Extracorporeal Shock Wave Therapy for Chronic Planter Fasciitis Associated with Enthesophytosis

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ABSTRACT:

BACKGROUND:

Painful heel is a common syndrome characterized by severe pain in the inferior or posterior aspect of the heel, which is aggravated by weight bearing, becoming progressively worse and often incapacitating, with evidence of a spur in about 50% of cases.

OBJECTIVE:

To evaluate the efficacy of extracorporeal shock wave treatment (ESWT) in calcaneal enthesophytosis (heel spur).

PATIENT AND METHODS:

Ninety four patients (66 women, 28 men) were examined who had heel pain associated with heel spur. A double blind randomised study was performed in which 52 patients underwent a standardized treatment (group 1) and 42 patients had sham treatment (group 2). Variations in symptoms were evaluated by visual analogue scale (VAS). Variations in the dimension of calcaneal spur were evaluated by x ray examination.

RESULTS:

A significant decrease of VAS was seen in group 1. Examination by x ray showed morphological modifications (reduction of the larger diameter >1 mm) of the enthesophytosis in 25 (48.1%) patients. In the control group no significant decrease of VAS was seen. No modification was observed by x ray examination.

CONCLUSION:

Extracorporeal shockwave therapy is an effective, safe method that improves the signs and symptoms of most patients with a painful heel.

KEY WORDS: extracorporeal shock wave, plantar fasciitis, enthesopathy, heel pain, enthesophytosis.

INTRODUCTION:

PLANTER FASCIITIS:

Painful heel is a common syndrome characterized by severe pain in the inferior or posterior aspect of the heel, which is aggravated by weight bearing. It may be associated with the presence of a calcaneal spur, and it seems that the existence or the size of the calcaneal spur has very little effect on the severity of the symptoms[(1)]. This condition is very often resistant to conservative therapies that include ingestion of non-steroidal anti-inflammatory drugs, use of insoles, local steroid injections, and physiotherapy [(2,3)] Patients who are resistant to all the above measures may revert to surgery.[(4)]

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Extra-Corporeal Shock wave therapy (ECSWT) has been adopted recently for the treatment of various tendenopathic and enthesopathic conditions such as tennis elbow, periarthritis of the shoulder, and for non-union of bones.[(5-12)]

This new mode of therapy has been studied in a single blind study on plantar fasciitis, with promising good results.[(13,14)] We carried the issue further and planned this study to be a double blind study as a further step in confirming the efficacy and safety of this new modality of treatment to add to our already existing armamentarium of therapies for this very common condition.

ESWT is based on the use of shock waves—that is, microsecond pressure impulses, which, depending on the energy used, can reduce painful symptoms and fragmentation of calcific deposits.[(15)]

ESWT is advocated as the alternative to surgery for those with longstanding, recalcitrant heel pain. It is non-invasive, has a relatively short recovery time, and claims a success rate comparable to surgery.[16]

PATIENTS AND METHODS:

The study protocol was approved by the ethical committees of the College of Medicine, of the University of Baghdad and the Directorate of the Medical City. All patients with clinical diagnosis of planter fasciitis associated with heel spur were included in our study. A written informed consent and permission for the study was obtained from the patients prior to participation.

Inclusion criteria were pain over the radiological examined heel spur for a mean duration of symptoms of 3 months, and unsuccessful conservative treatment (analgesics and non-steroidal anti-inflammatory drugs, insole supports, injections of local anesthetics and corticosteroids). All patients had used analgesic and non-steroidal anti-inflammatory drugs and most of them had a local injection.

Exclusion criteria were arthritis (rheumatoid arthritis, spondarthritis, and crystal induced arthropathies), neurological abnormalities, nerve entrapment syndrome, pregnancy, age under 18 years (for fear of injury to the epiphyses), infectious diseases, skin ulcerations, and bursitis

No other treatment or drug was used during the study period.

During the periods of treatment and follow up only the use of insole supports was permitted.

Consecutive patients were randomly assigned to one of two groups in a double blind designed grouping into: Group 1, (52 patients) receiving ESWT. Group 2 (42 patients) was the sham treatment group,

Groups 1 and 2 both received six treatments (twice weekly), each treatment consisting of (1800 shocks) with a frequency of (120 shocks/min) for five minutes ; the energy density used was (0.21 mJ/mm2) in group 1, and was (0 mJ/mm2) in group 2.

The heels of the patients were radiographed pre and post treatment (lateral views). The radiological modifications observed were classified as grade 1 (reduction in enthesophytosis <1 mm), grade 2 (reduction in enthesophytosis >1 mm).

Pain levels were evaluated by a visual analogue scale (VAS), ranging from (0=no pain to 10 = maximum pain), at rest, after walking on awakening, and after normal daily activity.

Such assessment was made before and at the end of the treatment. The improvements observed were classified as excellent (a VAS reduction of over 50%), good (a VAS reduction of between 30% and 50%), slight (a VAS reduction of between 15% and 30%).

A special emphasis was on checking for the safety of the procedure and the patients were asked to report any undesired effects of the treatment.

Statistical analysis:

SPSS (statistical package for social sciences), version 20, US, IBM, software, was used. All patients data were entered and reviewed, distribution of study subjects by gender and the site involved was presented as frequencies and percentages, descriptive statistic for Age, BMI and duration of disease was presented as (mean ± standard deviation(SD))., Students' *t* test was used to compare two means of VAS in between groups (after treatment and one month after) while ANOVA test (Analysis Of Variance) was used in comparing three means of VAS in between and within groups (before, after and one month after treatment). Chi square test was used to compare frequencies and proportion of VAS and radiological improvement in between both groups, Odds ratio was calculated and the 95% confidence interval of the odds ratio (95%CI) was identified.

The level of significance was set at $P \leq 0.05$ to be significant difference, and then all results and statistical finding were presented in tables and or graphs.

RESULTS:

The total number of patients involved in our study was 106 patients, 12 patients didn't complete the study because of difficulties in transportation, and 94 patients remained and completed our study.

The characteristics of these subjects are shown in table (1)

Table 1: Characteristics of study groups (N= 94).

Characteristic		Treatment group	Placebo group	P value
Number (%)		52 (55.3%)	42 (45.7%)	0.2 ns
Gender	Man	17 (32.7%)	11 (26.2%)	0.6 ns
	Woman	35 (67.3%)	31 (73.8%)	0.6 ns
Age (year)	Mean ± SD*	43.6 ± 9.4	41.7 ± 8.1	0.3 ns
	Range	19 - 72	18 - 66	-
BMI (kg\m^2)	Mean ± SD	31.3 ± 4.5	32.8 ± 5.2	0.13 ns
	Range	25.4 - 38.6	24.1 - 38.6	-
Duration of disease (month)	Mean ± SD	8.8 ± 6.3	7.9 ±7.1	0.5 ns
	Range	3 - 36	2.5 - 36	-
Site involved	Rt\Lt	23\29	19\23	0.9 ns
ns = not significant, hs = highly significant difference , * SD = standard deviation				

In group (1) a significant decrease in VAS ($p<0.05$) was seen just after the end of treatment and after one month later at the three reference points-at rest , after walking on awaking , and after normal daily activity (table 2), where it was not significant in group (2) as shown in (table 3)

Table 2: Pre and post treatment mean VAS of treatment group (N=52).

Pain onset	Before treatment	After treatment	After 1 month	P value
Pain at rest	4.8	2.9	2.1	0.0002 hs
Pain at morning	8.6	6.1	3.8	0.0003 hs
Pain during the day	6.5	4.7	3.2	0.0001 hs

Table 3: Pre and post treatment mean VAS of sham group (N=42).

Pain onset	Before treatment	After treatment	After 1 month	P value
Pain at rest	5.1	4.88	4.58	0.27 ns
Pain at morning	8.5	8.1	7.95	0.43 ns
Pain during the day	6.6	6.16	5.88	0.15 ns

Table 4: Comparison of post and one month after treatment mean VAS in between treatment group (cases) and placebo (control) group (N=94).

Pain onset	After treatment		P value	After 1 month		P value
	Cases	Control		Cases	Control	
Pain at rest	2.9	4.88	<0.001 hs	2.1	4.58	<0.001 hs
Pain at morning	6.1	8.1	0.002 hs	3.8	7.95	<0.001 hs
Pain during the day	4.7	6.16	<0.001 hs	3.2	5.88	<0.001 hs
Hs = highly significant difference.						

Patients on treatment were about 28 fold more likely to have improvement than placebo group, odds ratio = 28.7, and P.value < 0.001, table 5.

Table 5: Comparison of improvement in VAS in between both groups.

Improvement	Treatment group	Placebo group	Total
Improved	43	6	49
	(82.6%)	(14.3%)	(52.1%)
Not improved	9	36	45
	(17.4%)	(85.7%)	(47.9%)
Total	52	42	94
	(100%)	(100%)	(100%)
Odds ratio = 28.7 95%CI (9.3 - 38.2)		P.value = 0.00001[hs]	

Although the proportion of radiological improvement in both groups was lower than that of non improvement, but the treatment group get improvement much higher than placebo group(48.1% versus 4.76% respectively), treatment group were about 18 folded more likely to have radiological improvement rather than placebo group, (odds ratio = 18.5, and P.value = 0.00012), table (6).

Table 6: Comparison of radiological improvement in between both groups.

Improvement	Treatment group	Placebo group	Total
Improved	25	2	27
	48.1%	4.76%	
Not improved	27	40	67
	51.9%	95.24%	
Total	52	42	94
	(100%)	(100%)	(100%)
Odds ratio = 18.5 95%CI (4.1 - 34.7)		P.value = 0.000012[hs]	

Table 7: Comparison of Mean length of calcaneal spur in both groups(N=94).

Length of calcaneal spur	Before treatment	After treatment	P.value
Treatment group	7.4 mm	6.3 mm	< 0.001 hs
Placebo group	6.34 mm	6.29 mm	0.64 ns

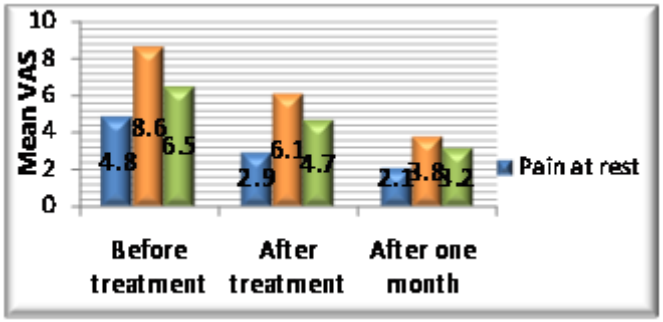

Figure 1: Mean VAS in treatment group before, after and one month after treatment.

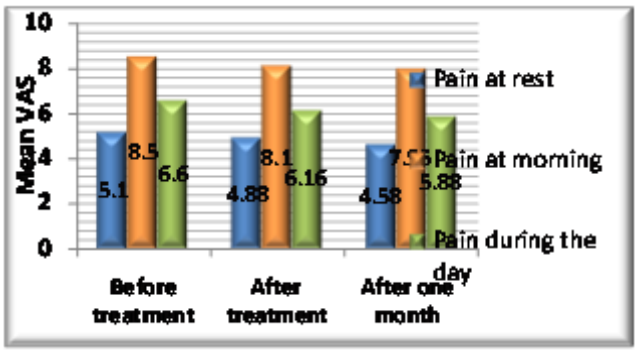

Figure 2. Mean VAS in placebo group before, after and one month after treatment.

Side effects or undesired effects of the procedure were not reported by any of the patients on the treatment or sham group

DISCUSSION:

In our double blind randomised study we evaluated the efficacy of ESWT on painful heel with heel spurs and noted its effects on pain levels, and on the dimension of the enthesophytosis. We also evaluated the placebo effect by comparing one group of patients who underwent treatment with another group in whom the treatment was simulated.

We found that ESWT proved effective in reducing the painful symptoms, and the reduction in pain seen at the end of treatment was maintained over the following six weeks. Since 1992, low energy ESWT has been used in the treatment of pain, in particular of enthesopathy, occurring in precisely locatable areas of the locomotor apparatus.[16]

Rompe *et al* suggested that the pain relief observed after ESWT at energy levels comparable with those used in our study might be similar to the hyperstimulation analgesia described by Melzack.[17, 18]

Valchanou reported the successful application of high energy shock waves in the treatment of pseudarthrosis and delayed union of fractures, stating that the stimulation of osteogenesis achieved by shock waves can be attributed to a local cortical destruction and fragmentation and that the same effect is assumed to lead to a disintegration of calcifications in the treatment of planter fasciitis with spur.[19]

Maier *et al* reported that low energy ESWT can be regarded as an optional non-invasive therapeutic method without major side effects which can be used to avoid surgical treatment in patients with chronic courses of plantar fasciitis associated with heel Spur.[20]

We observed a significant reduction in the diameter of the calcaneal spur on those patients who are treated with ESWT comparing with those in placebo group (in more than 40% of cases we saw a reduction in the enthesophytosis >1 mm). In the control group, no significant changes in pain levels or in the dimensions of the enthesophytosis were seen.

CONCLUSION:

Our results confirm that the presence and size of bony spurs do not correlate with clinical symptoms and that ESWT can be considered as one of the best treatment modalities fort chronic painful heel, owing to its lack of side effects, being repeatable and non-invasive.

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