

Research protocol

‘Efficacy of Modified *Putikadi* Ointment and Ketoconazole in the treatment of *Dadru* (*Tinea corporis*).’

ABSTRACT:

Dadru is one of the most common but miserable *Twak Vikar* affecting all the ages of population. Increasing urbanization and industrialization have posted greater danger due to pollution and contamination with toxic, allergic and chemicals in our daily life, this fungal infection is commonly found in higher society and also in lower society due to unhygiene. According to Ayurveda, *Dadru kushtha* is *Kapha-pitta* predominance disease. It is managed by *Shodhana*, *Shamana* and Local application which may be called as *Bahiparimarjan chikitsa*. In today’s fast life no one has spent so much time, they want quick relief so Local application is the best line of treatment. It works fast due to its physiological effect on external skin in the form of *Lepa* or ointment. ***Putikadi Lepa*** which is mentioned in *Sushruta Samhita* and *Ashtanga Hridaya* includes fresh leaves of *Karanja (Putik)*, *Arka*, *Aragwadha*, *Snuhi* and *Jati* with *Gomutra* reduces the symptoms of *Dadru*. All the drugs of *Putikadi Lepa* are *kushtaghna*, *kandughna*, and *krimighna* type. So it is more effective in *Dadru kushta*. But it is not possible every time to give fresh *Lepa* to the patients, so formulation was prepared in the form of ointment for convenience of patients in previous study. When the pilot study was carried out on *Putikadi* ointment, it was observed that the ointment has pungent smell after application due to *Gomutra*, so to remove this drawback some drugs should be added like *Manjistha* and *Yashtimadhu* to enhance the complexion of skin. This study should be taken to evaluate the efficacy of modified *Putikadi* ointment in the treatment of *Dadru*.

KEY WORDS: *Bahiparimajana*, *sthanikchikitsa*, *kushtaghna*, *kandughna*, *krimighna*

INTRODUCTION:

In today's modern era, peoples were attracting towards modern lifestyle, change their food habits like crazier about Chinese, Japanese or fast food but there is an ignorance about health, personal hygiene. Due to these foodie habits, disturb sleep and also by environmental pollution like humid and hot climate leads too many skin disorders mainly fungal and bacterial infections or so many allergic condition will occurred. Skin disorders might have got more importance from medical sciences as well as public health due to experiencing mental, physical and socio-economic embarrassment in the society by disfigured appearance.

In Ayurvedic classics, all skin diseases are included under the heading 'Kushta'. *Dadru kushtha* is one of the common skin disease which is described under the ***Mahakushta*** by Acharya Sushruta^[1] and Vagbhata^[2] and ***Kshudra Kushta*** by Acharya Charaka^[3]. *Dadru* is also a *rasa, rakta* and *mamsdhatu pradoshaja vikara, tridosha prakopak* with *kapha-pitta* predominance.^[4] The causative factors of *Dadru* explained by Acharya under three major classification that is *Ahar, Vihar* and *Krimi*.^[5] Ayurveda has given prime importance to *Aahar* (Diet) among the *Trividha upasthambha* (three sub-pillars) of life.^[6] Diet plays an important role in our life that means if we have taken proper diet, it results good health and if the diet is improper or *Viruddha* like incompatible food may leads to adverse effect on body like *Dushi Visha rogas*.

AIMS AND OBJECTIVIES:

Aim of study: Comparative efficacy of *Putikadi* Ointment and Ketoconazole in the treatment of *Dadru* (Tinea corporis).

Objectives of study:

- 1) To study the physiochemical property of Modified *Putikadi* ointment.
- 2) To study the efficacy of Modified *Putikadi* ointment in *Dadru*.
- 3) To compare the efficacy of Modified *Putikadi* ointment with Ketoconazole ointment.

MATERIAL AND METHODS:

MATERIALS: Data should be collected from different literary sources, research article, Ayurvedic Samhita and internet.

Concept of *Dadru*:

Dadru is one of *Dushi visha Roga* or *Vyadhi*. In Sushruta Samhita, we find *nidanas* like *prasanga, gatra samspaarsha, nishwasa, sahabhojana, sahashayya, saha asana,*

vastramalyanulepana which causes *upasarjarogas* ^[7] like *Dadru*. As *krimi* is also one of the causes of *Kushtharoga*. The *malaja krimi* which are produced in *mala* of *Meda dhatu* called as *sweda*. *Sweda* causes *Kandu*, *Kotha*, *Pidaka*, and *Vaivarnnyata*. So *krimi* produced by excess by *sweda* causes *Dadru*. ^[8] Excessive exercises and over exposure to sunlight causes excessive production of sweat, work place contradicting with hot and humid environment, day sleep late night sleep and complications of Panchakarma therapy which results in the production of *Krimi* casuses *Dadru*.

All the classical symptoms of *Dadru* are similar to Tinea infection. Dermatophytes are the main cause of Tinea infection or Dermatophytosis or Ringworm which is highly contagious and segmented mycelia fungus. ^[9] The route of transmission of Tinea infection is by direct contact of person to person, through pet animals, clothes exchanging and by unhygienic habits. ^[10] According to Charaka, the classical symptoms of *Dadru* are *Kandu*, *Raga*, *Pidaka* and *Udgata mandala* ^[11] which may similar to clinical features of Tinea infection such as itching, erythema, eruption or vesicles and elevated circular patches.

According to Sushruta, *Dadru kushtha* is liked *Atasipushpavarnani*, *tamrani*, *visarpani*, *pidakavat* ^[12], means linseed flowers or coppery, spreading and with boil and also elevation, round patches, itching. But by Dalhana commentary, *Dadru* is classified into *Sita* and *Asita Dadru*. ^[13] or *Dadru* is of two types like white (*Sita*) and black (*Asita*), the latter is difficult to treat and is more persistent and as such is included under major (*Maha*) *kushtha* by Sushruta whereas the white one is easily curable, does not enter successive *dhatu*s and free from severe pain and as such is read under minor (*Kshudra*) *kushtha* by Charaka.

Like that Tinea infection is also classified in two part such as superficial mycosis and deep mycosis. Tinea is classified depending on the affected area into Tinea faciei (ringworm of face), Tinea barbae (ringworm of beard), Tinea capitis (ringworm of scalp and hair), Tinea corporis (ringworm of extremities and thorax), Tinea cruris (ringworm of buttocks and groin), Tinea mannum (ringworm of palm), Tinea unguium (ringworm of nails) and Tinea pedis (ringworm of soles). ^[14]

According to Ayurveda, the causes of *Dadru kushtha* are *Aaharaj*, *Viharaj*, *Upasargaja* and *Krimi*.

Causes According to different Samhita: ^[15]

Table no.1: showing causes of *Dadru*

<i>Mithya Aahar</i>	Charak	Sushruta	Bhela	Harit	Madhava
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	Samhita	Samhita	Samhita	Samhita	Nidana
<i>Vishamashana</i>	+	+	-	-	-
<i>Adhyashana</i>	+	+	-	+	+
<i>Atyashana</i>	+	+	-	-	-
Intake of food during indigestion	+	+	-	-	+
Excessive and continuous use of <i>viruddha aahar</i>	+	-	-	-	-
Excessive <i>snehana</i>	-	-	-	-	-
<i>Vidahi Ahara</i> without emesis of undigested food	+	-	+	+	-
<i>Rasatah</i>					
Excessive intake of <i>Amla</i> and <i>Lavana Rasa</i>	+	-	-	-	+
<i>Dravyataha</i>					
Excessive intake of <i>anup, audaka, gramya, mamsa</i>	-	-	+	-	-
<i>Dadhi, masa, matsya, Navanna, ,mulaka, kshira, tila, guda, pishtanna</i>	+	-	-	-	+
<i>Dushivisha</i>	-	-	-	+	-
<i>Dushita Jala</i>	-	-	-	+	-
<i>Gunataha</i>					
Excessive use of <i>Dravya</i> and <i>snigdha aahar</i>	+	-	-	+	+
<i>Guru aahar</i>	+	+	-	-	+

(+ indicates symptom is present and – indicates symptom is not present in different Samhita)

According to Modern:

- Tinea infection or ringworm is highly contagious fungal infection caused by mycelia fungus or parasites which can live on the cell in the outer layer of skin. This Tinea infection spread by following three ways: Human to Human, Animal to Human and by touching external object.
- Human to Human: Tinea infection should be spread by direct skin to skin contact to an infected individual.

- Animal to Human: Tinea infection can be spread by rubbing or grooming cats and dogs.
- By touching external objects: Tinea infection can be spread by direct contact with surfaces or objects that has been touched by infected animals or humans such as towel, comb, brushes, clothes, bedding and linens.

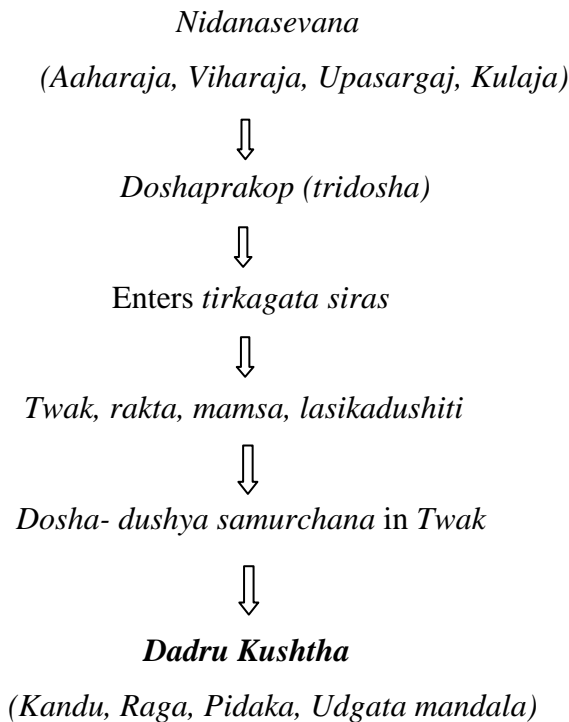
SAMPRAPTI OF DADRU: ^[16]

The knowledge of *Samprapti* not only helps in the comprehension of the specific features, but is also useful in deciding their line of management. All Acharyas have demarcated the common *Samprapti* of the disease *Kushtha* and they have not fractionalized it for sub types of *Kushtha*.

However, we know that, *Dadru* is a type of *Kshudrakushtha* and *Mahakushtha* according to different Acharya's.

Hence the common *Samprapti* of *Kushtha* is applicable in case of *Dadru Kushtha* also.

Samprapti (Figure no. 1)



SAMPRAPTI GHATAKA: ^[17]

Table no.2: showing *Samprapti Ghataka* of *Dadru*

<i>Samprapti Ghataka</i>	Examples
<i>Nidana</i>	<i>Aaharaja, Viharaja, Upasargaj, Kulaja</i>
<i>Doshas</i>	<i>Tridosha (Kapha, Pitta Pradhana)</i>

<i>Dushya</i>	<i>Twak, Rakta, Mamsa, Lasika dushti</i>
<i>Strotas</i>	<i>Rasavaha, Raktavaha, Mamsavaha, Swedavaha</i>
<i>Adhishthana</i>	<i>Twacha</i>
<i>Rogamarga</i>	<i>Bahyaroga marga</i>

DIFFERENTIAL DIAGNOSIS:

Table no.3: showing differential diagnosis of *Dadru*

Disease	Symptoms
<i>Pama</i> (Scabies)	In <i>Paama</i> , symptoms like Scattered <i>Pidaka</i> with different <i>Varna</i> (white, red, black)
<i>Vicharchika</i> (Eczema)	In <i>Vicharchika</i> , symptoms like <i>Pidaka</i> with <i>Bahusrava</i> .
<i>Dadru</i> (Tinea)	In <i>Dadru</i> , symptoms like <i>Pidaka</i> , <i>Varna</i> (<i>Atasipushpa</i>) with <i>Mandala</i> (Round patch)

Agadtantra is one of the branch of Ashtanga Ayurveda by classical texts which deals with detailed study of *Visha*, its classification, examination, and treatments. Acharya Charaka says that even a strong poison is used properly works as best medicine like effect of *Amruta* and medicine is used in improper dose, it acts as poison. ^[18]

Therefore, *Putikadi Lepa* mentioned in Sushruta Samhita ^[19] and Ashtanga Hridaya ^[20] which includes fresh leaves of *Karanja* (*Pongamia pinnata* Linn.), *Arka* (*Calotropis procera* Linn.) , *Aragwadha* (*Cassia Fistula* Linn), *Snuhi* (*Euphorbia nerifolia* Linn) and *Jati* (*Jasminum grandiflorum*) with *Gomutra* (cow urine) reduces the symptoms of *Dadru*.

In previous study, ointment was prepared for patient convenience. Due to pungent smell of *Gomutra* and to enhance the complexion of affected area, some drugs should be added like *Manjistha* (*Rubia cordifolia* Linn.) and *Yashtimadhu* (*Glycyrrhiza glabra*) for better result.

Composition of Material:

1) Collection of Drugs:

Fresh drugs will be collected from the Herbal Garden of Mahatma Gandhi Ayurved College Hospital and Research Centre, Salod (H), Wardha and crude drug from local market.

2) Identification and authentication of drugs :

Identification and authentication of drugs will be done from department of Dravyaguna Mahatma Gandhi Ayurved College Hospital and Research Centre, Salod (H) Wardha.

Table no 4: Ingredients of Putikadi ointment

Sr. no	Ingredients	Latin Name	Quantity
1	Putik (Karanj) leaf (Swarasa)	<i>Pongamia pinnata</i> Linn.	one part
2	Arka leaf (Swarasa)	<i>Calotropis procera</i> Linn.	one part
3	Snuhi leaf (Swarasa)	<i>Euphorbia neriifolia</i> Linn.	one part
4	Aragvadha leaf (Swarasa)	<i>Cassia fistula</i> Linn.	one part
5	Jati leaf (Swarasa)	<i>Jasminum Grandiflorum</i>	one part
6	Gomutra	Cow urine	One part
7	Manjishtha (Kwath)	<i>Rubia cordiafolia</i>	One part
9	Yashtimadhu (Kwath)	<i>Glycyrrhiza glabra</i>	One part
10	Sarshap Tail (Mustard oil)	<i>Brassica campestris</i> Linn.	one part
11	Ointment base (wax)		q. s.

METHODS:

1. For Analytical Study:

Preparation of Putikadi ointment:

i. Preparation of Taila: ^[21]

- Fresh mature leaves will be collected from the herbal garden of MGACH & RC, Salod (H).
- *Swarasa* of each five herbal drugs, kwath of Manjistha and Yashtimadhu and *Gomutra* will be taken in equal quantity to that of *Sarshap Tail*.
- The process of *Sarshapa taila Murchana* will be carried out.
- To be mentioned quantity of *Swarasa* and *Gomutra* will be added in that vessel containing *Murchita taila* and boil with frequent stirring.
- When the '*Sneha Siddha Lakshana*'s will occurred, the hot taila shall be filtered.
- When cool on its own, it will pack and preserve in appropriate air tight container.

ii. Preparation of Ointment: ^[22]

- Five parts of prepared oil will mix with one part of melted liquid paraffin wax.
- This mixture will be heated on *mandagani* for 15 mins.
- Filter the mixture through the clean cloth, and then stir with ladle for cooling.
- Ointment will form on cooling.
- Pack in 30ml small container.

iii. Physico-chemical Analysis: ^[23]

1. Organoleptic Character:
 - Colour
 - Consistency
 - Odour
2. Identification
 - Rancidity test
3. pH
4. Particle Size
5. Thermal stability
6. Total fatty matter
7. Loss on drying at 105 C
8. Spreadability
9. Microbial contamination

2. Clinical Study

Study Design: Randomized Standard Control Single Blind Study

Study Type: Interventional Study

Sample Size: 55 patients in each group

Source of study:

Patient will be selected from Kayachikitsa OPD, Mahatma Gandhi Ayurved College Hospital and Research Centre, Salod (H), Wardha and also from special camps conducted for the purpose.

Ethics Committee Approval – After approval from Institutional Ethical Committee (with reference number MGACHRC/IEC/August-2020/102, study will be carried out at Mahatma Gandhi Ayurved College, Hospital and Research Centre Salod (H), Wardha..

Grouping: Group A and Group B

Group A – 55 patients will be applied Ketoconazole ointment

Group B – 55 patients will be applied Putikadi ointment

Inclusion Criteria: [24]

- 1) The patients with classical *lakshanas* of *Dadru* will be included in the study.
- 2) Patients of either sex or age group between 18 -60 years will be included.
- 3) Patients of only *Tinea Corporis* will be selected.

Exclusion Criteria:

- 1) *Tinea* associated with other skin diseases will be excluded like eczema, scabies, psoriasis
- 2) Pregnant and lactating women will be excluded.
- 3) Other types of *Tinea* will be excluded.

Diagnostic Criteria: [25]

Patients will be classical *lakshanas* of *Dadru* (*Tinea*).

Withdrawal Criteria:

Patient will be withdrawn from the study if there will be any allergic reaction occurs

Intervention Table:

Group	Group A	Group B
Sample size	55 patients	55 patients
Intervention	Ketoconazole ointment	Modified <i>Putikadi</i> ointment
Dose	q. s. two times in a day	q. s. two times in a day
Duration	21 days	21 days
Follow up period	7 th , 14 th , 21 st , 45 th ,	7 th , 14 th , 21 st , 45 th
Total duration	45 days	45 days

ASSESSMENT CRITERIA:

Assessment with grading of Subjective parameters: [26]

Symptom	Gradation	Grade
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<i>Kandu/</i> Itching	No itching	0
	Continuous itching (no any disturbance in work)	1
	Continuous itching (work may be disturbed)	2
	Continuous itching (disturb sleep)	3
<i>Pidaka/</i> Eruption	No eruption or pidaka	0
	<i>Pidaka</i> or eruption in 0 – 25 % affected	1
	<i>Pidaka</i> or eruption in 25 - 50 % affected	2
	<i>Pidaka</i> or eruption in 50 -75 % affected	3
<i>Raga/</i> Erythema	No Erythema	0
	Light Red	1
	Moderate Red	2
	Bright Red	3

Assessment with grading of Objective parameters: [27]

Symptoms	Gradation	Grade
<i>Udgata mandala</i> (Elevated circular lesion)	No <i>mandal</i>	0
	1-3 <i>mandal</i>	1
	4-6 <i>mandal</i>	2
	>7 <i>mandal</i>	3
Size of <i>mandala</i>	No <i>mandal</i>	0
	< 5cm	1
	5 – 10 cm	2
	>10cm	3

Statistical Method: The data will be analysed by using ‘Wilcoxon’s sign rank test and X^2 test.

Assessment of Results:

- Result will be drawn in tabulated form by observation after completing the study.

DISCUSSION:

Normally 10-15% of the general practitioners encounter with all types of skin disorders in their day to day practice. 5 out of 1000 people are suffering from Tinea infection. In the contemporary science, management of Tinea is carried out with usage of tropical, systemic antifungal or corticosteroids. Long lasting use of these drugs produces the adverse effect or recurrences occurred after stopped the treatment and treatment goes to very costly also.

In all types of skin diseases due to unyielding nature, some conditions are easy to manage and some are complicated or difficult to manage, so proper classical diagnosis is more important. If it is neglected then there is a chance of recurrences and prognosis may be poor.

The present research work should be carried out to evaluate the comparative efficacy of Modified *Putikadi* ointment and Ketoconazole cream in the treatment of *Dadru*. Mostly common cause of *Dadru* is *Aaharaj*, *Viharaj* and *Krimi*. Tinea is not a life threatening disorder, but it makes worried the patient due to its appearance, severe itching disturbing the routine work. Tinea is just like a fungal infection and the drugs used in the modern treatment are tropical antifungal reagents which give only symptomatic relief. Most of the contents of Modified *Putikadi* ointment like *Karanj*, *Arka*, *Snuhi*, and *Jati* are *Katu*, *Tikta*, *Kashay rasatmaka*, *Laghu*, *Ruksha*, *Teekshna gunatmaka*, *ushna veeryatamaka*. *Aragwadha* has *Madhur gunatmaka*, *guru snigdha gunatmaka*, *sheeta veeratmaka* and all are *kandughna* (antipruritus), *kushthaghna*, *kaphavatahara*, *krimighna*, *raktaprasadana*, *vedanasthapa* and *vranaropan* (healing) property.

Out of them *Arka* and *Snuhi* are the *Upavisha*. The efficacy (action) of poison (*visha*) depends upon their qualities (*gunas*). *Visha* has properties like *Laghu*, *Ruksha*, *Aashu*, *Vishada*, *Vyavayi*, *Vikasi*, *Sukshma*, and *Ushna* etc. These properties removed the obstruction in the *svedavahi srotasa* and allowed the toxins localized out through the *sveda*, thus cleared the micro-channels and suppressed the aggravated *doshas* and *dhatu*s. *Upavisha* are the group of drugs which are less toxic in nature not so lethal but produce certain toxic symptoms on consumption or any type of route of administrations. *Upavisha* are not usually life threatening and their toxicity can be controlled by therapeutic measures. Most of the drugs of *Putikadi Lepa* are *Laghu*, *Ruksha*, *Teekshna*, *Snigdha*, *Madhur gunatmaka*, *Ushna* or *sheeta veeryatmaka*, so it reduces the *kapha-pitta* predominance.

Kandu is produced due to vitiated *kapha dosha* and *rasa, rakta dhatu dushti*. *Putikadi Lepa* has *Kaphashamaka, kushthaghna, kandughna, Ushna, Laghu, Ruksha* property which were antagonist to *Sitata, Guruta, Snigdha-picchila* property of *Kapha*, so that *Kapha* had reduced, ultimately *Kandu* was reduced. *Pidaka* are produced due to *Kapha-vata Pradhan tridosha*., *Teekshna, Ushna gunatmak, Katu, Tikta, Kashaya, Rasatmaka*, properties of *Putikadi Lepa* causes *Kapha shaman* which helps to reduce *Pidaka*. *Mandala* means *Visarpa* of lesion is due to *Rakta dushti* and *Tikshnata* of *Pitta*. This *lepa* is useful in *Pitta* and *Rakta* dominance disease by its *Tikta, Kashaya* and *Madhura Rasatmak* properties and reduced *Mandala* (circular lesions). *Raga* is due to *pitta prakop* and *rakta, mamsa dhatu dushti*. *Tikta, Kashaya* and *Madhura rasatmaka* drugs of *Putikadi Lepa* had reduced the *pitta prakop* and ultimately the symptoms of *Raga*.

As per modern researches, the contents present in the ointment possess antibacterial and antifungal properties. So it will be more effective in *Dadru kushta*.

Conclusion: Conclusion should be drawn after completing the study by their results and observation.

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