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A Case Series to know the Efficacy of Hypodermic Needle over Acupuncture Needle to perform Viddhagnikarma in the management of Pain due to Plantar Fasciitis - A Pilot Study

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Viddhagnikarma is a novel and unique method of pain management. It is the modification of the traditional Agnikarma narrated by Acharya Sushruta where in heat is applied over affected area with desired temperature to alleviate pain. In Viddhagni Karma a monopolar cautery machine probe is used to transmit the temperature through a needle pierced to area of concern. In order to achieve better pain management with minimal piercing and less scar formation, 26 1½ hypodermic needle and acupuncture needles were used in a sample of 10 subjects suffering from plantar fasciitis. It was observed that hypodermic needle was better compared to acupuncture needle in terms of tolerance of heat, minimal scar formation and overall improvement in pain. Hence hypodermic needles were considered over acupuncture needle to conduct Viddhagni Karma in the management of plantar fasciitis.

Keywords: Hypodermic Needle, Acupuncture Needle, Viddhagni Karma, Plantar Fasciitis, Case Series

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Introduction

Plantar fasciitis is the most common cause of pain beneath the heel, making up 11–15% of the foot symptoms requiring professional care among adults. [1] In Plantar fasciitis, inflammation of the plantar aponeurosis at its attachment on the tuberosity of the calcaneum occurs. The pain is worst early in the morning, and often improves with activity.[2] The condition is associated with impaired health related quality of life including poor perception of health status and reduced functional capabilities.[3] The contemporary management such as NSAIDS, heel splints, Extra Carporeal Short Wave Therapy and endoscopic plantar fasciotomy are expensive showed limited success rate.[4]

On scrutinizing Ayurveda for an effective, economical, and simple short-term therapy with non-recurrence in the management of Plantar fasciitis, we come across Vatakantaka a disease with pain in heel.[5] Acharya Sushruta emphasize on using Agnikarma in pain management.[6] It must be Mamsa Dagda, to reach the disorders of deeper structure Asthi, Snayu and Sandhi.[7] Acharya Vangasena specified Agnikarma using Suchi (needle) in Vatakantaka.[8] Suchi renders deeper penetration and minimal scar and is easily available. When needle is pierced at targeted area and heated using monopolar cautery device in order to avoid the repeated heating, it is called Viddhagni Karma. [9]

As there are many varieties of needles are available, to choose ideal needle for the current study was a challenge. Previously few studies were conducted using 26 1½ hypodermic needle. Also, acupuncture needle was used for *Viddha Karma* with minimal tissue damage. So, a pilot study was conducted comparing these two needles to know the better choice. It is observed that hypodermic needle better tolerated the procedure and caused least discomfort to patient. Hence 26 1½ needle was selected for the ongoing study.

Materials and Methods

A single centred prospective open label randomized case series was conducted at Sri Sri college of ayurvedic science and research hospital, with 6 voluntary subjects suffering from plantar fasciitis between June 2023 to May 2024.

Drug source

Materials for *Viddhagnikarma* using hypodermic needle:

- 26 No. Hypodermic needle QS
- Mono polar Cautery machine 1
- Cow's Ghee from ISO certified manufacturer -QS
- Sterile cotton and normal saline QS

Materials for *Viddhagnikarma* using acupuncture needle:

- Acupuncture needle QS
- Cow's Ghee from ISO certified manufacturer -QS
- Sterile cotton and normal saline QS

10 subjects presenting with symptoms of plantar fasciitis between the age group of 21-65 year of age and willing to enrol to the study were recruited for the study from the OPD of Sri Sri College of Avurvedic Science and Research Hospital, Bengaluru. Subjects with comorbidity and other foot pathologies were excluded. They were randomly assigned to two groups. 3 sittings of Viddhagni Karma with 7 days interval were planned. Entire procedure was performed and monitored by researcher and adopted standard operating procedures to ensure uniformity and no compromise in quality.

In each sitting, vitals were monitored, assessment of parameters were performed and documented.

Pre-Operative:

- Patients were taken in prone position and heel area was cleaned with sterile water.
- Maximum tenderness area was marked.
- Monopolar cautery machine kept ready with presetting at 0.50 mHZ
- Placement of patient plate / earthing plate under thigh of the patient.

Operative:

- 1. In group A $\it Viddhagnikarma$ was performed using 26 $1\frac{1}{2}$ hypodermic needle.
- 2. In group B *Viddhagnikarma* was performed using acupuncture needle.
 - Needle was pierced about 0.5 cm through the skin of the heel at marked points

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- Needle was touched with cautery probe in sequence for 1sec each
- Based upon pain threshold exhibited by the patient, cautery setting was raised up to 2Mhz
- The cycle was repeated 2 more times after a 2-5 minutes interval depending upon the capacity of individual patients.[10]

Post-Operative:

- Needles were removed from site
- Ghee was applied over area
- Patients were allowed take rest.



Figure 1: Showing materials required for Viddhagnikarma



Figure 2: Showing monopolar cautery machine



Figure 3: Showing Viddhagnikarma Hypodermic needle in group A



Figure 4: Showing Viddhagnikarma using Acupuncture needle in group B

Follow-Up

Subjects were asked to revisit OPDs on 28th and 42nd day and reassessment of parameters by doing clinical examination was performed. No loss of follow-ups was noticed.

Assessment Criteria

Diagnosed based on comprehensive history and physical examination.

Subjective:

- 1. Pain: Assessed using Visual Analogue Scale.[11]
- 2. Foot Function Index.[12]

Objective:

- 1. Tenderness.[13]
- 2. Windlass test.[14]

Observation

Demographic data

Among the 10 subjects, 5 were male and 5 females both belong to active lifestyle category. All had bilateral plantar fasciitis, predominantly on right foot. Majority of patients belongs to 30-40 year of age group.

Pre-operative

Procurement of both varieties of needles was easy & was done through Surgical (hypodermic needle) & Amazon online portal (acupuncture needle). They were made up of stainless steel by ISO certified manufacturers & come in sterile packing ensuring quality. Further their size & calibre were similar.

Operative

- Around 5-6 needles were required for single heel.
- They were placed at minimum distance of 1 cm.
- Piercing with hypodermic needle over heel skin was easy compared to acupuncture needle.
- On touching needle with cautery probe, both needles were withstanding heat for about 2 seconds. Upon continuing heat, acupuncture needles were getting cut while hypodermic needle better withstood prolonged heat application.
- Subjects observed more heat in acupuncture needle.
- Both needles were leaving minimal scar at the site of piercing
- Subjects had better threshold with each cycle of procedure and cautery setting were raised up to 2 MHz.

Post-operative

- Subject felt mild burning sensation which eventually reduced after application of ghee.
- All subjects adhered to intervention protocol and advice provided. They were regular to follow up and reminded on regular basis.
- No complications and adverse events noted during trial.

Result

1. Pain:

In Group A, there was a significant reduction in pain from Day 0-14 (p < 0.05), reflecting noticeable improvement. The highly significant difference between Day 0 and Day 42 (p < 0.001) indicates substantial long-term pain relief by the end of the study period.

In Group B, the p-value remained greater than 0.05, through-out the trail, indicating no statistically significant difference in pain levels over time.

However, on comparing between the groups, on day 28, there is statistically significant difference in the median values between the two groups (P = 0.032)

2. The Foot Function Index:

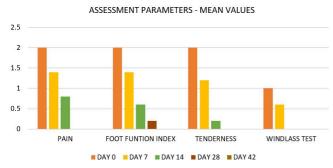
In Group A, showed consistent improvement, with significant changes from Day 0 to Day 28 (p < 0.05 across all intervals), implying that foot function steadily improves within the first month. However, between Day 28 and Day 42, the improvement levels off, as seen in the non-significant difference.

In Group B, however, all comparisons yielded non-significant results (p > 0.05), meaning there was no meaningful improvement in foot function across the measured time points.

In between the groups, though there was no statistically significant difference (P = 1.000) in the initial phase, on day 28, there was a statistically significant difference (P = 0.032)

Table 1: Showing Comparison of parameters in Group A based on level of significance

Parameters	Day 0 vs	Day 7 vs	Day 14 vs	Day 28 vs	Day 0 vs
	Day 7	Day 14	Day 28	Day 42	Day 42
Pain	Non-	Significant	Non-	Non-	Highly
	significant	p<0.05	significant	significant	significant
	p>0.05				p<0.001
Foot	Significant	Significant	Significant	Non-	Highly
Function	p<0.05	p<0.05	p<0.05	significant	significant
Index				p>0.05	p<0.001
Tenderness	Significant	Significant	Non-	Non-	Highly
	p<0.05	p<0.05	significant	significant	significant
					p<0.001
Windlass	Non-	Non-	Non-	Non-	Highly
Test	significant	significant	significant	significant	significant
	p>0.05	p>0.05	p>0.05	p>0.05	p<0.001



Bar diagram 1: Showing assessment of parameters in Group A based on mean value

3. Tenderness:

In Group A, similar to pain, there is significant improvement between Days 0 and 14, followed by non-significant changes thereafter. However, the difference from Day 0 to Day 42 is highly significant, reflecting a considerable reduction in tenderness over the entire period.

But in Group B, showed no significant improvement across all time intervals (p > 0.05). The consistent lack of significant change suggests the treatment was not effective in reducing localized tenderness or sensitivity.

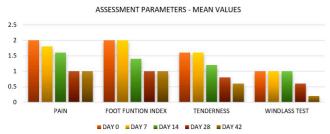
In between the groups, there was no statistically significant difference ((P = 0.690) except on day 28(P = 0.032)

4. The Windlass Test:

In Group A, it remains non-significant through all intermediate time points, showing little short-term change. However, the highly significant difference from Day 0 to Day 42 (p < 0.001) indicates that significant improvements are only evident in the long term.

In Group B, it showed non-significant results (p > 0.05) across all time intervals.

In between the groups, there was no statistically significant difference throughout the trial.



Bar diagram 2: Showing assessment of parameters in Group B based on mean value

Table 2: Showing comparison of parameters in Group B based on level of significance

Parameters	Day 0 vs	Day 7 vs	Day 14 vs	Day 28 vs	Day 0 vs
i urumeters	Day 7	Day 14	Day 28	Day 42	Day 42
Pain	Non-	Non-	Non-	Non-	Non-
	significant	significant	significant	significant	significant
	p>0.05	p>0.05	p>0.05		
Foot	Non-	Non-	Non-	Non-	Non-
Function	significant	significant	significant	significant	significant
Index	p>0.05	p>0.05	p>0.05		
Tenderness	Non-	Non-	Non-	Non-	Non-
	significant	significant	significant	significant	significant
	p>0.05	p>0.05			
Windlass	Non-	Non-	Non-	Non-	Non-
Test	significant	significant	significant	significant	significant
	p>0.05	p>0.05	p>0.05		

Overall Interpretation (Day 0 vs Day 42)

Overall, in Group A the data suggests early and sustained improvements in pain, foot function, and tenderness, with the most significant long-term changes becoming evident by Day 42

When comparing the starting point (Day 0) with the final time point (Day 42), in Group B, none of the parameters - pain, foot function, tenderness, or the Windlass test, showed statistically significant improvement. The data suggests the intervention failed to provide significant clinical benefits for the conditions being treated or measured.

Clinical Significance

The non-significant changes in Group B, suggest that the treatment protocol or therapeutic approach utilized in the study was not effective in significantly altering the pain, foot function, or tenderness over the 42 days. This may warrant a re-evaluation of the treatment regimen, or alternative therapeutic approaches.

Discussion

Agnikarma, the superior Para surgical technique of Ayurveda is known to achieve cure and non-recurrence in pain pathology. *Viddhagni* is the modification of *Agnikarma* where in heat transfer to tissue is achieved by needles touched using the monopolar cautery probe. Though previous studies used 26 1 ½ hypodermic needle for the procedure, it is ideal to compare similar needle before standardizing it.

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So, in the current study, two varieties of needles were compared to standardize them for upcoming trial on larger sample size. In group A, recruited 5 subjects of plantar fasciitis were treated with *Viddhagnikarma* using 26 1½ hypodermic needle while in group B, 5 subjects of plantar fasciitis were treated with *Viddhagnikarma* using acupuncture needle. Uniform pre-operative operative and post-operative measures were followed to avoid bias. Based on the observation done during study, following points were noticed:

- Both the needles were easy to procure, economical and comes in pre sterilized packs.
- They resembled each other in terms of size &, material.
- The long shaft of both needles ensured hassle free transfer of heat from cautery probe to individual needles.
- But acupuncture needle could not sustain heat for longer time and eventually cut during application of heat. On the other hand, hypodermic needles were better tolerated the heat. It could be attributed to the lesser heat retention capacity of acupuncture needle.
- Subjects also noticed more discomfort with the acupuncture needle. These needles were slender compared to hypodermic needles which might have demanded more effort from operator to pierce the thick heel skin.
- Both needles left minimal scar at site of piercing as both needles were of very thin caliber.
- Clinically, marked overall improvement was noticed in group A while in group B, though improvement noticed, it was not statistically significant. Both needles being thin yet sharp, efficiently rendered heat to targeted tissue.
- Among parameters, both groups showed signif. improvement in pain & tenderness, Group A was statistically better than Group B. This could be due to targeted delivery of heat to affected part.
- Foot function index showed significant improvement in Group A compared to Group B implies the superiority of hypodermic needle over acupuncture needle.
- The non-significance improvement in Windlass test through all intermediate time points in both groups shows little short-term change. It could be also attributed to insufficient sample size.

In current study, possible compounding factors were minimized by applying randomization, avoiding comorbidities among subjects and following uniform protocol throughout the sample.

Further, in all cases swell trained qualified single researcher conducted the study among the given sample. But as it was operator based treatment, double blinding could not be done.

Conclusion

Thus, as per the current study, it can be concluded that hypodermic needles are the better choice over acupuncture needle in performing *Viddhagnikarma*. Few single case studies reported earlier also suggests using hypodermic needle.

Though acupuncture needle is regularly used in management of pain, it may not be the ideal choice to render the heat while using mono-polar cautery.

Patient Perspective

In few patients with bilateral plantar fasciitis, the dominant symptomatic side was taken to study. The other side was performed with *Viddhagni Karma* using other needle. They were able to compare between the needles and appreciated hypodermic needle over acupuncture needle.

Informed Consent

Written informed consent was obtained from all the subjects after explaining the procedure with patient information sheet.

Other relevant disclosures: The current pilot study is not presented at any conference or regional meeting.

The report is formatted as per **Preferred Reporting of Case Series in Surgery(PROCESS) 2023 guidelines.**[15]

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