrease of 58.2% in group I; after 6 weeks, of 57.4%; after 12 weeks, of 72.5%; and after 24 weeks, of 72.0%. In group II the corresponding data were 13.6% ($P > 0.05$) and 8.1% ($P < 0.05$) at 3 and 6 weeks (Fig. 1).

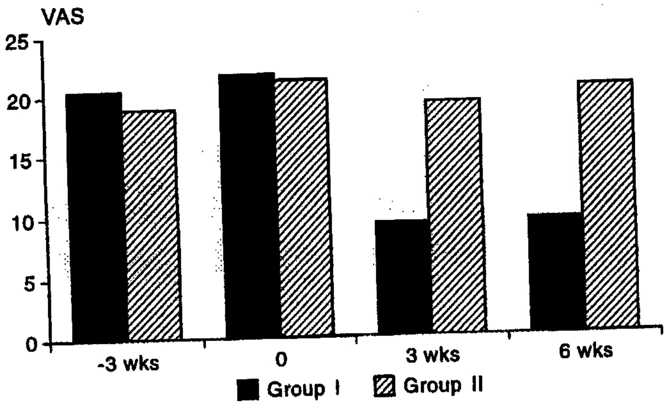

Fig. 1 Development of night pain over 6 weeks [*VAS*, visual Analog Scale score (mean)]

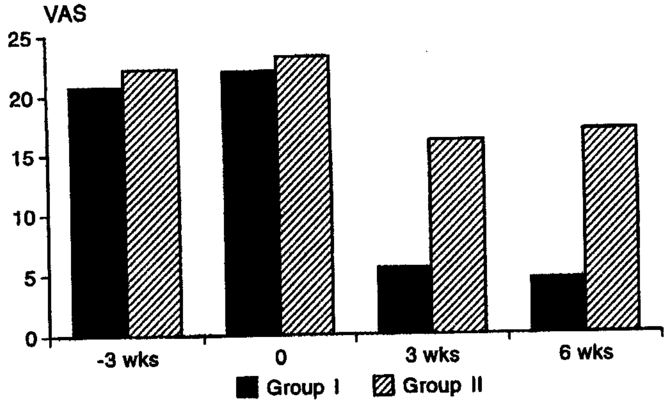

Fig. 2 Development of resting pain over 6 weeks

Resting pain varied in group I from a mean of 20.9 at the beginning of the study to 22.0 just before the start of ESWT, compared with 22.2 ($P > 0.05$) and 23.0 ($P > 0.05$) in group II, respectively. Three weeks later, there was a decrease of 75% in group I; after 6 weeks, of 79.6%; after 12 weeks, of 78.2%; and after 24 weeks, of 79.5%. In group II the corresponding data were 36.6% ($P < 0.05$) and 33.8% ($P < 0.01$) at 3 and 6 weeks (Fig. 2).

Local pressure pain varied in group I from a mean of 81.1 at the beginning of the study to 80.5 just before the start of ESWT, compared with 75.0 ($P > 0.05$) and 74.5 ($P > 0.05$) in group II, respectively. Three weeks later, there was a decrease of 66.7% in group I; after 6 weeks, of 67.2%; after 12 weeks, of 69.4%; and after 24 weeks, of 73.4%. In group II the corresponding data were 8.5% ($P < 0.0001$) and 7.5% ($P < 0.0001$) at 3 and 6 weeks (Fig. 3).

Objective outcome

The evaluation of painfree plantar pressure, graded from 1 to 4, varied in group I from a mean 3.5 at the beginning of

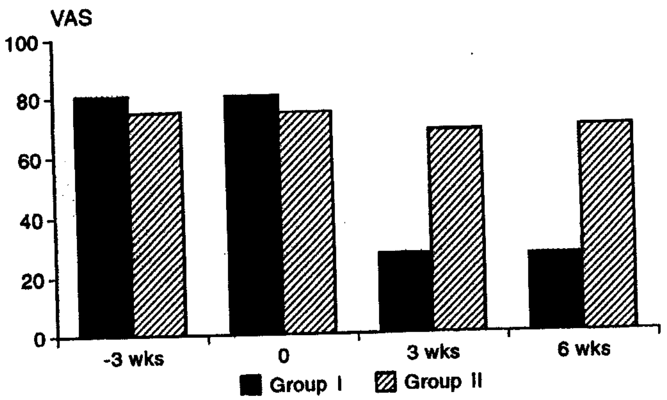

Fig. 3 Development of pressure pain over 6 weeks

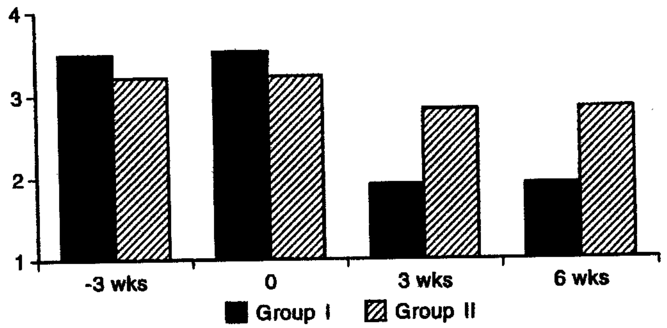

Fig. 4 Development of plantar pressure pain with regard to weight-bearing over 6 weeks (rating from 1 to 4: see text)

the study to 3.5 just before the start of ESWT, compared with 3.2 ($P > 0.05$) and 3.2 ($P > 0.05$) in group II, respectively. Three weeks later, there had been a decrease of 45.7% in group I; after 6 weeks, of 45.7%; after 12 weeks, of 48.6%; and after 24 weeks, of 48.6%. In group II the corresponding data were 12.5% ($P < 0.05$) and 12.5% ($P < 0.05$) at 3 and 6 weeks (Fig. 4).

Walking ability, rated from 1 to 5, was 1.4 in group I at the beginning of the study and 1.4 just before the start of ESWT, compared with 2.1 ($P < 0.05$) and 2.1 ($P < 0.05$) in group II, respectively. There weeks later, there was an increase of 171.4% in group I; after 6 weeks, of 178.6%; after 12 weeks, of 200%; and after 24 weeks, of 185.7%. In group II the corresponding data were 0% ($P < 0.0001$) and 4.8% ($P < 0.0005$) at 3 and 6 weeks.

Overall outcome

At 6 weeks there were 2 painfree, 8 improved and 5 unchanged patients in group I, compared with 4 improved and 11 unchanged in group II. In group I the improvement rating averaged 65.6% (0–100) at 3 weeks, 72.9% (0–100) at 6 weeks, 77.4% (0–100) at 12 weeks and 77.4% (0–100) at 24 weeks, compared with 12.4% (0–30) ($P < 0.0001$) at 3 weeks and 8.5% (0–20) ($P < 0.005$) at 6 weeks in group II.

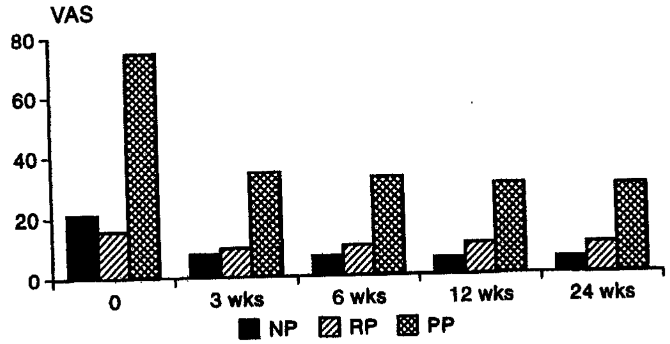

Fig. 5 Development of pain score after treatment of the control group (cross-over) (*NP*, night pain; *RP*, resting pain; *PP*, local pressure pain)

Outcome of cross-over

All 15 patients from group II received ESWT as they were not satisfied with the results at the 6 weeks' follow-up. The therapeutic regime was the same as that of group I.

Subjective outcome

Three weeks after the last shock wave application, there was a decrease of night pain of 62.3% ($P > 0.05$); after 6 weeks, of 69.0% ($P < 0.05$); after 12 weeks, of 75.7% ($P < 0.05$); and after 24 weeks, of 73.8% ($P < 0.05$).There was also a decrease of resting pain of 37.6% ($P > 0.05$); after 6 weeks, of 33.8% ($P > 0.05$); after 12 weeks, of 34.4% ($P < 0.05$); and after 24 weeks, of 32.4% ($P < 0.05$). Local pressure pain decreased by 54.5% after 3 weeks, by 56.9% after 6 weeks, by 60.8% after 12 weeks and by 61.6% after 24 weeks (all $P < 0.0001$) (Fig. 5).

Objective outcome

The evaluation of painfree plantar pressure, graded from 1 to 4, showed a decrease of 37.5% after 3 weeks; after 6 weeks, of 43.8%; after 12 weeks, of 46.9%; and after 24 weeks, of 53.1% to an average score of 1.5 (all $P < 0.0005$). With regard to walking ability, rated from 1 to 5, after 3 weeks there had been an increase of 85.7%; after 6 weeks, of 90.5%; after 12 weeks, of 95.3%; and after 24 weeks, of 100% to an average score of 4.1 (all $P < 0.0001$).

Overall outcome

At 3 weeks there were 3 painfree and 8 improved patients, 4 were unchanged. At 6 weeks the numbers were identical. At 12 weeks and at 24 weeks there were 4 painfree, 7 improved and 4 unchanged. At 3 weeks the improvement rating averaged 55.9% (0–100), 58.8% (0–100) at 6 weeks, 61.2% (0–100) at 12 weeks and 61.8% (0–100) at 24 weeks.

Discussion

The exact cause of the painful heel is uncertain, although age-related degenerative processes as well as overweight are supposed to play a major role [19] in exerting stress on the origin of the plantar fascia on the medial process of the calcaneal tuberosity, thus producing subsequently a local inflammatory reaction [5, 6]. The diagnosis, however, appears to be straightforward, especially when an inferior calcanear spur has been detected. The spur may be an incidental finding [14] and its role in causing painful heel is unclear [20]. More than 40 treatments have been suggested for tennis elbow [7], and there is hardly less argument over the appropriate conservative measures to relieve "tennis heel" [36]. The use of shoe inserts (cups and pads) [14], orthotics [3] night splints [34], non-steroidal anti-inflammatory drugs, local injections of steroids or anaesthetics will alleviate the condition in most patients [2, 12, 13, 20, 29]. In the case of failure usually surgical release of the plantar fascia, even endoscopically [1, 18], from the tuberosity of the calcaneus is recommended, possibly together with removal of the spur, neurolysis, release of the flexor digitorum brevis, excision of the anterior tuberosity of the calcaneus [2, 4, 11, 15, 17, 21, 24, 26–28, 30], with satisfying results of more than 80% reported in all studies. Rarely do critical evaluations reveal details concerning time to full recovery, requirement for additional treatment and persistent abnormalities of foot function [10].

Time and again, however, we were confronted with patients whose symptoms persisted over more than a year. Thus, we began looking for an alternative procedure to avoid surgical intervention.

At the beginning of the 1990s the first reports were published on the use of ESWT beyond nephrolithiasis and cholelithiasis. Valchanou and Michailov [33] and Sukul et al. [31] inaugurated high-energy ESWT for the treatment of delayed and non-union of fractures, describing local decortication and fragmentation with stimulation of osteogenesis. These positive aspects were corroborated by Haist et al. [16], who noticed bony consolidation in 32 out of 40 cases with a pseudarthrosis. In case reports Dahmen et al. [9] and Loew and Jurgowski [22] achieved good results in calcifying tendinitis of the shoulder with low and high energy ESWT.

In our prospective pilot study we found a significant decrease of pain and an increase of walking ability compared with a control group. After cross-over had been finished, all but 9 patients had improved – 6 had become painfree – after ESWT, but, just as after surgery [35], the average time to maximum improvement was 6 months. No side effects were noticed compared with calcification after steroid injections or postsurgical development of hypertrophic sensitive scars [26] or calcaneal fractures [23]. No hospitalization was required, and full weight-bearing was allowed immediately.

The success of this new outpatient treatment method warrants further controlled prospective studies concerning the most efficient energy level and the number of shock waves to be applied as well as the mechanisms of influencing pain symptoms. Comparison with other conservative or operative procedures is necessary but difficult, as studies are of a wide variety with regard to the scientific design, number of patients, period of persisting heel pain and time of follow-up.

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