



Research Article

**AN OPEN LABEL SINGLE ARM CLINICAL STUDY ON THE COMBINED EFFECTIVENESS OF
TILA BAKUCHI CHURNA AND NIMBADI LEPA IN DADRU (DERMATOPHYTOSIS)**

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ABSTRACT

Dadru is categorized under both *Kshudrakusta* and *Mahakusta*, which is a *Tridoshshajavyadhi* primarily vitiated by the *Pitta-kapha dosha* and characterized by *Kandu*, *Raga*, *Pidaka*, *Mandala* and *Rukshata*. It can be correlated to dermatophytosis on the basis of symptomatology and pathogenesis. As India being a tropical country, there has been a rise in chronic and relapsing dermatophytosis, with a prevalence of 65.3% and 34.6%, respectively. The study was undertaken with an intention to evaluate the combined effectiveness of *Tila bakuchichurna* internally and *Nimbadilepa* externally in the management of *Dadru*. The ingredients of the intervention possess *Tikta rasa*, *Ushnnaveerya*, *Tridoshaghna*, *Krimighna*, *Kandughna* and *Kushtaghna* properties in contrast to the properties of *Dadru*. **Objectives:** To clinically evaluate the combined effectiveness of *Tila bakuchichurna* and *Nimbadilepa* in the management of *Dadru* (dermatophytosis). **Methodology:** Among 34 registered participants, 30 of them completed the course of treatment. They were administered with 6gm of *Tila bakuchichurna* internally, once daily in the morning, before food, with *Anupana* of warm water and *Nimbadilepa* application externally, once daily in the daytime with water for a period of 30 days. Ordinal data was analysed with Friedman's test followed by Wilcoxon signed rank test after applying Bonferroni correction with a 95% confidence interval; $p < 0.05$ was considered significant. **Results:** Statistically significant improvement was observed on the parameters *Kandu*, *Raga*, *Pidaka*, *Mandala*, *Rookshata*, 5-D Pruritus scale and DLQI scale. **Conclusion:** *Tilabakuchichurna* and *Nimbadilepa* were found to be effective in the management of *Dadrucusht*.

INTRODUCTION

Kushta is the term used to describe the majority of skin disorders in Ayurveda. One of the frequently consulted skin conditions during clinical practice that can be correlated to the symptoms of dermatophytosis is *Dadru*. All skin conditions have been primarily categorized into two classes in Ayurveda: *Mahakushta* and *Kshudrakushta*.

Dadru is categorized under both *Kshudrakusta*^[1] and *Mahakusta*.^[2] *Kandu*, *Raga*, *Pidaka*, *Mandala*,^[1] *Rukshata*, *Daha*^[3] are the clinical characteristics of *Dadru*. This *Tridoshshajavyadhi* primarily vitiates the *Pitta-kapha dosha*.

Dermatophytosis is caused by dermatophytes, which are the most frequent causative agents of superficial fungal infections that can enter keratinized tissue, such as skin, hair and nails. The global burden of dermatophyte infection in humans is estimated to be 20–25%. As India being a tropical country, there has been a rise in chronic and relapsing dermatophytosis, which shows a prevalence of 65.3% and 34.6%, respectively.^[4] A relatively high frequency of dermatophytosis history among close contacts has been documented in recent studies. The infection rates

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were highest among the age groups involved in occupational and outdoor activities due to the increased exposure to fungal pathogens from the environment and increased perspiration, both of which predispose to fungal infection.

Dermatophytosis is a medical term for ringworms caused by pathogens (fungi from the genera trichophyton, microsporum, or epidermophyton) that infect the body, arms, and legs. It is frequently seen in the tropics and may become epidemic in places with high humidity, population density and unhygienic living conditions.^[5] It displays extreme itchy, erythematous, circular, or irregular scaly lesions with well-defined active borders consisting of papulo vesicles.^[6] Numerous immunological and non-immunological elements affect the aetiology and severity of a fungal infection.

Admixture anti-fungal therapy is one of the methods to prevent resistance, in addition to standard susceptibility testing and appropriate drug dosing. There is no specific description available in Samhita regarding the *Chikitsasutra* of *Dadru*. Hence, the treatment is to be carried out according to the predominance of *Dosha*. *Kushta* is mentioned as *Rakta pradoshajavikara* and *Tikta, Kashaya rasa dravyas* are the choice of treatment in *Dadru*.^[1]

The intervention internally contains *Tila bakuchichurna*,^[7] which consists of *Tila* and *Bakuchi*, where *Tila* is *Katu, Tikta, Madhura rasa, Guru, Snigdha*guna, *Ushnavirya* and *Katuvipaka* and properties like *Kapha-pittahara, twachya* and *Keshya*.^[8] *Bakuchi* having *Madhura, Tikta rasa, Ruksha, Sara, Laghuguna, Ushnavirya, Katuvipaka* and properties like *Kapha-rakta-pittahara, Kushtagna, Keshya, Twachya, krimighna*.^[9] The external intervention, i.e., *Nimbadilepa*,^[10] consists of *Nimba, Haridra, Tulasi, Patola* and others. It has *Tikta, Kashaya rasa, Ushnavirya, Katuvipaka, Tridoshaghna, Krimighna, Kandughna* and *Kushtaghna* properties predominantly. The purpose of this study was to statistically analyse the combined effectiveness of *Tila bakuchichurna* internally and *Nimbadilepa* externally in *Dadru* (dermatophytosis).

OBJECTIVES

To clinically evaluate the combined effectiveness of 6gm of *Tila bakuchichurna* internally, once daily in the morning, before food with *Anupanao* f warm water and *Nimbadilepa* application externally, once daily in the daytime with water for a period of 30 days in the management of *Dadru* (dermatophytosis).

MATERIALS AND METHODS

Source of Data

Participants fulfilling diagnostic and inclusion criteria were recruited from the outpatient and

inpatient Department of *Kayachikitsa*, Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Hassan.

Method of Collection of Data

Data was collected using a specially prepared case report proforma.

Screening of the patient

A screening form was prepared with all aspects of history, signs and symptoms of *Dadru* (dermatophytosis).

Diagnostic Criteria

Among screened patients, *Dadru* (dermatophytosis) was diagnosed based on *Lakshanas* such as *Kandu* (itching), *Raga* (erythema), *Pidaka* (eruption), *Mandala* (annular scaly patches) and *Rookshata* (dryness).

Inclusion Criteria

- Participants suffering with *Dadru* (dermatophytosis) up to 1 year of duration.
- Participants of either gender.
- Participants aged between 18-60 years.
- Participants willing to participate in the study and ready to sign informed consent form.

Exclusion criteria

- *Participants* with uncontrolled diabetes mellitus (HbA1C >8).
- Pregnant women and lactating mother.
- *Participants* with any systemic disease with impaired cardiac, hepatic and renal functions which interferes with the course of the treatment, were excluded.

Sampling technique – Convenient sampling

Sample size – 30

Ethical Clearance and CTRI registration

The ethics clearance certificate from the Institutional Ethics Committee of Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Hassan, was obtained with IEC No: SDM/IEC/42/2022. The trial was registered on the Indian clinical trial registry, CTRI/2023/06/054456.

Study Design

Open label single arm prospective clinical study with pre and post-test design, from outpatient department of a tertiary Ayurveda hospital attached to Ayurveda medical college located in district headquarters in Southern India.

Intervention

Internal Medication

a) *Tila Bakuchi Churna*

Dosage: 6gm per day in the morning before food^[11]

Anupana: Lukewarm water (24ml)^[12]

Route of administration: Oral

Duration: 30 days

External Application

b) Nimbadi Churna Lepa

Dosage: Once daily, in day time, of thickness- 1/4th angula (0.4cm) as *Doshagnalepa*^[13] and removed with water before drying.

Duration: 30 days

Source of Medicine and Authentication

The required raw drug for *Tila Bakuchi Churna* was obtained from the vendor and authenticated at *Dravya Guna* Department, Sri

Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Hassan, Karnataka. *Nimbadi Churna* was purchased from a GMP-certified pharmacy.

Assessment Criteria

A) Primary Criteria

1. Scoring based on gradation of *Lakshanas* of *Dadru*
2. 5-D Pruritus Scale^[14]

B) Secondary Criteria

3. Dermatology life quality index (DLQI) ^[15]

Assessments were done at baseline, 15th and 30th day of treatment.

Table 1: Scoring based on gradation of *Lakshanas* of *Dadru*

S.no	Parameter	Grade 0	Grade 1	Grade 2	Grade 3
1	<i>Kandu</i>	No itching	Mild (No disturbance to normal activity)	Moderate (Disturbs normal activity)	Severe (Even disturbs the sleep)
2	<i>Raga</i>	Normal skin color	Mild redness (Pink to reddish)	Moderate red	Severe/ deep brown (Severe inflammation with erythematous base)
3	<i>Pidaka</i>	No eruptions	Eruptions in 0-25% of affected area	Eruptions in 25-50% of affected area	Eruptions in 50-75% of affected area
4	Size of <i>Mandala</i>	Absent	Less than 5 cm	5 to 10 cm	More than 10cm
5	No. of <i>Mandala</i>	No lesion	1 to 3	4 to 6	More than 7
6	<i>Rookshata</i>	Absent	Whitening of skin	Scaling of skin	Cracking of skin

RESULTS

Table 2: Friedman’s test showing the effect of intervention on the assessment parameters between various intervals

Parameter	Variable	N	Mean Rank	X ²	P Value	Remarks
<i>Kandu</i>	BT	30	2.83	39.899	< 0.05	S
	15 th Day		1.75			
	30 th Day		1.42			
<i>Raga</i>	BT	30	2.58	24.507	< 0.05	S
	15 th Day		1.70			
	30 th Day		1.72			
<i>Pidaka</i>	BT	30	2.78	38.00	< 0.05	S
	15 th Day		1.75			
	30 th Day		1.47			
Size of <i>Mandala</i>	BT	30	2.23	15.935	< 0.05	S
	15 th Day		2.05			
	30 th Day		1.72			
Number of <i>Mandala</i>	BT	30	2.17	13.000	< 0.05	S
	15 th Day		2.07			
	30 th Day		1.77			
<i>Rookshata</i>	BT	30	2.65	29.769	< 0.05	S
	15 th Day		1.75			

	30 th Day		1.60			
5-D Pruritus scale	BT	30	2.60	29.045	< 0.05	S
	15 th Day		1.72			
	30 th Day		1.68			
DLQI Scale	BT	30	2.32	22.625	< 0.05	S
	15 th Day		2.12			
	30 th Day		1.57			

Wilcoxon Signed rank test showing the effect of intervention on the assessment parameters between various intervals

Table 3: Kandu

Parameter	Negative ranks			Positive ranks			Ties	Total	Z value	P value	Remarks
	N	MR	SR	N	MR	SR					
BT-15 th Day	25	13	325	0	.00	.00	5	30	-4.914	< 0.016	S
15 th -30 th Day	14	9	126	4	11.25	45	12	30	-1.964	> 0.016	NS
BT-30 th Day	26	14.19	369	1	9	9	3	30	-4.486	< 0.016	S

Table 4: Raga

Parameter	Negative ranks			Positive ranks			Ties	Total	Z value	P value	Remarks
	N	MR	SR	N	MR	SR					
BT-15 th Day	18	9.50	171	0	.00	.00	12	30	-4.146	< 0.016	S
15 th -30 th Day	6	5.50	33	6	7.50	45	18	30	-.504	> 0.016	NS
BT-30 th Day	19	11	209	2	11	22	9	30	-3.710	< 0.016	S

Table 5: Pidaka

Parameter	Negative ranks			Positive ranks			Ties	Total	Z value	P value	Remarks
	N	MR	SR	N	MR	SR					
BT-15 th Day	22	11.5	253	0	.00	.00	8	30	-4.60	< 0.016	S
15 th -30 th Day	10	7	70	3	7	21	17	30	-1.941	> 0.016	NS
BT-30 th Day	26	14.1	366.5	1	11.5	11.5	3	30	-4.57	< 0.016	S

Table 6: Size of Mandala

Parameter	Negative ranks			Positive ranks			Ties	Total	Z value	P value	Remarks
	N	MR	SR	N	MR	SR					
BT-15 th Day	4	2.50	10	0	.00	.00	26	30	-2.0	> 0.016	NS
15 th -30 th Day	7	4	28	0	.00	.00	23	30	-2.64	< 0.016	S
BT-30 th Day	10	5.50	55	0	.00	.00	20	30	-3.05	< 0.016	S

Table 7: Number of Mandala

Parameter	Negative ranks			Positive ranks			Ties	Total	Z value	P value	Remarks
	N	MR	SR	N	MR	SR					
BT-15 th Day	2	1.50	3.0	0	.00	.00	28	30	-1.41	> 0.016	NS
15 th -30 th Day	6	3.50	21	0	.00	.00	24	30	-2.44	< 0.016	S
BT-30 th Day	8	4.50	36	0	.00	.00	22	30	-2.82	< 0.016	S

Table 8: Rookshata

Parameter	Negative ranks			Positive ranks			Ties	Total	Z value	P value	Remarks
	N	MR	SR	N	MR	SR					
BT-15 th Day	20	10.5	210	0	.00	.00	10	30	-4.47	< 0.016	S
15 th -30 th Day	8	5.50	44	3	7.33	22	19	30	-1.06	> 0.016	NS
BT-30 th Day	21	12.24	257	2	9.5	7	7	30	-3.84	< 0.016	S

Table 9: 5-D Pruritus scale

Parameter	Negative ranks			Positive ranks			Ties	Total	Z value	P value	Remarks
	N	MR	SR	N	MR	SR					
BT-15 th Day	18	9.50	171	0	.00	.00	12	30	-4.24	< 0.016	S
15 th -30 th Day	3	3	9	2	3	6	25	30	-4.47	> 0.016	NS
BT-30 th Day	20	11.55	231	2	11	22	8	30	-3.80	< 0.016	S

Table 10: Dermatology Life Quality Index (DLQI) scale

Parameter	Negative ranks			Positive ranks			Ties	Total	Z value	P value	Remarks
	N	MR	SR	N	MR	SR					
BT-15 th Day	4	2.50	10	0	.00	.00	26	30	-2.00	> 0.016	NS
15 th -30 th Day	12	7.04	84.50	1	6.50	6.50	17	30	-3.00	< 0.016	S
BT-30 th Day	15	8	120	0	.00	.00	15	30	-3.77	< 0.016	S

Table 11: Pictures showing the effect of intervention before and after treatment

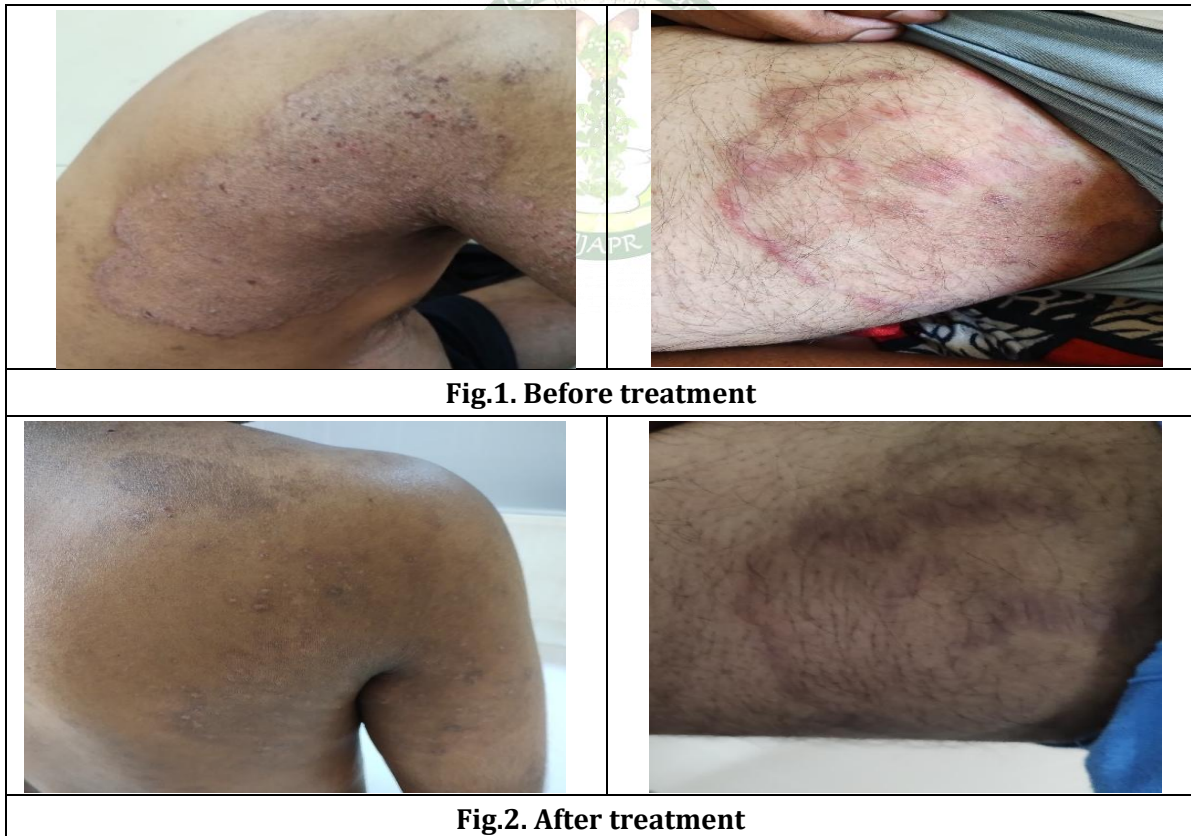


Fig.1. Before treatment

Fig.2. After treatment

DISCUSSION

Effect on *Kandu*

In this study, *Kandu* was significantly reduced with $p < 0.05$. The reduction in *Kandu* was noticed in the form of a decrease in the frequency of the appearance of itch, decrease in the duration of itching and in some participants, a complete reduction in itching. *Kandu*

occurs through the involvement of *Guru*, *Snigdha*, *Sheetaguna* of *Kapha dosha*, *Rooksha* and *Sheetaguna* of *Vata dosha*. The majority of the medications in this study have *Ushna veerya* and *Kledahara* properties, which aid in *Kapha-Vata shamana*, resulting in the reduction of *Kandu*.

Effect on Raga

In this study, *Raga* was significantly reduced with $p < 0.05$. In this study, *Raga* was observed in the form of variations in skin colour ranging from pinkish red to deep brown, which could be due to the predominance of *Doshas*, i.e., *Vata* causing *Aruna varnata* and *Pitta* causing *Ragata* in lesions. The medications in this study have *Ushna veerya*, *Tikta rasa pradhanata*, *Sara guna* and *Mrudu rechaka* properties that aid in *Pachana* and elimination of the *Dosha* out of the body by reducing excess *Pitta* from the body, thereby improving the quality of skin colour by correcting *Brajaka pitta* and reducing *Raga*.

Effect on Pidaka

In this study, *Pidaka* was significantly reduced with $p < 0.05$. *Pidaka* manifests from the imbalance of *Pitta* that is influenced by other *Doshas*. When *Sheeta* and *Snigdhas* of *Kapha* increase, they reduce the natural *Ushna guna* of *Pitta* and can lead to an increase in *Sneha* and *Drava gunas* of *Pitta* as well. *Ushna veerya* and *Tiktara* of the medicine may help in *Pachana* of *Pitta* and do *Kledashoshana* by reducing excess *Kapha*. The medication also helps to promote *Rasa dhatwagni* and rectify *Brajaka pitta*. Through this action, medicines might have helped in the reduction of *Pidaka*.

Effect on Mandala

In this study, *Mandala* was significantly reduced with $p < 0.05$. Subjective reduction in symptom was seen in the form of reduction in size and number of *Mandala*. The accumulation of *Kleda* and *Mala* in *Twak* causes skin thickening. *Twak* being *Sthana* of *Vata* and *Prakupitavata*, along with *Rasa* and *Raktadushti*, cause the disease to spread or increase its area of involvement. The properties of medications such as *Ushnaveerya*, *Vatahara*, *Lekhaniya*, *Shothahara*, *Twachya* and the influence of *Brajakapitta* may have contributed to the reduction in *Mandala*, as well as the inhibition of progression and the emergence of new lesions.

Effect on Rookshata

In this study, *Rookshata* was significantly reduced with $p < 0.05$. The accumulation of *Kleda* and *Mala* in *Twak* promotes thickening of skin, which, when influenced by the increased *Sheeta* and *Ruksha gunas* of *Vata*, may result in the loss of the natural *Snigdha* of *Kapha* and *Twacha*, resulting in whitening and scaling in the lesions. The properties of drugs in *Lepa*, such as *Ushna veerya*, *Vatahara*, *Lekhaniya*, *Shothahara* and *Twachya*, remove whitening/scales from the lesion. The *Ushna veerya* of the medicine may have influenced the improvement in quality of *Brajaka pitta* and when combined with the *Ishat snigdhas* of the medication, *Rookshata* may have decreased.

Effect on 5-D Pruritus scale

In this study, 5-D Pruritus scores was significantly reduced with $p < 0.05$. There was a significant reduction in pruritus (*Kandu*) on the criteria of duration, degree, direction, sleep, housework, outside work and distribution; as a result, the effect of pruritus on quality of life was decreased.

Effect on DLQI scale

In this study, DLQI scores was significantly reduced with $p < 0.05$. Since there was a significant reduction in itch (*Kandu*) and other parameters, the other secondary psychological parameters related to skin problem have also shown reduction.

Discussion on Probable Mode of Action of the Drugs

The purpose of this study is to evaluate the combined effectiveness of *Tila bakuchichurna* internally and *Nimbadi Lepa* externally in *Dadru Kushta*. The medication was administered orally in the early morning on an empty stomach. For *Kapha-pitta* disorders, medicine administration in the *Pratah kala* is advised, as it helps in detoxification.^[11] *Nimbadi Lepa* acts as *Doshaghna* by balancing aggravated *Doshas* through its anti-oxidant, anti-inflammatory, anti-fungal and detoxifying properties.^[13] *Tila bakuchichurna* predominantly has the property of *Ushna veerya*, which helps in improving the status of *Jatharagni*, thereby helping in *Sampraptivighatana* of the disease. *Ushna veerya* of the drug also acts as the *Kapha-Vatashamaka*, *Lekhana* and *Kledahara*. It does *Pachana* of *Pitta*, promotes *Rasa dhatwagni* and corrects *Brajakapitta*. It also helps as *Kushtagna*, *Kandughna*, *Krimighna* and *Twachya*. As the *Bakuchi* has properties of *Sara guna* and *Tila* has *Madhura vipaka* and *Mrudu rechaka* properties, both of which may help in *Pitta rechana*. Recent studies on *Psoralea corylifolia* Linn. (*Bakuchi*) seed have reported that it contains bioactive compounds like psoralen, isopsoralen, psoralidin, bavachin, corylin, coumarins and flavone that have antifungal properties.^[16] *Nimbadi Churna* comprises of *Nimba*, *Haridra*, *Tulasi*, *Patola*, *Kushta*, *Shigru*, *Sarshapa* and others. Collectively these drugs have *Tikta*, *Kashaya rasa*, *Ushnaviryya*, *Katuvipaka*, *Tridoshaghna*, *Krimighna*, *Kandughna* and *Kushtaghna* properties. *Azadirachtin* and *nimbolide* present in *Azadirachtaindica* L. (neem) are high in antioxidants that serve as free radical scavengers and inhibit the progression of diseases.^[17] The polyphenolic flavonoids, quercetin and β -sitosterol, which are extracted from purified *Neem* leaves, possess antifungal activities.^[18] *Haridra* is also referred to as *Vishodhini*, which means it does *Shodhana* naturally. *Haridra* is also known as *Vishothajita*, which implies it has anti-inflammatory properties and can help reduce skin erythema. It improves the complexion and may have aided in the

Vaivarnya of the skin. Recent investigations of *Haridra* have revealed its pharmacological activities, including antifungal properties.^[19] Secondary metabolites found in leaf extracts of *Tulasi (Ocimum sanctum)* exhibited inhibitory and fungicidal action against dermatophyte infections.^[20] Hence both formulations were helpful in *Samprapti vighatana* of *Pitta-kapha pradhana dadru kushta*.

Probable Mode of Action of *Nimbadi Lepa*

Skin is a multilayered structure, with the epidermis, the outermost layer, made up of stratum corneum containing keratinised epithelial cells. Keratohyaline granules are found in stratum granulosum, which bind the keratin filaments in a thick layer. Stratum basale contains keratinocytes, which produce keratin protein that helps to form the skin's outer layer and melanocytes, which produce melanin pigment that gives the skin its colour. *Avabhasini*, the first layer of *Twak*, may be correlated with Stratum Corneum, which is responsible for the exhibition of *Gaura, shyamadi varna* and *Prabha* with the help of *Bhrajaka pitta* present in this layer.^[21] *Adhishtana* of *Dadrukushta* is in the *Chaturtha* layer of the *Twak*,^[22] which may be correlated with stratum spinosum and basale. Dermatophytes display a wide range of fungal strains, predominantly surviving on the keratin-rich matter, which has the ability to penetrate and digest keratinised tissue. When *Lepa* is applied topically in the opposite direction of the hairs, the active components of the ingredients reach the deeper tissues via *Siramukha* of *Romakupa* and *Swedavahasrotas* due to its *Sukshma* and *Tikshna* properties. Because of its *Ushna, Tikshna, Vishada* and *Sukshma* properties, it removes obstructions in *Swedavahasrotas* and allows local toxins to flow out through the *Sweda*, clearing the microchannels. *Ushna veerya* of the *Nimbadi Lepa* possibly induced *Shoshana* of *Kleda* in skin by improving the *Brajaka pitta*. The potency of the drug may penetrate to the *Chaturtha* layer of the skin and help in scraping off the pathogens, thereby decreasing the pathogenesis of disease and bringing normalcy to the skin by improving the production of melanin. As a result, *Lepa* aids as *Doshaghna, Krimighna, Kandughna* and *Kushtaghna*.

CONCLUSION

The interventions were found effective in participants of *Dadrukushta* through *Ushna veerya, Tridosahara, Kandughna, Kushtaghna, Krimighna* and *Twachya* properties. Statistically significant improvement was observed in primary parameters on the *Kandu, Raga, Pidaka, Mandala, Rookshata*, 5-D Pruritus scale and in secondary parameters on the DLQI scale. Oral administration of 6gms of *Tila bakuchi churna* once daily in the morning before food and external application of *Nimbadi Lepa* once daily for a period of 30 days was effective in the management of

Dadrukushta (Dermatophytosis). Thus, the null hypothesis is rejected in favour of the alternative hypothesis.

Patient Perspective

The patients were satisfied with the treatment in terms of reduction in *Kandu, Raga, Pidaka, Mandala* and *Rookshata* and improvement in the quality of life.

Patient Consent

Informed consent for publication of this case study has been obtained from the patients.

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