

EFFICACY OF AGNIKARMA AS ADD ON THERAPY TO ULTRASOUND THERAPY IN THE MANAGEMENT OF HEEL PAIN W.S.R TO VATAKANTAKA - A RANDOMIZED CONTROLLED CLINICAL TRIAL

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Abstract

Introduction: Heel pain is a common problem encountered in clinical practice and treatment is mostly not satisfactory. Delayed treatment or negligence may cause complication which require surgical intervention. The prevalence rate of heel pain is 59 % among the Indian population. Vatakantaka is one among Vatavyadhi and lakshanas can be correlated with heel pain. Anu-shastra karma particularly Agnikarma is effective in the pain management of heel pain.

Method: In this current study included 30 patients ranging in age from 20 to 70 years old who met the inclusion criteria. The patients were divided randomly in two group on the basis of random number generator. The patients were treated with ultrasound therapy in standard group for 7 days and Agnikarma as add on to Ultrasound therapy treated in trial group. At different times, assessments were made using a variety of parameters, including pain, tenderness, range of motion, and walking ability. Statistical analysis was carried out utilizing SPSS 3.0 software. Results were evaluated both within and between groups using the Mann-Whitney U test and the Wilcoxon matched paired test, respectively.

Result: The study found that the trial group strategy produced substantial results in measures such as pain, tenderness, ROM, and walking capacity when compared to the control group at various time periods.

Conclusion: Agnikarma as Add on therapy with Ultrasound therapy is more effective in the management of heel pain.

Keywords: Agnikarma, Ultrasound therapy, heel pain, para-surgical procedure, Vatakantaka.

INTRODUCTION

Vatakantaka is a disease-causing pain in the heel which affects the quality of life. It develops due to walking on uneven surfaces, excessive walking, sports activities and wearing improper foot wear. [1] Heel pain is a most common condition which can persist for long time and turn into a chronic.[2] The reasons for heel pain includes various conditions such as Planter fasciitis, bursitis in Retro-calcaneal, heel pad Atrophy, inflammation of Achilles tendon, Haglund's deformity, calcaneal spur, and Achilles tendon degeneration.[3] since pain is complex phenomenon and nature of pain makes objective measurement difficult. So different subjective pain assessment parameters like VAS, VDS and tenderness measures the complexity of the pain mechanism to a great extent.

In western science heel pain has many treatment options with their own limitations including therapeutic ultrasound at a dosage of 0.5 w/cm², 3 MHz, pulsed 1:4, for eight minutes [4]

Hence, pain management in heel pain requires multisystemic approach. Acharya Susrutha explains Agnikarma (Therapeutic Thermal Cautery) as treatment for Vatakantaka [5]. So, the integration of ultrasound therapy and Agnikarma was required to study its effect in the heel pain management. So, in the present research study Agnikarma as an add on therapy with Ultrasound therapy were selected and its efficacy has been assessed in the heel pain management. Current study has revealed significant efficacy. Pain in Plantar heel region reduces wellness-related attributes of life.[6]

MATERIALS AND METHODS

The study enrolled individuals from the institute's outpatient and inpatient departments. The consort [7] and study's findings are reported using statement guidelines.

Subject- A total of 30 patients with heel discomfort were recruited from the Shalya tantra Department's OPD and IPD from KAHER Sri B.M Kankanawadi Ayurveda Mahavidyalaya ,Belagavi, Karnataka .

Study design- Open label Randomized controlled clinical trial

Inclusion criteria-

Diagnosed cases of heel pain w.s.r to Vatakantaka, either sex with age ranging from 20 years to 70 years and Yogya for Agnikarma(fig no.3) were included in the study.

Exclusion criteria-

Patients for Contraindication of Ultrasound therapy like- bone fracture, malignancy, active infection, ischemic tissue and being affected by a systemic illness such as diabetes or tuberculosis., Ulcers on Sole and Heel etc. Patients with diagnosed cases of Traumatic and Pathological Fracture and Dislocation of Ankle Joint, Foot and Sprain and Known case of Foot Infection like-Osteomyelitis, Athlete's foot (tinea pedis), pitted keratolysis. Patients having also known case of Congenital deformities of Ankle Joint like Club foot, talipes equinovarus, Rocker deformity, Flat foot, Metatarsus varus, Pes cavus, Paget's disease affecting the Calcaneum and injury of Achilles tendon were excluded.

Screening method-

The study's enrolled individuals were clinically assessed and data were meticulously recorded.

Research design- 30 Randomized sample was divided in two groups.

The study's CONSORT [7] Flow diagram is shown in Figure 1.

Intervention- The eligible participants were divided into two groups randomly.

Group A (Standard group)-received ultrasound therapy once daily for 8-9 min for 7 days with power (0.8 to 1.5 watts/cm²) watts, Frequency-1-2 MHz.

Group B (Trial group)- received ultrasound therapy for 3 days followed by one session of Agnikarma on 4th days with innovative instrument at 150 °C temperature at the marked site of maximum pain on affected Heel .

The patients gave their informed consent after learning about the nature and purpose of the trial. The institutional ethics committee accepted the study with protocol ID BMK/20/PG/ST/1, approval date 18/08/2021, and CTRI Registration Number CTRI/2021/11/037845.

Data was collected from January 2021 to June 2022. Patients were requested to follow the therapy and report any adverse effects to the researchers during the trial period. The physiotherapy techniques were performed under the supervision of a licensed physiotherapist from institute.

Assessment criteria-

Primary outcomes -

Parameters like Pain (by Verbal descriptive scale and verbal analogue scale), Tenderness (By frank painter's Scale), Range of Motion of ankle Joints (by Goniometry) (fig.2), walk by patients within 10 min were Using regular operating procedures, assessments were made at various time points.

Randomization- Randomization was done by the chief co-ordinator, Medical Research Centre , from KAHER Sri B.M Kankanawadi Ayurveda Mahavidyalaya, Belagavi, Karnataka.

by using random number generator software.

Statistical test –

SPSS version 20.0 was used for statistical analysis. Wilcoxon matched pair test, Mann-Whitney U test, and Paired t-test (Dependent t-Test) and independent t-test were used to compare different interventions from day one to day fourteen in terms of parameters such as pain and soreness. If the 'p' value was less than 0.05 and the data were presented as mean standard deviation, the parameters were deemed statistically significant

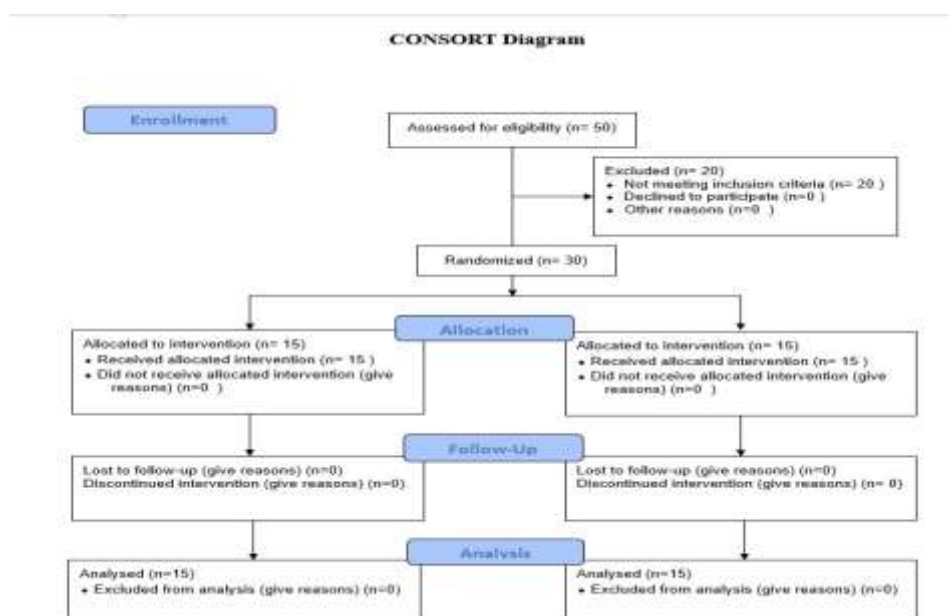


Fig. 1. CONSORT flow diagram of the study

RESULTS

The study was completed with a total of 30 participants participating, with no reported adverse events or drop outs.

As per the observations, in this study majority of patients were under the age group of 41 to 50 years with mean BMI of the sample being 25.59. Also the proportion of female patients was more at 56.67%.

Statistically significant results ($p < 0.05$) (Table 1 and table 2) were seen in the parameters like pain, tenderness, range of motion, walking capacity in all the three time points. On the first, fourth, seventh, and fourteenth days, there was a substantial improvement ($p0.007$) in pain and discomfort measures. Significant improvement ($p0.001$) was observed in parameters such as ankle joint range of motion and walking ability at three separate time points, including the 1-4th day, 1-7th day, and 1-14th day.

Significant improvement (0.005) was seen in range of motion i.e., over all planter flexion and dorsiflexion (1-4th day $p=0.0406$, 1-7th day and 1-14th day $p<0.0001$). significant improvement ($p<0.0001$) was seen in walking capacity in 10 minutes.

Adverse events-

Total of 30 patients were included in the present study, no adverse effect were seen during the study.

DISCUSSION

The higher incidence of heel pain in females can be due to the increased pressure on the heels either due to the unique foot anatomy in females or wearing high heels. Women feet are typically slimmer with wider forefoot and they tend to be narrower towards the heel with shorter arch length. Also, women have smaller feet proportion to the rest of their body meaning there is more pressure that needs to be distributed across a smaller area. [8] The plantar fascia may be relieved at its origin on the calcaneus thanks to the small elevation of the heel given by some styles of footwear. [9]. Therefore, the high amount of pressure causes extra stress on muscles tissues and bones in their feet leading to development of heel pain.

The higher frequency of the condition in the 41-60 years age group may be related to atrophy and thinning of the fat pad in the heel with increasing age, as well as loss of collagen and elastic tissue, limiting shock absorbency and calcaneus protection. With increasing age, this leads to heel pain. [10]

Both men and women are more prone to heel pain with an increase in weight and BMI. [11] One probable reason for this can be the reduced range of motion and increased higher peak plantar pressure with increased weight. The increased fat and body mass results in poor heel function and leads to heel pain.[12]

Ultrasound waves have constant amplitude, width, and pulse interval (fig. 3). Tissue is affected by the intensity, frequency, pulse pattern, duration of action, and application method. [13] In addition to acting as a "internal tissue massage," ultrasound waves affect intracellular pressure, which alters nerve conductivity, produces muscle relaxation, and raises the pain threshold. [14]

Acharya Sushruta clearly indicated that Agnikarma[fig. no.3] can be used for managing the pain originated from Twak, Mamsa, Sira, Snayu, Sandhi, Asthi and specially used word for pain as "Ategyra ruje".[15] The ushna guna produced by Agnikarma helps in pacifying the Vata-Kapha Dosha and helps in reducing the pain. The Agnikarma procedure uses the thermal heat which is delivered with the help of various heat conducting substances for targeting the specific tissues (skin, muscle, tendon, periosteum, joints, vascular region) acting through an inhibitory mechanism called Gate control theory and diffuse noxious theory.[16]

The enhanced tissue warmth and improved local blood flow provides relief in pain and muscle spasm causing a reduction in subjective pain parameters like VAS, VDS and TENDERNESS.

Ultrasound waves cause improved perfusion and oxygenation of tissues resulting in significant reduction in swelling and pain. Ultrasound waves also cause piezoelectric effect at the site of application which reduces the muscle tension, improves microcirculation, and thus increase the range of motion at joints.[17] Better tissue extensibility and reduction in the viscosity of fluid elements in the tissue improves the range of motion (dorsi flexion and plantar flexion). The closing of the physiological gate of pain caused by the heat energy results in the suppression of pain signals delivered by smaller diameter (A and C fibres) and increases joint flexibility. The Ushna guna of Agnikarma pacifying the Vata-kapha dosha reduces the pain and stiffness which facilitated the movement of the joint (fig no.2).[18]

Ultrasound improves ligament and tendon elasticity. Therapeutic ultrasound increases tissue warmth, metabolism, softens the tissue, increases blood circulation, increases tissue chemical activity, increases cell membrane permeability, and increases protein production. Soft tissue absorbs the most energy between 2 and 5 cm. [19] This might be the reason for normalizing patient's functional state and progressive walking distance. Agnikarma acts on dooshit Vata and Kapha doshas by which Vata dosha gets normalized and Kaph dosha Shaman will reduce the stiffness and thus facilitated in walking without pain. Here Agnikarma may accelerate the metabolic process, enhance circulation through vasodilation, minimize edema and hasten repair, all of which can reduce painful stiffness thus helped in restoring Prakruta karma.[18]

As it was the randomized clinical trail with the sample size 30, which is less and study can be done with the other inclusion parameter and for longer duration.

CONCLUSION

Integrated therapy (Agnikarma & Ultrasound therapy) in management of heel pain wsr to Vatakantaka has proved more effective as compared with the standard treatment (Ultrasound therapy). Study can be done with addition of Shamanoushadi with Agnikarma. The duration of surface contact time in Agnikarma can be standardized.

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Conflict of interest

None

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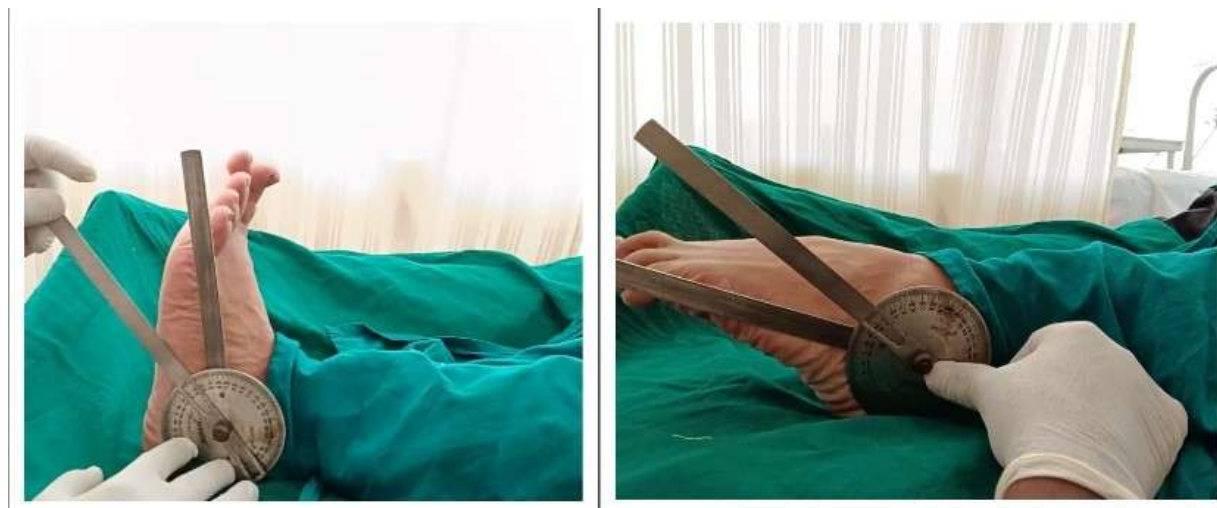


Fig.2 Assessment of ankle joint by goniometry



Fig.3 Various treatment procedure (Ultrasound therapy and Agnikarma)

Table 1- Statistical parameter of group A (Standard group)

Parameter	Mean change	S.D changes	%of changes	Z- value	P- value
VAS	2.53	0.83	41.30	3.4079	0.0007*
VDS	2.60	0.74	43.82	3.4079	0.0007*
Tenderness	1.40	0.51	70.00	3.4079	0.0007*
Plantar flexion	1.87	1.19	4.64	-6.0894	0.0001*
Dorsiflexion	1.60	0.83	7.95	-7.4833	0.0001*
Walking capacity within 10min	20.67	7.04	34.07	-11.3739	0.0001*

Table 2-Statistical parameter of group B (Trial group)

Parameter	Mean change	S.D changes	%of changes	Z- value	P- value
VAS	4.53	1.19	71.56	3.4078	0.0007*
VDS	4.40	1.06	71.77	3.4078	0.0007*
Tenderness	2.00	0.65	96.61	3.4078	0.0007*
Plantar flexion	4.13	1.41	10.35	-11.3739	0.0001*
Dorsiflexion	4.27	1.28	21.48	-12.9111	0.0001*
Walking capacity within 10min	30.00	11.95	51.13	-9.7211	0.0001*

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