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Research Article

Kitibha Kushta

An Open Label Single Arm Clinical Study to Evaluate the Combined Effectiveness of Oral Administration of Abhayarishta Churna and Aragwadha Patra Lepa in Kitibha Kushta (Psoriasis)

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Kitibha Kushta is a Raktapradoshaja Vikara where it is categorised under Kshudra Kushta. Acharya Charaka mentioned the involvement of Vata and Kapha in Kitibha Kushta and is compared with Psoriasis due to close resemblance of its symptoms. Psoriasis is a chronic inflammatory, non-communicable, painful, disfiguring, disabling, and hyperproliferative skin disease. It is a chronic, non-communicable, proliferative auto-immune skin disease affecting 2% of world population. The prevalence of psoriasis ranges between 0.09% and 11.4% in different populations around the world, making it a serious global concern. In India, the prevalence of psoriasis varies from 0.44 to 2.8%, According to Global Psoriasis Atlas (GPA) an estimated 3.59 million people in India and 100 million people world-wide are affected.

Objectives of the study: To evaluate the combined effectiveness of Abhayarishta Churna and Aragwadha Patra Lepa in management of Kitibha Kushta (Psoriasis).

Material and Methods: A total of 30 participants of either gender were included in the study using the random sampling method. Among 33 registered participants, 30 completed the course of study. They were administered with Abhayarishta Churna 6 grams twice a day after food with Anupana of Madhu for 30 days in combination with Aragwadha Patra Lepa application externally. Lakshanas of Kitibha Kushta were assessed as primary outcome measures and the PASI score was assessed as the secondary outcome. For statistical analysis, subjective parameters were assessed with Friedman's test, Wilcoxon sign rank test. Objective parameters were assessed by Repeated Measures ANOVA.

Results: Statistically significant improvement was observed in the primary and secondary outcome measures of Kitibha Kushta (Psoriasis).

Conclusion: Combination of Abhayarishta Churna and Aragwadha Patra Lepa was found to be effective in the management of Kitibha Kushta (Psoriasis).

Keywords: Abhayarishta Churna, Aragwadha Patra Lepa, Kitibha Kushta, Psoriasis, PASI

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Introduction

Kitibha Kushta is one among the *Kshudra Kushta*, presenting with the *Shyavavarna*, *Kinakhara Sparsha* and *Parusha Lakshanas*.**[1]** The disease which has spreading nature and which leads to disfiguration (*Kushnati*) of skin is known as *Kushta*. There is involvement of *Tridosha* in all *Kushta* but the predominance of *Dosha* makes the types & manifestation of *Kushta* different. *Acharya Charaka* has described the involvement of *Vata* and *Kapha Dosha* in *Kitibha Kushta.***[2]** It is comparable to Psoriasis due to its invariable similarities in the signs and symptoms of *Kitibha Kushta.*

Psoriasis is one of the most common skin disorders. It is a papulosquamous disorder of the skin characterized by sharply defined erythematosquamous lesions. It is chronic and is well known for its course of remission and exacerbation.**[3]** Psoriasis is a chronic inflammatory, noncommunicable, painful disfiguring, disabling, hyperproliferative skin disease with a strong genetic predisposition**[4]** and autoimmune pathogenic traits. **[5]** Psoriasis typically affects the skin, its complication can lead to psoriatic arthritis, and other systemic diseases. Thus, it has been postulated that psoriasis is a systemic entity rather than a solely dermatological disease.**[6]**

The prevalence of psoriasis ranges between 0.09% **[7]** and 11.4%**[8]** in different populations around the world, making it a serious global problem. In India the prevalence of psoriasis varies from 0.44 to 2.8%, According to global psoriasis atlas (GPA)an estimated 3.59 million people in India and 100million are affected Worldwide, the incidence of new cases increased from 92 per 100,000 in 1990 to 99 in 2017(29), twice more common in males compared to females and most of the patients are in their third or fourth decade at the time of presentation.**[9]** Psoriasis has been shown to affect quality of life to an extent similar to the effects of other chronic diseases.**[10]**

It has a substantial psychological and social impact on a person's life. Even though various treatment modalities are available in the contemporary system of medicine including topical therapy, corticosteroids, cytotoxic drugs, photochemotherapy, most of these treatment modalities have limitations.

It is important to note that they have substantial side effects when used for a longer period. With the increasing prevalence and its association with various co-morbidities, there is a need for study various aspects related to aetiopathogenesis, management, and impact on quality of life. Methods or modes of intervention in alternate.

It is one among the *Ashtamahagada***[11]** As progresses it expresses the *Lakshanas* of *Tridosha***[12]** leads to *Upadrava* stage and it is considered as *Kashtatara Roga*.**[13]** There arises the need for planning treatment. The combined formulations *Abhayarishta Churna* and *Aragwadha Patra Lepa* mentioned in *Bhaishajya Ratnavali Kushtaroga Chikitsa Prakarana* are indicated for *Kitibha Kushta*. *Abhayarishta Churna* comprises of *Haritaki* and *Nimba*. *Haritaki* has *Kashaya Rasa Pradhana Lavana Varjita Pancharasa, Ruksha-Laghu Guna, Madhura Vipaka* and *Ushna Virya*. It has properties like *Tridoshahara, Anulomana, Rasayana, Kushtaghna, Kandughna, Hrudya, Vranahara, Shophagna*.**[14]**

Nimba is *Tikta, Kashaya Rasayukta,* having *Laghu-Ruksha Gunas, Sheeta Virya, Katu Vipaka* and it has properties like *Kapha-Pitta Shamana, Kushtaghna, Krimighna, Rakta Shodhana, Shothahara, Vishaghna, Deepana*.**[15]**

Aragwadha Patra Lepa possesses *Tikta Rasa. Laghu-Ruksha Guna, Ushna-Sheeta Virya*, *Madhura Vipaka***[16]** and *Vatapitta Shamaka* and *Pittakapha Samshodhaka*.**[17]**

Present study is taken up to statistically evaluate the combined effectiveness of the *Abhayarishta Churna* and *Aragwadha Patra Lepa* in *Kitibha Kushta* (Psoriasis).

Objectives of the study

To clinically evaluate the combined effectiveness of *Abhayarishta Churna* and *Aragwadha Patra Lepa* in the management of *Kitibha Kushta* (Psoriasis).

Materials and Methods

Source of data

Subjects with *Kitibha Kushta* (psoriasis) were selected from OPD of Sri Dharmasthala Manjunatheshwara college of Ayurveda and Hospital, Hassan.

Table 1: Methods of collection of data

Type of study	Open label, single arm, clinical study
Group	Single
Sampling method	Convenience sampling method
Test design	Pre-test and post-test design.
Sample size	30
Total study duration	30 days
Observation during the study	16th day and 31st day

Screening

A screening form was prepared with all aspects of history, signs and symptoms of *Kitibha Kushta* (Psoriasis) and clinical examination was done to make the diagnosis keeping in view inclusion and exclusion criteria.

Diagnostic Criteria

Diagnosis was made on the basis of any two *Lakshanas* of *Kitibha Kushta***[18]** and any four clinical features of psoriasis.

- *Shyavavarna*
- *Kinakharasparsha*
- *Parushata*
- Sharpely demarcated papule with clear-cut borders
- Noncoherent silvery scales
- Glossy, homogeneous erythema
- Auspitz sign
- Candle grease sign

Inclusion Criteria

1. Subjects suffering with *Kitibha Kushta* less than 1 year of chronicity
2. Subjects of either gender, aged between 18-60 years**[19]**
3. Subjects willing to participate in the study and ready to sign informed consent form

Exclusion Criteria

1. Uncontrolled diabetes mellitus (HbA1C >7mg/dl)
2. Pregnant women
3. Lactating mother
4. Subjects with impaired cardiac, renal, and hepatic functions

Laboratory Investigation

1. Hemoglobin
2. Total Count & Differential Count
3. Erythrocyte Sedimentation Rate

Intervention

1. Abhayarishta Churna

Route of administration: Oral.

Quantity: 6gms twice a day after food.

Anupana: *Madhu* (Q.S)**[20]**

Duration: 30days**[21]**

2. Aragwadha Patra Lepa**[22]**

Route of administration: External application with *Kanji*

Quantity: Thickness of 1/4th *Angula* (1 *Angula* = 25.4mm) as *Doshaghna Lepa***[23]** once a day and removed before it dries completely

Duration: 30days

Institutional Ethics Committee (IEC): The ethics clearance certificate from the Institutional Ethics Committee of Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Hassan was obtained, and a photocopy is attached. IEC No: SDM/IEC/45/2022, CTRI Registration No: CTRI/2023/11/059880.

Assessment done on: Signs and symptoms of *Kitibha* (Psoriasis) were assessed by giving scoring on 1st day, 16th and 31st day of treatment.

Assessment criteria

1. Signs and symptoms of *Kitibha Kushta* (Psoriasis) was assessed on 1st day, 16th and 31st day of treatment, Scoring based on gradation of *Lakshanas* of *Kitibha kushta.*

- *Shyavavarna*
- *Kinakharasparsha*
- *Parusha*

2. The activity of disease will be assessed by Psoriasis Area Severity Index Score (PASI)

Observations

In the present study total of 41 participants were screened, out of which 33 subjects were registered for the study, among them 30 subjects completed the study. Among 30 subjects maximum (n=11) were from the age group of 51-60 years and predominance of males (n=24).

29 subjects were belonged to Hindu religion, 12 subjects were from upper-middle-class group and majority of them (n=17) were from urban areas. 30 subjects had gradual onset, none subjects had relevant past and family history, 33 subjects had treatment history and Diet-wise distribution showed maximum (n=32) were following a mixed diet.

Results

Table 2: Friedman's test applied to Subjective Parameters, showing significant improvement in symptoms like *Shyava Varna*, *Kinakhara Sparsha*, and *Parushata*.

Parameter	Variable	N	Mean Rank	X2	P Value	Remarks
Shyava Varna	BT	30	2.75	45.516	< 0.05	S
	16th Day		2.05			
	31st Day		1.23			
Kina Khara Sparsha	BT	30	2.93	57.617	< 0.05	S
	16th Day		2.05			
	31th Day		1.02			
Parushata	BT	30	2.83	53.509	< 0.05	S
	16th Day		2.10			
	31th Day		1.07			

BT - Before Treatment, N - Number of participants, P - Present, A - Absent, S - Significant, x2 - chi square

Table 3: Wilcoxon Signed rank test showing the combined effectiveness of *Abhayarishta Churna* and *Aragwadha Patra Lepa* On *Shyava Varna*

Parameter	Negative ranks			Positive ranks			Ties	Total	Z value	P value	Remarks
	N	MR	SR	N	MR	SR					
BT-16th Day	20	10.50	210	0	.00	.00	10	30	-4.130	< 0.05	S
16th-31th Day	21	11.00	231	0	.00	.00	9	30	-4.491	< 0.05	S
BT-31th Day	25	13	325	0	.00	.00	5	30	-4.462	< 0.05	S

BT- Before Treatment, N- Number of participants, P- Present, A- Absent, S- Significant, MR – Mean Ranks, SR – Signed Ranks

Table 4: Wilcoxon Signed rank test showing the combined effectiveness of *Abhayarishta Churna* and *Aragwadha Patra Lepa* on *Kina Khara Sparsha*

Parameter	Negative ranks			Positive ranks			Ties	Total	Z value	P value	Remarks
	N	MR	SR	N	MR	SR					
BT-16th Day	23	12	276	0	.00	.00	7	30	-4.564	< 0.05	S
16th-31th Day	26	13.50	351	0	.00	.00	4	30	-4.725	< 0.05	S
BT-31th Day	27	14	378	0	.00	.00	3	30	-4.820	< 0.05	S

BT - Before Treatment, N - Number of participants, P - Present, A - Absent, S - Significant, MR - Mean Ranks, SR - Signed Ranks

Table 5: Wilcoxon Signed rank test showing the combined effectiveness of *Abhayarishta Churna* and *Aragwadha Patra Lepa* on *Parushata*

Parameter	Negative ranks			Positive ranks			Ties	Total	Z value	P value	Remarks
	N	MR	SR	N	MR	SR					
BT-16th Day	16	8.50	136	0	.00	.00	14	30	-4.60	< 0.05	S
16th-31th Day	19	10	190	0	.00	.00	11	30	-1.941	< 0.05	S
BT-31th Day	21	11	231	0	.00	.00	9	30	-4.57	< 0.05	S

BT - Before Treatment, N - Number of participants, P - Present, A - Absent, S - Significant, MR - Mean Ranks, SR - Signed Ranks

Table 6: Friedman's test Showing the combined effectiveness of *Abhayarishta Churna* and *Aragwadha Patra Lepa* on PASI Score

Parameter	Variable	N	Mean Rank	X2	P Value	Remarks
PASI Score	BT	30	3.00	59.513	< 0.05	S
	16th Day		1.98			
	31st Day		1.02			

BT - Before Treatment, N - Number of participants, P - Present, A - Absent, S - Significant, x2 - chisqaure

Table 7: Wilcoxon Signed rank test showing the combined effectiveness of *Abhayarishta Churna* and *Aragwadha Patra Lepa* on PASI Score

Parameter	Negative ranks			Positive ranks			Ties	Total	Z value	P value	Remarks
	N	MR	SR	N	MR	SR					
BT-16th Day	30	15.50	465	0	.00	.00	0	30	-4.783	< 0.05	S
16th-31st Day	29	15	435	0	.00	.00	1	30	-4.705	< 0.05	S
BT-31st Day	30	15.50	465	0	.00	.00	0	30	-4.783	< 0.05	S

BT - Before Treatment, N - Number of participants, P - Present, A - Absent, S - Significant, MR - Mean Ranks, SR - Signed Ranks

Table 8: Repeated measure ANOVA test showing the combined effectiveness of *Abhayarishta Churna* and *Aragwadha Patra Lepa* on PASI Score

PASI Score	N	Mean	Greenhouse-Geisser			Greenhouse-Geisserdf-error	Remarks
			df	F	P		
BT	30	18.916	2.00	7.256	<0.05	28.00	S
16th day		14.736					
31st day		10.890					

N - Number of subjects, BT - before treatment, S - Significant, NS - Non-significant, df - Degree of freedom

Repeated measure ANOVA with Greenhouse - Geisser correction was determined to show statistically significant difference in PASI Score between means over three intervals, i.e., BT mean was 18.916, 16th day mean was 14.736 and on 31st day mean was 10.890 with F score - 7.256.

Table 9: Greenhouse-Geisser Correction of Repeated measure ANOVA

Gross Score I	Gross Score J	Mean Difference (I-J)	Std. error	Sig	95% confidence interval for difference		Remarks
					Lower	Upper	
1	2	4.180	1.209	<0.016	1.107	7.253	S
2	3	3.847	1.230	<0.016	0.720	6.973	S
1	3	-8.027	2.078	<0.016	2.746	13.307	S
BT - Before treatment, S - Significant							

The difference between the three means had statistically significant difference with P<0.05. Statistically significant improvement in PASI Score from 1st to 16th day with mean Difference 4.180. from 16th to 31st day mean difference at 3.847 and statistically significant decrease observed on 1st to 31st day (Gross 1-3) with a mean difference of -8.027.

Discussion

Present study was conducted to evaluate the combined effectiveness of *Abhayarishta Churna***[24]** and *Aragwadha Patra Lepa***[25]** in *Kitibha Kushta* (Psoriasis).

Nimba (*Azadirachta indica*) has *Tikta*, *Kashaya Rasa*, *Katu Vipaka* and *Ushna Veerya* by virtue of its properties it is *Kapha-Pitta Shamaka*, *Kushtahara* and *Shothahara*. It contains a variety of phytochemical compounds including Nimbin, Nimbidin, Nimbolide and limonoids, which contribute to the management of skin diseases by modulating various genetic pathways and other biological activities.**[26]**

Research indicates that the phenolic compounds in *Nimba* bark possess antioxidant and immunomodulatory properties. Immunomodulatory effects of *Nimba* might have helped in Psoriasis. **[27]***Haritaki* (*Terminalia chebula*) has *Tikta, Kashaya Rasa*, *Laghu Ruksha Guna*, *Ushna Veerya* and *Rasayana* by *Karma.* It is mentioned in *Bhavaprakasha* as *Varnya* and *Kushtahara, Anulomaka, Kanduhara and Tridosha Shamaka.***[28]**

Rasayanas have been claimed to possess immunomodulatory activity, they can depress or potentiate the host's capacity to resist infection and tumours non-specifically or react specifically to a foreign substance.**[29]** *Terminalia chebula* (*Haritaki*) is rich in bioactive compounds like chebulagic acid and chebulinic acid, which contribute to its significant anti-psoriatic effects via the heme oxygenase (HO)-1 pathway. This pathway inhibits oxidative stress and NF-κB activity, leading to reduced inflammation and keratinocyte proliferation. In IMQ-treated mice, treatment with *Terminalia chebula* improved erythema and scaling, decreased epidermal thickness, and lowered levels of TNFα, IL-17A, IL-23, and MMP-9. It also reduced TBARS levels and increased GSH content, while decreasing ROS levels and keratinocyte proliferation in M5-treated cells. The anti-psoriatic effects were inhibited by zinc protoporphyrin IX (ZnPP), an HO-1 inhibitor, highlighting the role of HO-1 in its mechanism. Additionally, Terminalia chebula suppressed p65 NF-κB upregulation under psoriatic conditions, and ZnPP blocked this effect. Overexpression of p65 NF-κB diminished the reductions in inflammatory markers and keratinocyte proliferation, suggesting that HO-1-mediated downregulation of p65 NF-κB is crucial for its anti-psoriatic action.**[30]**

Aragwadha (Cassia Fistula) synonymed as *Kushtasudana* means destroyer of skin diseases**[31]** *Kaphamedhavishoshanam***[32]** and *Maladosha Virechaka* is mentioned for the *Patra* of *Avaragwada*. It has *Madhura Rasa, Guru-Snigdha Guna, Sheeta Veerya, Madhura Vipaka*, *Tridosha Shamaka, Kandugna, Kushtagna.* It has *Sramsana* as *Prabhava.***[33]** The leaves primarily contain flavonoids glycosides, free rhein, sennosides A and B, isofavoneoxalic acids and oxyanthraquinones Pharmacological activities include anti-inflammatory, antioxidant, wound healing, anti-pruritic and antitumor. Studies shows Flavonoids are substances found in leaves of C. fistulas; Flavonoids have been recognized to play a role in inhibiting pro inflammatory enzymes activated during inflammation [34]. Another study was performed to check the effects of the extract of C. fistula on the growth of Ehrlich ascites carcinoma and on the life span of tumor-bearing mice, and the results revealed that the extract increased life span and decreased tumor volume and viable tumor cell count.

Another study evaluated the antioxidant activity of fistula bark, stems, leaves and roots. It showed higher antioxidant activity. Which play an important role as free radical scavengers.**[35]**

Kanji has *Madhura* and *Amla Rasa*, *Laghu Guna, Sheeta Veerya, Madhura Vipaka, Vata-Pitta Shamaka.***[33]** It is beneficial in conditions where the skin becomes dry, rough and cold due to *Vata* vitiation also reduces inflammation and redness in skin, Cleanses wounds and promotes healing due to its mild *Kashaya* and *Amlarasa*.

Discussion on probable mode of action of *Lepa*

Lepa pacifies *Prakupita Sthanika Dosha.***[36]**

Mode of action of *Lepa*

Lepa comes in contact with the *Roma* and *Romakupa* which in turn are connected to the *Tiryak Gata Dhamanis***[37]** which perform the function of *Sweda Vahana*. *Lepa* enters the sweat ducts and hair follicles. Hair follicles are important pathway for percutaneous absorption.**[38]** After the application of *Lepa*, *Paka* of *Dravya* occurs. *Paka* refers to the action of *Bhrajaka Agni* and *Rasa Dhatwagni*. It occurs by virtue of *Ushna Guna* of *Bhrajaka Pitta* which is responsible for *Varna Utkarsha.***[39]** *Rasa Tarpana* will occur by virtue of *Vyana Vata* and *Varna Utkarsha* is thus achieved. Hence, it is quoted that *Varnasampannah Rasapurnatvat.***[40]**

Conclusion

Abhayarishta Churna 6grams twice a day after food and *Aragwadha Patra Lepa* external application once a day is effective in the management of *Kitibha Kushta* (Psoriasis). It showed significant improvement in primary outcome measures such as *Shyava Varna, Kinakhara Sparsha* and *Parushata*. There was a significant improvement in the secondary outcome measure of the PASI score. The Null Hypothesis is thus rejected in favour of Alternative hypothesis.

Patient perspective

The patients were satisfied with the treatment in terms of reduction in *Kandu*, *Raga*, *Pidaka*, *Mandala* and*Rookshata* and improvement in quality of life.

Patient consent

Informed consent for publication of this case study has been obtained from the patients.

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