# A CLINICAL STUDY ON EFFICACY OF *MADANPHALADI LEPA* IN *PĀDADĀRĪ*

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## ABSTRACT

*Pādadārī* (cracked feet) is one of the most negligible diseases. In *Āyurveda, Pādadārī* is described in *kṣudra rōga* in *laghutrayees* and *Suśruta-samhita*. Many *Bāhya* (local) *lepās* are mentioned in *Pādadārī cikitsā* .In *Yōgaratnākara Madanphalādi lepa* is mentioned for "*Pādadārī*. So this study is carried out to know the efficacy of *Madanphalādi lepa* in *Pādadārī*. It was a randomized uncontrolled study .In the present study *Madanphalādi lepa* was tested against 7 parameters and had seen clinically effective in healing and decreasing the no. of cracks. It has been proved that *Madanphalādi lepa* is effective in *Pādadārī* by relieving pain, burning sensation and itching without any adverse effect. It is safe, can be easily prepared and cost effective.

**Keywords:** *Pādadārī, Madanphalādi lepa, kṣudra rōga*

## INTRODUCTION

Now days in developing countries like India, one has to compete for good economical status. In order to get such desired lifestyle, one has to face continuous busy and stressful life. All these factors including poor hygiene and negligence are predominating to develop *Pādadārī*. People may ignore this problem due to lack of consciousness about foot care or may be due to costly drugs.

The signs, symptoms, pathogenesis and treatment of *Pādadārī* are mentioned in details which indicate that this disease was affecting the people since ancient times[1]. It is mentioned that *Pādadārī* is caused due to *Vātaprakōpaka hetu atichankramaṇa* (i.e. excessive walking especially barefooted) and *rukṣa guṇa*[2].It can lead to severe symptoms as acute pain, burning sensation, itching and even bleeding from cracks. Many *Bāhya (*local) *lepās* are mentioned in *Pādadārī cikitsā* in *Āyurvedic samhitā*. In *Yōgaratnākara Madanphalādi lepa* is prescribed for "*Pādadārī*"[3].

## AIMS AND OBJECTIVES

This study is carried out to know the efficacy of *Madanphalādi lepa* in *Pādadārī*.

## MATERIALS AND METHODS-

The clinical study was done in Seth Tarachand Ramanath Charitable Hospital, Pune 11.
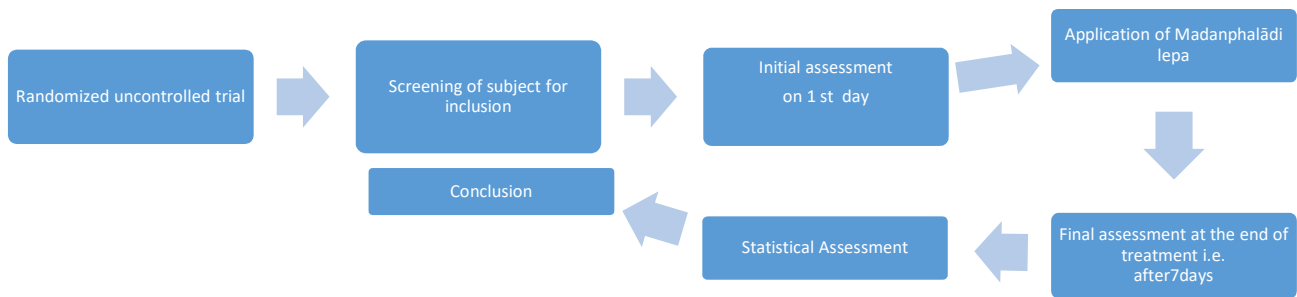
### 1. Selection of patients:

Randomized, uncontrolled clinical trial was carried out on 30 patients.

### Inclusion criteria:

- Patients having signs and symptoms of *Pādadārī* were included irrespective of sex, religion, economical status, education, occupation.
- Patients between age16 to 60 years were included.
- Patients who had given written consent.

### Exclusion criteria:

- Patients with bleeding cracks.
- Infectious cracks

### 2. Medications permitted during trials:

- Ongoing medications such as antihypertensive, anti diabetic treatment etc

### 3. Study Design



### 4. Preparation of *Madanphalādi lepa*

1. A pot was taken and heated on gas. Then *Siktha* (bee wax) was added in it. Allowed it to melt
2. *Madanphala cūrṇa* and *Sāmudra lavaṇa cūrṇa* were taken and mixed in the above melted *Siktha*.
3. It was mixed properly and then *navanīta* was added as per requirement.
4. The pot of mixture was kept in the hot water tub and was mixed continuously till it became smooth. Ointment was kept in sterile and clean container.

### 5. Method of administration:

- <u>Route</u> -     Topical (skin)
- <u>Form</u>-     Ointment
- <u>Kāla</u>-     At night
- <u>Duration</u> -   7 days

On the first visit patients were explained the nature of medicine, its purpose, its method of application. Before application thorough cleaning of the feet was advised. Patients were instructed to keep the feet in lukewarm water for 15 to 20 minutes and to clean with a brush or foot scrapper, then to wrap with a clean cloth and allow the feet to dry. Then *lepa* was applied uniformly over the planter aspect of the feet till all the fissures of feet get filled with *lepa* or ointment.

They were asked to use socks and sleepers the whole day during the treatment span.

**CRITERIA OF ASSESSMENT:**
1. A special case paper was prepared incorporating all signs and symptoms of *Pādadārī*.
2. The photographic record of patient's lesion was kept before and after treatment.
3. Gradation scale according to sign and symptoms was assessed before and after treatment on the basis of changes in gradation.
4. Visual analog scale was used.

**Efficacy Parameters:**
➢ Numbers of *dārī* (fissure)
➢ Measurement of *dārī*
➢ Visual analog scale.

**Table 1:** Gradation Chart

| Signs ↓ | Grade → | 0 (No) | 1 (Mild) | 2 (Moderate) | 3 (Severe) |
|---|---|---|---|---|---|
| 1.Average Length of *dārī* | | Absent | < 1cm | 1.0 – 1.5cm | > 1.5 cm |
| 2.Average Width of *dārī* | | Absent | < 0.1cm | 0.1-0.2cm | >0.2cm |
| 3. Distribution of *dārī* | | Absent | At heal | Heal with whole border of feet | Whole foot |
| 4. Number of *dārī* | | Absent | <20 | 20 to 30 | > 30 |
| 5.symptoms *Śūla, Dāha* and *Kaṇḍū* | | Absent | Precipitating Time to time | Continuous during movement | Unable to do any movement |

**Visual analog scale (VAS) -**
Visual analog scale was used to assess 3 parameters, mentioned in *Pādadārī* namely *śula* (Pain), *dāha* (Burning sensation), *kaṇḍū* (itching).

| % | Result |
|---|---|
| 0 | No improvement |
| 1-25 | Poor |
| 26-50 | Average |
| 51-75 | Good |
| 76-100 | Excellent |

**Percentage of efficacy:**
**OBSERVATIONS AND RESULTS**

**Figure 1:** Etiological Factor Wise Classification
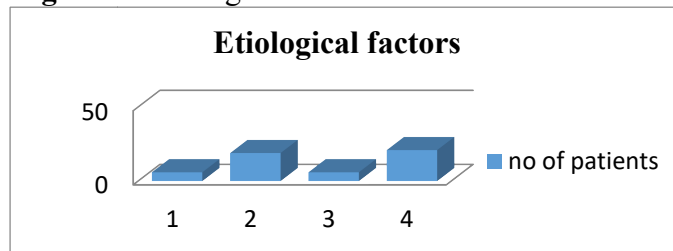


**Table 1**

| Sr No. | Nidāna | No. of patient | % of Patients |
|---|---|---|---|
| 1 | Exessive walking[2] | 6 | 20% |
| 2 | Excessive contact with cold | 19 | 63% |
| 3 | Not using footwear regularly | 6 | 20% |
| 4 | Others(*vāta- pitta prakōpak* ) | 21 | 70% |

**Figure 2:** Sex Wise Classification
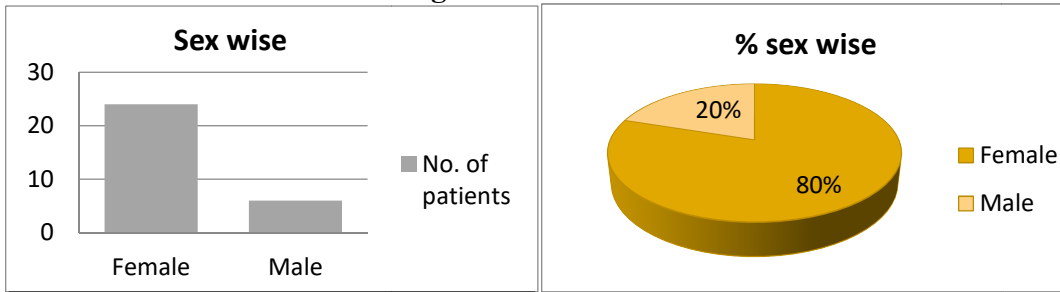


## Table 2

| Sex | No. of patients | % of patients |
|---|---|---|
| Female | 24 | 80% |
| Male | 6 | 20% |
| Total | 30 | 100% |

**Figure 3:** Prakriti Wise Classification
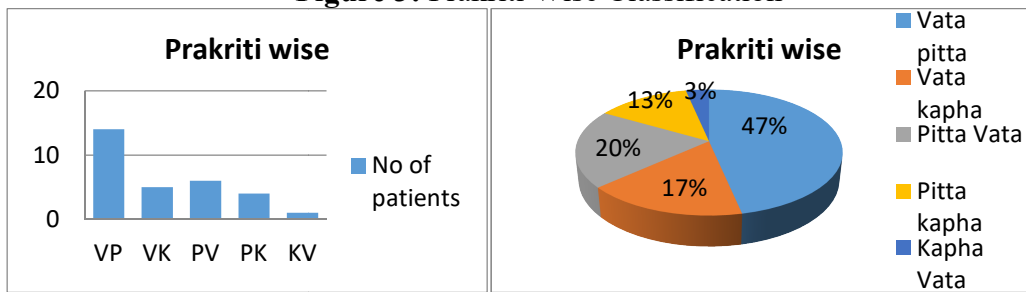


## Table 3:

| Prakriti | Vata pitta | Vata kapha | Pitta vata | Pittakapha | Kapha vata | Total |
|---|---|---|---|---|---|---|
| **No. of patients** | 14 | 5 | 6 | 4 | 1 | 30 |
| **% of patients** | 47% | 17% | 20% | 13% | 3% | 30% |

**Figure 4:** Classification according to generalized symptoms
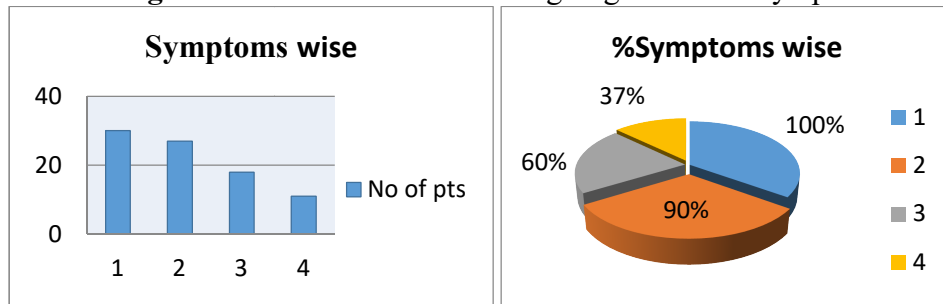
**Table 4**

| Sr. no. | Symptoms | No. of patient | % of patient |
|---|---|---|---|
| 1 | *Pādadāraṇa* | 30 | 100% |
| 2 | *Pādaśūla* | 27 | 90% |
| 3 | *Pādadāha* | 18 | 60% |
| 4 | *Pādakaṇḍū* | 11 | 37% |

**Figure 5: Classification of relief in *Śūla* as Per VAS**
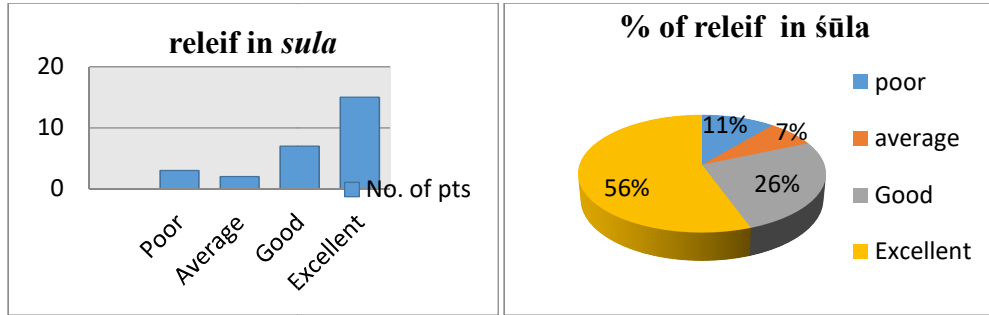


**Table 5**

| Result in *Śūla* | Poor | Average | Good | Excellent | Total |
|---|---|---|---|---|---|
| No. of patient | 3 | 2 | 7 | 15 | 27 |
| % of patient | 11% | 7% | 26% | 56% | 100% |

**Figure 6:** Classification of relief in *dāha* as per VAS
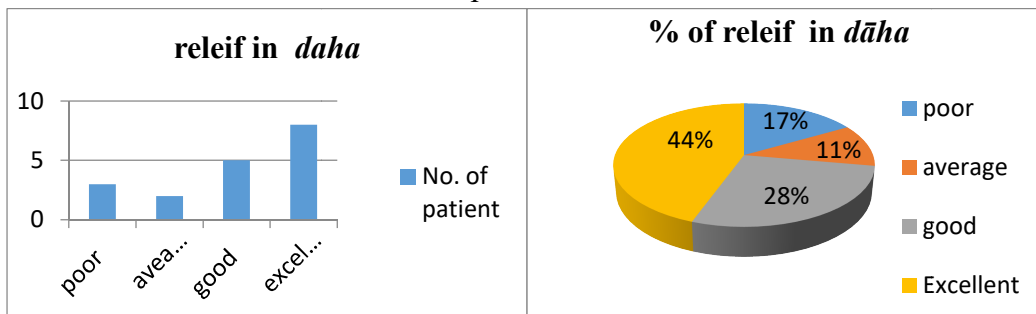


**Table 6**

| Result in dāha | Poor | Average | Good | Excellent | Total |
|---|---|---|---|---|---|
| No. of patient | 3 | 2 | 5 | 8 | 18 |
| % of patient | 17% | 11% | 28% | 44% | 100% |

**Figure 7:** Classification of relief in *kaṇḍū* as per VAS
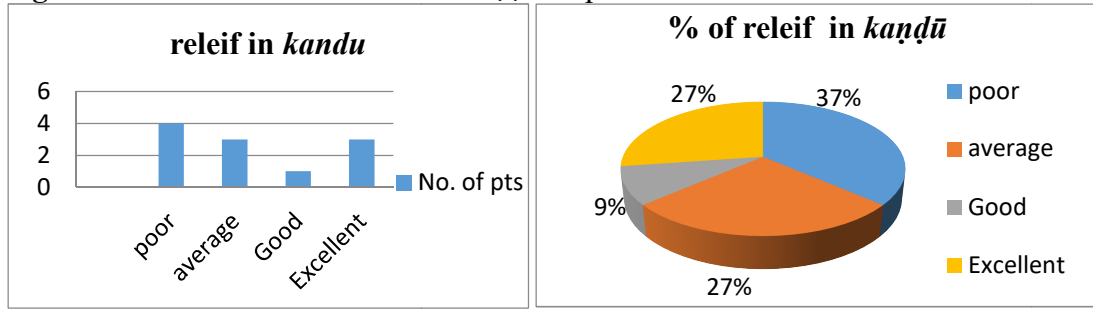


### Table 7

| Result in kaṇḍū | Poor | Average | Good | Excellent | Total |
|---|---|---|---|---|---|
| No. of patient | 4 | 3 | 1 | 3 | 11 |
| % of patient | 37% | 27% | 09% | 27% | 100% |

**Figure 8:** Total effect of treatment in *Pādadārī* in 7 days



### Table 8

| Total Result in *Pādadārī* | Poor | Average | Good | Excellent | Total |
|---|---|---|---|---|---|
| No. of patient | 6 | 12 | 2 | 10 | 30 |
| % of patient | 20% | 40% | 07% | 33% | 100% |

According to global assessment, among the 30 patients of *Pādadārī*, 10(33% ) patients got excellent relief (76-100%), 2(7%) patients got good relief (51-75%), 12(40%) got average relief (26-50%) and 6(20%) got poor relief (1-25%)

**STATISTICAL ANALYSIS**

As present study is randomized and uncontrolled with paired data of independent observations from one sample, Paired't' test is applied[4]. According to statistical data (Table 7.1 as per gradation) applied for 7 parameters and VAS scale (Table 7.2) *Madanphalādi lepa* is significantly effective in *Pādadārī*.

**Table 7.1 (as per gradation)**

| S.N. | Parameter | n | $\overline{X}$ | S.D. | S.E. | t cal | P | Significance |
|---|---|---|---|---|---|---|---|---|
| 1 | Total No. of cracks | 30 | 1.13 | 0.92 | 0.17 | 6.64 | <0.001 | Highly significant |
| 2 | Avg. length of cracks | 30 | 1.00 | 1.08 | 0.20 | 5.00 | <0.001 | Highly significant |
| 3 | Avg. width of cracks | 30 | 0.83 | 0.73 | 0.13 | 6.38 | <0.001 | Highly significant |
| 4 | Distribution of cracks | 30 | 0.73 | 0.74 | 0.13 | 5.61 | <0.001 | Highly significant |
| 5 | Śūla | 27 | 1.26 | 0.93 | 0.18 | 7.00 | <0.001 | Highly significant |
| 6 | Dāha | 18 | 0.89 | 0.54 | 0.13 | 6.85 | <0.001 | Highly significant |
| 7 | Kaṇḍū | 11 | 0.45 | 0.52 | 0.16 | 2.81 | <0.05 | Significant |
| 8 | Total effect | 30 | 5.56 | 2.73 | 0.50 | 11.12 | <0.001 | Highly significant |

**Statistical data Table 7.2 (as per VAS)**

| Sr.no | Symptom | n | $\overline{X}$ | S.D. | t cal | P | Significance |
|---|---|---|---|---|---|---|---|
| 1 | Śūla | 27 | 7.44 | 2.95 | 13.10 | <0.001 | Highly significant |
| 2 | Dāha | 18 | 7.11 | 3.12 | 9.73 | <0.001 | Highly significant |
| 3 | Kaṇḍū | 11 | 5 | 3.5 | 4.73 | <0.001 | Highly significant |

## DISCUSSION

- Clinically it was observed that females (observation table 2) and patients having *Vata-pitta prakruti* (observation table 3) were more prone to *pādadārī* due to incidence of etiological factors (observation table 1). Also symptoms like *pādaśūla, pādadāha, pādakaṇḍū and raktastrāva* which are not mentioned in *Āyurvedic samhitā* were also found in clinical trials. Clinically it was more effective in *pādaśūla* than *pādakaṇḍū*. No side effect or toxic effect of *Madanphalādi lepa* was seen.
- In the present study *Madanphalādi lepa* was tested against 7 parameters and had seen clinically effective in decreasing the no. of cracks, *śūla* and *dāh*a. *Madanphalādi lepa* had shown quick results in *pādaśūla* and *pādadāh*a within 4-5 days of treatment and filling of cracks totally within 7 days in 33% of the patients.

- It was also observed that patients who had followed *pathya- apathya* (e.g. using foot wears, avoiding contact with cold etc) properly got good results.
- Total effect of *Madanphalādi lepa* is *Vāta-Pittaśāmaka, Vraṇśōdhaka, Vraṇarōpaka, Vedanāsthāpaka* and *Dāhaśāmaka.* So it was seen effective in *Pādadārī*.
- The trial conducted in this study was a small scale trial including 30 patients with a small duration of 7 days. But after studying 15 patients for one more week (total 14 days), it was observed that 12 patients (80%) were totally symptom free. *Madanphalādi lepa* gives better effects in long duration with proper *pathyapālana*.

## CONCLUSION

- After analyzing all the data and the observations, we concluded that application of *Madanphalādi lepa (*ointment) is effective in Pādadārī.

- In *Pādadārī* symptoms like *dāha, kaṇḍū*, and bleeding is present which are not mentioned in *Āyurvedic* texts.
- *Madanphalādi lepa* (ointment) was more effective in symptoms like pain and burning sensation than itching approximately within 4 to 5 days. The fissures were filled totally within 7 days in 33% of the patients.
- *Madanphalādi lepa* had shown excellent result in 33% of the patients, good result in 7% and average result in 40% of the patients within 7 days.

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