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ORIGINAL ARTICLE

Comparative Study of Effect of Diclofenac Alone *vs* Diclofenac with Ultrasound Therapy in Patients with Inferior Heel Pain using Pedography

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ABSTRACT

Objectives: To study the additional benefits of ultrasonography in patients with inferior heel pain treated with diclofenac for foot pressure profile and pain.

Materials and methods: This was a randomized experimental trial. Comparison of the efficacy of two treatment modalities (diclofenac alone *vs* diclofenac with ultrasound therapy) with respect to pressure profiles using pedography and a visual analog scale (VAS) was carried out. Twenty-three patients with unilateral inferior heel pain were considered subjects. The main outcome measures were foot pressure profile using pedography and pain severity using VAS.

Results: In the diclofenac alone group, it was observed that there was significant decrease in pain score posttreatment. The rest of the parameters did not show any significant change. In the diclofenac and ultrasound group, a statistically significant increase in the rear foot pressure area and decrease in the VAS score posttreatment was observed. Changes in the rest of the parameters were not significant. Comparison of the difference between the two treatment modalities with respect to pressure areas and VAS scale for pain showed no significant change statistically.

Conclusion: Ultrasound therapy shows some increase in the ability to take more rear foot pressure while walking, but it does not have any other added benefit over diclofenac in treating inferior heel pain with respect to pressure profile and pain.

Keywords: Heel pain, Plantar fasciitis, Ultrasound therapy.

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INTRODUCTION

Inferior heel pain or plantar heel pain is a broad term describing a range of undifferentiated conditions affecting the plantar heel.[1] Plantar fasciitis (PF) has been reported as the most common cause of plantar heel pain,[2] and the terms are frequently used interchangeably in literature.[3] The other causes of inferior heel pain include calcaneal fracture, systemic arthritis, calcaneal infection, plantar calcaneal bursitis, or hindfoot osteoarthritis.[4] A patient history, proper physical examination and appropriate investigations (hematological/imaging) will help in correct diagnosis. Plantar fasciitis typically presents as pain beneath the heel, made worse by weight bearing after prolonged period of rest.[1] In this study, we have used the term inferior heel pain in patients clinically diagnosed with history and examination suggestive of PF. The etiology of PF is likely multifactorial. Numerous factors, including flatfoot, advancing age, obesity, inappropriate footwear, and decrease in ankle dorsiflexion, have been associated with plantar fascia disorders.[5-7] Chronic inflammation secondary to mechanically induced microtrauma has been the most widely cited mechanism,[8] though few studies quote it as a degenerative process of the plantar fascia.[9] Studies have also shown an alteration in the mechanical loading of the affected limb during gait in patients with PF[10] because of the pain. Conservative therapies have shown success in 85 to 90% of cases and thus remain the preferred approach to treating PF.[11] The various treatment modalities include rest, nonsteroidal anti-inflammatory drugs (NSAIDs), therapeutic ultrasound, stretching of plantar fascia, shoe modification, night splint, extracorporeal shock wave therapy, corticosteroid injection, platelet-rich plasma injection, and fasciotomy. The NSAIDs have been shown to relieve pain and decrease disability when used along with other conservative regimen like stretching the heel cord and shoe modification.[12] Therapeutic ultrasound used

routinely in the treatment of plantar heel pain[13] works by increasing the blood flow and helps in tissue healing,[14] but studies with respect to effect of therapeutic ultrasound in PF have shown conflicting conclusions.[15,16]

The present study was undertaken to compare the effect of diclofenac NSAID alone *vs* diclofenac with ultrasound therapy in patients with inferior heel pain using pedography. We hypothesized in consensus with Wearing et al[10] that patients with inferior heel pain tend to walk on the forefoot and not on the heel when there is pain, thereby changing the gait pattern. Many studies have suggested changes in the regional loading pattern during gait[17-19] and also changes in the various gait parameters in patients with PF. Hence, we have used gait analysis as an assessment tool for comparison. We aimed to study the additional benefits of ultrasonography in patients with PF treated with diclofenac on foot pressure profile and pain.

MATERIALS AND METHODS

Ethical Oversight

Ethical approval was obtained from the Institutional (All India Institute of Medical Sciences) Ethical committee prior to the onset of study.

Subjects

The study recruited 26 patients (09 males and 17 females) attending institutional Physical Medicine and Rehabilitation outpatient department with a history of unilateral inferior heel pain. The criteria for inclusion in this study were pain over the heel exacerbating after periods of nonweight bearing, with localized tenderness over the plantar fascia near its insertion into the medial calcaneal tuberosity.[20,21] The exclusion criteria included bilateral heel pain, history suggestive of inflammatory joint disease (supported by the appropriate hematological investigations), history of foot trauma (supported and also excluded by X-ray of foot), and history of hypersensitivity or contraindication to tablet diclofenac. In accordance with institutional ethics guidelines, written consent was obtained from all patients after a verbal and written explanation of the study.

Equipment

We used a Zebris gait analysis machine® setup in our department to assess the foot pressures of the patients. The system functions using 8,064 high-quality capacitative force sensors, which are arranged in a matrix form in a 1.5 m platform. The measuring plate enables the static and dynamic force distribution to be analyzed under the feet while standing and walking. The measuring plate is integrated in a level walking area and the measuring cycle can be repeated.

Patients were asked to rate their degree of heel pain on a 0 to 10 point VAS, where "0" was referring to no pain and "10" referred to unbearable pain.

Procedure

A randomized experimental study was done from June 2010 to August 2011. All patients satisfying the inclusion criteria were assessed for their body weight and standing height [to calculate body mass index (BMI)], for any flat foot on clinical examination and for heel spur (on X-ray foot). Age, duration of illness, and occupation of the patients were recorded. Patients were divided into two groups: one group was given diclofenac alone and the other group was given diclofenac with ultrasound therapy. Randomization was done by allocating every second person into diclofenac with ultrasound therapy. Patients in both these groups were in addition advised a hot water footbath, similar calf muscle and plantar fascia stretching exercises, and to use soft padded footwear.

For patients in both the groups, a tablet of diclofenac 50 mg was prescribed three times a day (two times if weight was less than 60 kg) after food, to be consumed with water for the first week and to be taken as and when needed for pain for the next week. Patients were also advised to have a tablet of rabeprazole 20 mg every day before breakfast to avoid the gastric side effects of diclofenac.

The therapeutic ultrasound therapy prescribed was pulsed, 1.5 W/cm^2 intensity, 3 MHz frequency, for 10 minutes over the maximal tender area on alternate days for seven sessions. Pulsed therapy was used in this study because in comparison to the continuous mode ultrasound, pulsed mode acts by nonthermal effects of the ultrasound and the nonthermal effects have shown to have better tissue healing.[13] The position of the patient while taking ultrasound therapy was short sitting with the affected foot supported on a stool.

The patients were made to get familiarized with the foot plate and, once comfortable, were made to walk at a self-selected walking speed. Four trials were recorded for each limb. The measurement parameters are automatically calculated in the software program. Pressure profile, force, and accompanying data were extracted for both the feet. The peak pressures were noted from the rear foot, fore foot, and toes on the affected and unaffected foot of the participants during the gait cycle. Because variability in plantar pressures is higher during walking, pressure areas were assessed during walking instead of only on standing. It was done at baseline and at 15 days after completion of the respective treatment in both the groups.

Table 1: Baseline study characteristics of patients

Characteristic	*Diclofenac (n = 13)*	*Diclofenac + ultrasound therapy (n = 13)*	*p-value*
Sex			
Male	7	2	0.08
Female	6	11	
Age (years)	39.96 ± 13.86	41.82 ± 10.05	0.61
Mean ± SD			
Body mass index	26.6 ± 3.83	27.0 ± 4.11	0.73
Mean ± SD			
Flat foot (%)	11 (45%)	5 (23%)	
Heel spur (%)	4 (17%)	3 (14%)	
Rear foot (N/cm^2)	20.5 ± 7.89	21.5 ± 7.65	0.78
Forefoot (N/cm^2)	26.7 ± 5.77	26.5 ± 10.17	0.62
Toe (N/cm^2)	21.5 ± 12.90	23.8 ± 11.90	0.94
Average force heel (N)	681.5 ± 181.68	701.2 ± 160.00	0.80
Average force forefoot (N)	686.5 ± 175.04	692.3 ± 143.18	0.94
Foot rotation (%)	8.9 ± 10.88	9.0 ± 5.35	0.63
Stance (%)	66.9 ± 2.90	66.4 ± 5.87	0.76
Swing (%)	33.0 ± 2.90	33.5 ± 5.91	0.74
Double support (%)	36.5 ± 12.81	42.8 ± 15.68	0.07
Cadence (steps/min)	52.5 ± 6.92	53.2 ± 8.82	0.84
Step length (%)	46.1 ± 12.70	46.9 ± 10.54	0.96
Stride length	99.6 ± 19.86	95.2 ± 21.49	0.72
Velocity (km/hr)	3.2 ± 0.99	2.9 ± 0.98	0.94
Visual analog scale	7.8 ± 1.78	8.7 ± 1.43	0.17

SD: Standard deviation

Statistical Analysis

Statistical analysis was done using STATA version 11.0. Various nonparametric tests were applied for analysis purposes as the sample size was low in each group. The difference between right and left foot was compared using Wilcoxon signed-rank test. The effect of treatment on pressure profiles and gait parameters was assessed using the Wilcoxon signed-rank test. The difference between the two treatment modalities was evaluated using rank sum test for all the given variables. The effect of BMI, flat foot, and presence of heel spur on pressure areas was evaluated using regression analysis. An alpha level of 0.05 was used as level of significance; any value above this was considered statistically insignificant result.

RESULTS

The mean age of patients in each group was around 40 years. The median symptom duration before treatment was 4 months (3 weeks to 13 months). The duration of symptoms did not have any significant correlation with the treatment outcome. There was no significant difference in the anthropometric variables between the two treatment groups (Table 1). The right foot was involved in 64% of patients and the left foot in 36%.

Effect of Inferior Heel Pain on Gait Parameters

The step length, stride length, and velocity are less. The double support phase was high. Comparison of ground reaction force variables between affected and unaffected feet in patients showed that average force over the fore foot was higher in the unaffected foot. The rest of the parameters did not show any significant changes (Table 2).

Effect of Treatment Modalities on Gait Parameters

Comparison of the two treatment modalities with respect to gait parameters showed some trend toward increasing rear foot pressure in the ultrasound with diclofenac group posttreatment. Rest of the parameters were statistically insignificant (Table 3).

Effect of Treatment Modalities on Pain

The two treatment modalities (diclofenac alone *vs* diclofenac with therapeutic ultrasound) showed significant decrease in pain score on VAS individually. But the addition of ultrasound did not have any benefit over diclofenac alone in reducing the pain score (Table 3).

Table 2: Comparison of variables (mean ± SD) between affected and unaffected foot in patients

Variables	*Affected foot*	*Unaffected foot*	*Difference*	*p**
Rear foot (N/cm^2)	22.0 ± 7.39	23.09 ± 4.83	−1.04 ± 7.20	0.45
Forefoot (N/cm^2)	28.5 ± 9.59	30.1 ± 11.57	−1.8 ± 7.37	0.13
Toe (N/cm^2)	23.18 ± 13.13	24.1 ± 13.45	−0.95 ± 17.25	0.53
Average force – heel (N)	715.7 ± 170.59	729.84 ± 148.29	−14.1 ± 63.35	0.62
Average force – forefoot (N)	704.7 ± 159.67	724.8 ± 135.74	−20.1 ± 58.56	0.03
Foot rotation (%)	9.20 ± 8.65	11.31 ± 5.32	−2.10 ± 8.56	0.30
Stance (%)	66.3 ± 6.79	67.7 ± 5.32	−1.43 ± 9.42	0.73
Swing (%)	33.8 ± 6.86	32.3 ± 5.32	1.5 ± 9.39	0.76
Step length (m)	49.3 ± 9.87	50.9 ± 8.86	−1.6 ± 8.39	0.57

*Based on nonparametric test; SD: Standard deviation

Association of Various Variables (Occupation, BMI, Flat Foot, Heel Spur) with Inferior Heel Pain

Among the 26 patients with PF, 70% of patients had a BMI greater than 25, 36% of patients had flat foot, and 29% of patients had heel spur. There was no significant association of the above variables with the pressure profile and ground reaction force. For every one point increase in BMI, there was an increase in pressure points by 0.4 units, though it was not statistically significant.

DISCUSSION

Plantar fasciitis being a self-limiting condition, Goff and Crawford[22] have intimated for the use of oral analgesics along with stretching exercise for several weeks. Oral NSAIDs have shown efficacy in the treatment of PF.[12] This supports the pain relief noted in our patients. Therapeutic ultrasound has shown benefits in *in vitro* studies, with literature showing cellular level effects, but the same has not been found in clinical trials.[16] Ultrasound therapy has shown inconsistent results.[15,16] A randomized clinical trial by Cleland et al,[23] manual physical therapy and exercise *vs* electrophysical agents and exercise in the management of plantar heel pain suggested that exercise was a superior management approach than an electrophysical agent like ultrasound therapy. There are many reasons quoted for clinical ineffectiveness, the majority have been technical problems and poor study design, besides a true lack of effect.[24] Reviewing the literature, the lack of additional benefit of ultrasound in our patients could be that few patients were in chronic stage of the disease and the degenerative condition *per se* may show little effectiveness to ultrasound therapy.[24]

Patients with inferior heel pain have been studied to make global adjustments in their gait pattern.[9] Inconsistent with the findings of Wearing et al,[10] patients in this study showed a decreased velocity, step length, and stride length and an increased double support phase. Also a review by Chandler and Kibler[25] in runners with PF shows stride adjustments by placing the affected foot in plantar flexion. This is to avoid bearing weight on heel and this reduces the step length,[9] as has also been found in our study. Wearing et al[10] have also mentioned specifically about decrease in heel loading pattern in their study. Our study also showed decreased loading patterns in the affected feet. Also our study showed an increase in the average force over forefoot of the asymptomatic limb. This can be explained when an affected foot is in the initial stance phase (heel contact), the unaffected foot is in the terminal stance phase. Thus, to avoid bearing weight on the affected heel, the unaffected forefoot and toes take the body weight, giving higher average force values over the fore foot.

Comparing pre- *vs* posttreatment effect on gait parameters, there was a trend toward increase in rear foot pressure posttreatment in the second group. Rest of the parameters were statistically insignificant. To the best of our knowledge, there have been no studies comparing the effect of ultrasonic therapy on gait parameters in patients with PF, thus making comparison with this study difficult.

Comparing pre- *vs* posttreatment pain score (VAS) in the diclofenac alone and diclofenac with ultrasound therapy groups showed significant decrease in the pain posttreatment. However, the addition of ultrasound therapy to diclofenac alone had no statistically significant benefit. There have been no studies comparing ultrasound and oral diclofenac therapy prior to our study to enable results comparison. Thus, our results show that adding ultrasound therapy did not make any significant change in the treatment effect with respect to pain score VAS and pressure profiles (pedography), except for trend that rear foot pressure increased following the addition of ultrasound therapy.

Table 3: Comparison of pressure profiles and gait parameters between pre- and posttreatment in the patients

	Diclofenac group (n = 13)				Diclofenac + ultrasound group (n = 13)				
Variable	*Pre*	*Post*	*Difference*	*p**	*Pre*	*Post*	*Difference*	*p**	*p*#
Rear foot (N/cm^2)	20.5 ± 7.89	20.5 ± 6.95	−0.1 ± 3.52	0.72	21.5 ± 7.65	25.5 ± 6.76	−3.9 ± 5.23	0.02	0.06
Forefoot (N/cm^2)	26.7 ± 5.77	28.9 ± 8.77	−2.2 ± 6.27	0.33	26.5 ± 10.17	30.5 ± 14.08	−4.1 ± 7.54	0.06	0.72
Toe (N/cm^2)	21.5 ± 12.90	17.1 ± 9.06	4.5 ± 11.75	0.25	23.8 ± 11.90	25.3 ± 8.84	−1.5 ± 7.54	0.67	0.27
Average force heel (N)	681.5 ± 181.68	672.3 ± 194.12	9.2 ± 53.41	0.89	701.2 ± 160.00	710.8 ± 152.05	−9.6 ± 92.27	0.78	0.98
Average force forefoot (N)	686.5 ± 175.04	661.9 ± 195.33	24.6 ± 69.08	0.21	692.3 ± 143.18	699.2 ± 133.50	−6.9 ± −70.41	0.86	0.24
Foot rotation (%)	8.9 ± 10.88	8.7 ± 11.63	0.3 ± 2.66	0.81	9.0 ± 5.35	10.0 ± 5.17	−0.9 ± 2.74	0.29	0.37
Stance (%)	66.9 ± 2.90	65.4 ± 7.52	1.5 ± 5.85	0.83	66.4 ± 5.87	65.9 ± 10.00	0.5 ± 10.47	0.75	0.88
Swing (%)	33.0 ± 2.90	34.6 ± 7.52	−1.5 ± 5.85	0.81	33.5 ± 5.91	33.4 ± 7.39	0.02 ± 8.38	0.91	0.94
Double support (%)	36.5 ± 12.81	35.8 ± 9.00	0.64 ± 5.98	0.62	42.8 ± 15.68	38.6 ± 7.50	4.2 ± 17.28	0.34	0.30
Cadence (steps/minute)	52.5 ± 6.92	54.4 ± 9.61	−1.9 ± 5.46	0.28	53.2 ± 8.82	53.9 ± 8.92	−0.8 ± 10.77	0.80	0.38
Step length (%)	46.1 ± 12.70	43.6 ± 14.16	2.5 ± 13.17	0.67	46.9 ± 10.54	46 ± 11.97	0.9 ± 10.11	0.48	0.50
Stride length	99.6 ± 19.86	99.1 ± 17.24	0.5 ± 15.41	0.86	95.2 ± 21.49	100.8 ± 21.94	−5.5 ± 17.34	0.19	0.33
Velocity (km/hr)	3.2 ± 0.99	3.2 ± 0.88	0.02 ± 0.97	0.70	2.9 ± 0.98	3.1 ± 0.97	−0.2 ± 0.79	0.60	0.90
VAS	7.8 ± 1.78	5.5 ± 2.36	2.3 ± 1.37	0.002	8.7 ± 1.43	5.5 ± 2.47	3.2 ± 1.86	0.002	0.47

*Based on nonparametric test; #Difference between pre- and postchange between two treatments (column 4 *vs* column 8) using nonparametric test

CONCLUSION

Ultrasound therapy shows some increase in the ability to take more rear foot pressure while walking, but it does not have any other added benefit over diclofenac in treating PF with respect to pressure profile and VAS scale for pain.

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