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An open label single arm prospective clinical study on the combined effectiveness of *Panchanimbakam Churna Vati* and *Pathyadi Lepa* in *Kitibha Kushta* (Psoriasis)

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ABSTRACT

Kitibha Kushta is mentioned under *Kshudra Kushta* and is one among the *Ashtamahagada*. There is the involvement of *Tridosha* in all *Kushta* but the predominance of *Dosha* makes the types & manifestations of *Kushta* different. Psoriasis is one of the most common skin disorders. It is a papulosquamous disorder of the skin characterized by sharply defined erythematous lesions. It is chronic and is well known for its course of remission and exacerbation. Prevalence of psoriasis in adults varies from 0.44 to 2.8%, with a much lower prevalence in children. The combined formulations *Panchanimbakam Churna Vati* and *Pathyadi Lepa*, mentioned in *Gadanigraha* and *Yogaratanakara* respectively, are indicated for the management of *Kitibha Kushta*. The combination collectively contains *Kushtaghna Dravyas* and has *Katu, Tikta and Kashaya Rasa, Laghu, Ruksha Guna, and Ushna Veerya* that are helpful in *Samprapti Vighatana* of *Vata* and *Kapha* dominant *Kushta*. **Material and Methods:** Among 30 registered participants, 25 completed the treatment. They were administered with *Panchanimbakam Churna Vati* orally 3 gm per day before food and *Pathyadi Lepa* externally for 30 days. The *Lakshanas* and PASI score was assessed on the 1st, 15th, and 30th. For Statistical analysis, subjective parameters were assessed by Cochran's Q test followed by McNemar test, and objective parameters were assessed by Repeated Measures Anova and Paired T-Test. **Results:** There was a statistically significant improvement in the signs and symptoms of *Kitibha Kushta* (Psoriasis) ($p < 0.05$). **Conclusion:** The combination of *Panchanimbakam Churna Vati* and *Pathyadi Lepa*, is effective in the management of *Kitibha Kushta* (Psoriasis)

Key words: *Kitibha Kushta, Psoriasis, Panchanimbakam Churna Vati, Pathyadi Lepa*

INTRODUCTION

Kushta is a condition in *Ayurveda*, where most skin diseases are discussed. *Kitibha Kushta* is one among the *Kushta* and is a *Ashtamahagada*.^[1] It is mentioned under *Kshudra Kushta*. All *Kushta* have involvement of

Tridosha and the type of *Kushta* depends on the predominance of particular *Dosha*. *Acharya Charaka* has described the involvement of *Vata* and *Kapha* in *Kitibha Kushta* and is compared with Psoriasis due to the maximum resemblance of its symptoms.

Psoriasis is a papulosquamous disorder of the skin characterized by sharply defined erythematous lesions. It is chronic and is well known for its course of remission and exacerbation.^[2]

Based on current evidence-based studies, the prevalence of psoriasis in adults varies from 0.44 to 2.8%, with a much lower prevalence in children. The global prevalence rate of psoriasis was 811 per 100,000 population, approximating 0.84% of the world population of about 64.6 million individuals. The incidence of new cases increased from 92 per 100,000 in 1990 to 99 in 2017.^[3] Adults' peak age at onset is in

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the third and fourth decade of life, with a slight male preponderance.

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, and photochemotherapy, most of these treatment modalities have serious limitations. It's important to note that they have substantial side effects when used for a longer period.

MATERIAL AND METHODS

Source of data

Tertiary *Ayurveda* hospital attached to *Ayurveda* medical college located in district headquarters in southern India.

Method of collection of data

Screening: Subjects were screened using a screening form and recruited participant's data was collected using a prepared case report form (CRF) by incorporating all aspects of *Kitibha Kushta* (Psoriasis)

Diagnostic Criteria

Among screened patients, *Kitibha Kushta* (Psoriasis) was diagnosed based on *Lakshana of Kitibha Kushta* such as *Shyava Varna*, *Kinakhara Sparsha*, and *Parushata*.

Inclusion criteria

- Participants with *Kitibha Kushta* with less than 5 years of chronicity
- Participants aged between 18-60 years and of either gender.
- Participants willing to participate in the study and ready to sign the informed consent.

Exclusion criteria

- Participants with uncontrolled diabetes mellitus and essential hypertension.
- Participants with impaired renal, hepatic, and cardiac function.
- Pregnant and lactating women.

Ethical clearance and CTRI registration

Ethics clearance certificate was obtained from Institutional Ethics Committee.

The trial was registered on www.ctri.gov.in (2021/2/031318 dated 2nd February, 2021)

Study design

The study was an open label, single arm, prospective clinical trial in *Kitibha Kushta* (Psoriasis) (n=25) selected using convenience (non-random) sampling technique with pre and post-design conducted in tertiary *Ayurveda* hospital attached to *Ayurveda* medical college located in district headquarters in southern India.

Dosage and Drug Administration

Internal Medication

Panchanimbakam Churna Vati^[4] : 2 tablets- 500mg each

Anupana : Warm water

External Application

Pathyadi Lepa^[5] : Mixed with warm water

Duration : 30 days

Assessment : Day - 0, 15th, 30th day

OBSERVATIONS

In the present study total of 45 participants were screened, out of which 30 subjects were registered for the study, among them 25 subjects completed the study. Among 30 subjects maximum (n=9) were from the age group of 41-50 years and predominance of males (n=20). 25 subjects were from upper-middle-class group and majority of them (n=21) were from urban areas. Diet-wise distribution showed maximum (n=21) were following a mixed diet.

RESULTS

McNemar test was run on subjective parameters and has shown significant improvement in symptoms like *Shyava Varna*, *Kinakhara Sparsha* and *Parushata*.

Results are placed at Paired t-Test was run on the objective parameter of PASI and showed significant improvement.

Effect of Panchanimbakam Churna Vati and Pathyadi Lepa on PASI score

Repeated measures ANOVA determined that the decrease in PASI score was statistically significant with $p < 0.05$. Post hoc tests using the Bonferroni correction 0.016 revealed that treatment elicited decrease in PASI score from 1st day - 30th day of treatment.

Table 1: McNemar test showing the combined effect of Panchanimbakam Churna Vati and Pathyadi Lepa on Shyava Varna.

Symptom	BT		15 th Day		30 th Day		N	P	Remark
	P	A	P	A	P	A			
Shyava Varna	25	0	24	1	20	5	25	>0.05	NS
	5	0	4	1	0	5			

BT- Before Treatment, N- Number of participants, P- Present, A- Absent, NS- Not Significant

Table 2: McNemar test showing the combined effect of Panchanimbakam Churna Vati and Pathyadi Lepa on Kinakhara Sparsha

Symptom	BT		15 th Day		30 th DAY		N	P	Remark
	P	A	P	A	P	A			
Kinakhara Sparsha	25	0	23	2	9	16	25	<0.05	S
	5	0	3	2	6	1			

BT- Before Treatment, N- Number of participants, P- Present, A- Absent, NS- Not Significant

Table 3: McNemar test showing the combined effect of Panchanimbakam churna Vati and Pathyadi Lepa on Parushata

Symptom	BT		15 th DAY		30 th Day		N	P	Remark
	P	A	P	A	P	A			
Parushata	24	1	20	5	11	14	25	<0.05	S
	4	1	0	5	1	4			

BT- Before Treatment, N- Number of participants, P- Present, A- Absent, NS- Not Significant

Table 4: Repeated measure ANOVA test showing the combined effectiveness of Panchanimbakam Churna Vati and Pathyadi Lepa on PASI Score

PASI Score	N	Mean	Greenhouse-Geisser			Greenhouse-Geisser error Df	Remarks
			Df	F	P		
BT	25	13.368	1.252	21.397	<0.05	30.053	S
15 th day		12.220					
30 th day		9.168					

N- Number of participants, Df- Degree of freedom, F- Frequency, P- P value, S- Significant

Table 5: Pair wise comparison of PASI Score at different interval of treatment

Gross Score I	Gross Score J	Mean Difference (I-J)	Std. error	Sig.	95% confidence interval for difference		Remarks
					Lower	Upper	
BT	15 th Day	1.148	0.350	<0.016	0.246	2.050	S
15 th Day	30 th day	3.052	0.702	<0.016	1.244	4.860	S
BT	30 th day	4.200	0.840	<0.016	2.039	6.361	S

BT - Before Treatment, S - Significant

DISCUSSION

Probable Mode of Action of Drug

Nimba, Khadira, Haritaki, Haridra and Karanja are Katu, Tikta in Rasa, and are Kapha Shamaka. Sarshapa

has *Madhura Rasa* and *Saindhava Lavana* has *Snigdha Guna*, which alleviates *Vata*. The comprehensive action of these ingredients is *Vata- Kapha shamana*.



Image 1: Before Treatment



Image 2: After Treatment

Nimba and *Khadira* has *Laghu* and *Ruksha Guna* and *Tikta, Kashaya Rasa* that act together as *Kapha Shamaka*. *Nimba* (*Azadirachta indica*) has a complex of

various constituents including *Nimbin*, *nimbidin*, *nimbolide*, and *limonoids*, and such types of ingredients play role in diseases management through modulation of various genetic pathways and other activities.^[6]

Studies have shown that phenolic components of *Nimba* bark have antioxidant and immunomodulatory activity. *Nimba* may have helped in the management of Psoriasis as its pathogenesis follows an autoimmune pathway.

Khadira is recommended for all types of *Kushta*. It has immunomodulatory action that may activate both cell-mediated as well as humoral immunity. Among various phytoconstituents present in *Acacia catechu*, catechins may contribute to its anti-inflammatory and antioxidant activities.^[7]

The water extract of *Acacia catechu* showed inhibition of pro-inflammatory cytokine *TNF-α* and a significant increase in cytokine *IL-10*. *IL-10* helps to control the secretion of pro-inflammatory cytokines by augmenting the proliferation of B cells, mast cells, and thymocytes.

Haritaki is *Tikta Kashaya* in *Rasa*, *Laghu Ruksha Guna*, *Ushna Veerya* and is *Rasayana* by *Karma*. It is mentioned in *Bhavaprakasha* as *Varnya* and *Kushtahara*.

A previous study showed that *Terminalia chebula* (*Haritaki*) exhibited potent anti-psoriatic effects via heme oxygenase (HO)-1-mediated inhibition of oxidative stress and *NF-κB* and the subsequent suppression of inflammation and keratinocyte proliferation.^[8]

Bakuchi and *Haridra* are *Katu Tikta* in *Rasa*, *Laghu, Ruksha* in *Guna*, *Ushna Veerya* and has *Katu Vipaka*. It helps in balancing *Vata* and *Kapha*. It is *Kushtaghna, Deepana, Paachana, Anulomana*, and *Vranashodhana* by *Karma*.

Haridra is also called by the name of *Vishothajita*, which means it can act as an anti-inflammatory and help in decreasing the erythema of the skin. It improves the complexion and might have helped in treating *Vaivarnya* of skin.

Curcumin, a chemical compound found in *Haridra* is a non-competitive inhibitor of Phosphorylase kinase (PhK), a serine/threonine-specific protein kinase. A study was conducted previously and it showed that decreased levels of PhK in samples of plaques treated with curcumin 1% alcoholic gel as well as other traditional topical treatments were associated with decreased keratinocyte transferrin receptor (TRR) expression and severity of parakeratosis.^[9] These observations may suggest that agents capable to inhibit PhK activity, such as curcumin, could be considered for the topical treatment of Psoriasis.

Karanja has *Katu*, *Tikta*, *Kashaya Rasa*, *Laghu Teekshna Guna* and *Ushna Veerya* and acts as *Kapha* and *Vata Shamaka*. It is *Kushtaghna*, *Shothahara*, and known as *Kushtajita* which means helpful in treating all types of skin disorders.

The free radical decimating property of *Karanjin* and *Pongamin* were experimentally studied. The scavenging effect of *Karanjin* (The highest activity of 95.60%) and *Pongamin* (68.05%) against nitric oxide. This study was found to be comparable to that of methotrexate, a known drug for treating Psoriasis and might also help in controlling the disease. Nitric oxide is the signaling molecule for keratinocyte growth and plays a pivotal role in this disease. These compounds were found to scavenge the excess nitric oxide from the psoriatic plaques.^[10] This study suggests that *Karanja* can a vital role in managing psoriasis.

CONCLUSION

Panchanimbakam Churna Vati in a dose of two tablets of 500mg thrice a day before food and *Pathyadi Lepa* application externally once a day for a period of one month showed significant results in subjective parameters like *Shyava Varna*, *Kinakhara Sparsha* and *Parushata* and also in objective parameters like PASI Score.

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