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An open label single arm clinical study to evaluate the combined effectiveness of Navakashaya and Vidangadi Lepa in Vicharchika (Dermatitis)

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ABSTRACT

Background: Vicharchika is one among the Kshudra Kushta with predominance of Kapha Dosha and it is characterized by, Kandu (Itching), Bahu Srava (Excessive exudation), Shyava Varna (Greyish black discolouration) and Pidaka (Papule). Vicharchika is similar to Dermatitis (Eczema). Dermatitis is a heterogenous group of disorders that share similarities in clinical appearance and histopathologic findings, but may have different etiologies. **Objectives:** To evaluate the combined effectiveness of *Navakashaya* and *Vidangadi Lepa* in the management of Vicharchika (Dermatitis). Methods: Among 34 registered subjects, 30 of them completed the course of treatment. They were administered with Navakashaya internally and Vidangadi Lepa application externally for a period of 30 days. Ordinal data was analyzed with Friedman's test followed by Wilcoxon signed rank test as post-hoc and Nominal data was analyzed with Cochran Q test followed by McNemar test as post-hoc. Continuous data was analyzed by Repeated Measures ANOVA and after applying bonferroni correction with Paired t test as post-hoc. Results: There was statistically significant improvement in the subjective and objective parameters of Vicharchika (Dermatitis). Conclusion: Navakashaya and Vidangadi Lepa are effective in the management of Vicharchika (Dermatitis).

Key words: Dermatitis, EASI Score, Navakashaya, Vicharchika, Vidangadi Lepa

INTRODUCTION

In Ayurveda, all skin disorders have been classified mainly into two groups - Mahakushta and Kshudra Kushta. Vicharchika is one among the Kshudra Kushta with the predominance of Kapha Dosha and it is

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characterized by the Lakshanas i.e., Kandu (itching), Bahu Srava (excessive exudation), Shyava Varna (blackish brown discolouration) and *Pidaka* (papule).[1]

On the basis of the symptoms, Vicharchika can be correlated with Dermatitis in modern science, which is a reaction pattern manifested by variable clinical and histologic findings. Dermatitis was estimated to affect 245 million people (3.34%) of the world population. [2] The prevalence of dermatitis is increasing because of rapid industrialization, use of chemicals, cosmetics, soaps and other irritants. About 10-20% of the general practice includes the patients suffering from skin disorders. Dermatitis accounts for a very large proportion of all the skin disease. Primary lesions may include papules, erythematous macules and vesicles which can coalesce to form patches and plaques. In severe dermatitis, secondary lesions such as weeping crusting may predominate. Long-standing

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dermatitis is often dry and is characterized by thickened, scaling skin (lichenification). The histologic features of Dermatitis have been divided into three patterns: acute, sub-acute and chronic. Acute dermatitis shows a mixture of epidermal vesiculation, and a mononuclear cell infiltrate. Chronic dermatitis demonstrates epidermal acanthosis, hyperkeratosis, upper dermal fibrosis, and a predominantly perivascular mononuclear cell infiltrate. Mixtures of these two histologic reaction patterns occur in sub-acute dermatitis.^[3]

In contemporary medical practice, antihistamines and topical steroids are the medications for Dermatitis. There is no specific description available in *Samhita* regarding the *Chikitsasutra* of *Vicharchika*. Hence the treatment is to be carried out according to the predominance of *Dosha*.

The Navakashaya^[4] Yoga explained by Chakradutta in Kushta Adhikara comprises of Triphala, Patola, Rajani, Manjishta, Rohini, Vacha and Nimba. These drugs have properties like Tikta Rasa, Laghu and Ruksha Guna, Ushna Veerya, Katu Vipaka and Kapha Pittahara, Deepana and Varnya action.

External intervention i.e., Vidangadi Lepa^[5] comprises of Vidanga, Saindhava, Shiva (Haritaki), Sasirekha (Bakuchi), Sarshapa, Karanja, Rajani (Haridra), along with Go Jala (Gomutra Arka) which is explained by Chakradutta in Kushta Prakarana. These drugs have properties like Tikta Rasa, Laghu, Ruksha Guna, Ushna Veerya and Kushtagna. Hence both formulations are helpful in Samprapti Vighatana of Kapha Pradhana Vicharchika.

OBJECTIVE

To assess the combined effectiveness of 45 ml of *Navakashaya* internally twice daily, before food with *Anupana* of warm water and *Vidangadi Lepa* application externally, once daily in day time with *Gomutra Arka* for a period of 30 days in the management of *Vicharchika* (Dermatitis).

MATERIALS AND METHODS

Source of data: Patients who attended the out-patient department of Kayachikitsa at Sri Dharmasthala Manjunatheswara Ayurveda Hospital, Hassan.

Method of collection of data: Data was collected using specially prepared case report form.

Screening of the patient

A screening form was prepared with all aspects of history, signs, and symptoms of *Vicharchika* (Dermatitis).

Diagnostic criteria

Among screened patients, *Vicharchika* (Dermatitis) was diagnosed based on *Lakshanas* of *Vicharchika* (Dermatitis) such as *Kandu* (itching), *Shyava Varna* (Greyish black discolouration), *Pidaka* (papule), *Bahu Srava* (exudation).

Inclusion criteria

- Subjects suffering with Vicharchika up to 1 year of chronicity
- Subjects of either gender, aged between 18-70 years
- Subjects willing to participate in the study and ready to sign informed consent form

Exclusion criteria

- Subjects with uncontrolled diabetes mellitus
- Pregnant and lactating women
- Subjects with impaired cardiac, renal, and hepatic functions

Sampling technique - Convenient sampling

Sample size - 30

Statistical method

Ordinal data was analyzed with Friedman's test followed by Wilcoxon signed rank test as post-hoc and Nominal data was analyzed with Cochran Q test followed by McNemar test as post-hoc. Continuous data was analyzed by Repeated Measures ANOVA and after applying bonferroni correction with Paired t test as post-hoc.

Ethical clearance and CTRI registration

The ethics clearance certificate from the Institutional Ethics Committee of Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital,

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Hassan was obtained, with IEC No: SDM/IEC/75/2021 (9/7/2021). Trial was registered on Indian clinical trial registry, CTRI/2022/05/042516.

Study design

Open label single arm prospective clinical study with pre and post-test design, from outpatient department of a tertiary Ayurveda hospital attached to Ayurveda medical college located in district headquarters in Southern India.

Intervention

Internal medication

1. Navakashaya

Dose: 45ml twice daily (Morning and Evening), before food

Route of administration-Orally

Anupana - Warm water

Duration - 30 days

External Application

2. Vidangadi Lepa

Vidangadi Lepa Choorna application mixed with Gomutra Arka

Dose - Once daily, in day time (Morning - 15 minutes), Thickness of 3mm.

Duration - 30 days

Source and Authentication of Raw Drug

Required raw drugs for the medicine preparation were purchased from GMP certified Pharmacy - CKKM Ayurveda Medicine Manufactures, Kerala along with authentication certificate.

Assessment Criteria:

Signs and symptoms of *Vicharchika* (Dermatitiis) like *Kandu* (itching), *Shyava Varna* (greyish black discolouration), *Pidaka* (papule), *Bahu Srava* (exudation) were assessed by giving suitable scoring at three intervals namely 1st, 15th and 30th day of treatment. The disease activity of the patient was assessed by Eczema Area and Severity Index Score (EASI Score).

Subjective parameter

Kandu

Objective parameter

- Shyava Varna
- Pidaka
- Bahu Srava

Table 1: Scoring criteria of Kandu^[6] (Pruritus)

Grade	Score
Nearly no itching	0
Mild or occasional itching (1-2 times in a day)	1
Itching on and off	2
Continuous itching without disturbance in routine	3
Continuous itching with disturbance in routine even in sleep	4

Table 2: Scoring criteria of Bahu Srava^[6] (Discharge)

Grade	Score
Nearly no weeping	0
Moisture on the skin lesion	1
Weeping from the skin after itching	2
Weeping from the skin	3
Profuse weeping making cloths wet	4

OBSERVATIONS

Table 3: Demographic profile of 34 patients of *Vicharchika*

Observation	Predominance	Percentage %
Age	31-40 years	11 (32.35%)
Gender	Female	20 (58.82%)
Socio-economic status	Lower middle	17 (50%)

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Table 4: Baseline distribution of *Lakshanas* of 34 patients of *Vicharchika*

Lakshana (Present)	Percentage %
Kandu	34 (100 %)
Shyava Varna	34 (100 %)
Pidaka	34 (100 %)
Bahu Srava	34 (100 %)

RESULTS

MC Nemar Test

Table 5: Effect of Intervention on the assessment of *Kandu* between various intervals

BT - 15 th Day									
Kandu BT	Kandu 15	th Day	N	Р	Remarks				
	Present	Absent							
Present	26	4	30	>0.016	NS				
Absent	0	0							
15 th Day - 30 th Day									
Kandu 15 th	Kandu 30	th Day	N	Р	Remarks				
Day	Present	Absent							
Present	14	12	30	<0.016	S				
Absent	0	4							
BT - 30 th Day									
BT - 30 th Day									
BT - 30 th Day Kandu BT	Kandu 30	th Day	N	P	Remarks				
Ť	Kandu 30 Present	th Day Absent	N	Р	Remarks				
Ť		-	N	P	Remarks				

Wilcoxon signed Rank Test

Table 6: Effect of Intervention on scoring of Kandu

Para met er	Negative Ranks N M SR R						Ti e s	T ot al	Z Va lu e	P Val ue	Re mar ks
		R			R	R					
BT -	1	9.	17	0			1	30	-	<0.	S
15 th	8	50	1.0		0	0	2		3.	01	
Day			0		0	0			86	6	
									6		

15 th	2	11	25	0			8	30	-	<0.	S
Day -	2	.5	3.0		0	0			4.	01	
30 th		0	0		0	0			45	6	
Day									6		
BT -	2	15	43	0			1	30	-	<0.	S
30 th	9	.0	5.0		0	0			4.	01	
Day		0	0		0	0			79	6	
									8		

MC Nemar Test

Table 7: Effect of Intervention on the assessment of Pidaka between various intervals

BT-15 th Day									
Pidaka BT	Pidaka 1	5 th Day	N	Р	Remarks				
	Present	Absent							
Present	29	1							
Absent	0	0	30	>0.016	NS				
15 th Day - 30 th Da	y								
Pidaka 15 th	Pidaka 30	O th Day	N	Р	Remarks				
Day	Present	Present Absent							
Present	22	7	30	<.016	S				
Absent	0	1							
BT - 30 th Day									
Pidaka BT	Pidaka 3	O th Day	N	Р	Remarks				
	Present	Absent							
Present	22	8							
Absent	0	0	30	<.016	S				

Cocharn Q Test

Table 8: Effect of Intervention on the assessment of Shyava Varna between various intervals

Paramet	Value		N	Cochran	Р .	Remar	
er	Prese Abse nt nt	's Q	value	k			
Shyava Varna BT	30	0	3 0	2.000	P<0.0 5	NS	
Shyava Varna 15 th Day	30	0					
Shyava Varna 30 th Day	29	1					

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MC Nemar Test

Table 9: Effect of Intervention on the assessment of Bahu Srava between various intervals

BT - 15 th Day								
Bahu Srava BT	Bahu Sra Day	<i>va</i> 15 th	N	Р	Remarks			
	Present	Absent						
Present	23	7		P<.016	S			
Absent	0	0						
15 th Day - 30 th Da	У							
Bahu Srava 15 th Day	<i>Bahu Sra</i> Day	va 30 th	N	Р	Remarks			
	Present	Absent						
Present	8	15	30	P<.016	S			
Absent	0	7						
BT - 30 th Day								
Bahu Srava BT	<i>Bahu Sra</i> Day	va 30 th	N	Р	Remarks			
	Present	Present Absent						
Present	8	22	30	P<.016	S			
Absent	0	0						

Table 10: Effect of Intervention on scoring of Bahu Srava

Para met	et Ranks e ot	ot	Z Va	P Val	Re mar						
er	N	M R	SR	N	M R	S R	S	al	lu e	ue	ks
BT - 15 th Day	1 5	8. 00	12 0.0 0	0	0 0	0 0	1 5	30	- 3. 62 4	<0. 01 6	S
15 th Day - 30 th Day	2	10 .5 0	21 0.0 0	0	0 0	0 0	1 0	30	- 4. 13 4	<0. 01 6	S
BT - 30 th Day	2 6	13 .5 0	35 1.0 0	0	0 0	0 0	4	30	- 4. 57 3	<0. 01 6	S

Repeated measure ANOVA Test

Table 11: Effect of Intervention on EASI Score

Param eter	N	Me an	Greei Geiss	nhouse- er		Greenho use-	Rema rks
(EASI)			df	F Valu e	P Val ue	Geisser error Df	
ВТ	3 0	9.1 8	1.6 62	12.4 43	<0. 05	48.194	S
15 th Day		7.6 8					
30 th Day		6.6 3					

Table 12: Effect of Intervention on EASI Score - Pair wise

Gro ss Sco re	Gro ss Sco re J	Mean differe nce (I-J)	Std Deviati on	Std. erro r Me an	t Val ue	Sig.	Rema rks
ВТ	15 th Day	1.493	3.132	.571	2.6 11	<.0 16	S
15 th Day	30 th Day	1.056	2.085	.380	2.7 76	<.0 16	S
ВТ	30 th Day	2.550	3.095	.565	4.5 12	<.0 16	S

DISCUSSION

Effect on *Kandu*

Statistically significant improvement was found in *Kandu* after treatment. Mc Nemar test (P value< 0.016) showed improvements in counts at intervals of 15th day - 30th day (p.000) and BT - 30th day (p.000). *Kandu* was present in 26 subjects and was absent in 4 subjects at interval of BT - 15th day. From 15th day - 30th day interval of treatment *Kandu* was absent in 12 subjects and from BT - 30th day interval of treatment *Kandu* was absent in 16 subjects. *Navakashaya* containing *Patola, Rajani, Nimba* and *Vidangadi Lepa* containing *Sarshapa, Haridra* and *Gomutra* have *Kandughna* property.

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Tikta Rasa is Kaphahara and Rakthaprasadhana. Navakashaya and Vidangadi Lepa possess Tikta Rasa, Laghu Rooksha Guna and Ushna Veerya which are opposite to the Guru, Snigdha and Sheeta properties of Kapha Dosha, which is responsible for Kandu.

Effect on Pidaka

Statistically significant improvement was found in *Pidaka* after treatment. Mc Nemar test (P value <0.016) showed improvements in count at intervals of 15th day - 30th day (p.016) and BT - 30th day (p.008). *Pidaka* was present in 29 subjects and was absent in 1 subject at interval of BT - 15th day. From 15th day - 30th day interval of treatment *Pidaka* was absent in 7 subjects and from BT - 30th day interval of treatment *Pidaka* was absent in 8 subjects. The vitiated *Pitta* when accumulates in *Twacha* and *Rakta*, it causes *Pidaka*. *Rakta* is the *Ashraya* for *Pitta Dosha*. *Tikta Rasa* is *Pittahara* and *Rakthaprasadhana*. *Navakashya* containing *Triphala*, *Rajani*, *Manjishta*, *Katuki Nimba* and *Vidangadi Lepa* containing *Haritaki*, *Bakuchi*, *Sarshapa*, *Karanja* and *Haridra* are *Pittahara*.

Effect on Shyava Varna

Statistically significant improvement was not noticed in *Shyavavarna* after treatment. The Cochran Q Test and Post hoc test with MC Nemar test showed no improvements in mean ranks of three intervals i.e., BT-15th day, 15th day-30th day and BT-30th day. But clinically there was reduction in *Shyava Varna*.

Effect on Bahu Srava

Statistically significant improvement was found in *Bahu Srava* after treatment. Wilcoxon signed rank test (P value<0.016) showed improvements in mean ranks at intervals of BT-15th day (p.016), 15th day-30th day (p.000) and BT-30th day (p.000). *Bahu Srava* was present in 23 subjects and was absent in 7 subjects at interval of BT-15th day. From 15th day-30th day interval of treatment *Bahu Srava* was absent in 15 subjects and from BT-30th day interval of treatment *Bahu Srava* was absent in 22 subjects. *Srava* can be due to both *Kapha* and *Pitta Dushti. Navakashaya* and *Vidangadi Lepa* containing ingredients are *Tikta Rasapradhana*, which is *Pittahara* and *Kaphahara*. Both formulations possess

Rooksha Guna, which is opposite to the Snigdha Guna of Kapha and Pitta Dosha which is responsible for Bahu Srava.

Assessment score of Dermatitis (Vicharchika)

EASI Score on Head and Neck

Statistically significant improvement was not found in the erythema, papulation, Scratching and lichenification in head and neck after three intervals of treatment i.e., BT-15th day, 15th day-30th day and BT-30th day. This may because of less number of subjects having involvement of head and neck region and because of less sample size lead to statistically not significant.

EASI Score on Trunk

Statistically significant improvement was not found in the erythema, papulation, Scratching and lichenification in head and neck after three intervals of treatment i.e., BT-15th day, 15th day-30th day and BT-30 th day. This may because of less number of subjects having involvement of head and neck region and because of less sample size lead to statistically not significant.

EASI Score on Upper limb

Statistically significant improvement was found in the erythema in upperlimb. Wilcoxon signed rank test (P value<0.016) showed improvements in mean ranks at intervals of BT-30th day (p.005). Statistically significant improvement was found in the papulation in upperlimb. Wilcoxon signed rank test (P value<0.016) showed improvements in mean ranks at intervals of BT-15th day (p.014), and BT-30th day (p.005). Statistically significant improvement was found in the scratching in upperlimb. Wilcoxon signed rank test (P value<0.016) showed improvements in mean ranks at intervals of BT-30th day (p.008). Statistically significant improvement was found in the lichenification in upperlimb. Wilcoxon signed rank test (P value<0.016) showed improvements in mean ranks at intervals of BT-30th day (p.008). This may because of majority number of subjects having involvement of upper limb region.

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EASI Score on Lower limb

Statistically significant improvement was found in the erythema in lowerlimb. Wilcoxon signed rank test (P value<0.016) showed improvements in mean ranks at intervals of BT-15th day (p.014) and 15thday-30thday (p.008) and BT-30th day (p.000). Statistically significant improvement was found in the papulation in lowerlimb. Wilcoxon signed rank test (P value<0.016) showed improvements in mean ranks at intervals of BT-15th day (p.014), 15thday-30thday (p.002) and BT-30thday (p.000). Statistically significant improvement was found in the scratching in lowerlimb. Wilcoxon rank test (P value<0.016) signed showed improvements in mean ranks at intervals of BT-30th day (p.008). Statistically significant improvement was found in the lichenification in lowerlimb. Wilcoxon (P rank test value<0.016) signed improvements in mean ranks at intervals of 15thday-30thday (p.005) and BT-30th day (p.001). This may because of majority number of subjects having involvement of lower limb region.

EASI Score

Statistically significant improvement was found in mean score of EASI Score in BT-15th Day with mean difference (1.493, p.014, SD 3.132) 15th Day- 30thDay with mean difference (1.056, p.010, SD 2.085) and BT-30th Day with mean difference (2.55, p.000, SD 3.095). Overall, the combination of *Navakashaya* and *Vidangadi Lepa* were found to show statistically significant result in relieving symptoms like erythema, papulation, excoriation and lichenification.

Discussion on Probable mode of action of drug

This study was intended to evaluate the combined effectiveness of *Navakashaya* internally and *Vidangadi Lepa* externally in *Kushta Chikitsa*. The ingredients of *Navakashaya* and *Vidangadi Lepa* possess *Tikta Rasa, Laghu Rooksha Guna, Ushna Veerya, Katu Vipaka* and *Kushtagna* properties which are opposite to the qualities of *Kapha*.

The administration of *Haritaki* extract helps in decreasing keratinization, mast cell infiltration and inflammation related mediators.^[7] *Amalaki* helps in

liver detoxification and it is rich in Vitamin C. It is good for the complexion (*Varnya*). The paste obtained from *Vibhitaki* offers distinctive advantages in wound healing.^[8]

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Patola possess anti-inflammatory and wound healing activity. Haridra is also called by the name of Vishothajita, which means it can act as an antiinflammatory and help in decreasing the erythema of the skin. It improves the complexion and might have helped in the Vaivarnya of skin. Manjishta root extract has been used as anti-inflammatory agent because of the presence of rubimallin. It inhibits the lipoxygense enzyme pathway, which catalyze the production of various inflammatory mediators such as leukotriens. [9] 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.[10] Alcoholic extract of Katuki and compounds kutkin, picroside-1 and kutkoside have been reported for their anti-inflammatory and antioxidant activity.[11] Vacha leave extract has, characteristics of restriction of interleukin. Bakuchi is 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, Pachana, Anulomana, and Vranashodhana by Karma. 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. Ethanol leaf extract and embelin isolated from Vidanga were proved good for wound healing in albino rats. Sarshapa balances Vata and Kapha Dosha.[12] Gomutra Arka is Kushtashamaka, Kanduhara, Kaphahara and useful in Alepana. Gomutra Arka is Kushtahara and Kanduhara. Hence, it can be concluded that Navakashaya and Vidangadi Lepa were effective in the management of Vicharchika (Dermatitis).

Mechanism of action of Lepa

Network of *Sira*, underneath the skin and their openings are attached to hair follicles which carry

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sweat and replenish Rasa inside and outside through the Veerya of Lepa. Dravyas enter the body after being transformed in skin. Because of application of Lepa, the skin temperature increases which helps in hastening the pilosebaceous uptake and skin permeation of the drug in topical formulation. Though small amounts of chemicals may enter the body rapidly through the glands or hair follicles, they are primarily absorbed through the epidermis. Chemicals must pass through the cell layers of epidermis before entering the dermis where they can enter the blood stream and circulate to other areas of body. The stratum corneum is the outermost layer of the epidermis and the rate limiting barrier in absorption of an agent. After penetrating through the stratum corneum and into viable epidermis and dermis the molecules of the formulation produce its characteristic pharmacological response through receptors even before the blood and lymph circulations remove it. Thus, Lepa helps to remove the toxins.[13]

CONCLUSION

45 ml of *Navakashaya* internally twice daily, before food and *Vidangadi Lepa* application externally, once daily in day time with *Gomutra Arka* for a period of 30 days was effective in the management of *Vicharchika* (Dermatitis). It showed significant improvement in symptoms such as *Kandu, Pidaka* and *Bahusrava*. There was no significant improvement in *Shyava Varna*. There was a significant improvement in the EASI score. Thus, Research hypothesis was accepted.

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