How to Cite:
Kulkarni, S. S., Misar, S., & Ade, V. N. (2022). Efficacy of Sarjadi Lepa Gutika and Terbinafine Ointment in Dadru (Tinea Corporis). *International Journal of Health Sciences*, *6*(S1), 2122–2130. https://doi.org/10.53730/ijhs.v6nS1.5018

Efficacy of *Sarjadi Lepa Gutika* and Terbinafine Ointment in *Dadru* (Tinea Corporis)

Shreyas S. Kulkarni
PG Scholar, Department of Kayachikitsa, Mahatma Gandhi Ayurveda College, Hospital & Research Center, Salod (H), Datta Meghe Institute of Medical Sciences, Wardha

Sadhana Misar
Professor, Department of Kayachikitsa, Mahatma Gandhi Ayurveda College, Hospital & Research Center, Salod (H), Datta Meghe Institute of Medical Sciences, Wardha

Vinod N. Ade
Professor, Department of Kayachikitsa, Mahatma Gandhi Ayurveda College, Hospital & Research Center, Salod (H), Datta Meghe Institute of Medical Sciences, Wardha

***Abstract*---**The term *'Kushtha'* can be referred to various skin disorders. *'Dadru'* is a type of *Kushtha*. In *Dadru* there is *pradhanata*of *Kapha*and *Pitta Dosha*. It exhibits clinical features of *Kandu, Raga, Pidika, Utsanna Mandala.* On basis of clinical features *Dadru* is similated with Tinea by many scholars. Tinea is superficial fungal infection in which the fungi colonises dead keratinized epidermal tissues of skin, hair and nails and produces annular lesions over skin surface. Efficacy of *Sarjadi Lepa Gutika* and Terbinafine Ointment in *Dadru* (Tinea Corporis)**.** Study contains 60 patients of *Dadru* which will divided at way into two groups (each group contain 30). In Group A (Intervention)-*Sarjadi Lepa Gutika* quantity sufficient for local application with sufficient quantity water at morning and night time and *Tiladi Churna* 6gm at morning after meal with warm water for 30 days and Group B (Experimental group) will be given Terbinafine Ointment quantity sufficient for local application at morning and night time and *Tiladi Churna* 6gm at morning after meal with warm water for 30 days. Assessment will be recorded on every 15th day (15th day, 30th day and 45th day). Subjective and Objectives outcomes will be assess. *Sarjadi Lepa Gutika* is effective in *Dadru* patients as compared to Terbinafine Ointmentwith minimum side effects.

International Journal of Health Sciences ISSN 2550-6978 E-ISSN 2550-696X © 2022.
***Corresponding author**: Kulkarni, S.S.; Email: shreyas.30.kulkarni@gmail.com*
Manuscript submitted: 27 Nov 2021, Manuscript revised: 09 Feb 2022, Accepted for publication: 18 March 2022

Keywords*---*Dadru, Sarjadi Lepa Gutika, Tiladi Churna, Terbinafine Ointment.

Introduction

The skin is highly complex organ which plays a vital role in the body. We notice that ordinary civic is too much aware about the purity of skin, as it is an ornament of the body. *Kushtha* is a disease which creates breakage of the charm of skin. Ayurvedic Classics have considered each type of *Kushtha* to be a *Tridoshaja* manifestation. Nonetheless their *Doshika* identity can be established on the basis of dominance of Dosha in the *samprapti*. All Acharyas have described this disease and its treatment. *Dadru*is one of them and much common to get its incidences from every place.

The term *'Kushtha'* can be referred to various skin disorders. It is classified furthur into '*Mahakushtha'* and *'Kshudrakushtha'. 'Dadru'* is a type of *Kushtha*(1). Which is explained by AcharyaCharaka in *'Kshudrakushtha'* (2) whereas AcharyaSushruta and AcharyaVagbhata have labelled under *'Mahakushtha'*(3) (4). *Kushtha*is a *TridoshajaVyadhi*(5). In *Dadru*there is *pradhanata*of *Kapha*and *Pitta Dosha*(6). It exhibits clinical features of *Kandu, Raga, Pidika ,Utsanna Mandala.*

On basis of clinical features *Dadru*is similated with Tinea by many scholars. Tinea is superficial fungal infection in which the fungi colonises dead keratinized epidermal tissues of skin, hair and nails and produces annular lesions over skin surface. Microsporon, trichophyton and epidermophyton are three types of dermatophytones responsible for various infections. Poor hygine, malnutrition, tropical climate, contact with infected person, immunosuppresive disease all predispose to infection.(7)

Due to changing life style and food habits there is increased incidence of *Dadru* in practice and other systems fail to find a permanent solution for it. Almost 12.4% amongst the total diseases come for treatment is related to skin. (8) Fungal infections occupy a major component among this , and currently up to 21% of the world's population may be infected by Ringworm alone. Therefore it is necessary to find a solution for it through Ayurveda.

A number of studies have been revealed on this topic of *Dadru.*(9-11)
*Dadru*can be managed by *Shodhana, Shamana and BahirparimarjanChikitsa.* Acharyas have explained various *Lepas*formanagement of *Dadru.* The physiological effect of heat aids the effect of *Lepa*on skin.
In Chakradatta*'SarjadiLepa'* (12) and *'TiladiChurna'* (13) are described in the management of *Dadru. SarjadiLepa*given for *Bahirparimarjan*whereas *TiladiChurna*for *Shamana.*Terbinafine is orally and topically active against dermatophytes belongs to allylamine class of antifungals and is fungicidal drug. (14)

Dadru is a commonly encountered condition in day to day practice. It is prevalent in both sexes and in all ages. Many research works have been carried on it, but none is found to cure the disease completely and prevent it's recurrence. So this

study is undertaken with aim to compare efficacy of *SarjadiLepaGutika*and Terbinafine Ointment with *TiladiChurna*internally to both groups in management of *Dadru.*

Trial plan: The study design isDouble arm Randomized Standard controlled single blind clinical trial. It is an interventional study having 1:1 ratio on both parallel groups

Methodology:

Type of trial
The trial is a parallel-group, randomized, single-blind, standard - controlled trial. It will include, a 30 days treatment period, and a 15th, 30th 45th day week follow-up period.

Allocation ratio
Total 60 patients will be selected for the study which will then be divided into two groups. Group A is experimental group where as Group B is standard controlled.

Drug collection / authentication

The raw material will be procured from reliable source and will be authenticated from Department of Dravayguna of Mahatma Gandhi Ayurved College, Hospital & Research Centre, Salod (H),Wardha.

Formulations:

SarjadiLepaGutika :

Sr.No.	Ingredient	Botanical Name	Part Used	Quantity
1.	*Chakramarda*	*Cassia torra Linn*	Seed	1 Part
2.	*Sarjarasa*	*Vateriaindica Linn*	*Niryasa*	1 Part
3.	*Haritaki*	*TerminaliachebulaRoxb*	Fruit	1 Part
4.	*Shastikshali*	-	-	1 Part

TiladiChurna :

Sr.No.	Ingredient	Botanical Name	Part Used	Quantity
1.	*Tila*	*Sesamumindicum Linn*	Seed	1 Part
2.	*Bakuchi*	*Psoraleacoryfolia Linn*	Seed	2 Parts

Terbinafine Ointment
1% Terbinafine topical ointment is used.

Study setting

Selection of patients will done from OPD (Room No. 30) and IPD of Department. of Kayachikitsa , Mahatma Gandhi Ayurved College, Hospital & Research Centre, Salod (H) , Wardha. Also patients will be selected from various specialized peripheral camps.

Registration number
The trial is registered under CTRI with trial number - REF/2020/11/029306.

Diagnostic criteria

The patients having cardinal features of *Kandu* (itching), *Raaga* (redness) and *Mandala utpatti* (circular patches) on skin will be diagnosed as *Dadru.*

Eligibility criteria

Selection of patients in between the age group of 20– 50 yrs of both gender and irrespective of the *SharirikPrakruti*will be considered. Patients with symptoms of *kandu, raaga*and *mandala utpatti*on skin and patients having number of *Mandala* less than or equal to 9 and size of *Mandala* less than or equal to 9cm and the cases of TineaCorporis are included in the study. Patients suffering from Diabetes Mellitus, having known allergy to Terbinafine, chronicity of *Dadru*more than 5 years, cases of Tineavesicolor, Tineamannum, Tineapedis, Tineacapitis, Tineacruris and also pregnant and lactating women are excluded.

Randomization

An independent statistician will create a block randomization sequence. The randomization will be stratified by site with qualified participants randomly assigned to either the experimental group or the standard controlled at a ratio of 1:1. A remote and web-based randomization system will be used by the researchers to assess the treatment allocation for each eligible participant. Total 60 patients will be selected for the study which will then be divided into two groups. Group A is experimental group where as Group B is standard controlled.

Blinding

The participants, clinicians, research assistants, drug managers, statisticians, and other staff members will be blinded about treatment allocations, and will not be made known until the study is completed. The clinicians will assess whether the patients are still eligible, after a run-in period. For each qualified patient, the clinician will apply for a randomized assignment by logging into the web-based randomization system, and prescription for "*SarjadiLepaGutika* Q.S. for local application by mixing with water at morning and night time and *TiladiChurna* 6gm at morning with warm water." Then the patients will be taken to the appointed drug managers at the Dattatraya Rasa Shala accompanied with research assistant. Discussing the assignment possibilities with the participants are forbidden to clinicians, research assistants, and drug managers during the trial periods. The blinding codes will not be broken during the trial and will be kept strictly confidential unless serious adverse events occur.

Interventions:

Group A (Experimental)-*SarjadiLepaGutika*quantity sufficient for local application over the skin lesions with sufficient quantity water at morning and night time and *TiladiChurna*6gm at morning after meal with warm water for 30 days.

Group B (Standard Control) **–**Terbinafine Ointment quantity sufficient for local application over the skin lesions at morning and night time and *TiladiChurna*6gm at morning after meal with warm water for 30 days.

Screening investigations (base line):
Blood Sugar – Fasting will be done as baseline investigation to rule out Diabetes Mellitus.
Investigation during treatment: Not applicable
Investigation (end line): Not applicable

Criteria for discontinuing or modifying allocated interventions

From the study if any untoward incidence, features of drug sensitivity or any other disease or problem arises, Subject will be withdrawn and free treatment will be offered to the subject till the difficulty subsides. We will measure quantity of *Churna* for the consumption of appropriate dose for assessment and to check drug adherence during treatment the subject will be followed up.

Follow up: Patients will be followed up on15th day and 30th day during the period of treatment and 15 days after completion of treatment. Patient will be advised to take normal routine and diet and no any specific precautions for food intake will be advised.

Primary Outcomes: The primary outcome of the trial is to check the effect of interventional drug on parameters of *kandu, raaga,* number of *mandala and* size of *mandala.*

Secondary Outcomes: The secondary outcome of the trial is to check for reoccurrence of the disease and to monitor adverse effects (if any) of the trial drug and to compare the effects of experimental group to that of the control group.

Relief and relapse incidents

The definition of relapse is the recurrence of *Kandu* (itching), *Raaga* (redness) and *Mandala utpatti* (circular patches) on skin in the patients of *Dadru* who have achieved treatment success. When the symptoms are relieved it means the patient have achieved treatment success. Time until relief, time until first relapse, and total relapse times are the relief and relapse incident outcomes. The time from patients receiving treatment to achieving treatment success is defined as time untill relief. The time from patients achieving treatment success to the recurrence of *Kandu* (itching), *Raaga* (redness) and *Mandala utpatti* (circular patches) on skin is defined as time until first relapse. The sum of relapse times during both the treatment period and the follow-up period refer to total relapse times.

Long-term effectiveness: Participants who will be weekly adequate relief responders for at least 45 days during the follow-up period will be considered long-term effectiveness responders.

Statistical analysis

A level of 5% (two-sided) type I error will be considered as statistically significant. Data with subjective criteria and grading will be analysed with the help of Wilcoxon test. Paired as well as Unpaired t test will be used to analyse the data having objective criteria. The McNamara's test will be used to analyse the data with subjective criteria.

Total follow up: Patient will be followed up thrice during the trial. First on 15th day after initiating the treatment and then on 30th day. Follow up will also be taken on 45th day i.e. 15 days after completion of the treatment.

Follow up time: The assessment of the patients will be done on day 0, day 15, day 30 and day 45 of the treatment period.

Enrolment and interventionstime schedule: Drugs will be given from 0 to 30 days with follow up on day 15th, day 30th and day 45th.

Recruitment: By computerized random chart sampling method 60 patient will be recruited (30 in each group)

Implementation: Principle investigator will enroll and allocate the patient.

Methods
Data collection, analysis and management

Data collection method

Subjective –*Kandu*and*Raaga*will be assessed by gradation of symptoms.
Objectives - Number of *mandala and* size of *mandala.*
Gradation with validation: Symptoms will seen before, during and after treatment using gradation of symptoms for clinical research methodology.

Grade	*Kandu* (Itching)	
0	No *Kandu*	
1	Episodic (no routine work disturbance)	
2	Frequent(disturbance of routine work)	
3	Continuous(disturbance of sleep)	
Grade	*Raaga* (Erythema)	
0	Absent	
1	Present	
Grade	Number of *Mandala*	Size of *Mandala*
0	No *Mandala*	Zero cm
1	1-3 *Mandala*	1-3 cm
2	4-6 *Mandala*	4-6 cm
3	7-9 *Mandala*	7-9 cm

Plan to promote participants retention and complete follow up

We will stay in touch with the patient by taking contact number and timely advise them proper medication practices and follow up and the data regarding follow up will be stored in the documentation with valid reasons.

Data management

The data will be collected from patients by assessor by doing clinical assessment after taking written consent form from the patient. Data will be collected using structured questionnaire filled during interview of the patient. Data will be entered in master sheet and analysed by using appropriate statistical technique and data coding will be done by principal investigator.

Safety assessment

Adverse events details including clinical manifestation, severity, occurrence time, recovery time, management and casualty will be recorded on case report form. If any serious adverse events occurs, it must be reported to principle investigator and the ethics committee within 24 hours and any necessary treatment will be provided as soon as possible. All serious adverse eventswill be followed up until they have been resolved.

Research Ethics Approval: Approval for the trial from research ethics committee has been taken. Ref. No.MGACHRC / IEC / August – 2020 / 94.

Consent or assent: The written consent will be taken before starting the study from the patient. During the study the confidentiality of each patient will be properly maintained.

Dissemination policy: The data will be disseminated by paper publication.
Any intended use and authorship eligibility guidelines of professional writers

Informed consent materials: The participants will be given model consent form and all related documentation with providing all information.

Results

Expected outcome result in control group with intervention Terbinafine ointment for local application and *TiladiChurna*per oralispotentially added effectual in subsiding the symptom of *Kandu, Raaga*and *Mandala utpatti*on skin. By following *Pathya* and *Apathya*, during treatment patient who will take all follow up will have a reduced amount of chance of reoccurrence of symptom as compare with intervention group *SarjadiLepaGutika*for local application and*Tiladi Churna*per oral.

Discussion

A number of related studies were reviewed [15-20]. This study will observe that both Terbinafine Ointmentand *SarjadiLepaGutika* along with *TiladiChurna*will

effectively reduced signs and symptoms of *Dadru*. The ingredients of *SarjadiLepaGutika*are *Sarjarasa(Vateriaindica Linn), Chakramrda (Cassia torra Linn), Haritaki (TerminaliachebulaRoxb)* and *Shashtikshali. Chakramarda*possess *katu rasa laghu* and *rukshaguna, ushnaveerya* and *katuvipaka* and is *kapha* and *vatashamaka*. It is also referred to as *Dadrughna*. *Sarjarasa* possess *kashaya rasa rukshagunasheetaveerya* and *katuvipaka* and is *kapha*and *pitta shamaka*. *Haritaki* possess *Madhura, amla, katu, tikta* and *kashaya rasa laghu* and *rukshaguna, ushnaveerya* and *madhuravipaka* and has *tridoshaharaprabhava*. While *Shashtikshali* has *madhura rasa, snigdha* and *aguruguna, sheetaveerya* and is *tridoshaghna.* Thus collectively they possess *tridoshashamaka*properties and hence can reduce the *kandu, raaga*and *mandala utpatti* on skin which are classical features of *Dadru*. The ingredients of *TiladiChurna* are *Tila (Sesamumindicum)* and *Bakuchi (Psoraleacoryfolia).Bakuchi* possess properties like *katu* and *tikta rasa*, *laghu*and *rukshaguna, ushnaveerya* and *katuvipaka* and hence is *vataghna* and *kaphaghna* in nature. *Bakuchi* has blood purifying properties. It is used to treat itching red papules, itching eruptions, extensive eczema with thickened dermis, ringworm, rough and discoloreddermatosis, dermatosis with fissures, and scabies. *Tila* is *tikta, madhura* and *kashaya rasa pradhan* having *guru* and *snigdhaguna, ushnaveerya* and *madhuravipaka* and possess *tridoshashamak* and *yogavahi*and*krumighna*property and can be used to reduce the features of *Dadru.*

Conclusion

Sarjadi Lepa Gutika is effective in *Dadru* patients as compared to Terbinafine Ointment with minimum side effects.

References

1. Sharma, P.V. 2008. KushthaChikitsa. In: Sharma ed. CharakSamhita of Agnivesha. Varanasi: ChaukhambhaOrientalia, pp. 183
2. Sharma, P.V. 2008. KushthaChikitsa. In: Sharma ed. CharakSamhita of Agnivesha. Varanasi: ChaukhambhaOrientalia, pp. 184
3. Yadavajitrikamji. 2005. KushthaChikitsa. In: Dalhanacharya ed. SushrutaSamhita of Sushruta with the NibhanhasangrahaCommentary. Varanasi: ChoukhambhaOrientalia, pp. 37
4. Lalachandrashastri. 1986. Kushtha. In: Ranajitarayadesai ed. AshtangaSangraha of SarvangaSundariVyakhyayaSamhita. Nagpur: ShriBaidyanath Ayurveda Bhavana, pvt Ltd , pp. 137
5. Shukla, V. KushthaNidana. In: Tripathi ed. CharakSamhita of Agnivesha. Delhi: Chaukhambha Sanskrit Pratisthan, pp. 513
6. Shukla, V. 2011. KushthaChikitsa. In: Tripathi ed. CharakSamhita of Agnivesha. Delhi: Chaukhambha Sanskrit Pratisthan, pp. 185
7. Shrivastava, S. 2013. Tinea. In: Shrivastava ed. APC Textbook Of Dermatology. : , pp. 44
8. Elisabeth, W.M. 2008. Skin diseases in family medicine: prevalence and health care use. Ann Fam Med. 6(4), pp. 349-354.
9. Deshmukh, S. 2015. A Clinical Study OfEdagajadiLepa In The Management Of DadruKushta. International Ayurvedic Medical Journal. 3(8), pp. 2259-2264.

10. Melashankar, S. 2016. Clinical evaluation of the efficacy of LaghuManjisthadiKwatha and ChakramardadiLepa in Dadru (Tinea). Journal of Ayurveda and Integrated Medical Sciences. 1(1), pp. 24-28.
11. Muralikrishnan et al.. 2015. A Comparison OfBhallatakadiLepaandGandhakaMalaharaLepa In The Management Of DadruKushta. International Ayurvedic Medical Journal. 3(6), pp. 1612-1617.
12. Sharma, P.V. KushthaChikitsa. In: Sharma, P.V ed. Cakradatta. Delhi: ChaukhambhaOrientalia , pp. 392
13. Sharma, P.V. KushthaChikitsa. In: Sharma, P.V ed. Cakradatta. Delhi: ChaukhambhaOrientalia , pp. 397
14. Tripathi, K.D. Anti microbials. In: Tripathi, K.D ed. Essentials of Medical Pharmacology. : Jaypee Brothers Medical Publishers Ltd, pp. 795.
15. Bhende S, Parwe S. Role of Nitya Virechana and Shaman Chikitsa in the management of Ekakushta with special respect to plaque psoriasis: A case study. Journal of Indian System of Medicine. 2020 Jan 1;8(1):57.
16. Dhakite, S.K., S.M. Wajpeyi, and R. Umate. “Effective Management of Dadru (Tinea Corporis) through Ayurveda - A Case Report.” European Journal of Molecular and Clinical Medicine 7, no. 7 (2020): 1878–86.
17. Henry, D., A. Singh, B. Madke, and P. Kedia. “A Case of Altered Clinical Picture of Extensive Tinea Corporis (Tinea as a Great Mimicker).” Iranian Journal of Dermatology 22, no. 3 (2019): 107–9.
18. Chavhan, Manish Hirasing, and Sadhana Misar Wajpeyi. “Management of Dadru Kushta (Tinea Corporis) through Ayurveda- A Case Study.” International Journal Of Ayurvedic Medicine 11, no. 1 (March 2020): 120–23.
19. Pradhan, Swetalina, Bhushan Madke, Poonam Kabra, and Adarsh Lata Singh. “Anti-Inflammatory and Immunomodulatory Effects of Antibiotics and Their Use in Dermatology.” Indian Journal Of Dermatology 61, no. 5 (October 2016): 469–81. https://doi.org/10.4103/0019-5154.190105.
20. Saoji, Vikrant, and Bhushan Madke. “Use of Low-Dose Oral Warfarin in Three Cases of Livedoid Vasculopathy.” Indian Journal Of Dermatology 62, no. 5 (October 2017): 508–11. https://doi.org/10.4103/ijd.IJD_564_16