

THE EFFECT OF NAVAKARSHAKA KASHAYA GHANA SATWA IN THE MANAGEMENT OF EKAKUSHTA (PSORIASIS) – A RANDOMIZED COMPARATIVE SINGLE BLIND CLINICAL TRAIL

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ABSTRACT

Background: It's difficult to lead the life with skin disease as it accounts for a great deal of misery, suffering, incapacity and economic loss. *Ekakushta* is a *vatakaphapradhanatridoshajavyadhi* and is a prime among the *Kshudrakushtas* and its *lakshanas* resembles with the Psoriasis. There is a need for more comprehensive, economical and safe method of management for Psoriasis. Hence the present study was conducted to evaluate the efficacy of *Navakarshaka Kashaya Ghanasatwa* in the management of *Ekakushta* (Psoriasis). **Methods:** 40 patients of *Ekakushta* fulfilling the inclusion criteria were randomly selected and divided into 2 groups, comprising 20 patients in each group. Clinical signs and symptoms were given suitable grading according to their severity along with Psoriasis Area and Severity Index scoring. After completion of the treatment results were assessed and statistically analyzed to know the significance. **Results:** In total Psoriasis Area and Severity Index 8.53% improvement was seen in Group A compared to Group B with significance of 0.0004. After considering overall therapy with all the parameters 47.07% i.e. moderate improvement by *Navakarshaka Kashaya Ghanasatwa* was observed.

Keywords: *Navakarshaka Kashaya, Kushta, Ekakushta, Psoriasis.*

INTRODUCTION

The word '*Kushta*' is a broad term, which covers almost all the skin diseases. It means which despises by vitiation as well as discoloration of the skin¹. *Ekakushta* is a prime among all the *Kshudrakushta*². In the present study *Ekakushta* is compared to Psoriasis due to its maximum resemblance. Pso-

riasis is the oldest recorded skin disease. It is a multifactorial disease of unknown origin and is universal in occurrence. The most characteristic lesions consist of erythematous, scaly, sharply demarcated, indurate plaques, present particularly over extensor surfaces and scalp³. Lesions vary in size from a pin point

papule to plaque that covers larger area of the body. Its prevalence in different populations varies from 0.1%-11.8%⁴. In India, it varies from 0.84%-5.6%⁵. It is equally common in both sexes Contemporary science treats Psoriasis with PUVA (Psoralen and ultraviolet A) and corticosteroids. But the therapy gives both sexes serious side effects like liver & kidney failure, bone marrow depletion⁶ etc. Hence it is the need of time to find out safe and effective medicine for psoriasis and here comes the role of Ayurveda. The unique treatment modality of ayurveda provides long lasting results and a better life to patients through its three basic principles of treatment i.e. – *Shamana*, *Shodhana*, and *Nidana-parivarjana*.

*Navakarshaka*⁷ *Kashaya* is used in *Kushta*, *Kapalakushta*, *Vatarakta*, *Pama*, and *Raktamandala* in *yogymatra*. *Kashaya* is prepared by *Triphala*, *Nimba*, *Manjistha*, *Vacha*, *Katukarohini*, *Guduchi* and *Daruharidra*. Thus obtained *Navakarshikakashaya* is subjected to prepare *Ghana* by the method of *Rasakriya*⁸ and filled to capsules of 500mg each to evaluate the effectiveness of preparation in treating *Ekakushta* (Psoriasis).

Aims and Objectives: The aim of the present study was to evaluate the “Efficacy of *Navakarshaka Kashaya Ghanasatwa* in the management of *Ekakushta* (Psoriasis)”.

Materials and Methods

Source of data:

A. Selection of clinical participants – 40 Patients of *Ekakushta* (Psoriasis) was selected from OPD and IPD of KLEU's Ayurveda hospital, Shaha-pur, Belgaum.

B. Drug procurement-The raw drugs of *Navakarshika Kashaya* were collected from GMP approved KLE Ayurved Pharmacy and were authenticated from AYUSH approved Central Research Laboratory of KLE University Shri BMK Ayurveda Mahavidyalaya, Belagum. ‘777’ oil^{9,10}

is procured from Dr. JRK's Siddha Research and Pharmaceuticals Pvt. Ltd.

Methodology:

Method of Preparation of *NavakarshikaKashaya*:

(Ingredients of *Navakarshaka Kashaya*⁷ Table 01)-*Kashaya* (Decoction) was prepared using 1 part of *Navakarshikakashaya* (course powder) *bharad* (18kg) and 16parts of water (288 lit) was added and boiled on medium flame (95-105⁰C) till it gets reduced to 1/4th part (72 liters). Then *kashaya* (Decoction) was filtered and stored in clean vessel. Obtained *Navakarshikakashaya* (71.5 liter) was heated on medium flame till water portion was evaporated⁸. The residue was scraped well, collected and kept in drier at the temperature of 40⁰C for 2 hours every day for 15days for complete drying. Later this was powdered (2kg) into finest form, filled in capsules (500mg/cap) and preserved in a sterile container.

C. METHOD OF COLLECTION OF DATA:

1. Study Design: This is a comparative single blind clinical study with pre-test & post-test design where in 40 diagnosed *Ekakushta* patients of either sex were randomly assigned into two groups each comprising of 20 patients. A specially designed proforma with all points of history taking, physical signs and routine laboratory investigations were employed.
 - a. **Group A-** Patients of this group were given *Navakarshakakashaya Ghanasatwa* (500mg) 2 Cap/ Bid internally after food and ‘777’ Oil for local application twice a day.
 - b. **Group B-** In this group patients were given Placebo (Wheat flour) 2 Cap/ Bid internally after food and ‘777’ Oil for local application twice a day.
2. Diagnostic criteria: Based on *lakshanas* of *Ekakushta* and signs of Psoriasis - *Mahavastu* (Effected Area), *Matsyashakhalopama* (Scaling), *Asweda* (*Rukshatwa*-Dryness), *Shyava* – *Aruna-*

varna (Erythema), *Kandu* (Itching), Candle grease Sign, Auspitz Sign, Koebner phenomenon

3. Inclusion criteria: Patients presenting with Signs and Symptoms of *Ekakushta* (Psoriasis), aged between 16-70 years and patients of either sex
4. Exclusion criteria: Pregnant and lactating women and Psoriasis patient presenting with other systemic disorders.

5. Assessment criteria:

- Grading of Signs and symptoms- Table No.2.
- PASI (Psoriasis Area and Severity Index) score¹¹

6. Overall Assessment of Therapy

- Complete remission: 100% relief in the signs & symptoms.
- Marked improvement: 61%-99% relief in the signs & symptoms.
- Moderate improvement: 31%-60% relief in the signs & symptoms.
- Mild improvement: below 30% relief in the signs & symptoms.

7. Duration and follow up: Duration of study was for 30 days, consists of screening and enrolment on baseline day. Follow up visits during the study period were on 7th, 14th, 21st & 28th days with window period of 2 days.

8. Statistics Analysis: For the statistical analysis, wilcoxon sign rank method, Mann Whitney method and 't' test is applied to assess the significance within the groups and between the groups.

Observations: The observations made on 40 patients showed that maximum number of patients 67.5% were in between Age group of 25 to 55 years, 57.5% were male, 92.5% were of Hindu religion, 40% belonged to lower middle class, Maximum number of patients i.e. 37.5% were Businessmen, 67.5% were habituated to mixed diet, 35% were addicted to Alcohol and smoking. Maximum number

of patients 42.5% was having *Vata-pitta Prakriti*. 12.5% patients reported both Anxiety (*Udvega*) and Irritation, 60% patients were suffering from disturbed sleep, 22.5% patients were taking frequently curd at night, *Dugda* with *Matsya* was taken by 7.5% patients. In this Study 50% patients belonged to *Madhyama Koshta*. Only 17.5% had positive family history, 45% patients had Chronicity from 1-5 years. 60% patients had aggravation during winter season and 72.5% showed plaque type of psoriasis. 75% patients had the involvement of more than one parts of body. 12.5% patients had the lesions only on the scalp.

Results:

In group A highly significant improvement was there in *Matsyashakalopama* (Scaling) and *Shyava-arunavarna* (Erythema) with 80.33% (P=0.0001) and 55.38% (P=0.0001) respectively. Other symptoms shown significant results with 89.47% (P=0.0015) reduction in *Kandu* (itching), 76.67% (P= 0.0002) in *Aswedana* (Dryness), and 50% (P=0.0014) of improvement was there in *Mahavasthu* (Area of Lesions). 86.67% improvement was assessed in the Candle grease sign with significance of 0.0004 and 96.00% in Auspitz sign (P=0.0010). In Total PAASI Score highly significant improvement of 57.80% (P=0.0001) reduction was observed. Good improvement of 70% (P=0.0028) was there in the head compared to other part of body. 53.88% (P=0.0007) reduction of PAA-SI score in upper limb, 56.70% (P=0.0004) in the lower limbs and 58.11% (P=0.0005) improvement observed in the Trunk region (Table no 3). In Group B Significant improvement of 35.71% (P=0.0038) in *Asweda* (*Rookshata*) and *Matsyashakalopam* (scaling) was reduced by 30.91% (P=0.0047). No significant changes were observed in other *Lakshanas*. In signs 33.33% of improvement was seen with significance of 0.0330 in Candle grease sign, and with no significance 46.67% (P=0.1095) improvement in Auspitz sign was observed. Total Psoriasis Area and Severity Index and other part of the body Psoriasis

Area and Severity Index do not show any significant results (Table no 4).

After comparing the percentage of improvement between the groups in Signs and symptoms, highly significant improvement observed in *Matsyashakalapoama* (Scaling) and *Shyavaarunavarna* i.e with difference of 50% (P=0.0001) and 44.27% (P=0.0001) respectively in group A compared to Group B. Significant improvement observed in other symptoms i.e 40.96% (P=0.0026) in *Rookshata*, 50% (P=0.0499) in *Kandu* and 27.5% (P=0.0146) in *Mahavasthu*. Group A shown 53.37% (0.0028) in Candle grease sign and 49.33% (P=0.0128) in the Auspitz sign more compared to Group B (Table no 5). Comparing both the Groups in Psoriasis Area and Severity Index (PASI) Score, Group A has shown significantly more improvement than group B with 60.29% (P=0.0162) in scalp psoriasis, 43.35% (P=0.0050) in upper limbs, 44.61% (P=0.0067) in Lower limbs and in Trunk 53.39% (P=0.0015). Where in Total PAASI 48.53% improvement was seen in Group A compared to Group B with significance of 0.0004. (Table no 8)

DISCUSSION

1. Mahavastu: Stress, Season and autoimmunity are the precipitating factors which exacerbate the existing disease condition leading to the further extension of the lesions¹² which can be understood as *mahavastu*. Stress results in the tissue injury by increasing the oxidative stress in the tissues. It can be inferred that increased Autoimmunity results in the increased activation of CD4 cells and CD8 cells which leads to the destruction of tissues by their phagocytosis¹³. In present study, *Navakarshakakashaya Ghanasatwa* retarded further expression of the lesions, which may be due to the Antioxidant and immunomodulatory activity of the drugs like *Triphala*, *Manjista*, *Daruharidra*. *Manjista* and *Daruharidra* with their *Rakthashodaka* property along with *Ushnavirya* of other drugs might have reduced the tendency of spreading by 27.5%.

2. MatsyaShakalopama (Scaling):

Studies have shown that autoimmunity when affect the dermatomes results in the excessive production of immature keratocytes with a reduced span results in hyper proliferation leading to scaling.¹⁴ Present study showed significant reduction of scaling by 49.42% which may be due to synergistic effect of the formulation, which exhibited through immunomodulatory action of *Guduchi*, *Manjista*, *Daruharidra*. Further *Guduchimanjista* etc. drugs are known for their leucocytosis action which results in suppression of the leucocytes i.e Monocytes which are responsible for the suppression of IL-6 and IL-8. Hence suppression of Leucocytes might have led to Suppression of Interleukin production resulting into reduction of scaling.

3. Shyava-aruna Varna: Researches showed that, in psoriasis inflammatory mediators like IL-17 and TNF cytokines disrupt the pigment production of melanocytes. Increased local blood circulation during inflammatory period exerts erythema of the skin¹⁵. *Triphala*, *Guduchi* are known for their anti-inflammatory action and might have corrected the impaired melanin production by 44.27%.

4. Kandu:

Local inflammatory mechanisms may induce pruritis in many dermatomes long with various inflammatory mediators (Neuropeptides), which are released because of inflammation from dermal nerve endings which results in Pruritis¹⁶. Neuropeptides, Mastocytes, Dendritic cells, Lymphocytes, Macrophages and Neutrophils will produce vascular changes in the skin by inducing angiogenesis, Dilatation of vessels.¹⁷ Ingredients of the formulations like *Guduchi*, *triphala*, *manjista*, *daruharidra* have anti-inflammatory properties by which it might have act over neuropeptides to reduce the itching by 50%.

5. Rookshata:

It is known that abnormalities of sweat gland function in the Psoriasis leads to lack of sweat in the lesion and causes the dryness.¹⁸In the diseases like Dry eczema and Psoriasis - dry, rough skin and lack of sweating is seen due to slow oxidation.¹⁹Antioxidant activity of *Triphala*, *Manjistha* and *Daruharidra* might have helped to reduce the *Rukshata* (Dryness). *Rukshata* is main property of *Vatadosha*. Except *Amalaki* and *Nimba* other constituents of *Navakarshakakashaya* are having *Ushanavirya* which acts as *Vatahara*, this might have reduced *rukshata* 40.96% in the present study.

Most of the drugs of *Navakarshakakashaya* with *Tiktha Rasa* and *KatuVipaka* do *agnidipana*, *Amapachan* and *Rakthashodana*. *Tiktharasa* and *kashaya rasa* are known for their *aphashoshana*, *Kledashoshana*, *Kanduhara*, *Ropana*, *Twakmamsasthirikarana karma*, thus desorption of excessive *Kapha dosha* which may be present in the form of *Kleda* in *Shareera*. Hence, this *Kapharukshana* leads to *shrotoshodana*. Further *Gunaslika Laghava*, *Vaishadya* also does *Kaphashoshana*. *Ushna* rectifies *Anulomagati* of *Vayu* which act as *Vatahara*. Hence correction of *Ama*, enhancement of *Jataragni* and *Dhatwagni*, restoration of normal functions of *Vata* might have suppressed the *EkakushtaLakshanas* as the definition of *Kushta* says- Pathology Manifesting inside in the *koshta* and exhibiting its *lakshana* in the *Twak*.

CONCLUSION

Present study with two groups one with trail drug *Navakarshaka Kashaya Ghanasatwa* and other with placebo but both groups has the same local application. With proper statistical application considering overall therapy, it was found that *Navakarshaka Kashaya Ghanasatwa* is having 47.07% efficacy in the management of *Ekakushta* (Psoriasis), i.e in total proves to be having moderate efficacy in treating the disease *Ekakushta* (Psoriasis).

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Table 1: Showing Ingredients of Navakarshaka Kashaya

Si. No	Name of the drug	Latin Name	Part used	Proportion
1.	<i>Amalaki</i>	<i>Emblicaofficinalis Linn,</i>	Fruit	1part
2.	<i>Bibhitaki</i>	<i>TerminaliabeliricaRoxb.</i>	Fruit	1part
3.	<i>Haritaki</i>	<i>Terminaliachebula Retz</i>	Fruit	1part
4.	<i>Nimba</i>	<i>Azadirachtaindica A. Juss.</i>	Stem bark	1part
5.	<i>Manjishtha</i>	<i>Rubiaccordifolia Linn, Root</i>	Root	1part
6.	<i>Vacha</i>	<i>Acoruscalamus Linn,</i>	Rhizome	1part
7.	<i>Katurohini</i>	<i>PicrorhizakurroaRoyle ex Benth</i>	Rhizome	1part
8.	<i>Guduchi</i>	<i>Tinosporacordifolia.Willd.miers</i>	Stem	1part
9.	<i>Daruharidra</i>	<i>Berberisaristata DC.</i>	Rhizome	1part

Table 2: Grading of *Lakashanas* and signs:

Signs and Symptoms	Observations	Score
<i>Mahaavaastu</i> (Area affected) Body Parts- Hand, Leg, Neck, Scalp, Trunk	No lesions	0
	Partial involvement of any one Part	1
	Partial involvement of any 2 parts	2
	Lesions on most part of body	3
	Lesions on whole body	4
<i>Rookshatwa</i> or <i>Asweda</i> (Dryness of lesion)	No line on scrubbing with nail	0
	Faint line on scrubbing by nails	1
	Lining & even words can be written on scrubbing by nail	2
	Excessive <i>Rukshata</i> leading to <i>Kandu</i>	3
	<i>Rukshata</i> leading to crack Formation	4
<i>Matsyashakalopama</i> (Silvery scaly lesions)	No scaling	0
	Mild scaling by itching/rubbing(from some lesions)	1
	Moderate scaling by itching/rubbing(from all lesions)	2
	Severe scaling by itching/rubbing(from all lesions)	3
	Scaling without rubbing/itching (from all lesions)	4
<i>Shyaava –Aruna Varna</i> (Erythema)	Normal skin.	0
	Faint or near to normal.	1
	Blanching + red colour.	2
	No blanching + red colour.	3
	Red colour + Subcutaneous.	4
<i>Kandu</i> (Itching)	No itching	0
	Mild / occasional itching	1
	Moderate (tolerable) infrequent	2
	Severe itching frequently	3
	Very severe itching disturbing sleep And other activities	4
Candle grease sign	Absent	0
	Improvement.	1
	Present.	2
Auspitz sign	Absent.	0
	Improvement.	1
	Present.	2

Table 3: *Lakshanas* of *Ekakushta* of Group A before and after the treatment (Mann-Whitney U test)

Parameters	Mean BT	Mean AT	Mean Diff. ± SD	P value	Sig	% of Change
<i>Mahavaasthu</i>	2.0±1.07	1.00±0.72	-1.0± 0.64	0.0014*	Yes	50.0%#
<i>Kandu</i>	1.90±1.45	0.20±0.89	1.70 ± 1.42	0.0015*	Yes	89.47%#
<i>Asweda</i>	3.00±1.03	0.70±1.03	2.30 ± 1.17	0.0002*	Yes	76.67%#
<i>Matsyashakalapoama</i>	3.05±0.76	0.60±0.94	2.45 ± 0.89	0.0001*	Yes	80.33%#
<i>Shyava-arunavarna</i>	3.25±0.85	1.45±0.83	1.80 ± 0.95	0.0001*	Yes	55.38%#
Candle grease sign	1.50±0.80	0.20±0.52	1.30±0.86	0.0004*	YES	86.67%#
Auspitz sign	1.25±0.97	0.05±0.22	1.20±0.95	0.0010*	YES	96.00%#

*P<0.05, #applied Wilcoxon matched pairs test

Table 4: Lakshanas of Ekakushta of Group B before and after treatment (Mann-Whitney U test)

Parameters	Mean BT	Mean AT	Mean Diff. \pm SD	P value	Sig	% of Change
Mahavaasthu	2.000 \pm 1.12	1.124 \pm 1.11	-0.45 \pm 0.51	0.4028	NO	22.5%#
Kandu	1.90 \pm 1.45	1.15 \pm 1.14	0.75 \pm 1.55	0.0609	NO	39.47%#
Asweda	2.80 \pm 0.95	1.80 \pm 1.36	1.00 \pm 1.17	0.0038*	Yes	35.71%#
Matsyashakalapoama	2.75 \pm 0.91	1.90 \pm 1.21	0.85 \pm 0.85	0.0047*	Yes	30.91%#
Shyava-arunavarna	2.70 \pm 0.80	2.40 \pm 1.10	0.30 \pm 0.66	0.0759	NO	11.11%#
Candle grease sign	1.20 \pm 0.62	0.80 \pm 0.62	0.40 \pm 0.68	0.0330*	YES	33.33%#
Auspitz sign	0.75 \pm 0.79	0.40 \pm 0.60	0.35 \pm 0.88	0.1095	NO	46.67%#

*P<0.05, #applied Wilcoxon matched pairs test

Table 5: Percentage of improvement in Lakshanas between the Groups A and B

Parameters	% of Change in Group A	% of Change in Group B	Diff. in %	Z- Value	P-value
Mahavaasthu	50%	22.5%	27.5	2.4887	0.0146*
Kandu	89.47%#	39.47%#	50	-1.7042	0.0499*
Asweda	76.67%#	35.71%#	40.96	-3.0161	0.0026*
Matsyashakalapoama	80.33%#	30.91%#	49.42	-4.0305	0.0001*
Shyava-arunavarna	55.38%#	11.11%#	44.27	-4.0305	0.0001*
Candle grease sign	86.67	33.33	53.37	-2.9890	0.0028*
Auspitz sign	96.00	46.67	49.33	-2.4886	0.0128*

*P<0.05, #applied Wilcoxon matched pairs test

Table 6: PASI scores of Group A before and after treatment (unpaired t test)

Parameters	Mean BT	Mean AT	Mean Diff. \pm SD	P value	Sig	% of Change
Head	0.50 \pm 0.57	0.15 \pm 0.23	0.35 \pm 0.46	0.0028*	Yes	70.00%#
Upper limbs	1.29 \pm 1.29	0.69 \pm 0.65	0.70 \pm 0.77	0.0007*	Yes	53.88%#
Lower limbs	3.51 \pm 3.33	1.52 \pm 2.06	1.99 \pm 2.07	0.0004*	Yes	56.70%#
Trunk	2.65 \pm 2.75	1.11 \pm 1.55	1.54 \pm 1.65	0.0005*	Yes	58.11%#
Total	7.95 \pm 6.27	3.36 \pm 3.99	4.60 \pm 3.91	0.0001*	Yes	57.80%#

*P<0.05, #applied paired t test

Table 7: PASI scores of Group B before and after treatment (unpaired t test)

Parameters	Mean BT	Mean AT	Mean Diff. \pm SD	P value	Sig	% of Change
Head	0.52 \pm 0.50	0.47 \pm 0.58	0.05 \pm 0.28	0.4283	NO	9.71%#
Upper limbs	1.33 \pm 1.37	1.19 \pm 1.32	0.14 \pm 0.32	0.0641	NO	10.53%#
Lower limbs	4.30 \pm 3.83	3.78 \pm 3.54	0.52 \pm 0.98	0.0284*	Yes	12.09%#
Trunk	2.76 \pm 3.31	2.63 \pm 3.40	0.13 \pm 0.82	0.4890	NO	4.72%#
Total	8.90 \pm 7.93	8.08 \pm 7.72	0.83 \pm 1.78	0.0522	NO	9.27%#

*P<0.05, #applied paired t test

Table 8: Percentage of improvement between the groups A and B in PAASI (applied paired t test)

Parameters	% of Change in Group A	% of Change in Group B	Diff. in %	t- Value	P-value
Head	70.00	9.71	60.29	2.5166	0.0162*
Upper Limbs	53.88	10.53	43.35	2.9826	0.0050*
Lower Limbs	56.70	12.09	44.61	2.8668	0.0067*
Trunk	58.11	4.72	53.39	3.4195	0.0015*
Total	57.80	9.27	48.53	3.9213	0.0004*



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Conflict Of Interest: None Declared

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