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Original Research

Treatment Outcomes of Corticosteroid Injection and Extracorporeal Shock Wave Therapy as Two Primary Therapeutic Methods for Acute Plantar Fasciitis: A Prospective Randomized Clinical Trial

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ABSTRACT

The outcome of corticosteroid injection (CSI) and extracorporeal shock wave therapy (ESWT) as primary treatment of acute plantar fasciitis has been debated. The purpose of the present study was to evaluate and compare the therapeutic effects of CSI and ESWT in patients with acute (<6-week duration) symptomatic plantar fasciitis. Of the 116 eligible patients, 68 were randomized to 2 equal groups of 34 patients, each undergoing either ESWT or CSI. The ESWT method included 2000 impulses with energy of 0.15 mJ/mm^2 and a total energy flux density of 900 mJ/mm^2 for 3 consecutive sessions at 1-week intervals. In the CSI group, 40 mg of methyl prednisolone acetate plus 1 mL of lidocaine 2% was injected into the maximal tenderness point at the inframedial calcaneal tuberosity. The success and recurrence rates and pain intensity measured using the visual analog scale, were recorded and compared at the 3-month follow-up visit. The pain intensity had reduced significantly in all patients undergoing either technique. However, the value and trend of pain reduction in the CSI group was significantly greater than those in the ESWT group ($p < .0001$). In the ESWT and CSI groups, 19 (55.9%) and 5 (14.7%) patients experienced treatment failure, respectively. Age, gender, body mass index, and recurrence rate were similar between the 2 groups ($p > .05$). Both ESWT and CSI can be used as the primary and/or initial treatment option for treating patients with acute plantar fasciitis; however, the CSI technique had better therapeutic outcomes.

Ten percent of the general population in their lifetime and 1% of the world population will present to orthopedic surgeons with heel pain due to degenerative changes in the plantar fascia (1–3). The main symptom is severe pain in the medial tubercle of the calcaneus during weightbearing in the morning that decreases during standing and increases with prolonged walking or running (4,5). The main predisposing risk factors are increasing age, increasing body mass index (BMI), certain anatomic risk factors such as leg length discrepancy, increased plantar fascia thickness, pes planus (excessive pronation of the foot), and certain extrinsic factors such as previous injury to the heel, improper shoe fit, and improper running pattern (6,7).

Although the etiopathogenesis of plantar fasciitis is poorly understood, it is probably multifactorial and caused by multiple microtears resulting from an increase in stress and repeated fascia stretching that has exceeded the self-limiting reparable capacity of the body (8,9). The continuous stress and microtears lead to a slight gap between the fascia and calcaneus joint. This small gap can become filled with new reactive bone tissue and form heel spur (10). The spur is not the cause of the pain, but, as stated by Johal and Milner (11), it can accompany the disease. The changes result in fibroblastic proliferation and chronic granulomatous tissues formation, which can ay be accompanied by vascular hypoperfusion, loss of elasticity of the connective tissue, and changes in nerve function and, eventually, lead to plantar fascia enthesis (10,12,13).

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The plantar fasciitis is a self-limiting disorder; however, because of its prolonged course (mean period of 16 to 18 months), patients experience severe pain and disability affecting their quality of life (9). The diagnosis is based on patient history and clinical examination findings (14). The treatment options are rest, cold or warm water compression, nonsteroidal anti-inflammatory drugs, other anti-inflammatory analgesics, plantar stretching exercises, heel pad orthotics, magnetic insoles, therapeutic shoes, night splints, tapings, short plasters, CSIs, ESWT, radiotherapy, platelet-rich plasma injection, botulinum toxin injection, and, eventually, surgical treatment (12,15–17). No conclusive treatment option is available for this painful disease, and physicians and patients will choose a routine treatment option according to their own experience and interests. DiGiovanni et al (18) argued that the controversy regarding choosing a specific treatment option should be clarified by qualitative studies. A questionnaire-based study reported that 75% of the physicians recommend CSIs as the second treatment of choice (19).

Recently, ESWT has been recommended as an appropriate and effective method in the treatment of plantar fasciitis (20). ESWT modalities are capable of producing sonic waves with high amplitude within a short period and propagating them on a small surface (16). Theoretically, this energy could inhibit demyelinated plantar sensory nerves, reduce calcification, increase the proliferation of growth factors, and increase peripheral blood circulation, angiogenesis, and neovascularization in the degenerative tissue of the heel (12,21,22). Despite these theoretical views, the exact therapeutic effect of ESWT has not been substantiated by various clinical trials and a myriad of therapeutic treatment protocol regimens (e.g., the number of impulses, energy amount, shock wave frequency, focusing methods) (10,23–29). Another important debate is the effectiveness of ESWT as a primary therapeutic regimen. The only controlled clinical trial evaluating radial ESWT versus a stretching technique demonstrated that the patients were not satisfied with the radial ESWT technique if it was applied as a primary treatment protocol (22).

Of 30 nonoperative treatment methods recommended for patients with plantar fasciitis, a few studies have compared CSI and ESWT, and a very few studies have compared the 2 methods as the primary technique for treating acute plantar fasciitis. The present clinical trial study was designed to examine and compare the effects of the 2 treatment options, CSI and ESWT, as primary treatment of acute plantar fasciitis.

Patients and Methods

This was a randomized clinical trial study including all patients with heel pain or a possible diagnosis of acute plantar fasciitis who had been referred to our orthopedic clinic from July 2011 to June 2012. The included patients were adults >18 years old, with morning heel pain that was relieved after a short walk, localized tenderness at the tuberosity of calcaneus in dorsiflexion, a symptomatic duration of <6 weeks, and a heel pain score of ≥5 of the visual analog scale (VAS) present at the first steps taken in the morning. Patients were excluded from the study if they had received any treatment during the previous 6 weeks before the beginning of the study; had osteoarthritis, diabetes mellitus, peripheral vascular disease, a history of trauma or calcaneal fracture, chronic heart disease, neurologic, hepatic, and/or metabolic disease, or dermatologic infections or trauma at the heel region; had clinical features suggestive of seronegative spondyloarthropathy, nerve-related diseases (e.g., radiculopathy, tarsal tunnel syndrome), or coagulopathy disorders; were undergoing anticoagulant therapy; or had undergone previous surgery for plantar fasciitis or a spur or CSI, ESWT, or physiotherapy for heel pain. Those for whom ESWT was contraindicated, such as pregnant women, and patients with a hypersensitivity to lidocaine or corticosteroids were also excluded.

All the patients provided written informed consent before enrollment. Of the 116 patients, 9 did not fulfill the inclusion criteria and 23 were reluctant to participate. All the patients underwent lateral and axial radiographs to rule out any possible lesions such as osteomyelitis, tumor, or fracture. The remaining 84 eligible patients were randomized using random blocks to the ESWT (43 patients) or CSI (41 patients) groups (Fig. 1).

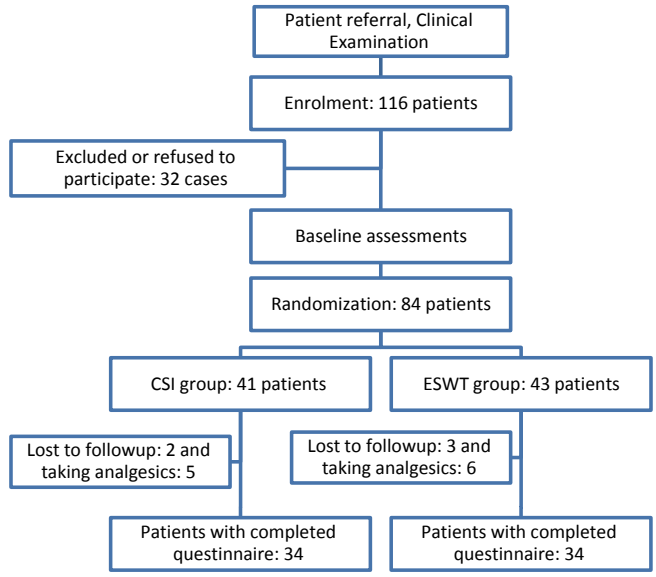

Fig. 1. The research flow chart. CSI, corticosteroid injection; ESWT, extracorporeal shock wave therapy.

ESWT Technique

The treatment protocol was intermediate shock wave therapy with an electrohydraulic shock wave system to apply an energy level of 0.15 mJ/mm^2. Two thousand shock wave impulses were applied for 3 times at weekly intervals. The total dose of 900 mJ/mm^2 was considered for each patient (23,30,31). The patient lay down in a comfortable position; the area of maximum tenderness was marked with a skin marker, and ultrasound gel was applied to the patient's heel as the coupling medium. No anesthetics or narcotics were used during the treatment protocol.

CSI Technique

For the CSI, 1 mL of methyl prednisolone acetate (40 mg) and 1 mL of lidocaine 2% were injected into the site of maximal tenderness at the inframedial calcaneal tuberosity (15,32). Care was taken to avoid injection into the skin, subcutaneous tissue, and/or fat pad.

After Treatment

The patients in both groups were instructed to not participate in any running or long walks for ≥10 days after the treatment and to not undergo any other alternative therapy such as night splints, massages, and/or narcotic or nonsteroidal anti-inflammatory drug usage.

All the patients were examined using the VAS to measure pain at 3, 6, and 12 weeks after treatment (in the ESWT group, the assessment was initiated after the final ESWT session) by another physician who was unaware of the study details. The worst daily pain intensity was recorded on the VAS for each patient at each visit. Pain was recorded on a scale of 0 to 10, with 0 indicating no pain and 10, the highest pain experienced by the patient. An increase of >2 values in the VAS pain score was regarded as disease recurrence. To minimize the interfering factors, the effects of the therapeutic methods on the reduction of pain without reference to gender, age, or BMI were also evaluated.

Statistical Analysis

After data summarizing, the 1-sample Kolmogorov-Smirnov test was used to assess the distribution of VAS score before and after treatment at 3, 6, and 12 weeks. The results indicated a normal distribution of the VAS score, except at the 3-week follow-up visit. Thus, for the comparative studies, the nonparametric statistics of the Wilcoxon signed ranks test and Mann-Whitney *U* test were mostly used to answer the hypotheses of the present study. To examine the VAS score changes before and after treatment at 3 weeks, the independent *t* test was used. The chi-square test was used to compare the success and recurrence rates. The chi-square test was also applies to examine gender frequency, and the independent sample *t* test was used to examine the age frequency. We applied repeated measure analysis of variance to analyze the VAS score trends for the interactions of the groups and demographic variables. SPSS software, version 19 (IBM, Armonk, NY) was used to analyze the data, and $p \leq .05$ were considered statistically significant.

Table 1
Demographic characteristics

	ESWT Group (n = 43)	CSI Group (n = 41)	*p* Value
BMI (kg/m2)	30.21 ± 3.85	29.10 ± 4.22	.26*
Gender			.74†
Female	29 (85.3)	28 (82.3)	
Male	5 (14.7)	6 (17.6%)	
Age (yr)	43.91 ± 7.96	44.68 ± 9.20	.72†
Pretreatment VAS score	9.16 ± 1.02	8.82 ± 1.26	.21*

Abbreviations: CSI, corticosteroid injection; ESWT, extracorporeal shock wave therapy; VAS, visual analog scale.
Data presented as n (%) or mean ± standard deviation.
* Independent sample *t* test.
† Chi-square test.

Results

The present study included 84 patients randomly assigned to receive either ESWT (43 patients) or CSI (41 patients). The following patients were excluded from the study: 3 from the ESWT group and 2 from the CSI group for being inaccessible and 6 from the ESWT group and 5 from the CSI group for taking analgesics or using other therapeutic modalities. Both groups (34 patients) were similar with regard to age, gender, and BMI (Table 1).

In the ESWT and CSI groups, the mean reduction in the VAS score from before treatment to the 3-week follow-up visit was 3.5 and 6, respectively. The mean VAS scores were significantly different between the ESWT and CSI groups ($p < .0001$), with the pain reduction score in the CSI group twice that in the ESWT group. The VAS scores before treatment and at 3, 6, and 12 weeks after treatment are listed in Table 2, and the changes in the VAS scores from the pretreatment evaluations are listed in Table 3.

In brief, the repeated measures analysis of variance test indicated that the VAS scores significantly changed from before to after treatment at all 4 visits. The differences between the 2 groups were also statistically significant ($p < .0001$). In general, the pain relief trend was in favor of the CSI group (Fig. 2).

The results indicated that 19 patients (55.9%) in ESWT group and 5 patients (14.7%) in the CSI group did not respond to treatment. Thus, the patients were nearly 4 times more irresponsive to ESWT than to CSI, and the difference was statistically significant ($p < .0001$). The odds ratio for no treatment response in the ESWT group was 7.35 compared with the CSI group (95% CI 2.29 to 23.5).

Recurrence, defined as an increase of 2 points in the VAS score after recovery, was observed in 7 of 15 recovered patients in the ESWT group (46.7%) and 9 of 29 recovered patients in the CSI group (31%). However, the difference was not statistically significant ($p = .307$). The odds ratio was 1.94 in the ESWT group compared with the CSI group, and the difference was not statistically significant (95% CI 0.539 to 7.019).

Age, gender, or BMI could potentially interfere with the therapeutic outcomes. Therefore, the epsilon Greenhonse-Geisser test was applied to indicate their possible effects. The VAS score trends were not significant for gender ($p = .46$), and both had similar patterns of change (Fig. 3). To examine the role of age, the patients in both groups were subdivided into 3 age groups (i.e., <40, 40 to 50, and >50 years); however, the VAS scores did not change significantly and had no interactions with the scores of the other groups ($p = .44$; Fig. 4).

The patients were also subdivided into 3 BMI subgroups (BMI 20 to 25 kg/m^2 as normal, 25 to 30 kg/m^2 as overweight, and >30 kg/m^2 as obese; Fig. 5). Repeated measures analysis of variance indicated no significant interactions with the other results ($p = .32$).

Table 3
Changes in VAS score at 3-, 6-, and 12-week visit

VAS Score Reduction	3-wk Visit		6-wk Visit		12-wk Visit	
	ESWT (n = 40)	CSI (n = 41)	ESWT (n = 38)	CSI (n = 39)	ESWT (n = 34)	CSI (n = 34)
Mean ± SD	3.5 ± 3.2	6.5 ± 3.5	2.7 ± 3	6.6 ± 3.7	2.3 ± 2.9	5.5 ± 3.9
Median	3	8	2	8	1	6.5
SE	0.54	0.60	0.51	0.64	0.51	0.66
95% CI	2.4 to 4.7	5.3 to 7.7	1.7 to 3.8	5.3 to 7.9	1.3 to 3.3	4.1 to 6.8
IQR	6.25	4	5.25	3.25	4.25	6.25
p Value						
Within group	< .0001	< .0001	< .0001	< .0001	< .0001	< .0001
Between groups	< .0001		< .0001		< .0001	

Abbreviations: CI, confidence interval; CSI, corticosteroid injection; ESWT, extracorporeal shock wave therapy; IQR, interquartile range; SD, standard deviation; SE, standard error; VAS, visual analog scale.

Discussion

The present prospective randomized clinical trial indicated that CSI method is effective in treating patients with acute plantar fasciitis that has been symptomatic for <6 weeks (treatment respond rate >85%). It seems that in the acute phase of plantar fasciitis, the ESWT method might result in more treatment failures and a greater recurrence rate.

Rompe et al (10) conducted the first placebo-controlled study to examine the effect of low-dose ESWT on chronic plantar fasciitis

Table 2
VAS score before and 3, 6, and 12 weeks after treatment

Group	VAS Score			
	Before Treatment	After Treatment		
		3 wk	6 wk	12 wk
ESWT (n = 34)				
Mean ± SD	9.1 ± 1	5.6 ± 3.3	6.4 ± 3.2	6.9 ± 3.1
Median	9	6	8	8
SE	0.18	0.56	0.54	0.53
95% CI	8.8 to 9.5	4.5 to 6.8	5.3 to 7.6	5.8 to 7.9
IQR	1	6	5	5
CSI group (n = 34)				
Mean ± SD	8.8 ± 1.3	2.3 ± 3.2	2.2 ± 3.5	3.4 ± 3.7
Median	9	1	0	1
SE	0.22	0.55	0.59	0.63
95% CI	8.4 to 9.3	1.2 to 3.4	0.9 to 3.4	2.1 to 4.6
IQR	2	3	3	6

Abbreviations: CI, confidence interval; CSI, corticosteroid injection; ESWT, extracorporeal shock wave therapy; IQR, interquartile range; SD, standard deviation; SE, standard error; VAS, visual analog scale.

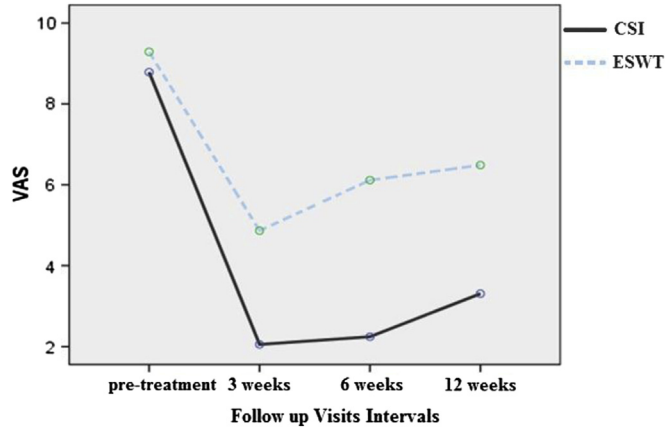

Fig. 2. The visual analog scale (VAS) score changes for 4 visits in the extracorporeal shock wave therapy (ESWT) and corticosteroid injection (CSI) groups.

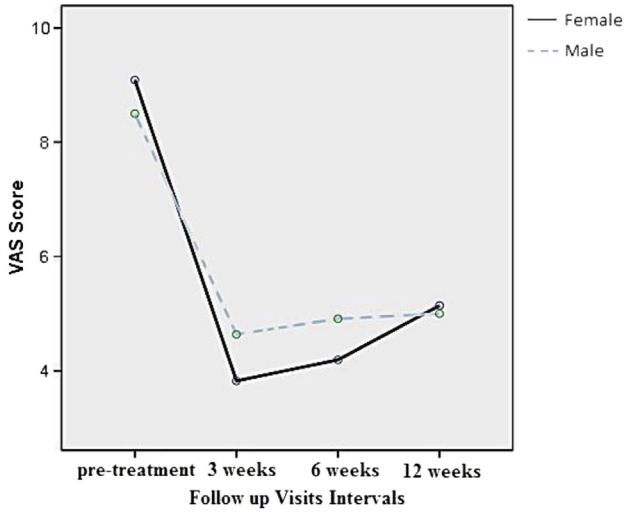

Fig. 3. The visual analog scale (VAS) score changes for 4 visits in the extracorporeal shock wave therapy and corticosteroid injection groups according to gender.

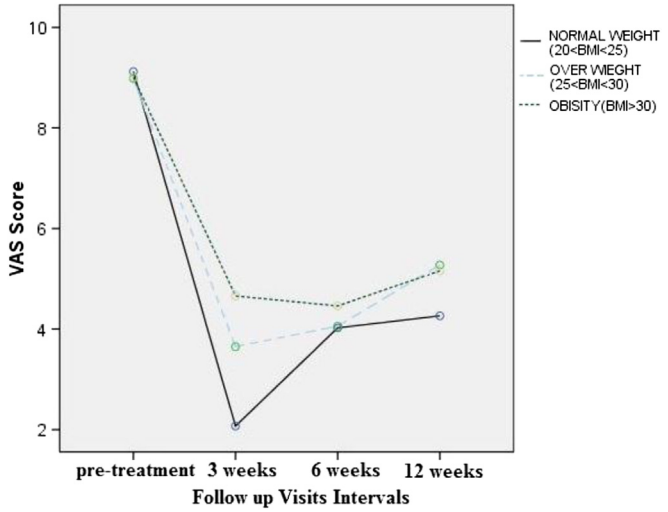

Fig. 5. The visual analog scale (VAS) score changes for 4 visits in the extracorporeal shock wave therapy and corticosteroid injection groups according to body mass index (BMI) subgroup.

(1000 impulses of 0.06 mJ/mm^2 energy flux for 3 consecutive weeks). At the 12-week follow-up period, they demonstrated a significant reduction in pain in patients undergoing ESWT compared with that in those undergoing sham therapy (10). Although the positive significant effects of ESWT on chronic plantar fasciitis have been addressed in several studies (10,24,26,27,29), a few studies using different treatment regimen protocols reported no significant differences in applying ESWT (25,28). Speed et al (28) used an energy flux of 0.12 mJ/mm^2 with 1500 impulses for 3 consecutive months and reported no significant differences in the treatment outcomes between the patients undergoing ESWT and those receiving placebo at the 4-week follow-up point. Haake et al (25) used 4000 impulses of 0.08 mJ/mm^2 energy density flux for 3 consecutive weeks using local anesthesia and found no significant differences in the success rate in patients undergoing ESWT (34%) or placebo treatment (30%) at the 12-week follow-up point. Buchbinder et al (23), in a double-blind randomized clinical trial, applied ESWT for 3 consecutive weeks using a total dosage of 1000 mJ/mm^2 and found no significant differences in relieving pain and quality of life among the patients undergoing ESWT or placebo treatment at the 6- and 12-week follow-up examinations. The discrepancy between the results reported by Buchbinder et al (23) and those reported in other studies could have resulted from several factors. The first is related to the inclusion criteria, in that patients with both acute and chronic plantar fasciitis were included, in contrast to most other studies, which included only chronic patients. Second, the patients with increased plantar fascia thickness were included and the focal point of ESWT was the thickest area of the fascia, in contrast to other studies in which the patients with maximal point tenderness at the medial calcaneal tuberosity were included and that was the focus point of ESWT.

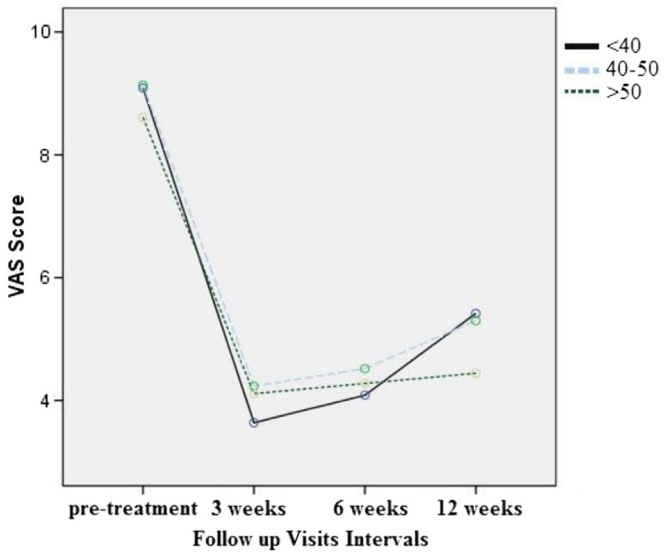

Fig. 4. The visual analog scale (VAS) score changes for 4 visits in the extracorporeal shock wave therapy and corticosteroid injection groups according to age subgroup.

The effects of ESWT and CSI in treating chronic plantar fasciitis were examined and compared in 3 different studies. In a randomized clinical study, Porter and Shadbolt (31) examined and compared the effects of CSI of 1 mL betamethasone and 2 mL of lidocaine in 64 patients, the application of low-dose ESWT (3 sessions using 0.08 mJ/mm^2 energy flux density with 1000 pulses and a total dose of 240 mJ/mm^2) in 61 patients, and standardized stretching treatment in 19 patients as a placebo group. The worst daily pain recorded on the VAS and the tenderness threshold measured using an algometer were compared before treatment and at 3 and 12 months after treatment. Their findings clearly indicated that although ESWT was nearly as effective as CSI in treating plantar fasciitis at 12 months of follow-up, CSI was more efficacious and much more cost effective than ESWT (31). In another similar study, Yucel et al (33) compared the effects of high-dose ESWT and CSI in patients with chronic plantar fasciitis lasting >6 months using the VAS score. The response to treatment was considered to be a 50% reduction in pain using the VAS or the heel tenderness index. At 3 months of follow-up, no significant differences were seen in the treatment outcomes between the 2 groups. The response to treatment was 82% (27 of 33 patients) in the ESWT group and 85% (23 of 27 patients) in the CSI group. They concluded that first-line treatment for their patients was CSI because of its cost effectiveness (33). In another recent study, the 2 methods of treatment of chronic plantar fasciitis, CSI (2 mL of betamethasone and 2 mL of lidocaine) and ESWT (2 sessions of therapy using 0.28 mJ/mm^2 energy flux density with 1000 to 1500 pulses), were compared using the plantar fascia thickness (determined by ultrasonography) and the subjective Mayo

Clinic scoring system. The treatment outcome was satisfactory and similar for both methods. They recommended CSI as the treatment of choice because of its reproducibility and cost-effectiveness and the ESWT technique as the last option before surgery (34).

Recently, ESWT has been recommended for the treatment of plantar fasciitis in several studies owing to its effectiveness in reducing morning pain in 61% and a reduction in VAS scores in 72% of the patients (32,33). Chang et al (16), in a systemic review of 12 studies (11,431 patients total) comparing different types of ESWT, reported that ESWT with the highest and medium energy density tolerable by the patients was the superior method. Radial ESWT was reported to be a substitute treatment method owing to its cost effectiveness and similar success rate (16).

In a study of patients with acute plantar fasciitis, symptomatic for <6 weeks, Rompe et al (22) investigated and compared the effects of low-dose radial ESWT (3 consecutive sessions of therapy using 0.16 mJ/mm^2 energy flux density with 2000 pulses and a total dose of 960 mJ/mm^2) without local anesthesia (48 patients) and a standardized stretching technique (54 patients). The functional outcome was compared using the Foot Function Index, pain, and patient satisfaction at the 2-, 4-, and 15-month follow-up visits. The patients in both groups were similar in age, gender, and BMI, and the treatment outcomes indicated that the stretching method was superior to radial ESWT (22). The ESWT group in our study was comparable with that in the study by Rompe et al (22) in terms of the inclusion criteria, treatment regimen, and functional outcomes.

Pain relief and the remission process after ESWT can be attributed to the following physiologic etiologies. First, ESWT could induce the desensitization effect on the exposure area with depletion of the sensory nerve fiber neurotransmitters. Second, it might provoke fibroblast proliferation and enhance the tissue healing process (35,36). It seems that in the acute phase (>6 to 8 weeks), the features of a failed healing response are not yet present; thus, the tissue healing process induced by ESWT would play no role at this time.

Because plantar fasciitis is a self-limited condition, it is difficult to attribute the healing to the treatment only, and this could distort the results of long duration treatment options (31). The discrepancy between the results of the present study and other studies using ESWT in the treatment of plantar fasciitis can be explained by the differences in the study design (e.g., patient number, chronic or acute condition, disease duration, sham group, comparisons with other treatment options), ESWT parameters (e.g., total energy use, radial or focused, low, intermediate, or high dosage, direct or indirect contact, differences in electrohydraulic, electromagnetic, and piezoelectric generators), and measurement criteria after treatment (e.g., follow-up duration, pain and tenderness assessment method, use of an algometer or a dolorimeter [objective assessment methods for sensitivity to pain], success rate assessment of each treatment protocol). The controversy over the use of radial or focused ESWT, energy amount, number of treatment sessions, use of image-guided or clinically guided methods, and the area undergoing ESWT has provoked more uncertainty about the preferred treatment.

The purpose of the present study was to examine the subjective pain score; therefore, one of the limitations of the present study was the absence of an objective evaluation of pain using an algometer. Not assessing the thickness of the plantar fascia using ultrasonography was another limitation of our study. Thus, additional studies using ESWT are needed to determine the clinically detected maximal point tenderness and ultrasound-detected maximal plantar thickness. Another limitation of the present study was the lack of a sham therapy group. This was because it was not justifiable or feasible to suggest a sham treatment to a patient who was experiencing severe pain, had a VAS score of >5, and was unable to tolerate more pain.

The prospective and randomized design and the stringent selection of the patients were 2 strong points of the present study. To reduce the interfering factors, the patients were carefully selected using the inclusion criteria, and the effects of age, gender, and BMI were also controlled. The main strong point was the comparison of the CSI and ESWT methods for patients with acute plantar fasciitis that had been symptomatic for <6 weeks. Because the disease is self-limiting, it is important it is treated in the first stages when the patient is experiencing severe pain. However, a very limited clinical trial study has been conducted on chronic plantar fasciitis. Thus, the present study can be regarded as the basis for other blind and multicenter studies of acute plantar fasciitis.

In conclusion, although the CSI technique had significantly better treatment outcomes, both CSI and ESWT could be preferred as the primary treatment of patients with acute plantar fasciitis.

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