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## Efficacy of Modified *Putikadi* Ointment and Ketoconazole in the Treatment of *Dadru* (Tinea Corporis)

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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**Study Protocol** 

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## 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 Manijistha 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.

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## **1. 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 socioeconomic 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]. Avurveda 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.

## 2. AIMS AND OBJECTIVIES

## 2.1 Aim of Study

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

## 2.2 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.

## **3. MATERIALS AND METHODS**

## 3.1 Materials

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

#### 3.1.1 Concept of *Dadru*

Dadru is one of Dushi visha Roga or Vyadhi. In Sushruta Samhita, we find nidanas like prasanga. aatra samspaarsha. nishwasa. sahabhojana, sahashavva. saha asana. vastramalvanulepana 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 Vaivarrnyata. 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 dhatus 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 ungium (ringworm of nails) and Tinea pedis (ringworm of soles) [14].

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

#### 3.1.2 Causes according to different Samhita [15]

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

Table 1.	Showing	causes	of	Dadru
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(+ indicates symptom is present and – indicates symptom is not present in different Samhita)

## 3.2 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.

## 3.3 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.



(Kandu, Raga, Pidaka, Udgata mandala)

#### Fig. 1. Flowchart of Samprapti

## 3.4 Samprapti Ghataka [17]

Table 2.	Showing	Samprapti	i Ghataka o	f Dadru

Samprapti Ghataka	Examples
Nidana	Aaharaja, Viharaja, Upasargaj,Kulaja
Doshas	Tridosha (Kapha, Pitta Pradhana)
Dushya	Twak, Rakta, Mamsa, Lasika dushti
Strotas	Rasavaha, Raktavaha, Mamsavaha, Swedavaha
Adhishthana	Twacha
Rogamarga	Bahyaroga marga

## 3.5 Differential Diagnosis

#### Table 3. Showing differential diagnosis of Dadru

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

## 3.6 Composition of Material

#### 3.6.1 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.

# 3.6.2 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.

## 3.7 Methods

## 3.7.1 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 Murcchana* will be carried out.
- To be mentioned quantity of *Swarasa* and *Gomutra* will be added in that vessel containing *Murcchita taila* and boil with frequent stirring.
- When the 'Sneha Siddha Lakshana's will occured, 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

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

#### Table 4. Ingredients of Putikadi ointment

#### 3.7.2 Clinical study

#### 3.7.2.1 Study design

Randomized Standard Control Single Blind Study.

3.7.2.2 Study type

Interventional Study.

3.7.2.3 Sample size

55 patients in each group.

#### 3.7.2.4 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.

#### Grouping: Group A and Group B

Group A – 55 patients will be applied Ketoconazole ointment Group B – 55 patients will be applied Putikadi ointment

#### 3.7.3 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.

#### 3.7.4 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.

#### 3.7.5 Diagnostic criteria [25]

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

#### 3.7.6 Withdrawal criteria

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

#### Table 5. Intervention Table

Group	Group A	Group B
Sample size	55 patients	55 patients
Intervention	Ketoconazole ointment	Modified Putikadi 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 <sup>th</sup> ,14 <sup>th</sup> ,21 <sup>st</sup> ,45 <sup>th</sup> ,	7 <sup>th</sup> , 14 <sup>th</sup> , 21 <sup>st</sup> , 45 <sup>th</sup>
Total duration	45 days	45 days

## 3.8 Assessment Criteria

#### Table 6. Assessment with grading of subjective parameters [26]

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

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

Table 7. Assessment with grading of Objective parameters: [27]

#### 3.9 Statistical Method

The data will be analysed by using 'Wilcoxon's sign rank test and  $X^2$  test.

#### 4. ASSESSMENT OF RESULTS

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

## 5. 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 treatment are tropical antifungal modern 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, Sukshma, and Ushna etc. These Vikasi, 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 dhatus. Upavisha are the group of drugs which are less toxic in nature not so lethal produce certain toxic symptoms but 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, Snigdh-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 Visarpana 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*.

## 6. CONCLUSION

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

## CONSENT

As per international standard or university standard, respondents' written consent will be collected and preserved by the author(s).

## ETHICS APPROVAL

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

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## **COMPETING INTERESTS**

Authors have declared that no competing interests exist.

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