Shockwave Therapy versus Local Corticosteroid Injection in the Treatment of Chronic Plantar Fasciitis: A comparative study

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Abstract:

Objectives: This study aimed to assess the reliability and safety of extracorporeal shockwave therapy (ESWT) versus local corticosteroid injection on pain intensity and functional disability, as treatment modalities of patients suffering from chronic plantar fasciitis (PF). **Patients and methods:** This study was conducted on 45 patients suffering from chronic PF who failed to respond to conservative treatments. Patients were divided into 3 groups: 15 patients treated with ESWT once per week for 6 successive sessions (Group I), 15 patients treated with a local corticosteroid injection (Group II) and 15 patients taking acetaminophen 500mg/6 hrs for 7 days and exercises, as controls (Group III). All patients were subjected to history taking, clinical examination and assessment of foot pain, disability and activity limitations using the Foot Function Index (FFI) at the beginning of the study and after 6 weeks. **Results**: At the beginning of the study, no significant differences were reported between the studied groups regarding the FFI (p value = 0.23). However, at the end of the study, a highly statistically significant difference was reported between the three groups regarding the outcome variables (p value =0.001). Improvement occurred in group I and II but it was superior among group I patients. Skin reddening occurred in 11 patients (73.3%) of group I and 2 patients (13%) of group II with a statistically significant difference ($p<0.001$) between the 2 groups. Pain was reported in 4 patients (26.7%) and 15 patients (100%) in group I and group II respectively with a highly significant difference ($p<0.001$). None of the cases reported allergy or fat bad atrophy. **Conclusion:** Both ESWT and local corticosteroid injection treatments improved pain and functional ability in patients with chronic PF.

Improvement of the FFI total scores was superior with the ESWT therapy that seems to be an unconventional but a safe method for the management of chronic PF.

Keywords*:* extracorporeal shockwave therapy, plantar fasciitis, PF. corticosteroid injection, foot function index, FFI.

Introduction:

Plantar fasciitis (PF) is considered among the most common causes of heel pain and accounts for 11%–15% of all foot symptoms necessitating specialized care. Pain and tenderness at the calcaneal origin of the plantar fascia upon weight bearing after prolonged periods of rest is considered the main presenting symptom (1).

Weak foot biomechanics, intrinsic foot muscle weakness, long periods of standing and walking, decreased elasticity of the plantar fascia, higher body mass index and foot deformities such as pes planus are considered common risk factors for PF (2).

Current treatments for PF are conservative and include rest, non-steroidal anti-inflammatory drugs (NSAIDs), stretching of the plantar fascia, physical therapy, foot padding, and orthotic devices, which can be used to suit patient's needs (3). Local steroid injections, platelet rich plasma, and intralesional botulinum toxin A (4) could be used. Corticosteroid injections are an effective and popular method to treat this condition (5). However, subsequent plantar fascia rupture following corticosteroid injections has been reported which is considered a serious side effect (6).

If patients do not respond to conservative treatments for at least 6 months thus other treatment modalities for PF, such as extracorporeal shockwave therapy (ESWT) and surgery are recommended (7).

Shockwaves are pulsed acoustic waves characterized by a short duration of time (<10 microseconds), very high pressure amplitudes, and relatively a low tensile wave (8). They are generated outside the human body in water and transmitted widely over a large skin area onto the target region where the acoustic energy is concentrated to a focal area of 2–8mm in diameter (9).

The aim of this study is to assess the reliability and safety of Extracorporeal Shockwave Therapy (ESWT) versus local

corticosteroid injection on pain intensity and functional disability, as treatment modalities of patients suffering from chronic plantar fasciitis (PF).

Patients and Methods

This comparative study was carried out on 45 patients suffering from chronic PF who did not respond to conservative therapies including physical therapy, NSAIDs, stretching exercise, and heel cushions for at least 6 months. They were recruited from those attending the outpatient's clinic of Rheumatology, Rehabilitation and Physical Medicine department, Benha University hospitals from August 2019 to February 2020.

PF was diagnosed based on Ibrahim et al., 2010 clinical criteria (10), as follows

1) Tenderness to pressure at the origin of the plantar fascia on the medial tubercle of the calcaneus, 2) A complaint of heel pain in the morning or after sitting for a long time, and 3) increasing foot pain with extended walking or standing for more than 15 minutes with the pain intensity ≥ 3 on a 1–10 visual analog scale (VAS).

A written informed consent was obtained from all the subjects prior to participation in this study which was approved by the ethical committee of Faculty of Medicine, Benha University.

Patients with certain disorders, defined by a careful history and clinical examination were excluded:

Patients with previous local foot surgery, or fracture of foot bones or any ankle and foot bones abnormalities, foot instability, associated dermatological problems at foot, malignancy, vasculitis, systemic inflammatory disease (rheumatoid arthritis, gout or systemic lupus erythematosus), diabetes mellitus, posterior heel pain due to Achilles tendon bursitis, S1 radiculopathy. Also, patients who had received a corticosteroid injection for PF within the previous 6 months or treated with physiotherapy within the previous 3 months. Lastly, patients on anticoagulant therapy and pregnant women.

Patients were randomly divided into 3 groups:

- Fifteen patients who will receive radial Extracorporeal Shockwave Therapy (ESWT) DolorClast Classic Equipment, Switzerland, once per week for 6 successive weeks (Group I).
- Fifteen patients who will receive one local corticosteroid injection at origin of plantar fascia (40 mg/2 ml of

methylprednisolone together with 1 ml of local anesthesia, once) (Group II).

In patients with bilateral PF, the most affected side based on clinical examination is treated.

- Fifteen patients who will take acetaminophen (500mg/ 6 hrs for 7 days and exercises, served as a controls (Group III).

Patients were subjected to full history taking, clinical examination including calculation of the body mass index (BMI) (11), routine laboratory investigations including a complete blood picture (CBC), erythrocyte sedimentation rate, blood urea, serum creatinine, alanine transaminase (ALT), aspartate transaminase (AST), and fasting blood sugar.

A plain radiograph of the affected foot-lateral view- to identify patients with calcaneal spur was done.

At the beginning of the study and before each session, assessment of heel pain using the Foot Function Index (FFI) (12) was done. It is a self-administered index consisting of 17 items divided into 3 sub-scales including Pain, Disability and Activity Limitation. Each question was scored on a scale from (0-10) that best describe the patients' feet status over the last week **(Appendix I).**

Group I treatment plan included: ESWT sessions where the patient sits or lays on a couch in a comfortable position then the area to be treated is cleaned. Treatment of the affected region was achieved by a sequence of 2000 shockwave pulses fired with a repetition frequency of 2 pulses per second. The energy level or intensity was set at a tolerable level by the patient to 0.2 mJ/mm^2. The entire session lasted 15 min and was performed without local anesthetic drugs. All patients received their sessions once per week for six successive weeks with no change in the treatment parameters.

The participants were instructed to evade using any other conservative treatment. Patients were also advised to stop using non-steroidal anti-inflammatory medications 2 weeks following treatment because of their inhibitory effects on the recovery process. Only acetaminophen 500 mg was allowed for controlling pain during this period.

Group II patients received only one injection of a corticosteroid where the skin was cleaned and draped before the injection, then, 40 mg of 2 ml methylprednisolone plus 1 ml of 1% lidocaine was injected under sterile conditions with a 22-gauge needle into the

most tender point (usually in the medial plantar or inferior calcaneal area). Patients were informed to have rest for 24–48 hours after injections and were directed to apply cold therapy two times a day for 10 minutes each.

Following treatment, patients of both groups were observed for 30 min to record any adverse reactions. They were also asked to avoid full weight-bearing on the heel for 2 days. If needed, heel pads and orthotic insoles were provided.

Patients of both groups were instructed for stretching exercises of the gastrocnemius muscle, plantar fascia, and hamstrings at home during the study period, in 3 sets each one holding for 10 seconds and repeating 10 times.

- The control group **(**Group III): received acetaminophen 500mg/6 hrs as well as stretching exercises 2 or 3 times a day for the whole 6 weeks.

Statistical analysis

The clinical data were recorded on a report form. These data were tabulated and analyzed using the computer program SPSS (Statistical package for social science) version 20 (Inc. Chicago, Ill, USA) to obtain:

- Descriptive statistics calculated for the quantitative data in the form of mean and standard deviation $(\pm SD)$ & frequency and distribution for qualitative data.

In statistical comparisons between the different groups, the significance of difference was tested using one of the following tests:

- Student's t-test, paired t-test and inter-group comparisons of categorical data performed using Chi square test (X^2-value), ANOVA Test and Fisher Exact Test (FET).

Correlation coefficients were used to find relationships between variables. P value <0.05 was considered statistically significant.

Results

This study included 45 patients suffering from chronic planter fasciitis (PF). Their ages ranged between (22-41) years. They were females (80%) and males (20%). They were randomly divided into 3 groups regarding the treatment regimen, Table (1):

Group I: 15 PF patients who received extracorporeal shockwave therapy for 6 weeks successive secessions (once per week). They were 10 females (66.7 %) and 5 males (33.3%) whose ages ranged

between 26 and 41 years (mean ± SD 28.8±7.9 years).

Group II: 15 PF patients who received local corticosteroid injection. They were 13 females (86.7%) and 2 males (13.3%) whose ages ranged between 22 and 39 years (mean± SD 25.9 ± 9.8) years.

Group III: 15 PF patients who were treated only with acetaminophen 500mg/6 hrs for 7 days and stretching exercise. They were 13 females (86.7%) and 2 males (13.3%) whose ages ranged between 20 and 29 years (mean± SD 26.1±4.3) years.

Table (1): Comparisons between the studied groups regarding the demographic data.

	Group (I) (n=15) Mean ± SD	Group (II) (n=15) Mean ±SD	Group III (n=15) Mean ± SD	ANOVA test	P value
Age (years)	28.8 ±7.9	25.9±9.8	26.1±4.3	0.51	0.62
Disease duration/ Months	16.13±8.82	14.8±7.6	15.1±3.2	0.44	0.66
BMI	32.47±3.92	30.93±4.71	29.3±3.1	0.89	0.38
Sex n (%)					
Male	5(33.3)	2 (13.3)	3 (20)	FET=	0.39
Female	10(66.7)	13(86.7)	12 (80)	0.75	

P>0.05= insignificant. BMI: Body Mass Index.

-Non-statistically significant differences were recorded between the studied groups as regards to age (p>0.05), disease duration (p>0.05), BMI (p>0.05), sex distribution (p>0.05) and occupation (p>0.05).

The most common factors associating PF were active jobs (hard work, heavy lifting, prolonged standing or walking for long periods) in 28/45 patients (62.6%); obesity in 28/45 patients (46.6%) and females wearing high heels in 16/45 patients (36%). No significant differences were reported regarding causes of PF among the studied groups (p=0.14, 0.71, 0.64 respectively).

-Nine patients (60%) of group I, 7 patients (47%) of group II 8 patients (53%) of group III experienced pain in one foot while 6 (40%) patients, 8 (53%) patients and 7 (47%) patients of the 3 groups respectively had pain in both feet with no statistical significant difference (P=0.3).

- In between the groups, no significant difference was reported among the studied groups regarding

the FFI at the beginning of study (p=0.23), while a highly statistically significant difference was reported among the studied groups at the end of the study (p= 0.001) with the improvement being best in group I patients, **Table (2).**

- Within the groups, the FFI showed a highly significant improvement (p=0.001) after treatment with the ESWT in group I, a significant improvement in group II (p=0.04) and a non-significant change in group III (p=1.37)

-Calcaneal spurs diagnosed by X-ray occurred in 25/45 of patients (60%). Eight patients (53.3%) in group (I), 10 patients (66.6%) in group (II) and 7 patients (47%) in group (III), **Table (3).**

Table (2): Comparison among the studied groups regarding FFI before and after treatment

	Group I (n=15)	**Group II (n=15)**	**Group III (n=15)**	**Statistical ANOVA test**	**P value**
	Mean ±SD	**Mean ±SD**	**Mean± SD**		
FFI Before	72.08±13.62	79.4±7.36	77.6±1.7	3.08	0.23
FFI after	17.83±14.89	59.88±25.21	69.2±3.4	2.78	0.001**
P value	0.001**	0.04*	1.37	--	--

P>0.05: non-significant, P<0.001**: highly significant.

Table (3): Comparison among patients with calcaneal spurs regarding FFI before and after treatment

	Group I (n= 8)	**Group II (n=10)**	**Group III (n=7)**	Statistical **ANOVA test**	**P value**
	Mean± SD	**Mean± SD**	**Mean± SD**		
FFI before	69.5±13.68	72.3±14.3	67.6±7.8	3.96	0.25
FFI after	18.12±11.1	52.9±18.6	58.1±3.2	2.81	0.001**
P value	0.001**	0.02*	0.89	--	--

P>0.05: non-significant, P<0.001**: highly significant.

- No significant differences were reported among patients with calcaneal spurs regarding the FFI at the beginning of the study (p value = 0.25).
- At the end of the study, a highly statistically significant difference in the FFI was reported among patients with calcaneal spurs that was superior in group I (p value= 0.001).
- Among patients with calcaneal spurs, the FFI showed a highly significant improvement (p=0.001) after treatment with the ESWT in group I, a significant improvement in group II (p=0.02) and a non-significant change in group III (p= 0.89).
- Patients without calcaneal spurs reported significant improvements (p=0.05) regarding FFI after treatment with the improvement being superior among group I patients.
- **Table (4),** shows correlations of FFI after treatment with studied variables among patients with PF.

Table (4): Correlations of FFI after treatment with studied variables among patients with plantar fasciitis

Variables	Group I (n=15) FFI after		Group II (n=15) FFI after		Group III (n=15) FFI after	
	r	**P value**	***r***	**P value**	***R***	**P value**
Age	0.20	0.47	0.24	0.38	0.56	1.54
BMI	0.52	0.4	0.001	0.12	1.4	0.82
Disease duration	-0.03	**0.01***	0.24	**0.04***	0.63	**0.03***
Active jobs	0.03	**0.02***	0.03	**0.02***	3.8	**0.05***
Calcaneal spur	0.26	**0.01***	0.02	**0.04***	1.6	**0.01***

r= correlation coefficient; p>0.05 insignificant; p<0.05 significant*

- Significant positive correlations of FFI with patients' jobs and presence of calcaneal spurs were found among group I, II and III. Correlations of FFI with disease duration was significantly positive in group II and III but was significantly negative in group I. Other variables (age and BMI) showed non-significant correlations in all studied groups.
- Regarding side effects after treatment; not all patients reported side effects ; skin reddening was reported in 11 patients (73.3%) of group I patients

versus 2 patients (13%) in group II, with a highly statistically significant difference between the 2 groups ($p<0.001$**). Patients of group I and II expressed pain in 4 and 15 patients (26.7% and 100% respectively) with a highly significant difference between the 2 groups ($p<0.001$). No other complaints were defined.

Discussion

Despite numerous publications and clinical trials, ESWT is considered a fair method used for treatment of chronic PF (13). In the present study, the most common factors associating PF were active jobs such as people doing hard work, heavy lifting and prolonged standing and walking for long period, in 28/45 patients (62.6%), obesity in 28/45 patients (46.6%), females wearing high heels in 16/45 patients (36%). This was similar with the results reported by the other studies (14, 15, and 16).

Although PF is considered to be self-limiting, chronic cases are recalcitrant and do not respond to routine conservative treatment (4). Some previous studies have reported that corticosteroid injections have a similar or better efficacy than other treatments in treating chronic PF (17). However, steroid injections are often not successful after 1 injection and thus required multiple injections which may be associated with potential complications, including planter fascia rupture and fat pad atrophy (18). Therefore, searching of alternative managements is important (19). Similarly, the efficacy of ESWT in the treatment of chronic PF has also been investigated and is usually recommended. The optimal treatment, however, still remains to be determined (20).

In the current study; treatment of the affected region was achieved by a sequence of 2000 Shockwave pulses fired with a repetition frequency of 2 pulses per second. Energy level or intensity was set at a tolerable level by the patient to 0.2 mJ/mm$^{2.}$ In 2006, Kudo et al (21) used approximately 3.800 total shockwaves (+/-10) reaching an approximated total energy delivery of 1,300 mJ/mm (2) (ED+) in a single session versus placebo treatment. This study demonstrated a statistically significant difference between treatment groups in the change from baseline to 3 months in the primary efficacy outcome of pain during the first few minutes of walking measured by a VAS. There was also a statistically significant difference between treatments in the number of participants

whose changes in VAS scores met the study definition of success at both 6 weeks and 3 months post treatment; and between treatment groups in the change from baseline to 3 months post treatment.

This may be explained as ESWT has been shown to increase blood circulation and activity in the cells in the treatment area, which intern speeds up the body's own healing process. The nerves can also be overstimulated by the shockwave, which leads to reduced pain station (22).

Others studies described the mechanism of action of shockwaves, that ESWT may affect topical pain factors by inducing excessive excitement of the axon. Then, a reflexive analgesic effect is generated and pain is reduced by destroying unmyelinated sensory fibers. Several recent studies have suggested that nitric oxide (NO) production induced by ESWT plays a critical role in suppressing the inflammatory process (9). Moreover, direct stimulation of healing and promotion of neovascularization has also been reported (23).

In our study, we only evaluated the short-term results of the first 6 weeks after treatment. Meanwhile, a previous study has shown that improvement of the pain scores with the use of ESWT was maintained for a long time (nearly 12 months) after a short-term (2 months) treatment regimen (24).

It is reported that corticosteroid injections are effective in the short-term and results regarding the long-term outcomes are controversy (25). Our patients received corticosteroid injection and were re-evaluated after 6 weeks only.

It was observed that better VAS scores for pain at 3 and 12 months after treatment in the corticosteroid injection group compared to the ESWT group (26). Some other researchers, also observed significant improvement in the VAS score for pain and heel tenderness index scores for both treatments, but without a significant difference between the groups; however, the authors preferred corticosteroid injections because of the low cost and availability (27).

To further prove the efficacy of short wave therapy in treatment of chronic PF, other researchers compared ESWT to other modalities. One of those researchers and his team, compared autologous conditioned plasma (ACP) injection, extracorporeal shockwave therapy, and conventional treatment for PF (28). They concluded that treatment with ACP or ESWT plus conventional treatments resulted in an improved pain and functional outcomes

compared to conventional treatment alone. There was no significant difference between ACP and ESWT in terms of VAS and American Orthopedic Foot and Ankle Score (AOFAS) ankle-hind-foot scale improvements, although the ACP group demonstrated greater reductions in plantar fascia thickness (28).

In the present study, significant positive correlations were reported between FFI with BMI and hard work and calcaneal spur (p value >0.5) among the studied patients.

A report was set forward that the cause of PF is multifactorial thus increased FFI may be associated with increased disease duration; hard work and the presence of calcaneal spur (13).

Regarding side effects occurring our patients, skin reddening was common in group (I) patients, while pain was common in group (II). These results were comparable to those reported by other studies (29 and 30)

The side effects caused by ESWT in treatment of PF were reported to be low and negligible (29). Local reddening, ecchymosis, or mild hematomas are the commonest. These side effects can be successfully managed conservatively and spontaneous recovery is anticipated. While another study reported post injection pain, subcutaneous atrophy, and skin depigmentation following corticosteroid injections (30)

Limitations of the present study were that the number of patients was small (15 patients in each group). The sample was mainly composed of females (82.5%) so we could not know whether both genders would show the same behavior. The differences between genders were not assessed because of the same reasons mentioned. Also, the duration of the follow-up period was short for long lasting results.

Conclusion:

Both ESWT and local corticosteroid injection treatments improved pain and functional ability in patients with chronic PF. Improvement of the FFI total scores was superior with the ESWT. ESWT seems to be an unconventional but a safe method for the management of chronic PF.

Conflict of interest: None of the contributors declared any conflict of interest.

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Appendix

Foot Function Index

Section 1: To be completed by patient Name:_____ Age:____ Date:_____

Occupation:_____ Number of days of foot pain:_____(this episode)

Section 2: To be completed by patient

This questionnaire has been designed to give your therapist information as to how your foot pain has affected your ability to manage in every day life. For the following questions, we would like you to score each question on a scale from 0 (no pain) to 10 (worst pain imaginable) that best describes your foot **over the past WEEK**. Please read each question and place a number from 0-10 in the corresponding box.

No Pain 0 1 2 3 4 5 6 7 8 9 10 **Worst Pain Imaginable**

	1.	In the morning upon taking your first step?		
	2.	When walking?		
	3.	When standing?		
	4.	How is your pain at the end of the day?		
	5.	How severe is your pain at its worst?		

Answer all of the following questions related to your pain and activities **over the past WEEK**, how much difficulty did you have? ***Disability Scale***

No Difficulty 0 1 2 3 4 5 6 7 8 9 10 ***So Difficult unable to do***

	6.	When walking in the house?		
	7.	When walking outside?		
	8.	When walking four blocks?		
	9.	When climbing stairs?		
	10.	When descending stairs?		
	11.	When standing tip toe?		
	12.	When getting up from a chair?		
	13.	When climbing curbs?		
	14.	When running or fast walking?		

Answer all the following questions related to your pain and activities **over the past WEEK**. How much of the time did you: ***Disability Scale:***

None of the time 0 1 2 3 4 5 6 7 8 9 10 ***All of the time***

	15.	Use an assistive device (cane, walker, crutches, etc) indoors?		
	16.	Use an assistive device (cane, walker, crutches, etc) outdoors?		
	17.	Limit physical activities?		

Section 3: To be completed by physical therapist/provider SCORE:_____/170 x100= _____% (SEM 5, MDC 7)

SCORE: Initial_____ Subsequent_____ Subsequent_____ Discharge_____

Number of treatment sessions:_____

Diagnosis/ICD-9 Code:_____

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