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TO EVALUATE THE COMBINED EFFECT OF NAVKARSHIKA KASHAYAM AND DADRUGHNA LEPA IN THE MANAGEMENT OF DADRU (DERMATOPHYTOSIS): A PILOT STUDY

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ABSTRACT*:*

Dadru is one among the *Kushtha* described in the classical text book of *Ayurveda* which bears greater resemblance with Tinea or Ringworm infection. Tinea or ringworm is one of the most common skin disorders encountered in the clinical practice. These infections are characterized primarily by their classic annular (ring-shaped) lesions with central clearing and raised, active, scaly borders. The lesions may vary in size and are typically erythematous (reddened) at the margins with a relatively less inflamed or pale centre, giving them a ring-like appearance. Itching (pruritus) is one of the most prominent and distressing symptoms, often exacerbated by heat, sweat, or friction. It is broadly considered as "Dermatophytosis" Superficial fungal infections of the skin found in unhygienic conditions of tropical and subtropical Countries. It is the most common dermatological manifestation affecting up to 20-24% of world's population in all age group, it is equally common in men and women. This Pilot study was conducted to evaluate the combined effect of administration of *Navkarshika Kashayam* (40 ml twice daily after meals) internally and application of *Dadrughna Lepa* externally with *sarshapa oil* once daily over 30 days in Ten patients with classical *Dadru* symptoms. Statistical analysis was performed using the Wilcoxon matched pairs signed-rank test; $p < 0.05$ was considered statistically significant. Statistically significant improvement was observed on the all parameters *Kandu, Daha, Raga,* No. of *Mandala, Pidika* on *Mandala* and Size of *Mandala.* The study concluded that *Navkarshika kashayam* and *Dadrughna Lepa* are highly effective in the management of *Dadru* (Dermatophytosis).

KEYWORDS: *Dadru, Navkarshika Kashyam, Dadrughna Lepa,* Dermatophytosis

INTRODUCTION

Tinea corporis, more commonly known as ringworm, is a superficial dermatophyte skin infection caused by fungi belonging to the genera, namely Trichophyton, Microsporum and Epidermophyton [1]. Dermatophytes are filamentous fungi that invade and feed on keratinized tissue like skin, hair and nails causing an Infections [2]. This condition typically affects the body's glabrous (non-hairy) areas and presents as annular, scaly plaques with central clearing and an active, erythematous, sometimes raised border. The infection is often pruritic and may become confluent or widespread in immunocompromised individuals. They are clinically classified by infection site as tinea capitis (head), tinea faciei (face), tinea barbae (beard), tinea manuum (hand), tinea cruris (groin), tinea pedis (foot) and tinea unguium (nails). Dermatophytes are grouped as either Anthropophilic, Zoophilic and Geophilic, depending on whether their primary source is human, animal or soil respectively. Tinea corporis occurs worldwide, which is most commonly observed in tropical region. The lifetime risk of acquiring tinea corporis is estimated to be 10-20%. The prevalence of this infection is ~2% among young adults. 39% of the world population is suffering from Tinea. In India also, 5 out of 1000 people are suffering from Tinea infection [3]. 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], without sex predominance. Human may become infected through close contact with an infected individual, an infected animal (in particular domestic dog or cat), contaminated fomites or contaminated soil. Fungal infections manifest a great challenge to clinicians due to higher rate of recurrences and if not treated early can lead to development of more extensive disease. In Morden medicine, tinea is managed with topical and systemic antifungal agents, as well as the use of corticosteroids [5]. It needs to take long term, may develop resistance to drug and more adverse effect, so its need of time to have some new and effective treatment on it.

Dermatophytes can be correlated with the *Dadru Kushtha* due to its characteristic features Sach as *Utsanna mandala* (elevated circular lesion), *Raga* (erythema), *Daha* (burning sensation), *Pidaka* (eruption) and *Kandu* (Itching) [6]. In *Vaidyaka Shabda Sindhu, Dadru* is mentioned as a type of *Kshudra kushtha* having the characteristics of tortoise [7]. As per Sir Monier William's Saskrit English Dictionary, *Dadru* is a type of Leprosy ('*Kushtha*' i.e. skin disease) characterized by skin lesions, which resembles tortoise [8]. In *Ayurvedic* Science Skin diseases are classified under broad heading of *Kushtha* which is futher classified into *Maha Kushtha* and *Kshudra Kushtha* [9]. *Acharya Charaka* included *Dadru Kushtha* in *Kshudra Kushtha* [10] where *Acharya*

Sushruta and *Vagbhata* have explained under *MahaKushtha* [11]. According to *Acharya Dalhan Dadru Kushtha* is classified into 2 types *Sitha* and *Asitha* [12] The predominance of *doshas* in *Dadru* are *Pitta* and *Kapha* according to *Acharya Charaka* and *Vagbhata*, whereas it is *Kapha* as per *Acharya Sushruta.* All the *nidanas* mentioned for *Kushtha* can be *nidanas* for *Dadru* also. These etiological factors are categorized into *aharaja, viharaja, chikitsa apacharaja, krimija* and *upsargaja.*

Dadru is managed by *Shodhana* and *Shamana* like local application which may be called as *Bahiparimarjana chikitsa*. There are numerous formulations mentioned in *Ayurveda* for the treatment of *Dadru* (Dermatophytosis). After reviewing the literature and keeping all above information and background of the disease in mind, two drugs were selected which are supposed to be effective in *Dadru kushtha*. Hence, considering this an attempt was made to evaluate the combined effect of *Dadrughna Lepa* once daily which is mentioned in *Sharagdhara Samhita* in *Vatarakta Chikitsa Rogadhikar* [13] and oral administration of *Navkarshika kashayam* mentioned in *Chakradutta* [14] and *Sahastra Yoga* [15] 40 ml twice a day (morning and evening) after meal for a period of 30 days in the management of *Dadru* (Dermatophytosis).

AIM AND OBJECTIVES

1. To evaluate the combined effect of *Navkarshika Kashayam* and *Dadrughna Lepa* in the management of *Dadru.*

NULL HYPOTHESIS (H0):

Navkarshika Kashayam and *Dadrughana Lepa* are not effective in the management of *Dadru*.

ALTERNATIVE HYPOTHESIS (H1):

Navkarshika Kashayam and *Dadrughna Lepa* are effective in the management of *Dadru.*

MATERIALS AND METHODS

Ten patients were enrolled from the OPD and IPD of the *Panchakarma* Department at Pt. Khushilal Sharma Govt. (Autonomous) *Ayurveda* College and Institute, Bhopal, regardless of caste or religion. A structured research proforma with an appropriate grading pattern was used for assessment. Written informed consent was obtained from all participants prior to treatment. *Navkarshika Kashayam* and *Dadrughna Lepa* were prepared in the Department of *Rasashastra* and *Bhaishajya Kalpana* of the same institute.

STUDY DESIGN; An Open Label Single Arm Clinical Study

SAMPLING TECHNIQUE: Convenient sampling

SAMPLE SIZE: 10

SCREENING OF THE PATIENTS: A Screening Proforma was prepared with all aspects of history, signs and symptoms of *Dadru* (Dermatophytosis).

CRITERIA FOR SELECTION OF PATIENTS:

INCLUSION CRITERIA:

1. Patient of either sex aged between 10 to 60 years.

2. Patients having classical signs and symptoms of *Dadru*.

3. Patients having history less than 2 years of origin.

4. Participants willing to participate in the study and ready to sign informed consent form.

EXCLUSION CRITERIA:

1.Patients having severe Cardiac, Renal, Hepatic disease, Tuberculosis,

Malignancy, AIDS and uncontrolled diabetes mellitus.

2.Patients having patches due to burning, chemical explosion.

3.Patients on long treatment of steroid.

4.Pregnant women and lactating mother.

WITHDRAWAL CRITERIA:

1. Patients are not willing to continue.
2. During the clinical trial, if a patient develops any serious condition which requires urgent treatment.
3. A patient her/his wants to withdraw from the clinical trial.

POSOLOGY AND INTERVENTION:

INTERNAL MEDICATION:

1.*Navkarshika Kashayam* 40 ml twice a day after meal.

Route of administration: Oral

Duration: 30 days

PREPARATION OF *NAVKARSHIKA KASHAYAM*:

1) The ingredients of *Navkarshika Kashayam* are *Triphala (Haritaki, Vibhitiki,Amalaki), Nimba, Manjishtha*, *Vacha, Katuki, Guduchi* and *Daruharidra.* All drugs are taken in equal parts, pounded to course powder and stored.

2) 20 gm of powder taken added with 16 times of water. Boiled and reduced to 1/8th part and filtered.

3) This *Kashaya* is administered 40 ml BID dose after meal for 30 days.

EXTERNAL APPLICATION:

1. *Dadrughna Lepa* with *Sarshapa* oil for local application on affected area (till it dry up)
Time: Once a day

Duration: 30 days.

PREPRATION OF *DADRUGHNA LEPA:*

1) *Chakramarda (Cassia tora), Siddhartaka (Sinapis Alba), Haridra (Curcuma longa), Kushth (Sausseria Lepa*), and *Tila (Sesamum Indicam)* were taken in equal amount and grinded separately in the mixer grinder of 17000 rpm and vigorously mixed with *Sarshapa oil (Brassica compestris*) to make homogeneous mixture having thick paste like consistency into *Lepa.*

2) Application of this fresh *Lepa* over an affected area in thickness of *Doshaghana lepa* as ¾ *angula* i.e 0.48cm approx.

3) This is to be applied once a day for 30 days.

TREATMENT PERIOD:

Duration of the treatment-30days

ASSESSMENT DAYS:

Pre Test Assessment- 1st day

1st Assessment – 15th day

Post Test Assessment- 30th day

FOLLOW UP PERIOD: 3 weeks.

CRITERIA OF ASSESSMENT:

Assessment was done mainly on the basis of subjective and objective criteria. These parameters were graded from 0-3 according to severity as given below [16]. Number, colour and length were assessed by taking photographs of the affected part.

Table:1

S.N.	SYMPTOMS	GRADE 0	GRADE 1	GRADE 2	GRADE 3
1	***Kandu* (Itching)**	Absent	Occasionally, does not disturb routine activity and sleep. Duration:4-6 min, frequency recurs 1-2 times in 12 hours	Frequent disturb routine activity but not sleep. Duration:7-9 min, frequency recurs 3-4 times in 12 hours	Intense and constant, disturb sleep and routine activity. Duration: 10-12 min, frequency recurs 8-10 times in 12 hours.
2	***Daha* (Burning sensation)**	Absent	Mild (Occasionally burning sensation)	Moderate (Often burning sensation)	Severe (always burning sensation, disturbing sleep and other activities)
3	***Raga* (erythema)**	Normal skin colour	Brownish	Blackish	Red (bright red or reddish black)
4	**Number of *Mandala***	No *Mandal*	1-5 *Mandala*	6-10 *Mandala*	>10 *Mandala*
5	***Pidika on Mandala***	No *Pidika*	*Alpa Pidika* (1-3)	*Madhyam Pidika* (4-7)	*Bahu Pidika* (>7)
6	**Size of *Mandala* (cm)**	0	<5	5-10	>10

OBJECTIVE PARAMETER- Photographs (B.T. & A.T.)

CRITERIA FOR OVERALL ASSESSMENT

Table:2

COMPLETE REMISSION	**100%**
MARKED IMPROVEMENT	**76-99%**
MODRATE IMPROVEMENT	**51-75%**
MILD IMPROVEMENT	**26-50%**
NO CHANGE	**0-25%**

OBSERVATION AND RESULT:

The observations of signs and symptoms and other clinical parameters were recorded before and after the treatment. The obtained data were analyzed statistically and significant result was found.

STATISTICAL ANALYSIS

The value of data was expressed as a percentage of relief. The result was analyzed statistically in term mean values of B.T. (Before treatment), A.T. (After treatment). Data was analyzed statistically using Wilcoxon matched pairs signed rank test with a 95% confidence interval; $p<0.05$ was considered as statistically significant by using graph pad**.**

RESULT:

Table: 3

S. N.	**Symptoms**	**Mean score**		**Mean difference**	**Percentage Relief**	**W**	**P value**	**Significance**
		BT	**AT**					
1	***KANDU***	2.3	0.40	1.90	82.60 %	55	.0020	**V. S.**
2	***DAHA***	1.3	0.10	1.20	92.30 %	36	.0078	**V.S.**
3	***RAGA***	2.2	0.50	1.70	77.27 %	55	.0020	**V. S**
4	***NO. OF MANDALA***	1.4	0.50	0.90	64.28 %	45	.0039	**V.S.**

5	***PIDIKA ON MANDALA***	1.4	0.30	1.10	78.57 %	55	.0020	**V. S.**
6	***SIZE OF MANDALA***	1.4	0.60	0.80	57.14 %	36	.0078	**V.S.**

(V.S.= Very Significant)

EFFECT OF THERAPY ON *KANDU*-

The mean score of *Kandu* before treatment was 2.3, which reduced to 0.40 after treatment, showing a mean difference of 1.90 and a percentage relief of 82.60%. The Wilcoxon signed-rank test indicated a statistically very significant improvement (p = 0.0020), confirming the efficacy of the treatment in reducing *Kandu*.

EFFECT OF THERAPY ON *DAHA*-

The mean score of *Daha* before treatment was 1.3, which reduced to 0.1 after treatment, showing a mean difference of 1.2 and a percentage relief of 92.30%. The Wilcoxon signed Rank test indicated a statistically very significant improvement (p = 0.0078), conforming the efficacy of the treatment in reducing *Daha.*

EFFECT OF THERAPY ON *RAGA*-

The mean score of *Raga* before treatment was 2.20, which reduced to 0.50 after treatment, showing a mean difference of 1.70 and a percentage relief of 77.27%. The Wilcoxon signed Rank test indicated a statistically very significant improvement (p= 0.0020), conforming the efficacy of the treatment in reducing *Raga.*

EFFECT OF THERAPY ON NO. OF *MANDALA*-

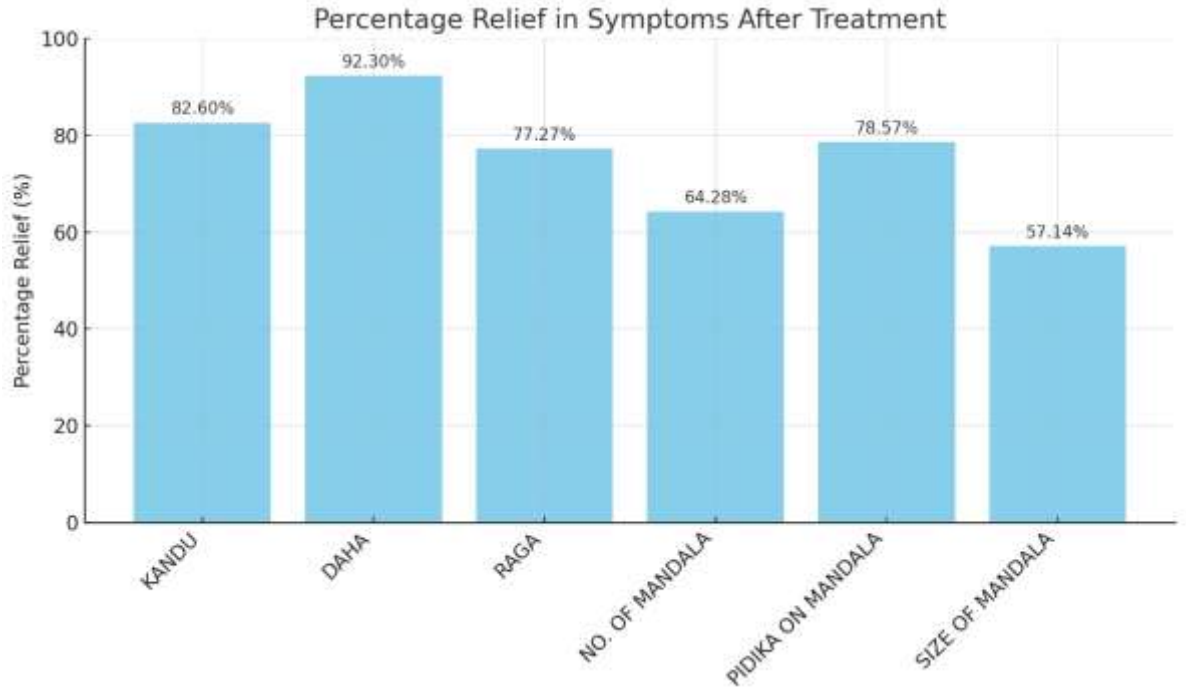
The mean score of No. of *Mandala* before treatment was 1.40, which reduced to 0.50 after treatment, showing a mean difference of 0.90 and a percentage relief of 64.28%. The Wilcoxon signed Rank test indicated a statistically very significant improvement (p= 0.0039), conforming the efficacy of the treatment in reducing *No. of Mandala.*

EFFECT OF THERAPY ON *PIDIKA* ON *MANDALA*-

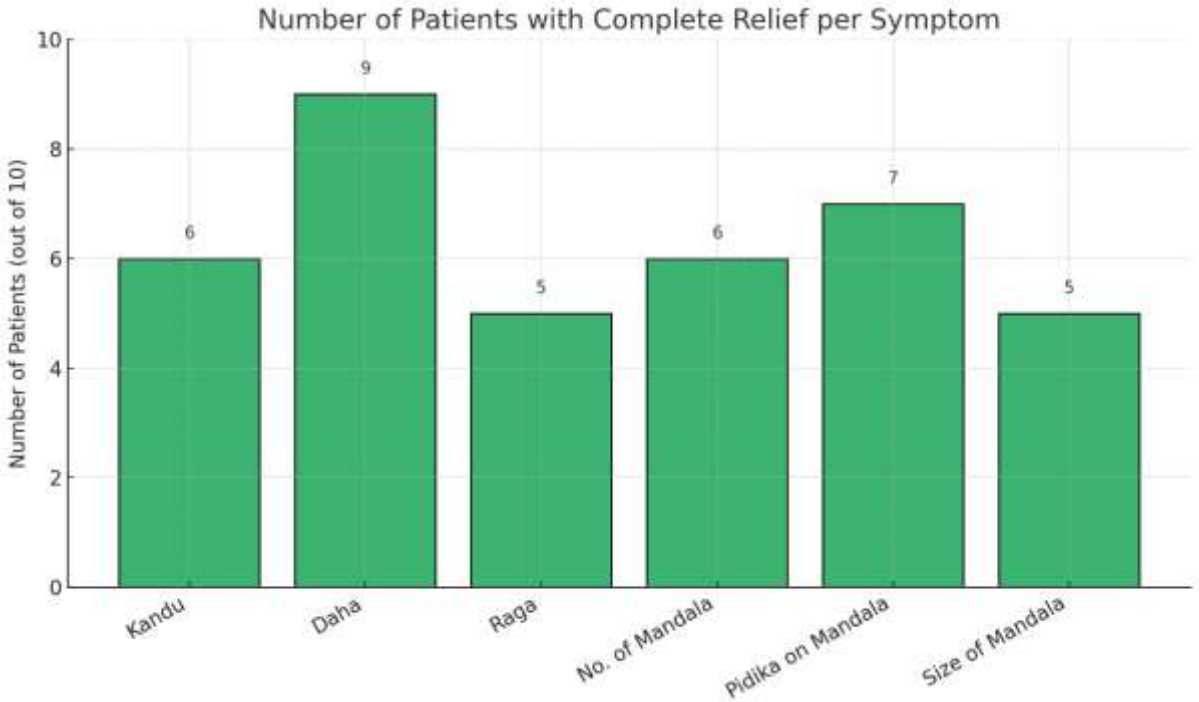
The mean score of *Pidika* on *Mandala* before treatment was 1.40, which reduced to 0.30 after treatment, showing a mean difference of 1.10 and a percentage relief of 78.57%. The Wilcoxon signed Rank test indicated a statistically very significant improvement *(p*= 0.0020), conforming the efficacy of the treatment in reducing *Pidika on mandala*.

EFFECT OF THERAPY ON SIZE OF *MANDALA*-

The mean score of Size of *Mandala* before treatment was 1.40, which reduced to 0.60 after treatment, showing a mean difference of 0.80 and a percentage relief of 57.14%. The Wilcoxon signed Rank test indicated a statistically very significant improvement (p= 0.0078), conforming the efficacy of the treatment in reducing Size of *Mandala.*



OVERALL EFFECT OF THERAPY:



FOLLOW UP PERIOD:

No complications were observed during the treatment or follow-up period. On follow-up, 2 out of 10 patients reported recurrence of symptoms, while 8 out of 10 patients expressed satisfaction with the treatment and experienced relief from previous symptoms.

DISCUSSION

The basic principles of *hetu* of *Dadru* have been mentioned in *Brihattraye* and *Laghutraye* in the *Kushtha nidana*. Most of the *Apathya ahara, vihara* mentioned in *Ayurveda* for causes of *Kushtha,* produces a healthy environment for the growth of fungal infection in the skin tissues. In *Ayurvedic* Science Skin diseases are classified under broad heading of *Kushtha* which is further classified into *Maha Kushtha* and *Kshudra Kushtha*. *Acharya Charaka* included *Dadru Kushtha* in *Kshudra Kushtha* where *Acharya Sushruta* and *Vagbhata* have explained under *Maha Kushtha*. According to *Acharya Dalhan Dadru Kushtha* is classified into 2 types *Sitha* and *Asitha*. In morden medicine also explained superficial and Deep Mycoses, which may be correlate with *Sitha* and *Asitha* type. *Dadru Kushtha* is predominantly *Pitta -Kapha* as per *Acharya Charaka* and *Acharya Vagbhata*. On other hand *Kaphaja* as per *Acharya Sushruta*.

In contemporary medicine, *Dadru Kushtha* is correlated to fungal infection that is Tinea. The symptoms of *Dadru* and Dermatophytosis (Tinea / Ringworm) shows tremendous similarities with each other. The fungal disease of the skin can be divided into Superficial mycoses and Deep mycoses. Superficial mycoses infections are restricted to invasion of horny structures like the stratum concern, the nails and the hair. While the Deep mycoses involve systemic conditions. Deep mycosis is much more common in immune compromised patients including those with AIDS, on corticosteroids etc. Clinically, these infections are referred to as tinea followed by a Latin term denoting the specific anatomical site of involvement, e.g. tinea capitis for ringworm of the scalp, Tinea barbae for Ringworm of beard and moustache, Tinea Corporis for Ringworm of thorax and extremities, Tinea Manuum for Ringworm of Palm, Tinea pedis for ringworm of the Feet (Athlete foot), Tinea Cruris for ringworm of the Groins, Perineum ,thigh, Scrotum , Tinea Unguium for ringworm of Nails (onychomycosis), and Tinea Faciei for Ringworm of face. It is one of the *Upsargik roga*. The disease mainly develops in *bahaya rogamarga* and involves *Rasavaha* and *Raktavaha srotas*. *Dadru kushtha* is *tridoshaja vyadhi* with *pitta-kapha* predominance, *Twacha, Rakta, Mamsa* and *Lasika are dushya.* This is the specificity of the pathogenesis o*f Dadru. Ayurvedic* therapy focuses on avoiding etiological variables and breaking down pathology which leads to *dhatu samya*. *Navkarshika Kashaya* and *Dadrughana Lepa* both

act on each and every *Sampraptighataka* and causes *Sampraptivighatana* resulting in healthy skin.

The Probable mode of Action of *Dadrughana Lepa*

The *Lepa Kalpana* is a wonderful scientific approach for transferring the active ingredients of medications to target cells, resulting in a speedy and successful healing process. The formulation is mentioned in *Sharangdhar Samhita,* the ingredients of *Lepa* are *Chakramarda (Cassia tora), Siddharthaka (Sinapis alba), Haridra (Curcuma longa), Kushth (Sausseria Lepa),* and *Tila (sesamum Indicam)* were taken in equal amounts and grinded separately mixed with *sarshapa oil (Brassica compestris*) to make homogeneous mixture having thick paste until consistency into *Lepa.* It includes *Snigdha, Tikshna Guna, Ushana Veerya,* and *Katu Vipaka.* The absorption and metabolism of *lepa* are the joint efforts of *Bhrajaka pitta, Samana vayu,* and *Slesaka Kapha. Bhrajaka pitta* metabolize the active principles of drugs that have been applied over the skin with the support of *samana* and *vyana vayu* [17]. *Agni* situated in skin in the form of *Bhrajaka pitta* facilitates *Pachana* of active principles of drug for absorption (catabolic degradation by enzymes) and pacify the provoked *Doshas* and alleviates local symptoms like *Kandu, Vaivarnya, Vidaha* by breaking pathogenesis.

Lepa Kalpana is given prime importance in the management of *Kushtha. Acharya Charaka* described *Lepa* (local application) as *Sadyah Siddhi karaka* (immediate effect) [18]. Various types of *lepa* are described for the treatment of *Dadru*. *Doshaghana lepa,* according to *Sharangdhara*, can be applied to treat diseases similar to *Dadru*. *Sharangdhara* specifies the thickness of *Doshaghana lepa* as ¾ *angula*, which is approximately 0.48cm. *Dadrughna Lepa* has high potential as an antifungal agent when it is mixed with *Sarshapa tailam*. Thus, it will be extremely effective when put in a thick coat. It also enhances the retention time of the medicine over the afflicted portion due to maximum drug absorption impact. According to modern medical science *Lepa Kalpana* can be understood in form of transdermal drug delivery system. herbal oil- based paste applied on the skin, oil is Lipophilic it can easily penetrate the skin fat layers. Most of the ingredients of *Dadrughna Lepa* have fat soluble phytochemicals. oil keeps the herbs moist and active for longer time specially when oil is slightly warm increases skin pore opening and improve blood flow, this it carries herbal actives deep inside tissues. Oil calms dryness and inflammation, herbs act locally (anti- inflammatory and antimicrobial activity), as well as enter bloodstream through capillaries and act systemic level.

The probable mode of Action of *Navkarshika Kashaya*

Navakarshika Kashaya formulation, cited by *Acharya Chakrapani* in *Chakradutta* as *Vatarakta chikitsa rogadhikar.* It is made up of two words: *"Nava"* indicates nine, and *Karsha* is an *Ayurvedic* measurement of weight. When all of these ingredients are combined in 1 *karsh* quantities, the total becomes *Nava Karsha*, hence the name *Navakarshika Kashaya*. It is used to cure a variety of skin conditions, including *Kushtha, Pama, Rakta mandala, Kapalika kushtha*, and *Vatrakta*. *Triphala (Haritaki, Vibhitiki, Amalaki), Nimba, Manjishtha, Vacha, Katuki, Guduchi, and Daruharidra* are the ingredients of *Navakarshik Kashaya,* and they have properties such as *Agnidipana, Ama pachana, Raktashodhana, Pitta Kaphahara,* and *Kushthaghna.* In *Dadru Kushtha Rasa, Rakta, Mamsa,* and *Lasika* are the main *Dushyas.* Vikrut *Rasa* is produced by *Rasa Dhatvagnimandhya* and *Jatharagnimandhya*. *Karma* like *Deepana, Pachana* help to proper *Rasa Dhatu* formation which correct *Kapha.* The drugs like *Vibhitaki* and *Amalaki* having properties like *Deepana.* Drugs having *Rakta Shodhaka* properties are *Manjishtha, Daruharidra. Nimba, Kutaki* causes *Pitta virechana* which help in term of *Pitta shodhana* and *Prakrit Pitta nirman.*

Triphala is considered to be effective in the treatment of *Dadru* (Dermatophytosis) because of its anti-inflammatory, astringent, and antifungal characteristics, which support to alleviate itching, redness, and inflammation associated with the condition. *Dadru* is thought to be a skin disorder produced primarily by an imbalance of *Pitta* and *Kapha doshas*, resulting in symptoms such as itching (*Kandu)*, redness (*Raga)*, eruptions (*Pidika*), and elevated circular lesion (*Utsana mandala)*. *Triphala* is considered to calm these *doshas* and has properties such as *Kushthaghna, Kandughna, and Raktaprasadana* [19].

Nimba is known for its various therapeutic properties, including anti-fungal, anti-inflammatory and skin soothing effect. It is believed to have *Krumighna, Vranashodhana* and *kandughna* properties [20].

Manjishtha is a drug used to normalize the complexion of skin. It acts as a skin protective, Blood purifier, Anti-oxidant, wound healing, Anti-microbial, Anti-fungal, and Anti-bacterial properties. *Manjishtha* with *Tikta* and *Kashaya Rasa* and *Madhur vipaka* causes *Daha shaman*. Due to its *Tikta Rasa* and *Katu vipaka Kandughana* and *Kushthaghana* action are performed [21].

Vacha is also known for its *Kushthagna* properties, which help in treating skin disease. It also has the insecticidal, antimicrobial, antioxidant, anticholinesterase and antifungal activity [22].

Daruharidra, In *Charaka Samhita* it has been classified under *Kandughna mahakashaya*.The alkaloid extract of the plant showed significant antimicrobial activity against the number of microbes including virus, bacteria fungi, protozoas, helminths and chlamydia. It also showed antifungal activity against different fungal pathogens [23].

Kutaki is known for its detoxifying properties in *Ayurveda.* It is often used in formulation for various ailments, including skin diseases, aiding in purging toxins and balancing *doshas* to improve skin condition like *Dadru* [24].

Guduchi is known for its anti-inflammatory, anti-arthritic and anti- immunomodulatory properties, as well as its antioxidant effects. It is used for its *Kushthahara* properties [25].

CONCLUSION

From these observations, it is concluded that*, Dadru* (Dermatophytosis) can be managed successfully with *Navkarshika kashayam* and *Dadrughna Lepa,* thus Null Hypothesis was rejected.

SUGGESTION FOR FUTHER STUDY:

Hence the treatment plan involving series of *Shodhana* therapy after *Samyak Snehana, Swedana* has to be adopted, which followed by long term *Shamana chikitsa* to avoid recurrences. *Ayurveda* medicine offers a good approach to manage *Dadru*, but to establish this fact, aforementioned study needs to be conducted in a large sample.

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CONFLICT OF INTEREST: Nill

BEFORE TREATMENT

AFTER TREATMENT

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