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 pradhanatao 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 Ointment with minimum side effects.
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 further 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' \(^3\) \(^4\). Kushthais a TridoshajaVyadhi \(^5\) \(^6\). In Dadru there is pradhanata of Kapha and Pitta Dosha. It exhibits clinical features of Kandu, Raga, Pidika and Utsanna Mandala.

On basis of clinical features Dadru 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, immunsuppresive 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.\(^9\)-\(^11\) Dadrucan be managed by Shodhana, Shamana and BahirparimarjanChikitsa. Acharyas have explained various Lepasformanagement of Dadru. The physiological effect of heat aids the effect of Lepaon skin.

In Chakradatta 'SarjadiLepa' \(^12\) and 'TiladiChurna' \(^13\) are described in the management of Dadru, SarjadiLepagiven for Bahirparimarjanwhereas TiladiChurnafor 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 is Double 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 :

<table>
<thead>
<tr>
<th>Sr.No.</th>
<th>Ingredient</th>
<th>Botanical Name</th>
<th>Part Used</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Chakramarda</td>
<td>Cassia torra Linn</td>
<td>Seed</td>
<td>1 Part</td>
</tr>
<tr>
<td>2.</td>
<td>Sarjarasa</td>
<td>Vateria indica Linn</td>
<td>Niryasa</td>
<td>1 Part</td>
</tr>
<tr>
<td>3.</td>
<td>Haritaki</td>
<td>Terminaliachebula Roxb</td>
<td>Fruit</td>
<td>1 Part</td>
</tr>
<tr>
<td>4.</td>
<td>Shastikshali</td>
<td>-</td>
<td>-</td>
<td>1 Part</td>
</tr>
</tbody>
</table>

*TiladiChurna :

<table>
<thead>
<tr>
<th>Sr.No.</th>
<th>Ingredient</th>
<th>Botanical Name</th>
<th>Part Used</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Tila</td>
<td>Sesamum indicum Linn</td>
<td>Seed</td>
<td>1 Part</td>
</tr>
<tr>
<td>2.</td>
<td>Bakuchi</td>
<td>Psoraleacoryfolia Linn</td>
<td>Seed</td>
<td>2 Parts</td>
</tr>
</tbody>
</table>

**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, Tineacurulis 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 Tiladi Churna 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 on 15th 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 until 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 intervention time 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.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Kandu (Itching)</th>
<th>Raaga (Erythema)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No Kandu</td>
<td>Absent</td>
</tr>
<tr>
<td>1</td>
<td>Episodic (no routine work disturbance)</td>
<td>Present</td>
</tr>
<tr>
<td>2</td>
<td>Frequent (disturbance of routine work)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Continuous (disturbance of sleep)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Grade</th>
<th>Number of Mandala</th>
<th>Size of Mandala</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No Mandala</td>
<td>Zero cm</td>
</tr>
<tr>
<td>1</td>
<td>1-3 Mandala</td>
<td>1-3 cm</td>
</tr>
<tr>
<td>2</td>
<td>4-6 Mandala</td>
<td>4-6 cm</td>
</tr>
<tr>
<td>3</td>
<td>7-9 Mandala</td>
<td>7-9 cm</td>
</tr>
</tbody>
</table>
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 TiladiChurnaper orallypotentially added effectual in subsiding the symptom of Kandu, Raagaand Mandala utpattion 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 SarjadiLepaGutikafor local application andTiladi Churnaper oral.

Discussion

A number of related studies were reviewed (15-20). This study will observe that both Terbinafine Ointmentand SarjadiLepaGutika along with TiladiChurnawill
effectively reduced signs and symptoms of Dadru. The ingredients of SarjadiLepa Gutikaare Sarjarasa (Vateriaindica Linn.), Chakramarda (Cassia torra Linn.), Haritaki (TerminaliachebulaRoxb) and Shashtikshali. Chakramardapossess 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 kaphaand 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 tridoshaghnah. Thus collectively they possess tridoshashamakaproperties and hence can reduce the kandu, raagaand 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, laghuand 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 discolored dermatosis, dermatosis with fissures, and scabies. Tila is tikta, madhura and kashaya rasa pradhan having guru and snidhaguna, ushnaveerya and madhuravipaka and possess tridoshashamak and yogavahian krumighnaproperty 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


