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A Comparative Study of *Dadrughni Vati* (*Lepa*) and *Dadrughna Malahara* in the Management of *Dadru*: A Randomized Clinical Trial

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Abstract

Introduction: Clinical studies are essential for validating traditional therapies and bridging the gap between ancient Ayurvedic practices and modern scientific approaches. One such condition, *Dadru* (a form of *Kshudra Kushtha*), is a chronic dermatological disorder resembling dermatophyte infections, prevalent in humid climates like India. Despite using Ayurvedic formulations like *Dadrughni Vati* (*Lepa*) for its management, limited clinical evidence supports its efficacy, particularly compared to newer treatments that may enhance patient compliance. To address this, a novel formulation, *Dadrughna Malahara*, has been developed to improve ease of use and treatment adherence while maintaining the therapeutic benefits of traditional remedies. This study aims to evaluate and compare the efficacy of *Dadrughni Vati* (*Lepa*) and *Dadrughna Malahara* in managing *Dadru* through a randomized controlled trial, providing evidence to refine treatment strategies for this challenging skin condition. Material and Methods: an interventional open-label parallel arm randomized clinical trial was conducted with 68 patients with *Dadru*. Participants were divided into two groups. Group A received *Dadrughni Vati* (*Lepa*), while Group B was treated with *Dadrughna Malahara*. The treatment duration was 4 weeks, and the patients were assessed for classical sign and symptoms. Results: Both *Dadrughni Vati* (*Lepa*) and *Dadrughna Malahara* demonstrated significant therapeutic efficacy in the treatment of *Dadru Kushtha*, providing substantial relief from symptoms such as *Kandu, Raga, Pidika*, and *Utasanna Mandala*. *Dadrughna Malahara* showed slightly better results, particularly in Kandu and *Utasanna Mandala* (Numbers and Size), though the differences were statistically nonsignificant. Conclusion: The study suggests that these Ayurvedic formulations can be a viable treatment option for *Dadru*.

Keywords: Ayurveda, *Kshudra Kushtha*, Dermatophyte Infection, Skin disorders.

INTRODUCTION

Clinical studies are pivotal in validating traditional therapeutic approaches and bridging the gap between ancient wisdom and modern scientific practices. While Ayurvedic medicine offers a wealth of knowledge regarding natural formulations' properties and therapeutic effects, there is a growing need to substantiate these claims through rigorous clinical research. This is particularly important in treating skin diseases, which have significant physical, psychological and social impacts. One such skin condition is *Dadru*, a form of *Kshudra Kushtha*, [1] as described in Ayurvedic texts. *Dadru* is a persistent dermatological disorder often resembling dermatophyte infections, which are common fungal infections that affect a 20 % of the global population [2] and 32.4% of the population in India [3]. In India, where humid tropical climates contribute to the prevalence of such skin conditions, *Dadru* remains a challenging issue, both in terms of treatment and social stigma.

Ayurvedic texts, including the *Bheshaja Samhita*, provide a range of formulations aimed at managing *Dadru*, with therapies typically falling into internal and external categories. Among the various external treatments, *Dadrughni Vati (Lepa)* has been noted for its therapeutic potential. The *Bheshaja Samhita* details its preparation, medicinal properties, and indications for use [4]. Despite its historical and widespread use, however, there is a lack of comprehensive clinical research evaluating the efficacy of *Dadrughni Vati (Lepa)*, particularly in comparison to newer formulations that may improve patient compliance and ease of application.

To address this gap, a novel formulation, *Dadrughna Malahara*, has been developed with the aim of enhancing the applicability of the treatment while preserving the efficacy and safety demonstrated in

traditional formulations. The introduction of *Dadrughna Malahara* seeks to overcome some of the limitations associated with *Dadrughni Vati (Lepa)*, such as issues related to application, handling, and patient adherence.

In light of the existing challenges and the potential for improving treatment outcomes, this clinical study is designed to evaluate and compare the therapeutic efficacy of *Dadrughni Vati (Lepa)* and *Dadrughna Malahara* in the management of *Dadru*. Through a randomized controlled trial, aim to provide evidence-based insights into the comparative effectiveness of these two Ayurvedic formulations, ultimately contributing to the refinement of treatment strategies for *Dadru*.

MATERIALS AND METHODS

Procurement of the raw materials

Tankana, Sphatika and *Tila Taila* were procured from the Government Ayurved Pharmacy, Rajpipla, Gujarat. *Gandhaka, Sarjarasa, Chakramarda Beeja, Siktha, Go-ghrita* and *Go-dugdha* were procured from the local traders of Vadodara, Gujarat. *Jambiri Nimbu* was procured from the farmer of Amreli, Gujarat.

Identification of raw material

The samples of *Chakramarda* (*Cassia tora* Linn), *Sarjarasa* (*Shorea robusta* Gaertn), and *Jambiri Nimbu (Citrus jambhiri* Lush.) were identified in the Pharmacognosy Laboratory, Upgraded Department of Dravyaguna, Government Ayurveda College, Vadodara, Gujarat. The samples of *Gandhaka*, *Sphatika*, and *Tankana* were identified at the Quality Testing Laboratory of the Upgraded Department of Rasashastra and Bhaishajya Kalpana, Government Ayurveda College, Vadodara, Gujarat. *fssai* (Food Safety and Standards Authority of India) standard *Tila Taila, Go-ghrita* and *Go-dugdha* were procured.

Preparation of *Dadrughni Vati* (*Lepa*) and *Dadrughna Malahara*

All the batches of *Dadrughni Vati* (*Lepa*) were prepared as per the reference of Bheshaj Samhita [5] and *Dadrughna Malahara* was a modified dosage form of *Dadrughni Vati* (*Lepa*) prepared in the Pharmaceutical Laboratory of Upgraded Department of Rasashastra and Bhaishajya Kalpana, Government Ayurved College, Vadodara, Gujarat.

Study design

The study was an interventional open-label parallel arm randomized clinical trial. Written informed consent was taken prior to patient enrolment as per the Helsinki Declaration after offering sufficient explanations about the study and its aims. 68 subjects were randomized in blocks of 34:34 from http://www.randomization.com (Created on 18th April 2024). Patients with classical symptoms of *Dadru* were selected from the OPD and IPD of Govt. Ayurved Hospital, Vadodara.

Ethical compliance

The study was conducted in compliance with Institutional Ethics Committee Approval (GAV/ VAD/ IEC/ 78/ 2023, Dated 13/03/2023) for the study protocol, participant information sheet, and informed consent form before the study initiation. The study was prospectively registered with the Clinical Trials Registry of India vide no. CTRI/2023/07/055376; dated 19/07/2023.

Diagnostic Criteria

Diagnosis was made based on classical signs and symptoms of *Dadru* [6] like *Kandu* (Itching), *Raga* (Redness), *Pidika* (Eruption), *Utsanna Mandala* (Slightly elevated patches on Skin).

Inclusion Criteria

Known cases of *Dadru* with classical signs and symptoms of *Dadru* of either sex and religion with age between 18 to 60 years and willing to give written consent were eligible to participate in the trial.

Exclusion Criteria

The study will exclude patients who are below 18 years of age or above 60 years. Additionally, individuals suffering from systemic diseases such as Diabetes Mellitus, Hypertension, Malignancy, Tuberculosis, Renal diseases, Liver diseases, or those who test positive for VDRL will not be included in the trial.

Study intervention

Group A received *Dadrughni Vati* (*Lepa*), while Group B received *Dadrughna Malahara* for the external application once at night on the affected area with a dose of 2 capsules of placebo once a day after a meal internally. Patients with classical signs and symptoms of *Dadru* were selected from the OPD of Government Ayurved Hospital, Vadodara, Gujarat. The total duration of the trial was 4 weeks, followed by 2 weeks follow-up period. A comprehensive examination of the patients was conducted, along with guidance on the *Pathya-Apathya* diet. Patients were advised to avoid all causative factors of *Kushtha*, such as heavy foods (*Guru Anna*), sour foods (*Amla Rasa*), milk (*Paya*), yogurt (*Dadhi*), fermented foods (*Pishtanna Sevana*), incompatible food combinations (*Viruddha Bhojana*), meat consumption (*Mansa Sevana*), jaggery (*Guda*), and sesame seeds (*Tila*) during the study period.

Data Collection Procedure

The screening and enrollment of trial participants were carried out based on the established inclusion criteria. Informed consent was obtained from all participants and relevant data were recorded in a specially designed Case Record Form. This form included a comprehensive medical history, clinical examination findings, and necessary assessments for each subject.

Criteria for Assessment

After completion of treatment, Changes in signs and symptoms were monitored weekly and documented in the clinical proforma. The treatment's effect was evaluated using subjective and objective criteria.

Subjective Criteria: Signs and symptoms were assessed using a Grading Analog Scale (GAS) before and after treatment, with scores assigned to different symptoms.

Objective Criteria: Routine hematological tests, including hemoglobin (Hb), total count (TC), differential count (DC), and erythrocyte sedimentation rate (ESR), were conducted to assess the clinical response.

The detailed assessment of clinical signs and symptoms is discussed in Table 1.

Outcome Measures

The data obtained from the clinical study were analyzed using statistical methods, with results expressed as the mean and standard error of the mean. As the data were not normally distributed, non-parametric tests, including the Wilcoxon Signed Rank test and Mann-Whitney Rank Sum test, were applied. Percentage improvement for each parameter was calculated in both treatment groups, and statistical analysis was performed using Sigma Stat 3.2 software [7]. The level of significance for both tests was determined by the 'p' value: for the Wilcoxon Signed Rank test, a p-value > 0.05 was considered non-significant, ≤ 0.05 to ≤ 0.02 as significant, and ≤ 0.001 as highly significant; for the Mann-Whitney Rank Sum test, a p-value > 0.05 was non-significant, ≤ 0.05 to ≤ 0.01 as significant, and ≤ 0.001 as highly significant. The overall effect of therapy was categorized based on the improvement in signs and symptoms as follows: complete remission (100% relief), marked improvement (76-99% relief), moderate improvement (51-75% relief), mild improvement (26-50% relief) and unchanged (< 25% relief).

Table 1: A detailed assessment of clinical signs and symptoms

Subjective criteria

S. No.	1. *Kandu* (Itching)	Grades
1	No Itching	0
2	Mild Itching: Which comes occasionally, does not disturb the mind, duration is 2/3 min; usually scratching is not required	1
3	Moderate Itching: Which occurs frequently disturbs the mind, lasts for longer time, scratching every time is essential, recurs 3/4 times in 12 hours	2
4	Severe Itching: Frequently occurs, disturbs mind & sleep, lasts for 20/30 min, scratching very essential, recurs 8/10 times in 12 hours	3
5	Excessive Itching: Continuous itching, scratching marks present on body, drastically disturbs mind, sleep not possible.	4
S. No.	**2. *Raga* (Redness)**	**Grades**
1	Normal skin colour	0
2	Faint discolouration & near to normal skin colour	1
3	Blanching & red colour	2
4	Red colour	3
S. No.	**3. *Pidika* (Eruption)**	**Grades**
1	No papules per circular patch	0
2	1 to 3 numbers of papules in most of circular patches	1
3	4 to 6 numbers of papules in most of circular patches	2
4	More than 6 numbers of papules in most of circular patches	3
S. No.	**4. *Utsanna Mandala* (Numbers of Slightly Elevated patches on skin surface)**	**Grades**
1	No clear circular patch	0
2	4-6 numbers of circular patch	1
3	7-9 numbers of circular patch	2
4	More than 10 numbers of circular patch	3
S. No.	**5. *Utasnna Mandala* (Size of Slightly Elevated patches on skin surface)**	**Grades**
1	No clear circular patch.	0
2	Most of circular patches are less than 5 cm in size.	1
3	Most of circular patches are 5-10 cm in size.	2
4	Most of circular patches are more than 10 cm in size.	3

Associate Symptoms

Associated Symptoms	No Symptom	Mild	Moderate	Severe	Very Severe
Vibandha (constipation)	0	1	2	3	4
Guruta (heaviness)	0	1	2	3	4
Klama (fatigue without work)	0	1	2	3	4
Alasya (lethargy)	0	1	2	3	4
Adhmana (flatulence)	0	1	2	3	4
Urodaha (burning in chest)	0	1	2	3	4
Any other	0	1	2	3	4

Table 2: Cardinal symptom-wise distribution

Cardinal Symptoms	No of patients		Total (n=68)	Percentage (%)
	A (n=34)	B (n=34)		
Kandu	34	34	68	100.00
Raga	34	34	68	100.00
Pidika	34	34	68	100.00
Utsanna Mandala	34	34	68	100.00

Table 3: Associate symptom-wise distribution

Associated Symptoms	No of patients		Total (n=68)	Percentage (%)
	A (n=34)	B (n=34)		
Vibandha	13	15	28	41.18
Guruta	11	13	24	35.29
Klama	05	07	12	17.65
Alasya	05	06	11	16.18
Adhmana	07	11	18	26.47
Urodaha	06	08	14	20.59

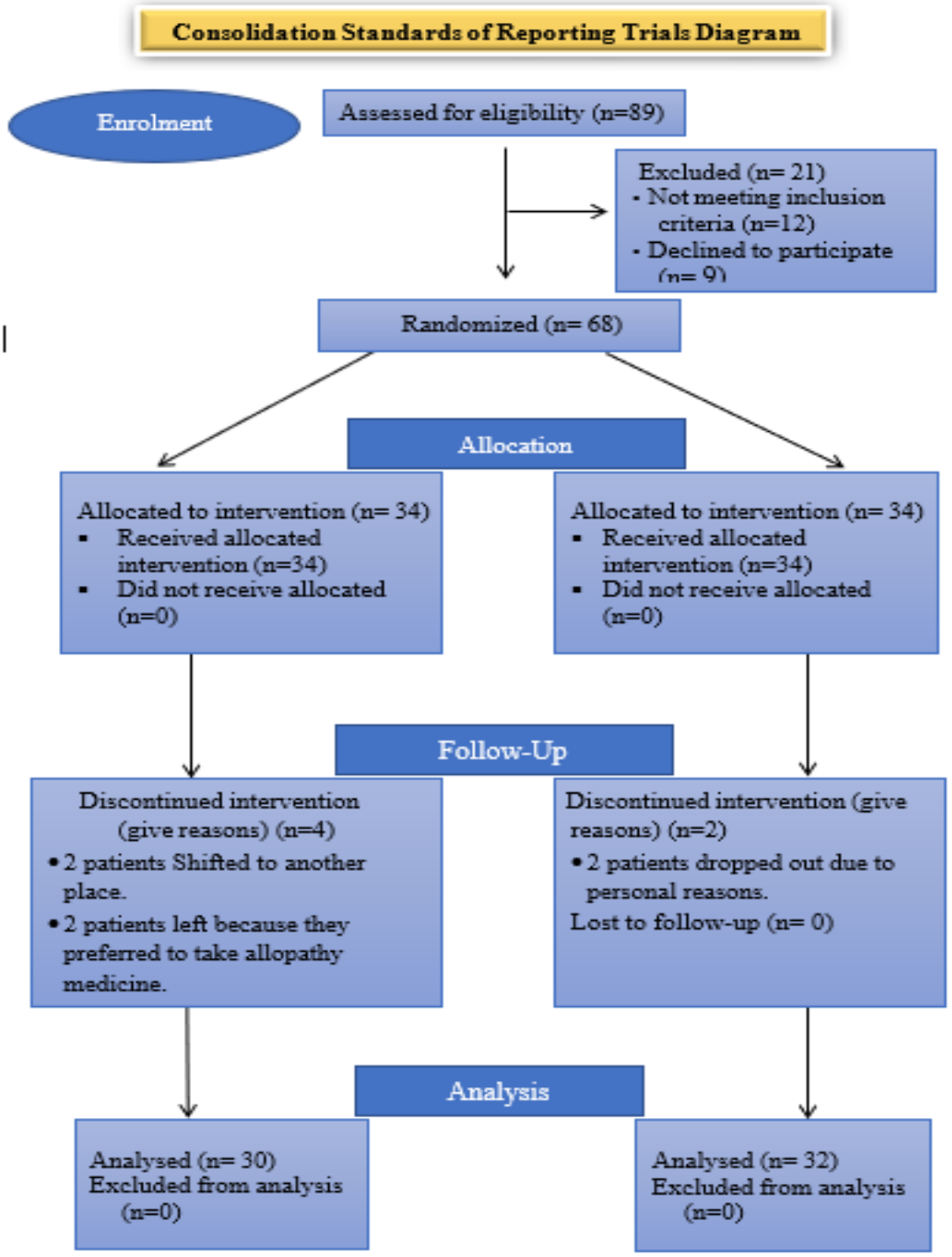

Figure 1: CONSORT Diagram

RESULTS

In the present study, a total of 89 patients were screened for eligibility. Among them, 21 patients did not meet the inclusion criteria, and 9 declined to participate. 68 patients were randomized in blocks of 34:34 from http://www.randomization.com (Created on 18th April 2024). Out of these 62 patients completed the treatment, 30 patients in group A and 32 patients in group B. 4 patients in group A and 2 patients in group B discontinued the treatment for various reasons. In Group A, two patients were shift to another location and chose to discontinue their participation. Additionally, two other patients from the same group left because they preferred to pursue allopathic medicine instead. In Group B, two patients dropped out due to personal reasons. The CONSORT diagram is given in Figure 1. Cardinal Symptoms Distribution is Shown in Table 2.

All the patients were having complaint of *Kandu, Raga, Pidika* and *Utsanna Mandala.* Associated Symptoms Distribution is Shown in Table 3.

Table 3 shows that 41.18 % of patients had *Vibandha* followed by 35.29 % with *Guruta*, 26.47 % with *Adhmana*, 20.59 % with *Urodaha*, 17.65 % with *Klama* and 16.18 % with *Alasya* in associated symptoms.

The effect of the test drug on Subjective Criteria of Cardinal Symptoms in Group A showed that 63.33 % decrease in symptom of *Kandu*, 52.22 % decrease in *Raga,* 76.11 % decrease in *Pidika*, 41.67 % decrease in *Utasanna Mandala* (No. of lesions) and 50.56 % decrease in *Utasanna Mandala* (Size of circular lesions)**.**

The effect of the test drug on the subjective criteria of cardinal symptoms in Group A is shown below in Table 4.

The effect of the test drug on Subjective Criteria of Cardinal Symptoms in Group B showed that 69.27 % decrease in symptom of *Kandu*, 51.56 % decrease in *Raga,* 76.04 % decrease in *Pidika*, 51.82 % decrease in *Utasanna Mandala* (No. of lesions) and 58.85 % decrease in *Utasanna Mandala* (Size of circular lesions)**.**

The effect of the test drug on the subjective criteria of cardinal symptoms in Group B is shown below in Table 5.

The effect of the test drug on Subjective Criteria of Associate Symptoms in Group A showed that 20.00 % decrease in symptom of *Vibandha*, 16.67 % decrease in *Guruta,* 6.67 % decrease in *Klama, Alasya* and *Adhmana,* 3.33 % decrease in *Urodaha.*

The effect of the test drug on the subjective criteria of Associated symptoms in Group A is shown below in Table 6.

The effect of the test drug on Subjective Criteria of Associate Symptoms in Group B showed that 18.75 % decrease in symptom of *Vibandha* and *Guruta,* 6.25 % decrease in *Klama* and *Alasya*, 12.50 % decrease in *Adhmana,* 9.38 % decrease in *Urodaha.*

The effect of the test drug on the subjective criteria of Associated symptoms in Group B is shown below in Table 7.

Highly Significant change was found in ESR, Significant change was found in Monocyte while Nonsignificant change was found in all other hematological parameters in patients of Group A. Highly Significant change was found in ESR while Nonsignificant change was found in other all hematological parameters in patients of Group B.

The effect of the test drug on hematological parameters in Group A is shown below in Table 8.

The effect of the test drug on hematological parameters in Group B is shown below in Table 9.

Table 10 shows comparative effect between both groups on chief complaints. There was Nonsignificant ($p > 0.05$) significance observed between both the drugs.

Table 11 shows comparative effect between both groups on associated complaints. There was Nonsignificant ($p > 0.05$) significance observed between both the drugs.

Table 12 shows the comparative effect between both groups on Heamatological Parameters. There was Nonsignificant ($p > 0.05$) significance observed between both the drugs.

Total Effect of Therapy on 62 patients of Dadru mentioned in Table 13.

It is evident from the above data that in Group A, 40 % of the patients showed moderate improvement, 26.67% showed mild and marked improvement, 3.33 % of the patients showed complete remission and remained unchanged.

In Group B, 34.38 % of the patients showed marked improvement, 25.00 % showed moderate and mild improvement, 9.38 % of the patients showed complete remission and 6.25 % of the patients remained unchanged.

Table 4: Effect of Test Drugs on Subjective Criteria (Cardinal Symptoms) in Group A

Criteria	N	Mean±SEM			Relief (%)	Rank (W)	T+	T-	P	SS
		B.T.	A.T.	Change						
Kandu	30	3.333± 0.111	1.233± 0.149	2.100± 0.147	63.33↓	-435.00	0.000	-435.00	<0.001	HS
Raga	30	2.567± 0.114	1.233± 0.141	1.333± 0.138	52.22↓	-351.00	0.000	-351.00	<0.001	HS
Pidika	30	1.967± 0.131	0.400± 0.113	1.567± 0.164	76.11↓	-395.00	5.500	-400.50	<0.001	HS
Utasanna Mandala (No.)	30	1.533± 0.142	0.867± 0.142	0.667± 0.138	41.67↓	-136.00	0.000	-136.00	<0.001	HS
Utasanna Mandala (Size)	30	1.800± 0.147	0.867± 0.150	0.933± 0.159	50.56↓	-210.00	0.00	-210.00	<0.001	HS

Table 5: Effect of Test Drugs on Subjective Criteria (Cardinal Symptoms) in Group B

Criteria	N	Mean±SEM			Relief (%)	Rank (W)	T+	T-	P	SS
		B.T.	A.T.	Change						
Kandu	32	3.094± 0.145	1.031± 0.177	2.063± 0.162	69.27↓	-465.00	0.000	-465.00	<0.001	HS
Raga	32	2.625± 0.097	1.281± 0.129	1.344± 0.132	51.56↓	-406.00	0.000	-406.00	<0.001	HS
Pidika	32	2.219± 0.140	0.500± 0.149	1.719± 0.181	76.04↓	-453.00	6.000	-459.00	<0.001	HS
Utasanna Mandala (No.)	32	1.688± 0.152	0.938± 0.174	0.750± 0.110	51.82↓	-231.00	0.000	-231.00	<0.001	HS
Utasanna Mandala (Size)	32	2.000± 0.156	0.813 ±0.152	1.188 ±0.165	58.85↓	-300.00	0.00	-300.00	<0.001	HS

Table 6: Effect of Test Drugs on Subjective Criteria (Associated Symptoms) in Group A

Criteria	N	Mean±SEM			Relief (%)	Rank (W)	T+	T-	P	SS
		B.T.	A.T.	Change						
Vibandha	10	0.333± 0.0875	0.133± 0.0631	0.200± 0.0743	20.00↓	-21.00	0.000	-21.000	0.031	S
Guruta	08	0.267± 0.0821	0.1000± 0.0557	0.167± 0.0692	16.67↓	-15.00	0.000	-15.00	0.063	NS
Klama	05	0.167± 0.0692	0.1000± 0.0557	0.0667± 0.0463	6.67↓	-3.000	0.000	-3.000	0.500	NS
Alasya	05	0.167± 0.0692	0.1000± 0.0557	0.0667± 0.0463	6.67↓	-3.000	0.000	-3.000	0.500	NS
Adhmana	06	0.200± 0.0743	0.133± 0.0631	0.0667± 0.0463	6.67↓	-3.000	0.000	-3.000	0.500	NS
Urodaha	05	0.167± 0.0692	0.133± 0.0631	0.0333± 0.0333	3.33↓	-1.000	0.000	-1.000	1.000	NS

Table 7: Effect of Test Drugs on Subjective Criteria (Associated Symptoms) in Group B

Criteria	N	Mean±SEM			Relief (%)	Rank (W)	T+	T-	P	SS
		B.T.	A.T.	Change						
Vibandha	13	0.406± 0.0882	0.219± 0.0742	0.188± 0.0701	18.75↓	-21.000	0.000	-21.000	0.031	S
Guruta	12	0.375± 0.0870	0.188± 0.0701	0.188± 0.0701	18.75↓	-21.00	0.000	-21.000	0.031	S
Klama	07	0.219± 0.0742	0.156± 0.0652	0.0625± 0.0435	6.25↓	-3.000	0.000	-3.000	0.500	NS
Alasya	06	0.188± 0.0701	0.125± 0.0594	0.0625± 0.0435	6.25↓	-3.000	0.000	-3.000	0.500	NS
Adhmana	11	0.344± 0.0853	0.219± 0.0742	0.125± 0.0594	12.50↓	-10.000	0.000	-10.000	0.125	NS
Urodaha	07	0.219± 0.0742	0.125± 0.0594	0.0938± 0.0524	9.38↓	-6.000	0.000	-6.000	0.250	NS

Table 8: Effect of Test Drugs on Hematological Parameters in Group A

Criteria	N	Mean ±SEM			Relief (%)	Rank (W)	T+	T-	P	SS
		B.T.	A.T.	Change						
Hb	30	13.680± 0.353	13.637± 0.354	0.0433± 0.0666	0.30↓	-37.000	199.0	-236.00	0.696	NS
TLC	30	7743.33± 306.80	7743.33± 325.56	0.000± 259.620	-1.11↑	22.000	243.5	-221.50	0.829	NS
Neutrophils	30	59.500± 1.430	60.433± 1.317	0.933± 0.659	-1.90↑	108.00	229.5	-121.5	0.172	NS
Lymphocyte	30	34.033± 1.320	33.667± 1.202	0.367± 0.697	0.02↓	-47.00	152.0	-199.0	0.556	NS
Eosinophil	30	2.833± 0.0692	2.767± 0.0785	0.0667± 0.0463	2.22↓	-3.000	0.000	-3.000	0.500	NS
Monocyte	30	3.633± 0.122	3.167± 0.160	0.467± 0.190	9.17↓	-49.00	8.500	-57.500	0.024	S
ESR	30	19.73± 32.743	16.43± 32.301	3.300± 1.156	14.5↓	-310.00	34.00	-344.00	<0.001	HS

Table 9: Effect of Test Drugs on Hematological Parameters in Group B

Criteria	N	Mean ±SEM			Relief (%)	Rank (W)	T+	T-	P	SS
		B.T.	A.T.	Change						
Hb	32	13.113± 0.362	12.991± 0.347	0.122± 0.0701	0.79↓	-110.00	162.5	-272.50	0.238	NS
TLC	32	8525.0± 403.613	8306.25± 330.168	218.750± 218.104	0.79↓	-92.000	218.0	-310.00	0.395	NS
Neutrophils	32	60.906± 1.183	62.938± 1.203	-2.03± 1.318	- 4.13↑	174.00	290.0	-116.0	0.048	NS
Lymphocyte	32	32.844± 1.050	31.375± 1.041	1.469± 1.191	2.58↓	-123.00	127.5	-250.50	0.141	NS
Eosinophil	32	2.875± 0.0594	2.750± 0.0778	0.125± 0.0870	3.13↓	-18.000	9.000	-27.000	0.250	NS
Monocyte	32	3.375± 0.154	3.125± 0.154	0.250± 0.196	0.52↓	-43.00	46.50	-89.500	0.274	NS
ESR	32	24.06± 33.343	20.56± 32.822	3.500± 1.247	5.77↓	-251.00	37.00	-288.00	<0.001	HS

Table 10: Comparative effect of therapy on chief complaints

Chief Complaints	No.		Group A	Group B	Change	'U'	P	SS
	A	B	Mean±SEM	Mean±SEM	Mean±SEM			
Kandu	30	32	2.100±0.147	2.063± 0.162	0.037± 0.015	1.000	1.000	NS
Raga	30	32	1.333±0.138	1.344± 0.132	0.011± 0.006	0.000	1.000	NS
Pidika	30	32	1.567±0.164	1.719±0.181	0.152±0.017	1.000	1.000	NS
No. of *Utsanna Mandala*	30	32	0.667±0.138	0.750± 0.110	0.083±0.028	0.000	1.000	NS
Size of *Utsanna Mandala*	30	32	0.933±0.159	1.188 ±0.165	0.255±0.006	1.000	1.000	NS

Table 11: Comparative effect of test drugs on associated complaints

Associated Complaints	No.		Group A	Group B	Change	'U'	P	SS
	A	B	Mean±SEM	Mean±SEM				
Vibandha	10	13	0.200±0.074	0.188±0.0701	0.012±0.004	0.000	1.000	NS
Guruta	08	12	0.167±0.069	0.188±0.0701	0.021±0.001	1.000	1.000	NS
Klama	05	07	0.066±0.046	0.062±0.0435	0.004±0.003	0.000	1.000	NS
Alasya	05	06	0.066±0.046	0.062±0.0435	0.004±0.003	0.000	1.000	NS
Adhmana	06	11	0.066±0.046	0.125±0.0594	0.059±0.013	1.000	1.000	NS
Urodaha	05	07	0.033±0.033	0.093±0.0524	0.060±0.019	1.000	1.000	NS

Table 12: Comparative effect of test drugs on Heamatological Parameters

Heamatological Parameters	No.		Group A	Group B	Change	'U'	P	S
	A	B	Mean±SEM	Mean±SEM				
Hb	30	32	0.0433±0.0666	0.122±0.0701	0.079±0.004	1.000	1.00	NS
TLC	30	32	0.000±259.620	218.75±218.10	218.75±41.52	0.000	1.00	NS
Neutrophils	30	32	-0.933±0.659	-2.031±1.318	1.098±0.659	1.000	1.00	NS
Lymphocytes	30	32	0.367±0.697	1.469±1.191	1.102±0.494	1.000	1.00	NS
Eosinophils	30	32	0.0667±0.0463	0.125±0.0870	0.059±0.041	1.000	1.00	NS
Monocytes	30	32	0.467±0.190	0.250±0.196	0.217±0.006	1.000	1.00	NS
ESR	30	32	3.300±1.156	3.500±1.247	0.200±0.091	1.000	1.00	NS

Table 13: Total effect of Therapy on 62 patients of *Dadru*

Group	Group A (n=30)		Group B (n=32)		Total (n=62)	
Relief	**No. of Patients**	**%**	**No. of Patients**	**%**	**No. of Patients**	**%**
Complete remission	1	3.33	3	9.38	4	6.45
Marked Improvement	8	26.67	11	34.38	19	30.65
Moderate Improvement	12	40.00	8	25.00	20	32.26
Mild Improvement	8	26.67	8	25.00	16	25.81
Unchanged	1	3.33	2	6.25	3	4.84

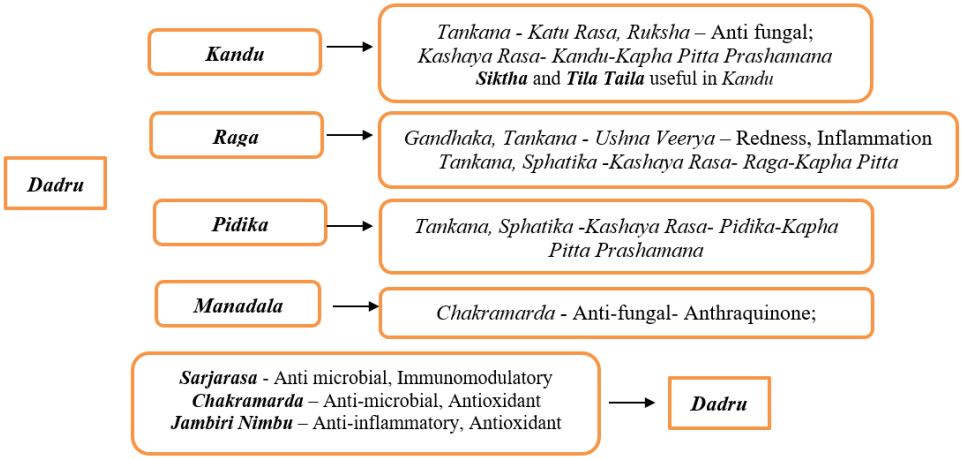

Figure 2: Probable Mode of Action Flow Chart

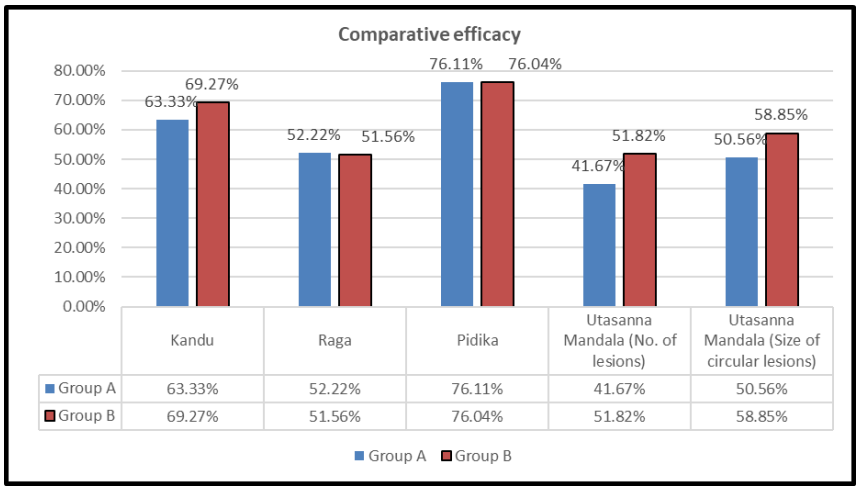

Figure 3: Comparative efficacy of both groups on *Dadru Kushtha*

DISCUSSION

The clinical study was planned to assess the comparative therapeutic efficacy of *Dadrughni Vati* (*Lepa*) and *Dadrughna Malahara* in the management of *Dadru*.

Dadrughni Vati (*Lepa*) relieved *Kandu* in 63.33 % of patients and *Dadrughna Malahara* provided 69.27 % relief in *Kandu* (Figure 3). The results observed in both groups were highly significant statistically (<0.001). *Dadrughni Vati* (*Lepa*) provided relief in other features of *Dadru Kushtha* like *Raga* (52.22 %), *Pidika* (76.11 %), *Utasanna Mandala* (Numbers) (41.67 %), *Utasanna Mandala* (Size) (50.56 %). The results observed were highly significant statistically (<0.001). All the other features of *Dadru Kushtha* relieved in the group treated with *Dadrughna Malahara* also i.e. *Raga* (51.56 %), *Pidika* (76.04 %), *Utasanna Mandala* (Numbers) (51.82 %), *Utasanna Mandala* (Size) (58.85 %). The results were also highly significant statistically (<0.001).

Dadrughni Vati (*Lepa*) relief on associated symptoms, e.g. in *Vibandha* (20 %), *Guruta* (16.67 %), *Klama* (6.67 %), *Alasya* (6.67 %), *Adhmana* (6.67 %), *Urodaha* (3.33 %). Among the patients treated with *Dadrughna Malahara* relief of associated symptoms, e.g. in *Vibandha* (18.75 %), *Guruta* (18.75 %), *Klama* (6.25 %), *Alasya* (6.25 %), *Adhmana* (12.50 %), *Urodaha* (9.38 %) were observed. The results observed in both groups in *Vibandha* symptoms and *Guruta* symptoms in Group B were significant (≤ 0.05, ≤ 0.02) statistically. while in both groups all other associated symptoms results were nonsignificant statistically (> 0.05).

Due to *Pathya Sevana* (Dietary restrictions) during the treatment period, it may be affected on associated complaints like *Vibandha, Guruta* etc. So, here associated complaints were also observed in this study.

Hematological parameters were found statistically nonsignificant while Monocytes were found statistically significant in group A and ESR was found statistically highly significant in both the groups. The drugs under trial were topical applications, though a significant result was obtained in

Monocytes and ESR. This was unexplainable clinically but it was found that topical antifungals (e.g., clotrimazole, terbinafine) target the fungal pathogens directly. By eradicating the infection, these medications can reduce associated inflammation, which may lower ESR levels [8]. So in this way both the trial drugs affect ESR. The same types of results were also found in previous clinical research work with only external medicaments [9].

Above mentioned chart (Figure 2) showed the comparative effect of *Dadrughni Vati* (*Lepa*) (Group A) and *Dadrughna Malahara* (Group B) done by applying the Wilcoxon Signed Rank test, it was showed that slightly better relief was found in Group B in the symptoms. The *Kandu* was better relieved by *Dadrughna Malahara* because *Siktha* and *Tila Taila* were used for the preparation of *Malahara*. based on percentage of relief i.e. 69.27 % than by *Dadrughni Vati* (*Lepa*) i.e. 63.33 %. This comparative data is statistically nonsignificant (> 0.05). The comparative *Dadrughni Vati* (*Lepa*) showed a better percentage of relief *Raga* i.e. 52.22 % when compared with the group *Dadrughna Malahara* i.e. 51.56 %. Almost the same percentage of relief was found in both groups in *Pidika.* On relieving *Utasnna Mandala* (Numbers) Group B showed a better result i.e. 51.82 %, than that of Group A which is 41.67 %. On relieving *Utasnna Mandala* (Size), Group B showed a better result i.e. 58.85 %, than that of Group A which is 50.56 %.

The result of the present study was assessed as Complete remission, marked improvement, Moderate improvement, Mild improvement and Unchanged. The overall effect of the therapy on 62 patients of *Dadru Kushtha* in both groups has been evaluated 9.38 % of patients in Group B and 3.33 % in Group A were in complete remission. 34.38 % of patients in Group B and 26.67 % of patients in Group A showed marked improvement. 40 % of patients in Group A and 25 % of patients in Group B were moderately improved. While 26.67 % of patients mildly improved in Group A and 25 % in Group B. 4.84 % of patients in Group B and 3.33 % of patients in Group B remain Unchanged.

Tankana inhibits fungal growth and prevents infections through its *Katu Rasa* [10]. Its *Ruksha* (dry) quality absorbs excess moisture, making it effective for conditions like *Dadru* (fungal infections) where moisture is a contributing factor. The *Ushna* (heating) *Virya* of *Tankana* and *Gandhaka* can help soothe inflammation, reducing redness and swelling in affected areas [11]. *Kashaya* (astringent) *Rasa* of *Sphatika* tightens tissues, which can help reduce swelling and provide relief from skin irritations [12]. *Kashaya Rasa* has properties like *Sleshma-Rakta-Pitta Prashamana*, and it has also the quality of drying *Kleda* [13] This *Rasa* is formed by *Vayu* and *Prithivi Mahabhuta* [14] having properties opposite to *Kapha* and *Pitta* by these properties it eases *Kandu* as well as reduces *Raga* and *Pidika*. *Tankana* possesses *Laghu* and *Sara Guna*. This property may pacify vitiated *Kapha* and *Kleda. Kandu* is the chief complaint of *Dadru Kushtha* and *Kandu* is mainly due to *Kapha*. So, it's affecting on *Kandu* [15]. *Gandhaka* is known for its effectiveness against various skin infections and fungal growths, making it suitable for treating skin conditions like *Kushtha* and *Dadru*. *Sarjarasa* resin promotes tissue regeneration and healing, making it effective for treating cuts, abrasions, and ulcers (*Vrana*) [16] and protects against infections due to its antimicrobial action, especially beneficial in open wounds (*Krimi*) [17]. In *Chakramarda* (Cassia tora), the phytochemical primarily responsible for its antifungal activity is anthraquinone [18]. This compound has demonstrated effectiveness against various fungal infections, contributing to *Chakramarda's* use in treating skin conditions like *Kandu* (itching) and *Dadru* (fungal infections). Additionally, other compounds such as flavonoids and saponins may also play a role in its antifungal properties. The sour properties of *Jambiri Nimbu* provide antioxidant benefits, helping to protect the skin from damage caused by free radicals. The anti-inflammatory and wound healing [19], antimicrobial agent [20], immunomodulatory [21]. pharmacological activity of *Sarjarasa*; anti-microbial [22] and anti-oxidant activity [23] of *Chakramarda*; Antioxidant [24] and anti-inflammatory activity [25] of *Jambiri Nimbu* were proven.

So, these combined effects make these formulations useful in treating the *Dadru*. (Figure 2)

CONCLUSION

Both *Dadrughni Vati* (*Lepa*) and *Dadrughna Malahara* demonstrated significant therapeutic efficacy in the treatment of *Dadru Kushtha*, providing substantial relief from symptoms such as *Kandu, Raga, Pidika,* and *Utasanna Mandala*. *Dadrughna Malahara* showed slightly better results, particularly in *Kandu* and *Utasanna Mandala* (Numbers and Size), though the differences were statistically nonsignificant.

The clinical improvements were supported by the pharmacological actions of the ingredients, including *Tankana, Gandhaka* and *Chakramarda*, which provided antifungal, anti-inflammatory, and skin-healing properties. Overall, while *Dadrughna Malahara* showed a slight edge in terms of complete remission and marked improvement, both treatments proved effective in managing *Dadru Kushtha*. Further studies with larger sample sizes are needed to confirm these findings and explore the long-term efficacy of these formulations.

Conflict of interest

There is no conflict of interest.

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