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RANDOMISED CONTROLLED CLINICAL TRIAL TO COMPARE LAGHUMANJISTHADI KWATH GUTIKA WITH PANCHATIKTA GHRITA GUGGUL IN MANAGEMENT OF DADRU KUSHTHA

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ABSTRACT

Context: Tinea infection (dermatophytosis), This infection primarily affects adults aged between 18 to 50 years, significantly impacting the productivity and comfort of the younger generation, is a significant issue in modern society. The nearest correlation of tinea can be made with Dadru Kushtha in Ayurveda. Typically spreads through contact between individuals, emphasizing the importance of hygiene and overall health. Ayurvedic medicines break down Dadru's pathophysiology, relieving symptoms and reducing relapse. Mild Dadru managed topically; advanced requires internal treatment. Diverse lifestyles hinder adherence to Sodhana followed by Shamana. Busy individuals struggle with topical treatments, causing discomfort. **Aim:** To assess the efficacy of *Laghu manjisthadi kwath gutika* in *Dadru kushtha.* **Study design:** A randomised controlled open label Clinical trial. **Material and Methods:** The study was conducted on patients of age group 18-60 years having classical symptoms of dadru for a period of 30 days. Clinical features were documented before, during and after the treatment. **Statistical analysis used**: Observations of the study were analysed and findings were evaluated by using statistical methods (Wilcoxon Signed Rank test and Mann Whitney U Test). **Results:** After treatment, Group A (Laghumanjisthadi kwath gutika) exhibits a higher overall effect at 55.63%, while Group B (Panchatiktaghrita guggul) shows a slightly lower effect at 48.29%. These findings suggest that the intervention yielded a more pronounced impact within Group

A compared to Group B. **Conclusions:** Thus, the results suggest that Laghumanjisthadi kwath gutika is more effective in treating Dadru Kushtha.

KEYWORDS: Tinea, Dadru Kushtha, Dermatophytosis, Shamana Chikitsa.

INTRODUCTION

The skin, our body's largest organ[1], is a complex interface between our inner selves and the external environment. Particularly in regions like India, where tropical climates prevail alongside evolving healthcare systems, dermatological disorders have surged in recent years. This phenomenon has prompted a meticulous exploration of these afflictions within both medical and cultural contexts. In this article, we delve into the captivating subject of dermatological disorders, drawing attention not only for their clinical significance but also for their cultural and social ramifications. Our research aims to unravel the complexities of skin integrity, shedding light on subtle deviations from normalcy through the discerning lens of clinical scrutiny. We explore the rich heritage of Ayurveda, India's ancient system of medicine, which offers profound insights into dermatological maladies under the comprehensive framework of Kushtha.[2] Through an examination of Ayurvedic principles such as Mithyaahara vihara (dietary habits), Dosha vaishamyam (humoral imbalances), and Srotavarodham (physiological channel obstructions), we uncover a nuanced understanding of skin disorders.[3] Specifically, we focus on Dadru whose classical symptoms are Kandu, raga, pidaka and udgata mandla[4], colloquially known as Tinea[14,15], which serves as an emblematic archetype of the complex interplay between environmental factors and individual susceptibility.[5] By integrating traditional Ayurvedic wisdom with contemporary dermatological science, our endeavor aims to advance the holistic management of skin disorders, fostering a deeper appreciation for the interconnectedness of mind, body, and environment in maintaining skin health.

Dadru poses a significant challenge in modern society, with effective treatments still elusive in allopathic medicine. Ayurvedic medications offer relief by addressing the underlying pathophysiology, reducing symptoms, and preventing relapse. While mild cases may respond to topical applications, advanced stages often require internal intervention. However, adhering to traditional treatment sequences like Sodhana Chikitsa and Shamana Chikitsa can be difficult due to diverse lifestyle habits, especially for individuals with demanding schedules.

Laghumanjistadi[6] kwath gutika, containing Manjistha, Triphala, kutki, Vacha, Daruharidra, and Nimba, is a preferred choice for Dadru due to its multifaceted therapeutic actions, including Tridoshagna, varnya, raktastambhan, Kushthaghna, Rasayan, krumighna, and Kandughna properties.[7] Dermatophytosis prevalence stands at 65%.

MATERIAL AND METHODS

Brihattrayi and Laghutrayi, along with their respective Tika and other Ayurvedic and modern textbooks, journals, magazines, M.D. dissertations, and research papers from online databases like Google Scholar and PubMed, were reviewed for the study.

DISEASE REVIEW

Relevant information regarding Kustha Roga Adhyaya was reviewed from Brihattrayi and Laghutrayi, along with sangraha granthas.

Detailed review regarding Tinea infection and dermatophytosis was done from modern textbooks.

METHODOLOGY

Study Design

A randomised controlled open label Clinical trial was conducted in patients suffering from Dadru (Tinea infection).

Selection of cases

For the study patients having classical symptoms of Dadru were selected, according to inclusion and exclusion criteria of the study. Group allocation by Randomization with sealed envelope method was done.

Inclusion criteria

1) Patients above 18 yrs. and below 60 yrs.
2) Both males and females.
3) Irrespective of Religion.
4) Patients with classical *lakshanas* of *Dadru*, like *kandu, raga, pidaka, udagata mandal*
5) Both fresh and on treatment cases of *Dadru.*
6) Patient having chronicity less than 2 years.
7) Tinea waist.

Exclusion criteria

1) Patient on steroid treatment.

2) Patients suffering with systemic disorder like uncontrolled DM, HIV, TB, Cardiac, Hepatic disease, Endocrinal Disorders.

3) *Dadru* associated with other skin disease, like Koch's, Hansen's disease, scabies, herpes zoster, diabetic wound, malignancy, eczema.

4) Steroid Folliculitis, Flexural Psoriasis, Psoriasis Vulgaris, Scabies on buttocks.

5) Patient having patches due to burning, chemical explosion.

6) Pregnancy and lactating mother.

7) Lichenified conditions, lesions with raised margins wrt. Tinea certintia facialie, tinea onychomycosis, Dhobi's itch.

Criteria for withdrawal of patients

1) Patients willing to discontinue Trial.

2) Death of patient due to any cause.

3) If patient develops any allergic condition.

4) Unbearable, Aggravation of symptom itself.

Selection of the Drug

A) Laghumanjisthadi Kwath Gutika

The chosen drug for the trial group, *Laghumanjisthadi kwath gutika*, as referenced in Bhaishjyaratnavali Kushthrogadhikara[6], is indicated for kapha-pittaja Kushtha. Its ingredients, including Triphala, Manjistha, Kutki, Vacha, Nimba, and Daruharidra, possess properties beneficial for skin disorders. Triphala, Nimba, and Manjistha, known for their Kushthagna properties, combat fungal infections effectively. The tikta rasa of most ingredients aids in reducing kapha and treating skin disorders like Dadru. Laghumanjisthadi kwath gutika cleanses and nourishes the Rakta dhatu, pacifies pitta, eliminates visha, and facilitates wound healing. The bioactive compounds in Triphala contribute to its antimicrobial and antifungal activities. Nimba's bark contains compounds with antimicrobial and antifungal properties. Manjistha's quinones and anthraquinones promote skin healing. Vacha's Krumighna properties and balance of kapha and vata doshas make it beneficial for skin disorders. Thus, Laghumanjisthadi kwath gutika effectively addresses Kushtha through its constituent herbs and therapeutic actions.[21,22]

B) Panchatikita ghrita guggul Vati

The drug selected for the control group in the study was Panchatikta ghrita guggul, referenced from Bhaishjyaratnavali Kushthrogadhikara.[8] It comprises Panchatikta gana dravyas, Ghruta, and Guggul, exhibiting Tikta rasa, Laghu, and Ruksh guna. Its mechanism of action targets Kandughna properties, alleviating Kleda and Vikrut meda, and promoting Vranaropana. The constituents like Nimba, Guduchi, Vasa, Patol, Nidigdhika, and Guggul contribute to its antioxidant, immunopotentiator, anti-inflammatory, and skin-restorative effects. Ghrita's lipophilic action aids in cellular-level delivery, reducing keratinization and improving the cell cycle, alleviating symptoms and restoring normal skin texture. Panchatikta ghrita guggul acts by targeting the cellular level of the skin, reducing keratinization, and improving the cell cycle. This results in a reduction of symptoms such as Kandu, Pidika, Kleda, Raga and Mandala, ultimately restoring the skin to its normal condition.[21,22]

Approval from Institutional ethics committee

Institutional ethics committee's approval was taken for the prospective, randomized, open label, active control, parallel group study.

Procurement of the drug

The trial drug was prepared in the pharmacy, according to the SOP mentioned in the Sarangdhara Samhita[9,10], and subsequently were subjected to further analysis, and standardization procedures were carried out. The control group medication was procured from a GMP-certified company and subsequently subjected to additional analysis, followed by standardization procedures.

Contents of Laghumanjisthdi kwath gutika

Table 1: Contents of Laghumanjisthadi kwath gutika with its properties.[11]

Drug name	Latin name	Rasa	Virya	Vipaka	Karya	Upyuk tanga
Haritaki	Terminalia chebula	Pancharasa (lavan varjit) Kashya Pradhan	Ushna	Madhur	Tridoshagna	Phala
Manjistha	Rubia cordifolia	kashay, Tikta,Madhur	Ushna	Katu	Varnya	Mula
Bibhitaki	Treminalia belirika	Kashay, Madhur	Ushna	Katu	Raktsastambhan	Phala
Amalaki	Embilika officinalis	Pancharas (lavanvarjit)	Shita	Madhur	Kushthaghna Rasayan	Phala
Kutki	Picrrorhiza	Tikta	Shita	Katu	Krumighna	Bhaumik

	kurro					kanda
Vacha	Acromus calamus	Katu tikta	Ushna	Katu	Lekhnana	Mula
Nimba	Azadirecta indica	Tikta kashay	Shita	Katu	Kandughana	Twaka
Daruharidra	Berberis aristate	Tikta, Kashaya	Ushna	Katu	Kapha Pittaghna, Kandu kushthahar	Twaka

Shedule of the treatment

- **Group A:** Patients included in this group were treated with Laghumanjisthdi kwath gutika (trial drug).

500 mg (twice daily), Adhobhakta kaal (after meals), with water as anupana, for 30 days.

- **Group B:** Patients included in this group were treated with Panchatikta ghrita guggul (Control Drug).

500 mg (twice daily), Adhobhakta kaal (after meals), with water as anupana, for 30 days. Follow ups were done at the end of every week.

Followed by follow up at the end of 1 month after 30th day, to check relapse of the symptoms.

Assessment criteria

The results of clinical study were assessed on the basis of classical symptoms of dadru. Following parameters were opted for assessing the response of the treatment.

Clinical assessment

The following clinical findings were assessed before, during and after the treatment:

*kandu (*itching*), Raga (r*edness*), Pidaka (*number of patches*)* and *Udgata mandal* (size of mandalas).[12]

[13]Description of grades and its relation with grade points

1. RAGA (REDNESS)

R0 NORMAL SKIN COLOUR

R1 MILD REDNESS (PINKISH) RASH

R2 MODERATE RED

R3 DEEP BROWN.

2. KANDU (ITCHING)

K0 NO ITCHING

K1 MILD (NO DISTURBANCE WHILE DOING WORK)

K2 MODERATE (DISTURBS THE WORK)

K3 SEVERE (DISTURBS THE SLEEP).

3. PIDAKA (NUMBER OF PATCHES)

P0 NONE

P1 1 TO 3 PATCHES

P2 4 TO 6 PATCHES

P3 MORE THAN 7 PATCHES.

4. MANDALA (SIZE OF MANDALAS)

M0 ZERO CM.

M1 LESS THAN 5 CM.

M2 5 TO 10 CM.

M3 MORE THAN 10CM.

Overall assessment of result

All parameter will be assessed before and after treatment

1. Complete Relief - 100%
2. Marked Relief - 76 % - 99 %
3. Moderate Relief - 51% - 75 %
4. Mild Relief - 26% - 50%
5. No Relief - < 25%.

Analysis of data and use of statistical methods

Observations documented during the study were analyzed and findings were evaluated by using statistical methods (Wilcoxon Signed Rank test and Mann Whitney U Test).

OBSERVATION AND RESULTS

In the present clinical study 74 patients were sampled[16] of dadru kushtha, which were randomly divided into two groups, viz Group A 37 patients (trial group) and Group B 37 patients (control group), which completed the treatment.

Observations regarding Demographic Data

- **Age:** Among 74 patients' maximum number of patients reported were between the age group of 31-40 years i.e., 36 patients followed by the age group between 20-30 years i.e., 19 patients.
- **Gender:** Out of 74 patients 61 were males (82.4%) and 13 were females (17.5%).
- **Occupation:** Out of 74 patient's majority of them were shopkeepers i.e., 26 patients. Next comes students and job personals, they were 11 in each group. 26 patients were considered under business, farmers, housewife's and vendors.
- **SES:** Out of 74 patients 69 were from middle class and 5 were from lower class.
- **Marital Status:** In 74 patients 79.7% were married and 20.2% were unmarried.
- **Chronicity:** Here 34 patients had the chronicity below 6 months, 30 patients had chronicity between 6- 12 months. And 10 patients were from 12-18 months range.
- **Type of Tineae:** Among 74 patients, 52 patients were having tinea corporis, 12 patients were having tinea cruris and 10 patients were having tinea barbae, faciei and pedis.

After treatment, Group A exhibits a higher overall effect at 55.63%, while Group B shows a slightly lower effect at 48.29%. These findings suggest that the intervention yielded a more pronounced impact within Group A compared to Group B.

DISCUSSION

Dadru typically spreads through direct contact between individuals[17], emphasizing the importance of hygiene and overall health. This infection primarily affects adults aged between 18 to 50 years, significantly impacting the productivity and comfort of the younger generation. It's particularly prevalent among adults who wear clothing made of synthetic materials, which trap heat and moisture. Prompt recognition and appropriate treatment of dermatophyte infections are crucial to reduce discomfort, morbidity, and the risk of transmission. there is a growing concern about resistance to modern antifungal drugs. Neglect of basic hygiene and overall health often leads to excessive sweating, contributing to common skin issues like itching and rashes. Since modern medicine still lacks a satisfactory and effective treatment for this disease, and recurrences are common with *Dadru*. The main focus of this study was *Shamana Chikitsa*[18], which involves oral medication. While mild cases of the disease can be effectively managed with topical treatments, more advanced conditions require internal intervention.

In this research, there is a prevalent occurrence of disease among both the younger and

middle-aged groups. The probable cause for the increased prevalence in this age cohort might be the consumption of *Asatmaya Ahara*, *Vihara, due to their professional responsibilities.*[19]

The disease was more commonly seen in who were consuming Mixed as well as Veg diet. Probable reason could be more sweating due to *Rajasa* and *Tamsa guna* of such diet which is *Abhishyandini* and *Ushna* in nature creating favourable condition for onset and progression of disease. *Dadru Kushtha* (Tinea) is contagious disease and can spread from husband to wife and vice versa.

Kandu, or itching, is the primary indicator of Dadru. It results from imbalanced Kledaka Kapha, leading to Raktagata Kleda accumulation in the skin. In the study, all patients experienced itching, with severity correlating with erythema and being more pronounced in areas prone to excessive perspiration, such as the inguinal and popliteal regions. Sedentary work profiles also exacerbated itching, with aggravation often occurring at night.

Both treatment groups effectively reduced Kandu symptom scores, with a greater decrease observed in Group A (80.00%) compared to Group B (75.00%). However, recurrence rates post-treatment was higher in Group A (23.00%) compared to Group B (4.84%). [Table 2 and Fig. 1 and 4].

Raga, or skin discoloration, arises from vitiated Vikruta Bharajaka pitta due to Tridosha prakopa and Ama, resulting in reddish to brownish skin discoloration. Both treatment groups effectively reduced Raga symptom scores, with Group A (45.83%) demonstrating a greater decrease compared to Group B (37.88%). However, recurrence rates post-treatment was higher in Group A (29.80%) compared to Group B (4.84%).

Pidaka, or patches, result from imbalances in the three doshas and impaired agnimandya, leading to disturbances in rasa and rakta metabolism and the formation of raktagata kleda and vikruta Mansa Dhatu. Both treatment groups effectively reduced Pidaka symptom scores, with Group A demonstrating a greater decrease compared to Group B. However, Group A showed a higher efficacy in reducing Pidaka (46.67%) compared to Group B (39.47%). However, Group A had a 20.00% recurrence rate, while Group B did not exhibit any recurrence.

Mandala, characterized by circular lesions, arises from vitiated Tridosha and impaired Rasa-Rakta dhatwagni, leading to rakta Dhatu dushti and formation of raktagata kleda and vikruta

Mansa Dhatu. Both treatment groups effectively reduced Mandala symptom scores, with Group A (50.00%) showing a greater decrease compared to Group B (40.79%). However, recurrence rates post-treatment was higher in Group A (17.98%) compared to Group B (6.56%) in Mandala.

In Group A, 81% reported improvement, with 40.54% experiencing marked improvement and 40.54% reporting mild improvement. In Group B, 59.46% showed improvement, with 32.43% marked improvement and 27.03% mild improvement. Overall, Group A had slightly more marked and mild improvements compared to Group B. [Figure 2]

Table 2: Showing comparison between Group A and B.

Variable	Group	N	Mean Rank	Sum of Ranks	Mann-Whitney U	P-Value	Result
Kandu	Group A	37	39.69	1468.50	540.500	0.00596	Sig
	Group B	37	35.31	1306.50			
	Total	74					
Raga	Group A	37	40.99	1516.50	492.500	0.00284	Sig
	Group B	37	34.01	1258.50			
	Total	74					
Pidaka	Group A	37	40.91	1513.50	495.500	0.00270	Sig
	Group B	37	34.09	1261.50			
	Total	74					
Mandala	Group A	37	40.26	1489.50	519.000	0.00444	Sig
	Group B	37	34.74	1285.50			
	Total	74					

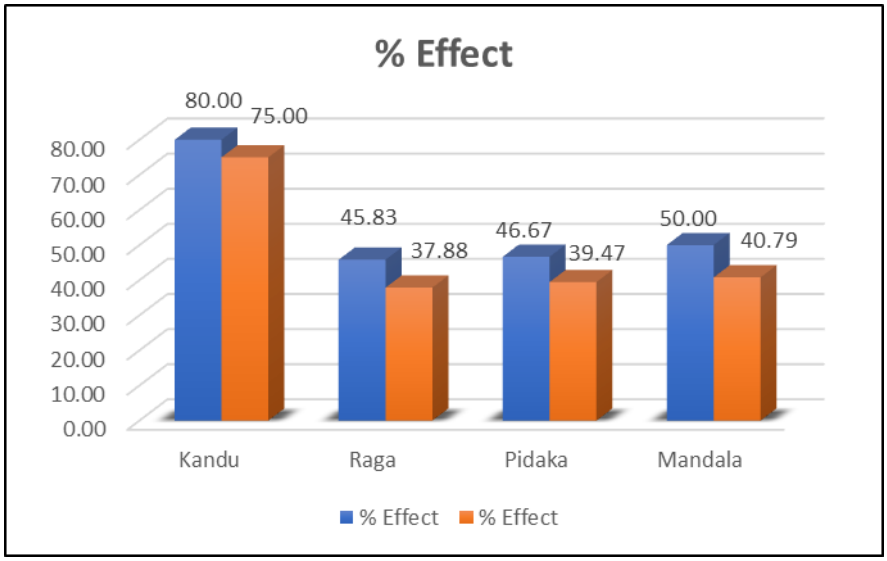

Figure 1: Percentage effect of Parameters among Group A & B.

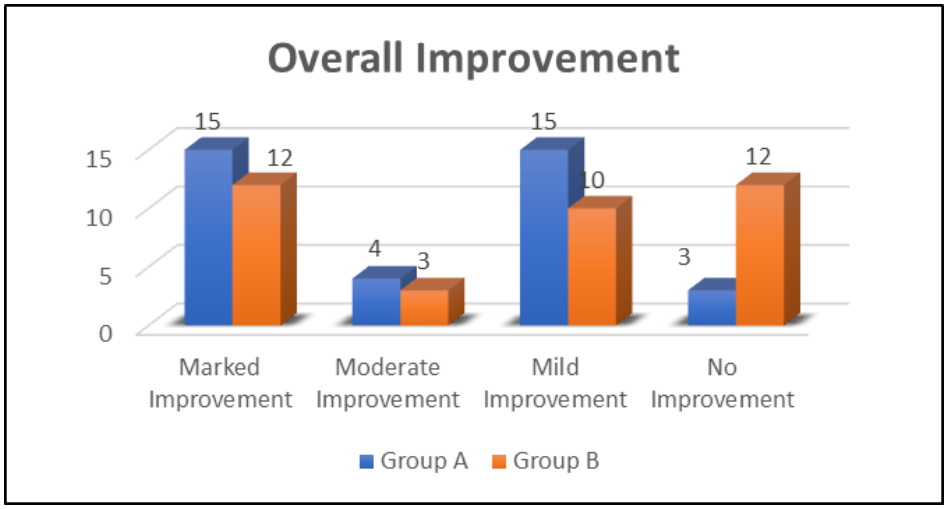

Figure 2: Showing Overall Improvement of treatment in group A and B.

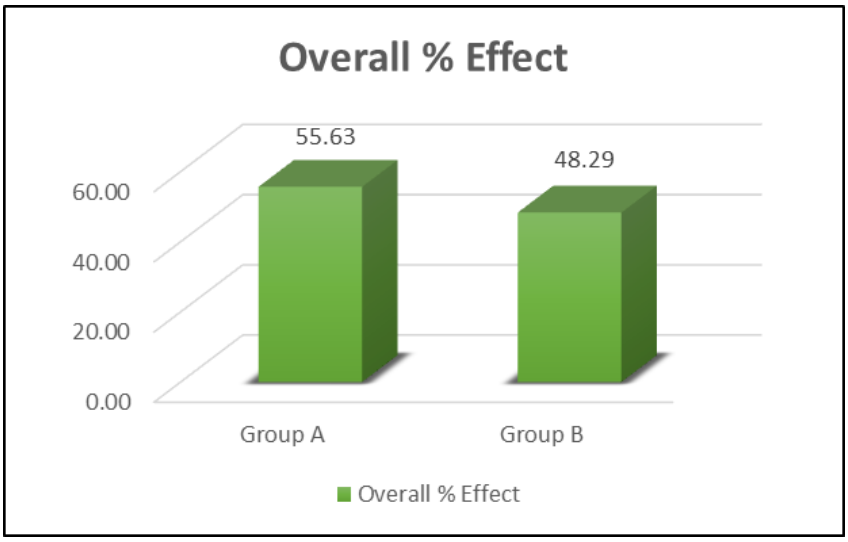

Figure 3: Showing Overall effect of therapy in group A and B.

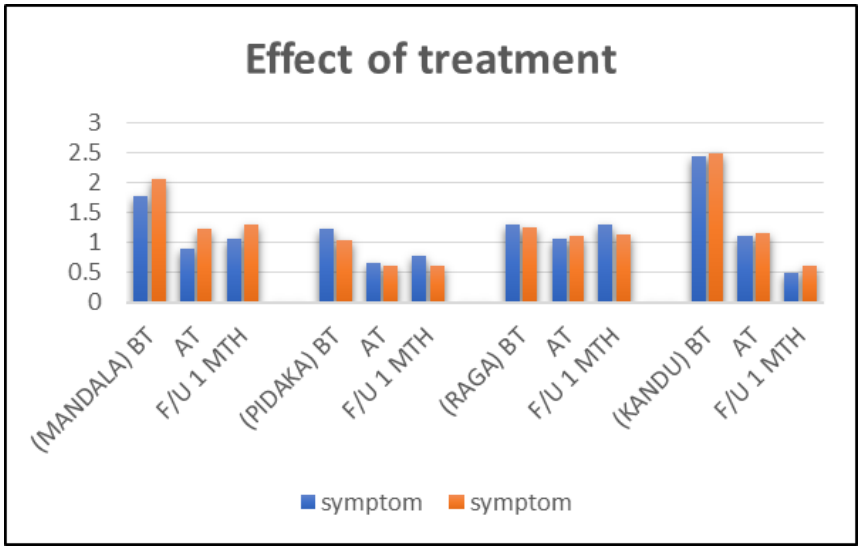

Figure 4: Showing change in mean of symptoms during treatment.

Samprapti bhanga of dadru

1) Fate of Dosha and Dushya: *Hetu Sevana* leads to aggravation of *Kapha* and Pitta doshas (Tridosha prakopa), which then enters Tiryak Sira, affecting *Dushya*, leads to *Shaithilya* mainly of *Twacha, Rakta, Mansa* and *Ambu*, leading to *Sthansanshrya* at *Twacha*.[20] While most of the *dravyas* from *Laghumanjisthadi kwath gutika* and *Panchatikta ghrita guggul* possesses *Tikta rasa*, which is mainly *Ruksha, Shita* and *Laghu gunatmaka*. Beneficial in *Pitta Shamana, Rakta Sodhana,* L*ekhana* of *Dushita Kleda, Meda, Lasika, Ambu, Sweda,* and *Mansa*, thereby help in reduction of *Dadru.*

2) Effect as Kushthaghna Properties: Most of the *dravyas* among *Laghumanjisthadi kwath gutika* and *Panchatikta ghrita guggul* possesses *Kushthaghna* property, either due to its *Rasadi Gunadharma, Prabhava* or Chemical constituents present in it. This property directly aids in combating skin diseases like *dadru Kushtha*.

3) Properties of Medications: Among *Laghumanjisthadi kwath gutika* and *Panchatikta ghrita guggul*, all d*ravyas* either possess one or the other properties like *Rakta Sodhana, Vishahara, Kandughna, Twak dosha hara, Krumighna, Sophahara, Shoolhara, Vrana ropaka, Varnya, Raktastambhana* and *Jantughna*. Which in turn helps in relieving l*akshans* like *Kandu, Raga, Pidaka,* and *Mandala.*

4) Role of Rasayana Karma: *Rasayana Karma* aids in fortifying *Vyadhikshamatva* (immunity) against infections, thereby contributing to the prevention of disease relapse. The constituents within *Laghumanjisthadi kwath gutika and Panchatikta ghrita guggul* possess *Rasayana* effects, which bolster immunity and act as antioxidants.

Recommendation for further study, as this can be carried out on a larger scale of population to find results. The same study can be continued by increasing the duration of the treatment. There is further scope for new researchers to compare *Shaman Chikitsa* against *Sodhana Chikitsa.*

Figure 5: Showing Before treatment and After treatment photographs of Group A & B.

CONCLUSION

Our study evaluated the effectiveness of Laghumanjisthadi kwath gutika and Panchatikta ghrita guggul in managing Dadru Kushtha (Tinea). Both drugs possess properties such as Kushthaghna, Ama pachana, Kandughna, Rasayana, Varnya, Krumighna, and Kledapachana, which aid in enhancing, purifying the channels, and improving the quality of blood, addressing the root causes of Dadru. Both treatments showed significant improvements in clinical symptoms associated with Dadru. Laghumanjisthadi kwath gutika demonstrated a higher efficacy rate (55.63%) compared to Panchatikta ghrita guggul (48.29%). Thus, Laghumanjisthadi kwath gutika is concluded to be more effective in treating Dadru Kushtha, confirming the alternative hypothesis.

DECLERATION OF PATIENT CONSENT

The authors certify that they have obtained all appropriate patient consent forms. In the form the patients has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

CONFLICTS OF INTREST

There are no conflicts of interest.

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