AYUSHDHARA
ISSN: 2393-9583 (P)/ 2393-9591 (O)
An International Journal of Research in AYUSH and Allied Systems

Research Article

CONTROLLED RANDOMIZED CLINICAL TRIAL ON USING *TALISADI TAILAM* FOR TREATING PATIENTS OF TINEA PEDIS W.S.R TO *ALASA*

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KEYWORDS: Athlete's foot, Tinea pedis, *Kshudra roga, Talisadi tailam.*

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ABSTRACT

Skin is the general covering of the entire external surface of the body. Because of a large number of its functions, the skin is regarded as an important organ of the body. There are so many skin disorders of which Tenia pedis is a very common fungal infection that affects a significantly large number of people globally. This fungal infection is called Athlete's foot because it is commonly seen in athletes. In *Ayurveda*, various skin disorders are described under the heading of *Kshudraroga*. A brief description about *Kshudraroga* has been given in many *Ayurvedic* classics. *Alasa* is a variety of *Kshudraroga* occurring in between the skin of toes manifesting with *Kleda*, *Kandu*, *Daha* and *Ruja*. *Talisadi tailam* mentioned in *Sushruta Samhita* is an excellent formulation prepared of drugs which are effective against this disease. Current study includes 30 patients from OPD Department of Shalya Tantra, Jammu Institute of Ayurveda and Research, Jammu and Sri Sain Charitable Hospital, Janipur, Jammu diagnosed to have Tenia pedis based on signs and symptoms. Therapeutic effect was evaluated before and after treatment. The present clinical study has shown symptoms of *Kandu, Daha, Ruja, Kleda* significantly reduced after application of *Talisadi tailam*.

INTRODUCTION

Skin is the largest organ of the body.[1] Skin is the general covering of the entire external surface of the body.[2] Because of a large number of its functions, the skin is regarded as an important organ of the body.[3] It is not uniformly thick.[4] At some places it is thick and in some places, it is thin.[5] The average thickness of the skin is about 1 to 2mm. In the sole of the foot, palm of the hand and in the insterscapular region, it is considerably thick, measuring about 5mm. in other areas of the body, the skin is thin.[6] Skin is made up of two layers i.e. outer epidermis and inner dermis.[7] Normal epidermis is a terminally differentiated, stratified squamous epithelium comprising predominantly keratinocytes.[8] Many skin diseases affect keratinocytes. Common hallmarks of epidermal involvement are: Abnormal scaling of skin, vesicle formation, erosion caused by complete loss of the epithelial layer.[9]

One of the common disorder of the skin mentioned in *Ayurvedic* classic " *Sushruta Samhita*" as *Kshudra roga* is *Alasa* which resembles to Tenia pedis/ Athlete's foot in modern science. *Sushruta* has described *Alasa* as an affection, caused by contact of poisonous mire appearing between the toes, which is characterized by pains, burning, itching and exudation.[10] Tenia pedis is an infection of feet or toes due to dermatophytes only.[11] More common in adults especially those who have to wear shoes and socks for long periods. It is very pruritic, may be vesicobullous in nature and occurs on the instep and plantar surface of the foot.[12] The term Athlete's foot implies toe cleft intertrigo which can be due to Dermatophytes, Non-Dermatophytes molds, Bacteria or Candida.[13]

Clinical Forms of Tenia Pedia/ Athlete's Foot [14]

Intertriginous Dermatitis Type	Most common form and is characterized by chronic maceration and fissuring in lateral toe clefts
Squamous Hyperkeratotic Type	It is caused by Trichophyton rubrum. Chronic and resistant to treatment. Usually affects bilateral heels, soles and sides of feet which becomes pinkish with fine slivery scales. May be associated with nail infection, hyperhidrosis, foul smelling, itching and secondary bacterial infection.
Vesicular Type	Vesicles tend to rupture and leave behind collarettes of scaling with in between normal skin.
Acute Ulcerative Type	It is due to secondary bacterial infection and can cause cellulitis, lymphadenopathy and fever.

Dermatophytic (fungal) infections in the humans are caused by three genera of dermatophytes namely: Microsporon, Trichophyton and Epidermophyton and there are several species of each of these generas which can infect the humans. These dermatophytes infect the skin, the hair and the nails. Most of the infections in India are caused by Trichophyton rubrum.[15] These infections are generally worse during the summer and the rainy season and tend to heal spontaneously during winter. Patients with immune deficiency tend to have widespread infections.[16]

Talisadi tailam [17] contains drugs like *Talispatra, Padmakh, Jatamasi, Renukabeej, Agaru, Chandan, Haldi, Daruharidra, Kamalgatta, Khas, Mulethi* and the oil prepared by these drugs is described as as excellent formulation for the healing of skin wounds. *Talisadi tailam* is used as a management modality in patients suffering from *Alasa* (Tenia pedia) by application on affected site.

Objective of the Study

To evaluate the effect of *Talisadi tailam* (external application) in *Alasa* (tenia pedis).

Source of Data: OPD Department of Shalya Tantra, Jammu Institute of Ayurveda and Research, Nardani, Jammu and Sri Sain Charitable Hospital, Janipur, Jammu

Sample Size : 30

Criteria for Selection of Patient

Inclusion criteria

Patients fulfilling diagnostic criteria between age group of 15-60 years of either sex

Exclusion criteria

1. Patients associated with other type of *Kshudra roga.*

2. Patients below 15 years and above 60 years of age.

3. Patients presenting with *Alasa* suffering with any other systemic disorders.

4. Lesions with secondary infections.

Diagnostic criteria

Patient presenting with *Kandu, Daha, Ruja* and *Kleda* occurring in between the skin of toes and positive for Dermatophytes (By 10% of KOH, microcsopic examination).

Assessment criteria

The assessment was made before and after the treatment on scoring of signs and symptoms of *Alasa* (Tenia pedis). Results were analyzed statistically as per the assessment chart. Scoring pattern was developed according to severity of symptoms.

Method of Clinical Study

Patients fulfilling the diagnostic and inclusion criteria were included for the study. Among included patients, skin scraping was evaluated for presence of Dermatophytes with 10% KOH and observed under microscope. In the same patients *Talisadi tailam* was given for external application on lesion and assessment was made regarding the changes. A proper detailed history was recorded from the patients. *Talisadi taila*m was applied on the site of *Alasa* (Tenia pedis) in sufficient quantity externally, two times a day, in morning and evening for 15 days. Assessment was done before intervention and after 15 days based on grading given for signs and symptoms of *Alasa* (Tenia pedis)

***Kandu* (Itching)**

0- No itching/Absent

1- Mild localized itching

2- Moderate localized itching

3- Severe itching

***Daha* (Burning sensation)**

0- No burning
1- Mild localized burning
2- Moderate localized burning
3-Continuous burning

***Ruja* (Pain)**

0- No pain/Absent
1- Present on walking
2- Mildly present at rest
3- Severely felt at rest

***Kleda* (Discharge)**

0- No discharge
1- Mild discharge
2- Moderate discharge
3- Severe discharge

METHOD OF PREPARATION

All the *Ayurvedic dravyas* were cleaned, dried and were coarse powdered. After that these *dravyas* were soaked in water for sometime then *Tila taila* was kept over *Mandagni*, warmed till bubble rise off. First the *Kalka dravya* and then water was poured into the *Tila taila*. The *tail* was again kept on Gas stove on *Mandagani* till *Sneha siddhi lakshanas* appeared. Then the *Taila* was sieved, collected and packed in clean, sterilized air tight container.

Sneha siddhi lakshanas

1. *Sneha Kalka* became wick like structure when rolled between fingers.
2. No cracking sound from oil and *Kalka* when put over the fire.
3. Appearance of *Kalka* was like black thick foam.
4. Colour of oil- Greenish yellow

OBSERVATIONS

The effect of *Talisadi tailam* was studied on 30 patients suffering from *Alasa* (Tenia pedis), fulfilling the inclusion criteria. The observations were as follows: Maximum numbers of patients were obtained in the age group of 35-45 years that is 71% followed by 22% patients in the age group of 25-35 years and 7% patients in the age group of 18-25 years. Male patients were 80.45% and female patients were 19.55%. Most of the patients 65% were manual labours and the maximum number of patients 70% were from lower-middle income group.

RESULTS

Talisadi tailam used on 30 patients provided a significant effect on the symptoms of *Kandu, Daha, Ruja, Kleda.* The relief percentage in individual symptoms of *Alasa* (Tenia pedis) showed a better clinical effect of *Talisadi tailam* as shown in the tables below.

Table 1: Effect of *Talisadi tailam* on *Kandu*(Itching)

BT	AT	Difference mean	%Relief	SD	SE	't' value	P value
3.31	0.89	2.42	73.12	0.51	0.09	14.74	P<0.001

Table 2 : Effect of *Talisadi tailam on Daha (*Burning)

BT	AT	Difference mean	%Relief	SD	SE	't' value	P value
3.08	1.19	1.89	61.40	0.50	0.09	10.68	P<0.001

Table 3 : Effect of *Talisadi tailam* on *Ruja*(Pain)

BT	AT	Difference mean	%Relief	SD	SE	't' value	P value
3.01	1.09	1.92	63.79	0.54	0.10	11.28	P<0.001

Table 4: Effect of *Talisadi tailam* on *Kleda* (Discharge)

BT	AT	Difference mean	%Relief	SD	SE	't' value	P value
2.94	1.12	1.82	61.91	0.60	0.11	10.18	P<0.001

The table below shows the overall assessment of the patients and most of the patients, which are 16 showed (53.00%) moderate response, followed by 06 patients(20.55%) were completely cured and 04 patients(13.45%) showed marked improvement and rest 04 patients(13.00%) showed mild improvement.

Table 5: Overall effect of *Talisadi tailam* in 30 patients of *Alasa* (tinea pedis)

Complete Cure	06	20.55%
Marked Relief	04	13.45%
Moderate Response	16	53.00%
Mild Improvement	04	13.00%
No Response	0	0

DISCUSSION

Alasa (Tenia pedis) is a disease occurring in between the skin of toes manifesting with *Kleda, Kandu, Daha, Ruja.Talisadi tailam* is a formulation used as an external application in the management of *Alasa* (tenia pedis). 30 patients were assessed before and after treatment and analyzed statistically. The effectiveness of *Talisadi tailam* on the individual signs and symptoms of *Alasa* (tenia pedis) is being discussed here as follows.

Kandu- Symptoms of *Kandu* was complained by all 30 patients. Assessment of *Kandu* was done before and after treatment. Result shows that *Kandu* reduced after application of *Talisadi tailam*. It is statistically highly significant.

Daha- Symptoms of *Daha* was complained by all 30 patients. Assessment of *Daha* was done before and after treatment. Results shows that *Daha* reduced after application of *Talisadi tailam*. It is also statistically highly significant.

Ruja- Symptoms of *Ruja* was complained by all 30 patients. Assessment of *Ruja* was done before and after treatment. Result shows that *Ruja* reduced after application of *Talisadi tailam*. It is also statistically highly significant.

Kleda- Symptoms of *Kleda* was complained by all 30 patients. Assessment of *Kleda* was done before and after treatment. Result shows that *Kleda* reduced after application of *Talisadi tailam*. It is also statistically highly significant.

Probable Mode of Action

Talisadi tailam contains drugs as mentioned below along with their active constituents and uses.

Sr.No.	Drugs	Botanical name	Active Constituents	Uses
1.	*Talispatra* [18]	*Abies webbiana*	Essential oil and alkaloid	*Krimi, Amadosa*
2.	*Padmaka* [19]	*Prunus cerasoides*	Flavanoids	*Daha, Kustha, Visphota*
3.	*Jatamasi* [20]	*Nardostachys*	Essential oil and resinous matter	*Kustha, Daha*
4.	*Renukabeej*[21]	*Vitex negundo*	Hydrocarbons such as n-tritriacontane, n-hentriacontane, n-pentatriacontane, nonacosane. other constituents- *β*-sitosterol, p-hydroxybenzoic acid and 5 oxyisophthalic acid.	*Daha, Dadru, Kandu*
5.	*Agru* [22]	*Aquilaria agallocha*	Essential oil	*Kustha*
6.	*Chandan* [23]	*Santalum album*	a-santalol and B-santalol, $C_{15}H_{24}O$-isomeric sesquiterpene alcohol, aldehydes and ketone	*Kandu, Daha*
7.	*Daruharidra* [24]	*Berberis aristata*	Alkaloids	*Kandu, Vrana*
8.	*Haridra* [25]	*Curcuma longa*	Curcuminoids, curcumin,essential oil, ar-termerone, *α* and β termerone circuma	*Kandu, Vrana, Kustha*
9.	*Kamalgatta* [26]	*Nelumbo nucifera*	Glucose, metarbin, tannin, nelumbine	-
10.	*Khas* [27]	*Vetiveria zizanoides*	Essential oil	*Vrana*
11.	*Mulethi* [28]	*Glychrriza glabra*	Glycyrrhizin, glycyrrhetinic acid, glycyrrhetol, glabrolide, isoglabrolide, asparagines, sugars, resin and starch.	*Vrana*

Most of the ingredients used in *Talisadi tailam* are effective against *Kandu* and *Daha*. Further, In *Jatamasi*, the ethanolic extract (50%) of the rhizome showed antifungal activity against candida albicans, cryptococcus neoformans, Trichophton mentagrophyts, microsprum canis and aspergillus niger. (Bhakuni et. al. 1969).[29] In *Haridra*, the in vitro screening of the oil against some representative bacteria and fungi, including plant and human pathogens shows that the oil has potent anti-microbial effect. (Banerjee and Nigam, 1978 and Banerjee et al, 1978).[30] Also in *Chandan, the* essential oil is antifungal.[31]

CONCLUSION

In the present clinical study, *Talisadi tailam* application for 15 days on lesion of *Alasa* (tenia pedis) has demonstrated decrease in signs and symptoms *Kandu, Daha, Ruja* and *Kleda* which was statistically highly significant. Therefore *Talisadi taliam* application on *Alasa* (tenia pedis) lesions for

15 days is beneficial in reducing signs and symptoms of *Alasa* (tenia pedis). Hence from this study, it is concluded that application of *Talisadi tailam* alone on lesions is an effective modality in management of *Alasa* (tenia pedis).

ACKNOWLEDGEMENT

It is an inexplicable pleasure to offer my sincere and respectful regards to Mrs Suman Sharma, Chairperson, Shri Sai Charitable Trust for higher education and research, Jammu, Dr. Kulwant Singh Director, Ex VC IPG &RT, Jamnagar and Dr. Raghuvir Singh, Dean Academic Affairs, Shri San Charitable Trust for higher education and Research, Jammu who have been kind enough to provide me an opportunity to study in this esteemed institution and provide necessary things to carry out this research work. We are grateful to Principal, Prof Dr. Paramvir Singh, J.I.A.R, Dr.Nitin mahajan vice principal J.I.A.R and Dr.K.Sreedhar Ex-HOD Department of Shalya tantra and all the staff for helping me and devoting much of their time in guiding me and providing necessary facilities whenever needed. This timely help and explicit way of explaining made this article a possible task.

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Cite this article as:
Gupta Sudesh, Manhas Raman, Prasher Aarushi, Sharma Sakshi, Sharma Arun. Controlled Randomized Clinical Trial on Using Talisadi Tailam for Treating Patients of Tinea Pedis w.s.r to Alasa. AYUSHDHARA, 2021;8(1):3104-3108.
Source of support: Nil, Conflict of interest: None Declared