Management of *Padadari* (cracked feet) with *Rakta Snuhi* (*Euphorbia caducifolia* Haines.) based formulation: An open-labeled clinical study

Shashi Gupta, Rabinarayan Acharya

Department of Dravyaguna, Institute for Post Graduate Teaching and Research in Ayurveda, Gujarat Ayurved University, Jamnagar, Gujarat, India

Abstract

Introduction: Ayurveda considers, *Padadari* (cracked feet) as disease condition, under *Kshudra Kushtha* (minor diseases of skin). Cracked feet also known as heel fissures is a common foot problem characterized by yellowish color of the skin on the heel of the foot, hard skin growth, hardening and cracks in the feet associated with pain, bleeding or itching. Vaidya Manorama, Ayurvedic compendia, recommended *Snuhi* oil as a remedy for *Padadari*. An open-labeled clinical trial has been conducted to evaluate the effect of *Rakta Snuhi*-based formulation in *Padadari*. **Materials and Methods:** *Snuhi* oil was prepared by mixing *Saindhava Lavana* (Rock salt) 24 g; 300 ml latex of *Rakta Snuhi* (*Euphorbia caducifolia*); 4.8 l. of water, *Sarshapa Taila* (mustard oil) 1.2 l. and further heating of oil, following classical guidelines of *Sneha Kalpana*. For better acceptability, the medicated oil was then gradually mixed with "Aerosil," a thickener, for converting the mixture into gel form. Twenty-six patients, diagnosed with *Padadari*, were treated by applying 3 g (or as per requirement) of *Rakta Snuhi Ksheera* gel twice daily for 21 consecutive days. **Results:** Response to the treatment was recorded on a weekly basis and therapeutic effect was evaluated through symptomatic relief. **Conclusion:** The study yielded statistically highly significant results in symptoms such as cracks associated with pain (*P* < 0.001), *Rukshata* (dryness) (*P* < 0.001) and *Kandu* (itching) (*P* < 0.001).

Keywords: Cracked feet, Euphorbia caducifolia, Kshudra Kushtha, minor disease, Padadari, Rakta Snuhi

Introduction

Ayurveda treatise considers certain disease conditions under *Kshudra Kushtha* (minor diseases of skin) and categorizes *Padadari* under this group of diseases.^[1,2] Cracked feet is a clinical condition, having dry, itchy skin, hardness around the rim of the heel and cracks or fissures on the outer edge of the heel.^[3] The distinct branch dealing with signs and symptoms along with treatment called as Podiatry.^[4]

Ayurvedic recommendation of the management of *Padadari* includes *Siravedha* (puncture) of the veins of the feet and treatment of affected part with fomentations and unguents. Ayurveda also recommends plastering of the affected part with an ointment composed of *Madhucchishta* (wax), *Vasa* (lard), *Majja* (marrow), powder of *Sarja Rasa* (resin obtained from *Shorea robusta*), clarified butter, *Yavakshara* (alkaline formulation prepared from ash of *Hordeum vulgare*) and *Gairika* (Red ochre). [1] Different compound formulations such as *Upodikadi* oil and *Madhucchishtadi* paste are also

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10.4103/ayu.AYU_57_18

recommended for the treatment of *Padadari* which contains *Sarja Rasa* (resin obtained from *Shorea robusta*), *Saindhava Lavana* (rock salt), *Madhu* (honey), *Ghrita* (ghee) and mustard oil. The trial drug, *Snuhi* oil, a compound formulation, recommended by two known Ayurvedic Pharmacopoeia Bharata Bhaishajya Ratnakara and Vaidya Manorama, The a remedy for *Padadari* as an external application. A recent review of the literature shows that no scientific study had been reported on efficacy of this classical formulation on *Padadari*. *Euphorbia caducifolia* is a commonly available plant in Saurashtra region of Gujarat and also one of the botanical sources of *Snuhi*.

Address for correspondence: Dr. Shashi Gupta, PhD. Scholar, Department of Dravyaguna, Institute for Post Graduate Teaching and Research in Ayurveda, Gujarat Ayurved University, Jamnagar - 361 008, Gujarat, India. E-mail: shashi.gpt@gmail.com

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How to cite this article: Gupta S, Acharya R. Management of *Padadari* (cracked feet) with *Rakta Snuhi* (*Euphorbia caducifolia* Haines.) based formulation: An open-labeled clinical study. AYU 2018;39:208-12.

Aims and objectives

The aim is to evaluate the effect of *Rakta Snuhi Ksheera* gel in treating *Padadari* (cracked feet) through an open-labeled clinical trial.

Materials and Methods

Preparation of Snuhi gel

A classical Ayurvedic formulation "Snuhi Taila," recommended by Bharata Bhaishajya Ratnakara and Vaidya Manorama, was prepared by mixing Saindhava Lavana (rock salt), latex of Rakta Snuhi (E. caducifolia), Sarshapa Taila (mustard oil) and water, following recommended methods of Sneha Kalpana (procedure for medicated Ghrita preparation). [8] Details of the ingredients of drugs are presented in Table 1.

Selection of patients

Clinically diagnosed 30 patients of *Padadari* (Cracked feet, heel fissures) visiting an outpatient department of the Dravyaguna, I.P.G.T. and R.A., after obtaining the informed consent were registered. The trial was approved by the Institutional Ethics Committee (PGT/7/-A/ethics/2015-16/1470 dated: 25-08-2015) and was registered in the Clinical Trial Registry of India (CTRI) (Reg. no. CTRI/2016/02/006687 (Registered on: 26/02/2016).

Inclusion criteria

Patients aged between 18 and 70 years of either sex, with classical sign and symptoms^[3] of *Padadari* (dry, itchy skin, hardness around the rim and cracks or fissures on the outer edge of the heel; deep fissures, bleeding and painful; infected fissures, cause a great deal of pain and discomfort) and having chronic exposure to water, dust, dryness were included in the study.

Exclusion criteria

Patients aged <18 years and >70 years, with any suppurative infections, chilblains and with the history of allergic or hypersensitive reaction to any ingredients of the regimen were excluded from present clinical trial.

The detail of application of formulation is presented in Table 2.

Criteria for assessment

Details of self-assessment for the efficacy of the gel were questioned and were noted. Photography was also taken. Responses to the treatment were evaluated using a specially prepared grading scale for clinical features. Grading of the signs and symptoms of *Padadari* is given below.^[3]

Cracks associated with pain

- 0 = No pain
- 1 = Mild pain in cracked areas
- 2 = Moderate pain in cracked areas
- 3 = Severe pain in cracked areas and the patient is unable to walk in the sun due to pain
- 4 = Sleep is disturbed due to pain at cracked areas.

Table 1: Details of the ingredients of the Rakta Snuhi gel

Ingredients	Quantity
Rakta Snuhi Ksheera (Euphorbia caducifolia latex)	300 ml
Sarshapa Taila (mustard oil)	1.2 L
Saindhava Lavana (rock salt)	24 g
Water	4.8 L
Aerosil	84 g

Table 2: Details of application of formulation

Subject	Group
Drug	Rakta Snuhi Ksheera Gel
Dosage form	Gel
Dose	3 g, or as required, for the affected area of patches
Route	Local application
Time	Morning 8 A.M., night 9 P.M.
Duration	21 days
Follow-up	After 7 days

Cracks of the feet

- 0 No cracks
- 1 Mild 1–2 cracks
- 2 Moderate 3–15 cracks
- 3 Severe 16–25 cracks
- 4 Very severe more than 25.

Depth of the crack

- 0 = No cracks/fissures in the feet
- 1 = One or two superficial cracks/fissures in the feet
- 2 = Some superficial cracks/fissures in the feet
- 3 = Deep cracks/fissures in the feet but does not bleed
- 4 = Deep cracks in the feet and sometimes bleeding.

Roughness in the feet

- 0 = No roughness in the feet
- 1 = Slight roughness to touch in the feet
- 2 = Mild roughness in the feet that can be seen and felt
- 3 = Moderate roughness that can be easily seen and felt
- 4 = Coarse roughness that can prominently seen and felt.

Dryness of the feet

- 0 = No dryness
- 1 = Slight dryness to touch in the feet
- 2 = Mild dryness in the feet that can be seen and felt
- 3 = Moderate dryness in that can be easily seen and felt
- 4 = Severe dryness that can prominently seen and felt.

Itching of the feet

- 0 = No itching
- 1 = Occasionally feels itching sensation
- 2 = Intermittently feels itching sensation
- 3 = Often feels itching sensation
- 4 = Always feels itching sensation.

Criteria for assessment of the overall effect of therapy

The total effect of therapy was assessed considering the overall improvement in signs and symptoms. After the completion

of the treatment course, the total effect was assessed in the following categories.

Total effect of therapy

Steps for calculating the overall percentage of improvement of individual patient:

 Percentage improvement in each patient of every symptom was calculated by the formula

$$\frac{(B.T-A.T)}{B.T} \times 100$$

- ii. Average of the percentage improvement was calculated
- iii. The obtained results were measured according to the grades given in Table 3.

Statistical analysis

The obtained data were analyzed statistically using the Student's paired t-test, for difference in score before and after the treatment and level of value of P < 0.05 was considered as statistically significant (Sigmastat-Software).

Observations and Results

Total 30 patients were registered, among them 26 patients completed the treatment and 4 discontinued due to their personal reasons. Almost 40% of patients belonged to the age group of 18–30 years; among the registered patients, only 13.33% were male and 86.67% were females and about 96.67% of the patients in the present study belonged to Hindu religion, whereas 3.33% belonged to Muslim religion [Figure 1]. Effect of therapy, on chief complaints and associated complaints are showed in [Figures 2 and 3]. There was statistically highly significant results in symptoms such as cracks associated with pain (P < 0.001), Rukshata (dryness of the feet) (P < 0.001) and Kandu (itching of feet) (P < 0.001) [Figure 4]. Effect of Rakta Snuhi gel in one case of Padadari (cracked feet) is presented in Figure 5.

Statistical analysis on the effect of therapy

There was mild-to-marked improvement in the score after treatment. One patient did not show any improvement. Two patients showed marked improvement and complete remission in each. Mild-to-moderate improvement was seen in the rest of the patients in the symptoms of *Padadari*.

Discussion

The test drugs formulation is composed of latex of *Euphorbia* caducifola, *Saindhava Lavana* and mustard oil where in mustard

Table 3: Grades for assessment of overall therapy		
Criteria	Percentage	
Complete remission	75-100 - complete remission	
Marked improvement	51-74	
Moderate improvement	26-50	
Mild improvement	1-25	
Unchanged	0	

oil forms the base. Mustard oil is having *Snigdha* (unctuous), *Ushna* (hot) and *Kapha Vataghna* (pacify to *Kapha* and *Vata Dosha*) properties and possesses *Krimighna* (wormicidal), *Kandughna* (anti-pruritic) and *Kushthaghna* (treating skin diseases) properties.^[9]

The Snuhi Ksheera (latex of E. caducifolia) is having Ushna Virya (hot potency), Laghu (light), Snigdha (unctuous) property and pacifies to Kapha and Vata Dosha. [10] Saindhava Lavana is also stated to have Laghu (light), Snigdha (unctuous), Tridohaghna (pacifies to Tridosha) and Sukshma (subtle) properties. [11]

In case of *Padadari*, a precise description about its pathogenesis is not available in the classical texts of Ayurveda. Features of crack feet like dry, hard, thickened skin around the rim of the heel can be considered due to Vitiated *Vata Dosha* leading to *Padadari*. Exacerbations of *Padadari* are seen after constantly having close contact of feet with water.^[12] Cold climate leads to aggravation of *Vata Dosha*, thus leading to exacerbations of

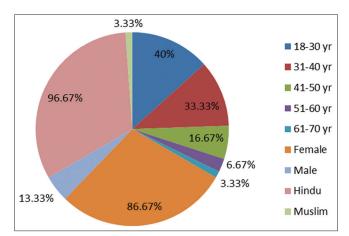


Figure 1: Demographic data

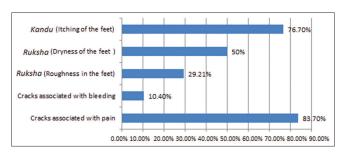


Figure 2: Chief complains

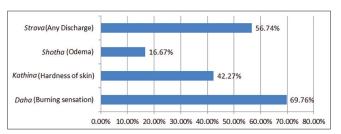


Figure 3: Associated complains

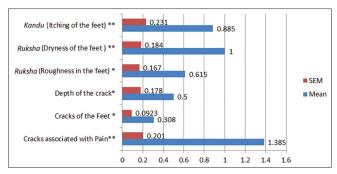


Figure 4: Difference in score before and after treatment. **Highly significant: (<0.001), *Significant: (P<0.05), SEM: Standard error of the mean

symptoms of *Padadari*, conversely, hot climate shows gradual relief of symptoms.^[1]

Mode of action

Many organic substances like lipids act as penetration enhancer and hence give an additional edge to the organo-gel formulations prepared from them. Snigdha (unctuous) and Ushna (hot) properties of mustard oil, Saindhava Lavana and Snuhi Ksheera may subside triggered Vata Dosha which is responsible for the development of Padadari. Among the ingredients of formulation, mustard oil has also been reported to be having flavonoids that inhibit PG COX as well as it has been reported to possess antimicrobial^[13] and antifungal properties.[14] Saindhava Lavana has Ropana as (wound healing) activities.[15] E. caducifolia latex is also reported for its antibacterial, antifungal and antimicrobial properties. [16] Its latex is rich in lupeol, a terpene that has a role in inhibiting ergosterol and having wound healing activities.[17] Thus, Rakta Snuhi (E. caducifolia) gel, in total, possesses a combination of ingredients with a lipid base, ergosterol inhibitors and having wound healing properties. This formulation probably regains the Sneha and Ushna Guna which subside vitiated Vata, thereby healing of the crack heel.

Conclusion

It can be concluded that in the management of Padadari, $E.\ caducifolia\ Ksheera$ gel, when applied locally, provides statistically highly significant results in symptoms such as cracks associated with pain (P < 0.001), dryness of the feet (P < 0.001) and itching of the feet (P < 0.001). No adverse reactions were observed during the treatment. The present study was carried out as an observational study on a small sample size and for a limited time. Encouraging results in present study should be further verified with large sample size and for longer duration through controlled clinical trial.

Financial support and sponsorship

This study was financially supported by IPGT and RA, Gujarat Ayurved University, Jamnagar, India.

Conflicts of interest

There are no conflicts of interest.



Figure 5: A single case study on the effect of Rakta Snuhi gel on Padadari (cracked feet). (a) Affected area before treatment. (b) Effect of Rakta Snuhi gel after 7 days on affected area. (c) Effect of Rakta Snuhi gel after 14 days on affected area. (d) Effect of Rakta Snuhi gel after 21 days on affected area

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