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Extracorporeal Shockwave Therapy (ESWT) in Patients with Chronic Proximal Plantar Fasciitis

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ABSTRACT

The aim of this study was to compare the effect of extracorporeal shockwave therapy (ESWT) in patients with chronically painful proximal plantar fasciitis with a conventional conservative treatment consisting of nonsteroidal anti-inflammatory drugs, heel cup, orthoses and/or shoe modifications, local steroid injections and electrotherapy. Forty-seven patients (49 feet) with a previously unsuccessful conservative treatment of at least six months were randomized to two groups. Treatment of Group 1 (25 heels) started immediately with three sessions of ESWT (3000 shockwaves/session of 0.2 mJ/mm²) at weekly intervals. In the patients of Group 2 (24 heels) treatment was continued for 12 weeks. After this period they were treated using the protocol of Group 1. No significant difference of pain and walking time after further non-ESWT treatment (three months) was seen. Six months after ESWT pain decreased by 64% to 88% on the visual analog scale (VAS) and the comfortable walking time had increased significantly in both groups.

Key Words: Plantar Fasciitis; Painful Heel; Extracorporeal Shockwave Therapy (ESWT)

INTRODUCTION

Plantar fasciitis is a common cause of heel pain. A heel spur at the inferior surface of the calcaneus is evident in 50% but is not considered pathognomonic of the disorder.[13,14] The exact cause is unknown and multiple treatment modalities are often unsuccessful (10 to 30% failure).[4,10] In cases resistant to nonsurgical treatment, surgical intervention was recommended as an ultimate therapeutic approach.[2,20]

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Extracorporeal shockwave therapy (ESWT) was introduced 10 years ago as a nonsurgical treatment for soft-tissue pain in orthopaedic disorders such as calcifying tendinitis of the shoulder,[9,17,21] chronic epicondylitis at the elbow[5,7,15,16] and painful heel.[5,8,17,18]

Controlled studies regarding the effect of extracorporeal shockwave therapy (ESWT) in the treatment of persistent painful heel have been reported with success rates between 48% and 77%.[8,17,18]

The aim of this study was to compare the effect of ESWT in chronically painful plantar fasciitis associated with a heel spur with further nonoperative treatment.

PATIENTS AND METHODS

Between January 1999 and August 1999, 48 patients with 50 feet suffering from insertional plantar fasciitis underwent low-energy extracorporeal shockwave therapy in a prospective study.

Inclusion criteria were an unsuccessful treatment of at least six months consisting of nonsteroidal anti-inflammatory drugs (NSAID), heel cup, orthoses and/or shoe modifications, local steroid injections and electrotherapy (iontophoresis with diclofenac). In order to facilitate ultrasound detection of the insertion of the plantar fascia only patients with heel spurs were selected. On clinical examination, typical pain at the medial process of the calcaneal tuberosity had to be elicited (proximal plantar fasciitis). The subgroup of patients with plantar fasciitis who had no pain at the insertion but had disabling pain on the plantar surface was not included. This allowed us to have a very homogenous group of patients. We also excluded patients with neurological disorders, local infections, local tumors, coagulation disorders and pregnancy.

On presentation at our outpatient department the patients were randomized to two groups. All patients wore heel cups throughout the study which were prescribed. Treatment of Group 1 started immediately with three sessions of ESWT (3,000 shockwaves/session of 0.2 mJ/mm²) at weekly intervals and no further treatment. In the patients of Group 2 conservative treatment

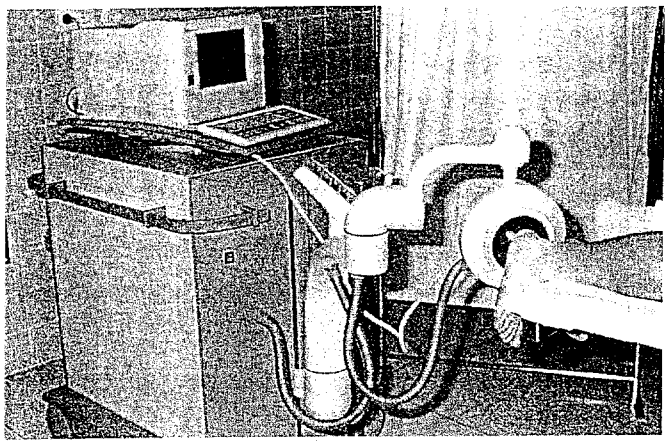

Fig. 1: Position of the patient for extracorporeal shockwave therapy (ESWT) at the medial aspect of the calcaneal tuberosity with the application tube in place.

was continued with iontophoresis with diclofemac and an oral NSAID. After 12 weeks they were treated using the protocol of Group 1. The extracorporeal shockwave therapy (ESWT) was performed with the Piezoson 300 (Richard Wolf, Knittlingen, Germany), a piezoelectric system with ultrasound detection (Fig. 1).

The shockwave itself is a sonic pulse with certain physical characteristics. It is characterized by an extremely high increase of pressure (50-80 MPa) and a steep decrease with subsequent negative pressure wave (10 MPa). The life circle is short (10 ms). The frequency spectrum is broad in the range of 16 Hz to 20 MHz. The shockwave is defined by following physical details: focus geometry (length and diameter [mm]), focus pressure maximum [bar], and focus energy density [mJ/mm^2].[12] The focus energy density is used to compare treatment protocols of ESWT performed with machines of different induction principles (electrohydraulic, electromagnetic, and piezoelectric systems).

One patient was lost to follow-up. Group 1 consisted of 24 patients, five men and 19 women, with 25 painful heels. The age averaged 51 years (26 to 73), the duration of symptoms 8.6 months (six to more than 12). The length of the heel spur on a lateral X-ray measured 3.2 mm (0.5 to 11). The body mass index was 29.6 kg/m^2 (21.5 to 41.4) and the European shoe size 40 (36 to 48). Group 2 comprised 23 patients, 10 men and 13 women, with 24 painful heels. The average age was 48 years (24 to 79). The duration of symptoms averaged 10.2 months (six to more than 12) the length of the heel spur on a lateral X-ray 3.0 mm (1 to 8). The average body mass index was 28.7kg/m^2 (20.2 to 45) and the European shoe size 41 (36 to 45).

Before ESWT and at follow-up appointments (six, 12 and 24 weeks after completion of ESWT) a clinical evaluation was carried out. The pain intensity, measured on a visual analog scale (VAS)[6] ranging from no pain (0) to maximal pain (100), under different circumstances (rest, everyday life activities, single leg stance, pressure applied with a strong thumb grip) and the comfortable walking time were estimated by the patients. Statistical analysis was done with the nonparametrical Wilcoxon test for paired samples.

RESULTS

The patients' estimation of pain on the VAS 24 weeks after ESWT improved in Group 1 in all test situations significantly with $p<0.01$ (Table 1). At rest the pain decreased by 64%. Accordingly there was also a pain reduction during everyday life activities of 71%, during single leg stance of 64% and during firm thumb pres-

Table 1: Pain on the visual analog scale (VAS) before and after extracorporeal shockwave therapy (ESWT) in Group 1 (25 heels with plantar fasciitis) and Group 2 (24 heels with plantar fasciitis); significant decrease from t=0 to t=24 weeks ($p<0.01$) in both groups without significant difference between the groups.

		t=-12 weeks	t=0	t=6 weeks	t=12 weeks	t=24 weeks
Group 1 n=25 VAS±SD	rest		34.0±27.1	13.8±26.0	11.8±19.8	12.0±25.9
	everyday life		78.2±17.5	28.2±31.4	29.0±31.6	22.6±33.6
	single leg stance		78.8±20.2	25.6±31.9	36.4±37.4	28.2±37.2
	firm thumb pressure		79.4±22.7	31.4±31.6	37.8±38.1	28.0±37.6
Group 2 n=24 VAS±SD	rest	43.1±26.7	43.1±26.9	18.8±29.8	10.2±24.4	5.0±20.4
	everyday life	70.2±22.4	70.4±22.2	37.1±32.8	26.0±30.1	11.9±23.5
	single leg stance	74.6±25.1	74.8±24.9	38.5±36.8	29.2±36.9	11.9±24.6
	firm thumb pressure	84.2±16.6	84.2±15.9	49.6±35.5	33.5±38.0	14.2±24.3

sure of 65%. In Group 2 there was almost no difference on the VAS scale before and after the waiting period of 12 weeks. At 24 weeks after ESWT the pain estimation decreased significantly with $p<0.01$ in all test situations (Table 1). The pain at rest diminished by 88%. Correspondingly a decline could be noticed during everyday life activities of 83%, during single-leg stance of 84% and during firm thumb pressure of 83%. No significant difference was found between the two groups.

The comfortable walking time increased significantly ($p<0.01$) in Group 1 at 24 weeks after treatment (Table 2). In Group 2 there was no difference between the comfortable walking time 12 weeks prior to ESWT and at the moment of treatment. At the 24 weeks follow-up the time had significantly ($p<0.01$) improved (Table 2). The difference between both groups was not significant.

Patients with less than 30 points on the VAS scale were defined as having little complaint. The percentage of those patients increased significantly ($p<0.01$) in all test situations from prior to ESWT to 24 weeks later in both groups (Table 3). No significant difference was noticed between the groups. Accordingly patients with less than 10 points on the VAS were defined as being nearly free of complaint. The percentage of those patients also increased significantly ($p<0.01$) in all four categories from prior to ESWT to 24 weeks later in both groups (Table 4). No significant differences were noticed between the groups.

Comparing those patients having little complaint (VAS < 30 points) 24 weeks after ESWT with the remaining patients regarding shoe size (Group 1: 40.3±2.3 vs. 39.5±2.2; Group 2: 40.8±2.1 vs. 40.4±1.7), length of spur (Group 1: 3.0±1.2 vs. 3.5±3.1 mm; Group 2: 2.9±1.6 vs. 3.3±1.6 mm) and body mass index (Group 1: 29.3±5.7 vs. 30.2±5.4 kg/m²; Group 2: 28.6±4.4 vs. 29.0±7.9 kg/m2) no significant differences could be found. Correspondingly the difference between those patients having no complaint (VAS<10 points) 24 weeks after ESWT with the remaining patients regarding shoe size (Group 1: 40.2±2.4 vs. 39.8±2.1; Group 2: 40.9±2.4 vs. 40.4±1.4), length of spur (Group 1: 3.0±1.3 vs. 3.4±2.8 mm; Group 2: 3.0±1.7 vs. 3.0±1.5 mm) and body mass index (Group 1: 29.6±5.9 vs. 29.7±5.2 kg/m²; Group 2: 29.0±4.8 vs. 28.1±5.8 kg/m²) also showed no significant differences.

DISCUSSION

Plantar fasciitis is a common pathological condition of the foot. Its etiology is unclear but predisposing factors like obesity, pes planus, increased pronation of the foot, repetitive stress, cavus foot or Achilles tendon

Table 2: Comfortable walking time in hours (h) before and after extracorporeal shockwave therapy (ESWT) in Group 1 (25 heels with plantar fasciitis) and Group 2 (24 heels with plantar fasciitis); significant increase from t=0 to t=24 weeks ($p<0.01$) in both groups without significant difference between the groups.

		t=-12 weeks	t=0	t=6 weeks	t=12 weeks	t=24 weeks
Group 1 n=25	comfortable walking time ±SD [h]		0.4±1.0	5.7±7.2	5.3±6.9	7.8±7.5
Group 2 n=24	comfortable walking time ±SD [h]	0.3±0.5	0.3±0.5	5.9±7.5	7.8±7.8	10.9±6.9

Table 3: Patients with less than 30 points on the visual analog scale (VAS; maximum 100) before and after extracorporeal shockwave therapy (ESWT) in Group 1 (25 heels with plantar fasciitis) and Group 2 (24 heels with plantar fasciitis); significant increase from t=0 to t=24 weeks ($p<0.01$) in both groups without significant difference between the groups.

		t=-12 weeks	t=0	t=6 weeks	t=12 weeks	t=24 weeks
		n(%)	n(%)	n(%)	n(%)	n(%)
Group 1 n=25 VAS<30	rest		11(44)	21(84)	20(80)	20(80)
	everyday life		0(0)	15(60)	15(60)	18(72)
	single leg stance		1(4)	15(60)	14(56)	16(64)
	firm thumb pressure		0(0)	15(60)	13(52)	14(56)
Group 2 n=24 VAS<30	rest	8(33)	8(33)	18(75)	21(88)	23(96)
	everyday life	1(4)	1(4)	9(38)	16(67)	20(83)
	single leg stance	1(4)	1(4)	10(41)	16(67)	20(83)
	firm thumb pressure	0(0)	0(0)	7(29)	14(58)	19(79)

Table 4: Patients with less than 10 points on the visual analog scale (VAS; maximum 100) before and after extracorporeal shockwave therapy (ESWT) in Group 1 (25 heels with plantar fasciitis) and Group 2 (24 heels with plantar fasciitis); significant increase from t=0 to t=24 weeks ($p<0.01$) in both groups without significant difference between the groups.

		t=-12 weeks	t=0	t=6 weeks	t=12 weeks	t=24 weeks
		n(%)	n(%)	n(%)	n(%)	n(%)
Group 1	rest		7(28)	16(64)	16(64)	20(80)
n=25	everyday life		0(0)	10(40)	10(40)	14(56)
VAS<10	single leg stance		0(0)	10(40)	8(32)	13(52)
	firm thumb pressure		0(0)	6(24)	8(32)	13(52)
Group 2	rest	2(8)	2(8)	13(54)	19(79)	21(87)
n=24	everyday life	1(4)	1(4)	8(33)	11(46)	15(63)
VAS<10	single leg stance	1(4)	1(4)	8(33)	11(46)	17(71)
	firm thumb pressure	0(0)	0(0)	4(17)	10(42)	14(58)

contracture may exert stress on the origin of the plantar fascia at the medial process of the calcaneal tuberosity.[1,4,13,14]

Studies regarding the outcome of nonsurgical treatment protocols for insertional plantar fasciitis reported a total pain relief in 44% to 82% of the patients. These protocols included one or more of the following nonoperative treatments: stretching exercises for the Achilles tendon and plantar fascia, night splints, thermotherapy, nonsteroidal anti-inflammatory drugs (NSAID), orthoses, heel cups, shoe modifications, casting and steroid injections.[3,22,24] Martin et al.[10] recommended surgery for those subjects whose pain was not improved after six months of a strict conservative treatment protocol. The outcome of surgery in patients who failed to respond to nonsurgical treatment differs in the literature from 48% to 90% after various surgical procedures.[2,14,20]

With ESWT Rompe et al. quoted success rates of 48% after six months[18] and a success rate of 77.4% after 24 months.[17] Further studies reported success rates of 70% after five months (Hammer et al.[5]) and 58% after 12 months (Krischek et al.[8]). Our results with improvement of the pain on the VAS six months after ESWT between 64% and 88% (depending on the test situation) were consistent with the above quoted literature.

Our study also indicated that continuing nonoperative treatment (three months) in patients with at least six months did not affect the pain level and the comfortable walking time. A reason for possible bias in our study was that the patients of Group 2 were aware they would receive ESWT treatment if they did not improve. They were in an intention-to-treat situation which might have produced a placebo effect. Further controlled studies are needed to answer this question.

We could not detect any influence of different morphologic factors such as the length of a heel spur, the body mass index or shoe size on the outcome of ESWT treatment. A heel spur is not considered to be pathognomonic but in theory could influence the distribution and absorbtion of the shockwaves locally. However we did not find the length of the spur to be predicative of the outcome.

Previous studies regarding ESWT in painful heel had different treatment protocols. Rompe et al. applied 3x1,000 shockwaves[18] of 0.08 mJ/mm^2 and 3x1,000 shockwaves[17] of 0.06 mJ/mm2 respectively. Krischek et al.[8] used 3x500 shockwaves of 0.08 mJ/mm^2 and Hammer et al. 5 3x3,000 shockwaves of 0.12 mJ/mm^2. In the present study we applied 3x3,000 shockwaves of 0.2 mJ/mm^2 which was about twice the overall energy density used by Rompe and Krischek. Krischek et al.[8] as well as Rompe et al.[17,18] applied less than half of our overall energy and achieved almost similar results. It remains unclear whether a higher amount of shockwaves or a higher energy density has a positive influence on the clinical outcome. Regarding the results of Krischek et al.[8] and Rompe et al.,[17,18] who achieved almost similar results to those obtained in our study with less than half the overall density, this seems questionable.

The definite mechanism of ESWT remains unclear. It is proposed that local inflammatory reaction at the insertion of the plantar fascia could lead to stimulation of the central nervous system ascending pain pathways. Hyperstimulation of the painful spot by shockwaves could cause an activation of descending inhibitory fibers on brain stem level.[11] This could lead to a control of transmission through the dorsal horns as well as at higher levels in the somatic projection system and thus to suppression of pain. The concept of shockwaves in orthopaedic disorders is that they stimulate or reactivate healing processes in tendons, surrounding tissue and bone probably through microdisruption of avascular or minimally vascular tissues to encourage

revascularization, release of local growth factors, and the recruitment of appropriate stem cells conductive to more normal tissue healing.[23]

In summary, our study showed that ESWT was able to decrease pain and increase the comfortable walking time significantly in patients with previous unsuccessful nonsurgical treatment for proximal plantar fasciitis. Up to 80% of the patients experienced a complete or nearly complete pain relief after a follow-up of six months.

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