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Effectiveness of Extracorporeal shock wave therapy in the management of Plantar fasciitis: a Randomized Controlled Trial

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Abstract:*Plantar fasciitis is the most common cause of heel pain. Approximately 10% of the United States population experiences bouts of heel pain, which results in 1 million visits per year to medical professionals for the treatment.Extracorporeal shock wave therapy(ESWT) is a new therapeutic modality and has become increasingly used worldwide in the treatment of plantar fasciitis. Despite increasing use of ESWT, its effectiveness is still controversial. A randomized controlled trial was conducted in the Department of Physical Medicine and Rehabilitation (PMR),Regional Institute of Medical Sciences(RIMS), Imphalamong patients suffering from planter fasciitis from September 2016 to August 2018.Patients were randomizedinto theintervention (ESWT)and control (Ultrasound therapy) groups (n=36 in each group).The outcome of interest were VAS and MRM scores which were assessed at the end of 1st, 3rd and 6thmonths. Independent Sample t-test was used for analysis between the groups and paired t-test was used in analysis within the groups. Out of the 72 patients recruited, majority were females(68%). The mean age of the study participants was 44.91±10.2 years in the intervention group and 41.88 ±11.6 years in the control group.Both groups showed significant improvement over the course of the study (p<0.001), though VAS scores and MRM scores were significantly more reduced in the ESWT group than ultrasound therapy group. The study thus shows that ESWT is more effective than Ultrasound therapy in the management of plantar fasciitis.*

Key words:*Plantar fasciitis, ESWT, VAS scores, MRM score*

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I. Introduction

Plantar fasciitis is the most common cause of heel pain for which professional care is sought.[1]Approximately 10% of the United States population experiences bouts of heel pain, which results in 1 million visits per year to medical professionals for treatment of plantar fasciitis. The peak incidence occurs between ages 40 and 60 years.[2] The etiology of plantar fasciitis is multifactorial. Suggested risk factors include obesity, prolonged standing, flat feet and reduced ankle dorsiflexion.[3]The diagnosis of plantar fasciitis is clinical and local point of tenderness is the hallmark for diagnosis. There is no role of laboratory test inthe diagnosis of planter fasciitis.[4]Patients typically present with heel pain when weight bearing,especially with the first few steps in the morning or after periods of inactivity.The pain improves after further walking.Patients usually have maximum point of tenderness at the anteromedial aspect of the calcaneous.[5]The treatment of plantar fasciitis is primarily conservative, initially with rest and icing to give pain relief. Non-steroidal anti-inflammatory drugs (NSAIDs), local injection of steroids, electrotherapy and physiotherapy with stretching exercises were also used.[6]

Extracorporeal shock wave therapy (ESWT) is a noninvasive procedure used in the treatment of plantar fasciitis. The exact mechanism remains undefined.There may be an effect on local pain receptors leading to hyper-stimulation of axons and a reflex analgesic effect .[7]Theremight also be increased metabolic response at the area of healing with cellular changes including release of nitric oxide and growth factors along with neovascularization.[8]

Despite increasing use of ESWT in the treatment of plantar fasciitis, few well documented trials have been conducted to approve its efficacy with conflicting results.Therefore,this study was conducted to determine the effectiveness of ESWT in the management of plantar fasciitis.

II. Material and Methods

This experimental studywas conducted among patients suffering from planter fasciitis who attended the PMR Department, RIMS, Imphal during the study period from September 2016 to August 2018.

Study design: Randomized controlled trial

Study Location: Physical Medicine and Rehabilitation Department, Regional Institute of Medical Sciences, Imphal, Manipur.

Study duration: September 2016 to August 2018

Sample size: 36 for each group

Sample size calculation:

Assuming a minimum expected difference in the mean VAS scores between the two treatment groups as 1, SD of 1.5, 90% power at 5% significance level, the calculated sample size was 32. Expecting a 10% dropout rate, the final calculated sample size was 36 for each group.

Subjects and selection method: Patients with planter fasciitis attending Outpatient department of Department of PMR during September 2016 to August 2018 were the study subjects.

Inclusion criteria: Patients having plantar fasciitis for at least 3 months, who are not responding to analgesics and between 20 – 60 years of age were included in the study.

Exclusion criteria: Patients with foot deformity, vascular abnormalities, tarsal tunnel syndrome, rheumatoid arthritis, hemorrhagic disorders and on anti-coagulant therapy, pregnancy and un-cooperative patients were excluded the study.

After obtaining informed consent, patients were assigned to intervention group (ECSW therapy) and control group (Ultrasound therapy) by using block randomization. A block size of four was used for the study.

Intervention:

The intervention group was given Extra Corporeal Shock Wave Therapy and the control group was given Ultrasound therapy.

Study instruments:

1. **Interview schedule**
2. **ESWT Cart SWISS Dolorcast Smart 20 made inSwitzerland**
3. **UST ENRAF NONIUS SONOPLUS 490 made in Neherland**

Procedure methodology:

Patients were asked to lie in prone position with foot supported on the edge of the bed. In the intervention group, ESWT applicator was placed perpendicular to the area of maximum tenderness and applied with 2000 beats of shock wave, at frequency of 6 Hz and pressure of 3bar. The session was performed once per week for a total of three sessions. In the control group Ultrasound therapy was given at a frequency of 1HZ and intensity of 1.2 watt/cm^2 in continuous mode for 5 minutes for 10 days. Data were collected using an interviewer administered questionnaire. Socio-demographic variables like age, gender, weight, height and occupation along with the outcome measurements (VAS scores and MRM scores) of the study participants were ascertained by interviewing the participant and was based on self-reports only.Follow up were done at 1, 3 and 6 months. Approval from the Research Ethics Board, RIMS, Imphal were taken.

Statistical analysis:

The data wasanalyzedby using IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY - IBM Corp. Descriptive statistics like mean,standard deviation and percentages were used. Chi-square test was used to test for differences in proportions.Independent Sample t-test and paired t test were used for comparing the difference between and within groupmeans. P value <0.05 was considered to be significant.

III. Results

A total of 72 patients (36 in each group) were recruited for the study.

Table 1. Baseline characteristics of the study population

Characteristics		**ESWT n=36**	**UST n=36**	**p-value**
Gender	Male	11(47.8%)	12(52.2%)	.800
	Female	25(51.0%)	24(49.0%)	
Religion	Hindu	32(50.0%)	32(50.0%)	.091
	Christian	-	3(100.0%)	
	Muslim	4(80.0%)	1(20.0%)	
Occupation	Business	4(33.3%)	8(66.7%)	.771
	Govt. employee	4(57.1%)	3(42.9%)	
	House wife	18(58.1%)	13(41.9%)	
	Police	3(50.0%)	3(50.0%)	
	Student	3(42.9%)	4(57.1%)	
	Teacher	4(44.4%)	5(55.6%)	
Right side		16(44.4%)	27(75.0%)	.058
Left side		20(55.6%)	9(25.0%)	
Age (Years)		44.91± 10.28	41.88± 11.66	.247
Duration		4.38± 0.96	4.66± 1.04	.244
MRM0		3.08±.439	3.27±.513	.089
VAS0		7.13±.487	7.16±.971	.879

Table 1showsthe baseline characteristics of the study participants.49 patients were females(68%) and 23 were males (32%). There was no significant difference between the groups.

Table 2. Mean MRM score of the study population at baseline and different follow up

MRM score	**ESWT n=36**	**UST n=36**	**P-value**
	Mean±SD	**Mean±SD**	
At baseline	3.08±.43	3.27±.51	.089
1st follow up	1.52±.50	2.75±.73	<.001
2nd follow up	1.72±.45	2.22±.54	<.001
3rd follow up	1.86±.54	2.00±.41	.026

Table 2 showedthat there were significant differences in the MRM score between the intervention and control groups at all follow ups.

Table 3. Mean VAS score of the study population at baseline and different follow up

VAS score	**ESWT n=36 Mean ±SD**	**UST n=36 Mean ±SD**	
At baseline	7.13±.48	7.16±.97	.879
1st follow up	3.61± 1.24	5.44± 1.69	<.001
2nd follow up	3.77± 1.26	4.47± 1.31	.026
3rd follow up	3.25 ± 1.20	4.50± 1.18	<.001

Table 3 showed that there were significant differences in the VAS score between the intervention and control groups at all follow ups.

Table 4. Within group comparison of mean MRM score at baseline and subsequent follow-up for the treatment groups

Treatment Group	**Mean±SD**		**Mean ± SD**		**P-value**
ESWT	Baseline	3.08±.43	1st follow up	1.52±.50	<.001
	Baseline	3.08±.43	2nd follow up	1.72±.45	<.001
	Baseline	3.08±.43	3rd follow up	1. 86±.41	<.001
UST	Baseline	3.27±.51	1st follow up	2.75 ±.73	<.001
	Baseline	3.27±.51	2nd follow up	2.22 ±.54	<.001
	Baseline	3.27±.51	3rd follow up	2.00±.54	<.001

Table 4 showed that the MRM Score at baselinediffered significantly from the MRM scores at all stages of follow up for both ESWT group and Ultrasound group.

Table 5. Within group comparison of mean VAS at baseline and subsequent follow up for the treatment groups

Treatment group	Mean ± SD		Mean ± SD		P-value
ESWT	Baseline	7.13±.48	1st follow up	3.61± 1.24	<.001
	Baseline	7.13±.48	2nd follow up	3.77± 1.26	<.001
	Baseline	7.13±.48	3rd follow up	3.25± 1.20	<.001
UST	Baseline	7.16±.97	1st follow up	5.44± 1.69	<.001
	Baseline	7.16±.97	2nd follow up	4.47 ±1.31	<.001
	Baseline	7.16±.97	3rd follow up	4.50± 1.18	<.001

Table 5 showed that the VAS Score at baseline differed significantly from the VAS scores at all stages of follow up for both ESWT group and Ultrasound group

IV. Discussion

Chronic plantar fasciitis is a frustrating condition for both physician and patients.ESWT is a new therapeutic modality that is used for musculoskeletal pain therapy,including plantar fasciitis.But despite the increase use of it in the treatment of plantar fasciitis,its effectiveness is still controversial.

In the present study,patient were mostly females(68%) and mostly overweight with mean BMI of 23.9±2.2 which was similar with the study conducted by Krishnan E et al where 70% of the patient were females and 87% of the patients were overweight.

In the present study,there was significant improvement in the mean of VAS Score in both the groups at 4 weeks,12 weeks and 24 weeks follow up ($p<0.05$) and significant improvement was also found in MRM Score in both the groups at 4 weeks,12 weeks and 24 weeks follow up ($p<0.05$) with significantly more effective in ESWT group.Similar findings was demonstrated in the study conducted by Rompe et al andChen et al.

In ESWT group,the mean VAS Score improved from 7.13±.48 to 3.61±1.24 at 4 weeks and further improved to 3.25±1.2 and3.12±1.2 at 12 weeks and 24 weeks follow up respectively with a p value of <0.01 and the mean MRM score improved from 3.08±0.43 to 1.52±0.5 and to 1.72±0.45 and 1.86±0.41 at 4 weeks,12 weeks and 24 weeks respectively with a p value of <0.001.In a study conducted by Kongen N et al. found similar statically significant improvement of VAS Score at 1 week, 3 weeks,12 weeks and 24 weeks. In a study conducted by Ibrahim M et al similar statistical significant improvement of VAS Score and MRM Score was observed at 4 weeks, 12 weeks and 24 weeks from baseline.

The VAS Score and MRM Score difference between before and after treatment was significantly decreased in both groups with more difference in ESWT therapy group than in Ultrasound therapy group.

Patients who receivedESWT therapy and ultrasound therapy did not have any serious adverse effects during or after the procedures.

The limitations of this study are: Blinding was not done for study participants as well as the investigators which might have led to bias in results.Long term follow-up is required to study the long term effect of ESWT in plantar fasciitis.

V. Conclusion

ESWT is a safeand easy treatment for patients with plantar fasciitis and is found to be effective in the management of plantar fasciitis.

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