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Research Article

Evaluation of Comparative Efficacy of Internal and External Use of *Kushthadi Yoga* in The Management of *Ekakushtha* (Psoriasis)

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ABSTRACT: *Ekakushtha*is one of the types of *Kustha rogas*. The *Dosha* predominance in *Ekakushtha* is *Vata-kapaha*. It exhibits clinical features of *Aswedanam, Mahavastu, Ashaklopam* and *Kandu*. On basis of clinical features *Ekakushtha*is similar with Psoriasis by many scholars.External and internal factors, including as mild trauma, sunlight, infections, systemic medicines, and stress, can all provoke psoriasis. It can be treated by the use of topical, systemic antifungals, or corticosteroids as per modern science. Long-term use of these drugs may produce adverse effects or there may be more chances of recurrences after the stoppage of treatment. Hence there is need to study to study the *Shodhana* and *Shaman chikitsa* mentioned in Ayurveda whichare considered the most effective in *twakvikar*. The aim and objective of this study is to compare the effects of Kusthadi yoga and a placebo capsule in the treatment of Ekakushta (Psoriasis). A total of 40 patients were enrolled, and they were divided into 2 groups at random. For 30 days, Group A received Kushthadi Ointment and Kushthadi Capsule, whereas Group B received Kushthadi Ointment and Palcebo capsule. Patients were assessed for *Kandu* and PASI score on 0, 15thand 30th day. Both groups showed significant improvement in Kandu and PASI scale after treatment. But improvement was observed in a greater number of patients in group A treated with *Kushthadi* Ointmentand *Kushthadi* Capsule.The improvement was observed due to *Kushthaghna, Kandughna, Krumighna, Tridoshshamaka, Raktavikarnashak,Rasayana* and*Virechaka*properties of ingredients of Kushthadi yoga.It possesses antipsoriatic, anti-inflammatory, antipruritic, antibacterial and antioxidants which helps in reducing symptoms. *Kushthadi Yoga* is effective in the management of *Ekakushtha* and ifit is given internally along with local application then it shows better results.

Keywords: *Chakramarda, Ekakushtha,Kusthadi Yoga,* PASI Scale, Psoriasis and Yoga.

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1. INTRODUCTION

Skin is the organ of touch, temperature, and pain sensation being a natural covering of the body which acts as a protector for core underlying organs. Subjects with skin disease may experience physical, socio-economic, and psychological embarrassment in society. Skin and its appearance remain the priority for both men and women throughout life. In this competitive generation, beauty is known to be the most important aspect. Healthy skin represents the personality of an individual.[1] A healthy and beautiful skin reflects the general health and fitness of the patient and it is the target organ for many infectious diseases.[2]In tropical and developing countries like India, the incidence of skin problems has risen dramatically in recent years.[3]Today's changing lifestyle (*ahar, dincharya*, etc), environmental factors like air pollution and changing food habits like consumption of junk, spicy and unhealthy food, ignorance towards health, personal hygiene, and inadequate sleep may cause many dermatological diseases.[4]In medical sciences as well as in public health, skin diseases might have got more importance, because it affects physical, mental and socio-economic embarrassment in the society[5]. Ayurveda, described all the skin disorders under the term *Kushtha* and classified as seven *Mahakushtha* and eleven *Kshudrakushtha*. *Ekakushtha* is one among eleven varieties of *Kshudrakushtha*.[6] *Ekakushtha* involves *Vata* as a *pradhanadosha* and *Kapha* as an *anubandhadosha.* There is the contribution of *Rasa, Rakta, Mamsa,* and *Lasika* in the pathogenesis. *Nidan* of *Ekakushtha* is explained under the *Kushtharoga* like *aharaja, viharaja, upasargaja* and *krimi*. *Pratyatma lakshana* (cardinal features) of *Ekakushtha* are *Msyashakalopama, Asvedanam, Mahavastu*[7,] and *Krishna Arunavarna.*[8] In modern science, this disease can be correlated with Psoriasis characterized by erythro-squamous lesions with different morphological types vulgaris, guttate, pustular, and erythroderma[9]. Psoriasis is a persistent, non-communicable, severe, disfiguring, and disabling skin condition for which there is no cure and which negatively affects the quality of life of patients.[10] External and internal factors, including as minor trauma, sunburn, infections, systemic medicines, and stress, can all provoke psoriasis.[11] It is mostly inherited and mainly characterized by sharply margined scaly, erythematous plaques that develop in a relatively symmetrical distribution.[12] This disease is chronic with a tendency to relapse. In this disease, the skin possesses scaling as flakes called Psoriatic plaques due to rapid and excessive growth of epidemics cells which appearance like fishy skin & finally peels off as exfoliation. According to the World Health Organization, the estimated prevalence of psoriasis in countries ranges from 0.09 percent[13] to 11.43 percent[14], making it a severe global problem affecting at least 100 million people .[15] Psoriasis was most common in people aged 50 to 69, and it was more common in adult males than adult females up to 75 years of age[16]. The common treatment principle of *Kushtha* described by Acharya *Charaka* is the administration of *sarpi* (ghrit) in *Vata pradhan Kushtha*, *Vamana* in *Kapha pradhan,* and *Virechana* and *Raktamokshan* in *Pitta pradhan Kushtha.*[17]*Shodhana* (purification procedures*)* and *lepa kalpana* (external application*)* is considered as the most effective in *twakvikar*. *Shaman chikitsa* comprises*Bahirparimarjana* (external) and *Antaparimarjana* (Internal) *chikitsa.*[18] In *CharakaSamhita Kushthadi Yoga* is indicated for the treatment of *Ekakushtha* which consists of *Chakramarda* (*Cassia tora* linn), *Aragvadha* (*Cassia fistula* linn.), and *Vayvidang* (*Embelia ribes* burm f.) [19]. Among these *Aragvadha* and *Vayvidang* are from *Kushthaghna Dashemani Mahakashaya* described by Acharya *Charaka* and *Chakramarda* is well known for its *Kushthaghna, Kandughna* and *Dadrughna* property.[20]*Aragvadha* acts as *Virechaka* for the elimination of aggravated *doshas.* Hence this formulation was selected to study its efficacy in *Ekakushtha*. Generally, 10-15% of practitioners deal with all types of skin diseases in their day-to-day practice. 2.30–3.21 cases per 1000 populacesuffer from Psoriasis. It can be treated by the use of topical, systemic antifungals, or corticosteroids as per modern science. Long-term use of these drugs may produce adverse effects or there may be more chances of recurrences after the stoppage of treatment. *Ekakushtha* is one of the most common but miserable *twakvikar* affecting all the ages of the population. Many research works have been done on *Ekakushtha* but no drug has yet been claimed to cure it completely or to prevent its recurrence. *Shodhana* and *Shaman* are considered the most effective in *twakvikar*. *Shamana Chikitsa* can be given to patients, contraindicated for *ShodhanaChikitsa* and not willing for *ShodhanaKarma*. In *Shaman, Bahirparimarjana Chikitsa*in the form of *lepa* is the best for all *twakvikaras* as it gets absorbed locally and gives fast relief. *Kushthadi Yoga* had *Kushthghna*, *Kandughna*, and *Dadrughna* properties and there is no comparative study available on its internal and external use to date. Hence this study was conducted to assess the effectiveness of *Kushthadi* Ointmentwith & without *Kushthadi* Capsulesin the management of *Ekakushtha* (Psoriasis).

2. AIM AND OBJECTIVES

2.1 Aim

Evaluation of comparative efficacy of *Kushthadi Yoga* in the management of *Ekakushtha*(Psoriasis).

2.2 Objectives

1. To assess the effectiveness of *Kushthadi* Ointment along with *Kushthadi* Capsule on subjective and objective parameters of *Ekakushtha.*
2. To assess the effectiveness of *Kushthadi* Ointment along withPlacebo Capsules on subjective and objective parameters of *Ekakushtha.*
3. To compare the efficacy of both groups.

3. MATERIALS AND METHODS

3.1 Source of Data

Total 40 patients, divided into Group A and Group B (20 patients in each group) reported to outdoor and Indoor patients of Kayachikitsa department, of MGACH & RC and also from peripheral camps were enrolled for this study. Ethics committee approval: - Study was started after obtaining approval from Institutional Ethics Ref no DMIMS (DU)/IEC JUN 2019/8025) on dated 26/06/2019. The study was begun after the CTRI registration – CTRI/2020/04/024890. Before commencement of the study, consent was taken from each subject and case proforma was also filled

3.2 Study Design

Randomized Standard controlled Double arm Open label Study.

3.3 Study Type

Interventional Study.

3.4 Inclusion Criteria

- Patients of either sex and Prakruti between the ages of 20 and 70.
- Subjects Having Cardinal features of *Ekakushtha*
- *Aswedanam* (Loss of Sweating)
- *Mahavastu* (covering of large surface area)
- *Matsyashaklopamam* (fishy Scaling)
- *Kandu* (Pruritis)
- Mild to Moderate Psoriasis according to PASI Scale.

3.5 Exclusion Criteria

- Diagnosed diseases like Diabetes Mellitus, Cancer, AIDS, and Tuberculosis.
- The subject of other dermatological infectious conditions.
- Pregnant or lactating women.
- History of any operative conditions.
- Severe Psoriasis Cases according to PASI Scale.

3.6 Intervention

Group A- Treated internally with *Kushthadi* Ointment and *Kushthadi* Capsule
Group B- Treated internally with *Kushthadi* Ointment and Placebo Capsule

Table. 1 Posology

SN	Drug	Dose in Unit	*Anupama*	*Kala*	Frequency
1	***Kushthadi* Capsule**	500mg	*Koshna Jala*	After meal	Two times a day
2	***Kushthadi* Ointment**	Q.S.	-	Morning after bath	Once a day
3.	**Placebo Capsule**	500mg	*Koshna Jala*	After meal	Two times a day

3.7 Composition of Material

Table. 2: Showing Ingredients of *Kushthadi* Capsule

SN	Content	Botanical Name	Part used
1	*Edagaj(Chakavad)*	*Cassia tora* Linn.	*Beeja*
2	*Vayvidanga*	*Embeliaribes* Burm.F.	*Beeja*
3	*Aragvadha*	*Cassia fistula* Linn	*Mula*

3.8 Preparation of Material

The raw drugs were identified and authenticated from the Department of *Dravyaguna* of our institute.

3.8.1 Preparation of Kushthadi Capsule

- Raw *Vayvidanga*, *Aragvadha*, *Chakvada* were taken and fine churna was prepared.
- The 500 mg churna was filled in each empty Capsule through a capsule filling machine.

Table. 3-Ingredient for *Kushthadi* Ointment

Sr. No	Chemicals	Botanical Name	Quantity
1.	*Edagaj (Chakavad)*	*Cassia tora* Linn.	500gm
2.	*Vayvidanga*	*Embelia ribes* Burm.F.	500gm
3.	*Aragvadha*	*Cassia fistula* Linn	500gm
4.	E-wax	-	250 gm
5.	Stearic acid	-	250gm
6.	EDTA	-	2 gm
7.	Above prepared oil	-	1 ½ liter
8.	Essence	-	3-4 drops
9.	Water	-	1 liter

3.8.2 Preparation of Kushthadi Ointment

In Ayurveda, for external application of drugs, *Lepa Kalpana* is mentioned in *Samhita*. For feasibility and better absorption, the *Kushthyadi Yoga* is prepared in the form of Ointment.

- *Tila taila* was taken in a steel vessel and heated on a mild fire to remove moisture and was allowed for self-cooking.
- From the above-mentioned ingredient bolus of *Kalka* was prepared by adding little water
- *Kalka* was added to the oil and continuous stirring was done for homogenous mixing.
- Four times of *kwath* were added to the above vessel and heated over *Mandagni* with continuous stirring.
- After 4 hours and 15 min heating it was allowed to self-cool and was covered with a plate to prevent the dust
- On the 2nd day, 3 hours of the heating process was continued till the oil becomes moisture free and *siddhi lakshan* were attained.
- After confirming all the *siddilkshanas* the heating was discontinued and the oil was filtered through doubled muslin cloth in the warm condition itself.
- The filtered *taila* was filled in an airtight bottle and labeled and stored.

- Oil in water emulsion cream was prepared initially by boiling water at 60^0 -70^0 c taken in a container.
- Emulsifying wax, steric acid was melted in a water bath 70^0c separately and added in boiled water.
- Above prepared *taila* (oil) was added to these aqueous solutions with continuously stirring for 5 to 10 minutes in a water bath.
- The mixture was taken out of the water bath and continued to be stirred until it became cold.
- EDTA was used as a preservative.
- The mixture was stirred with a hand blender for 15 min until the formulation becomes uniform.
- The Ointment was transferring to a wide-mouth plastic bottle and label.

Table 4 -Ingredient for Placebo Capsule

Sr. No.	Drug Name	Quantity
1.	StarchPowder	½ kg

3.8.3 Preparation of Placebo Capsule

- Take Fine Starchpowder from a local market and authenticated it from Daravyaguna Vigyan Department.
- Fill the Powder in the capsule through the Capsule filling machine.

Study Duration: 30 days.

Follow Up Period: On 0, 15thand 30thday (after treatment)

Investigation: Blood sugar level (Random) – before treatment.

3.9 Assessment Criteria

a) Subjective Parameters

Table 5- Gradation of Pruritis

Kandu (Pruritis)	0thDay (BT)*	15th Day (DT)*	30thDay (AT)*
Present			
Absent			

b) Objective's Parameters

Table 6 -PASI Scale

Plaque Characteristics	Lesion Score	Head	Upper Limb	Trunk	Lower Limb
Erythema(Redness)	0- none				
Induration(erosion)	1- mild				
Scaling	2- moderate				
	3- severe				
	4- very severe				
Addition of scores of each of the 3 for each body parts to give 4 separate sums (A)					
Lesion score sum (A)					

Statistical Analysis

Percentage area affected	Area score	Head	Upper limb	Trunk	Lower limb
Area score (B) Degree of involvement as a percentage for each body region affected (score each region with score between 0-6)	0 - 0% 1 - 1% - 9% 2 - 10% - 29% 3 - 30% - 49% 4 - 50% - 69% 5 - 70% - 89% 6 - 90% - 100%				
Multiple lesion score sum (A) by area score (B). for each body region to give 4 individual subtotals (C).					
Subtotals (C)					
Multiply each of the subtotals (C) by the amount of body surface area represented by that region, × 0.1 for head × 0.2 for the upper body, ×0.3 for a trunk, and × 0.4 for lower limbs.					
Body surface area		**× 0.1**	**× 0.2**	**× 0.3**	**×0.4**
Total (D)					
Add together each of the scores for each body region to give the final PASI score.					

4. STATISTICAL ANALYSIS

All the patients were assessed on 0, 15th and 30th day for subjective (*Kandu*) and objective (PASI scale) parameters as shown in table no. 5 and 6 respectively. The chi-square test, Wilcoxon Signed Rank Test, and Mann Whitney U test were used in the statistical analysis, and the software utilised in the analysis was SPSS 27.0 version and GraphPad Prism 7.0 version, with p0.05 being regarded the level of significance.

5. RESULTS

Statistical analysis was done by using descriptive and inferential statistics using chi square test, student's paired and unpaired t test and Mann Whitney U test and software used in the analysis were SPSS 27.0 version and Graph Pad Prism 7.0 version and $p<0.05$ is considered as level of significance.

Table 7: - Showing age wise distribution of patients

Age group (years)	Group A	Group B	Total	X 2-value
21-30	3(15%)	4(20%)	7(17.5%)	6.53 P=0.16, NS
31-40	2(10%)	4(20%)	6(15%)	
41-50	2(10%)	0(0%)	2(5%)	
51-60	13(65%)	9(45%)	22(55%)	
>60	0(0%)	3(15%)	3(7.5%)	
Total	20(100%)	20(100%)	40(100%)	
Mean±SD	47.3±11.58	46.85±14.69	47.07±13.06	
Range	23-58 yrs	26-73 yrs	23-73 yrs	

Table 8: Showing gender wise distribution of patients

Gender	Group A	Group B	Total	X 2-value
Male	16(80%)	14(70%)	30(75%)	0.26 P=0.70, NS
Female	4(20%)	6(30%)	10(25%)	
Total	20(100%)	20(100%)	40(100%)	

Table 9: - Showing religion wise distribution of patients

Religion	Group A	Group B	Total	X 2-value
Hindu	13(65%)	15(75%)	28(70%)	0.80 P=0.66,NS
Buddhist	4(20%)	2(10%)	6(15%)	
Muslim	3(15%)	3(15%)	6(15%)	
Total	20(100%)	20(100%)	40(100%)	

Table 9: - Showing religion wise distribution of patients

Diet	Group A	Group B	Total	X 2-value
Vegetarian	5(25%)	4(20%)	9(22.5%)	0.14 P=0.70, NS
Mixed	15(75%)	16(80%)	31(77.5%)	
Total	20(100%)	20(100%)	40(100%)	

Table 11:- Showing marital status wise distribution of patients

Marital status	Group A	Group B	Total	X 2-value
Married	16(80%)	16(80%)	32(80%)	-
Unmarried	4(20%)	4(20%)	8(20%)	
Total	20(100%)	20(100%)	40(100%)	

Table 12: - Showing socio-economic status wise distribution of patients

socio-economic status	Group A	Group B	Total	X 2-value
Lower	2(10%)	5(25%)	7(17.5%)	1.67 P=0.43, NS
Middle	13(65%)	10(50%)	23(57.5%)	
Upper	5(25%)	5(25%)	10(25%)	
Total	20(100%)	20(100%)	40(100%)	

Table 13: - Showing distribution of patients according to family history				
Family history	**Group A**	**Group B**	**Total**	**X 2-value**
Positive	13(65%)	12(60%)	25(62.5%)	0.10 P=0.74, NS
Negative	7(35%)	8(40%)	15(37.5%)	
Total	20(100%)	20(100%)	40(100%)	

Table 14: - Showing *prakriti* wise distribution of patients				
Prakriti	**Group A**	**Group B**	**Total**	**X 2-value**
Vatakaphaj	15(75%)	10(50%)	25(62.5%)	3.69 P=0.15, NS
Vatapittaj	5(25%)	8(40%)	13(32.5%)	
Pitta kaphaj	0(0%)	2(10%)	2(5%)	
Total	20(100%)	20(100%)	40(100%)	

Table 15: - Showing occupation wise distribution of patients				
Occupation (vyavsay)	**Group A**	**Group B**	**Total**	**X 2-value**
Bank manager	4(20%)	3(15%)	7(17.5%)	7.29 P=0.29, NS
Farmer	8(40%)	7(35%)	15(37.5%)	
Housewife	0(0%)	3(15%)	3(7.5%)	
Police officer	1(5%)	1(5%)	2(5%)	
Social worker	1(5%)	0(0%)	1(2.5%)	
Student	4(20%)	1(5%)	5(12.5%)	
Private job	2(10%)	5(25%)	7(17.5%)	
Total	20(100%)	20(100%)	40(100%)	

Table 16: - Showing habit wise distribution of patients				
Habit (*vyasan*)	**Group A**	**Group B**	**Total**	**X 2-value**
Cigarette smoking	9(45%)	8(40%)	17(42.5%)	4.51 P=0.34,NS
Tea	3(15%)	2(10%)	5(12.5%)	
Alcohol	0(0%)	2(10%)	2(5%)	
Tobacco	7(35%)	5(25%)	12(30%)	
Not any	2(10%)	6(30%)	8(20%)	

Table 17: - Showing distribution of patients according to type of sleep				
Type of sleep	**Group A**	**Group B**	**Total**	**X 2-value**
Adequate	7(35%)	9(45%)	16(40%)	0.41 P=0.51, NS
Disturbed	13(65%)	11(55%)	24(60%)	
Total	20(100%)	20(100%)	40(100%)	

Table 18: - Distribution of patients according to stress in two groups				
Stress	**Group A**	**Group B**	**Total**	**X 2-value**
Present	12(60%)	13(65%)	25(62.5%)	0.14 P=0.70,NS
Absent	8(40%)	7(35%)	15(37.5%)	
Total	20(100%)	20(100%)	40(100%)	

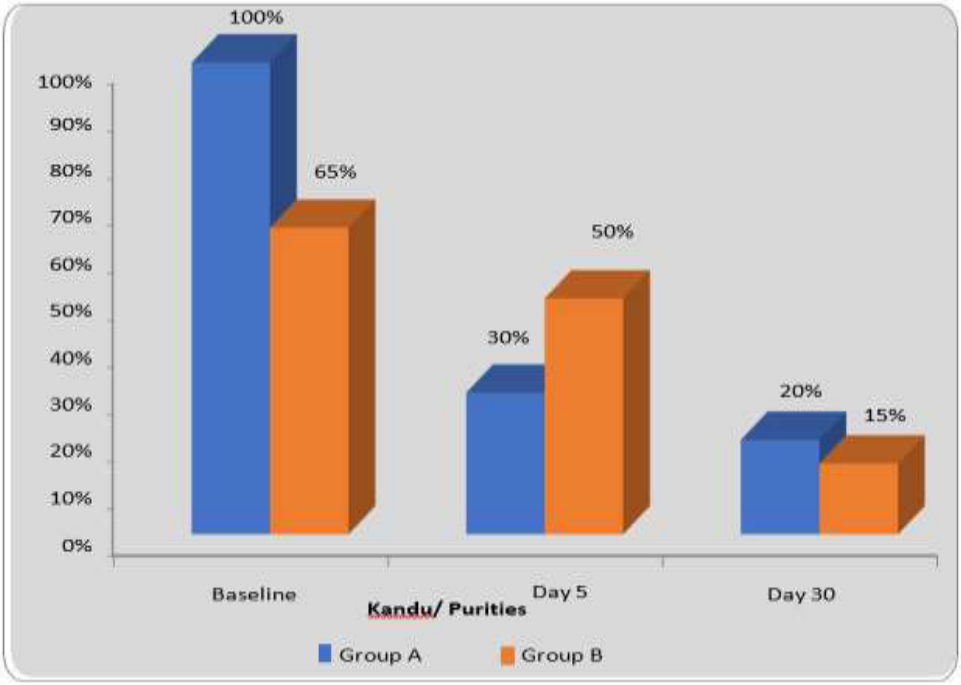
Table 19: - showing distribution of patients according to menstrual history				
Aggravation during Menstruation	**Group A**	**Group B**	**Total**	**X 2-value**
Aggravated	3(75%)	5(83.33%)	8(80%)	0.63 P=0.72,NS
Not aggravated	1(25%)	1(16.67%)	2(20%)	
Total	4(100%)	6(100%)	10(100%)	

Table 20: - Distribution of patients according to *ritu, sun exposure and* source of water for bathing in two groups				
Ritu	**Group A**	**Group B**	**Total**	**X 2-value**
Hemant	7(35%)	5(25%)	12(30%)	5.72 P=0.05, NS
Varsha	13(65%)	10(50%)	23(57.5%)	
Grishma	0(0%)	5(25%)	5(12.5%)	
Total	20(100%)	20(100%)	40(100%)	
Sun exposure	**Group A**	**Group B**	**Total**	**X 2-value**
Yes	12(60%)	12(60%)	24(60%)	-
No	8(40%)	8(40%)	16(40%)	
Total	20(100%)	20(100%)	40(100%)	
Water for bathing	**Group A**	**Group B**	**Total**	**X 2-value**
Bore water	10(50%)	9(45%)	19(47.5%)	0.56 P=0.90,NS
River water	1(5%)	1(5%)	2(5%)	
Tap water	4(20%)	6(30%)	10(25%)	
Well water	5(25%)	4(40%)	9(22.5%)	
Total	20(100%)	20(100%)	40(100%)	

Demographic data showed that *Ekakushtha* was more prevalent in the 51-60 years of age group as shown in table no. 7, (75%) Male gender as shown in table no. 8, (70%) Hindu religion as shown in table 9 and (80%) having Mixed diet as shown in table 10. In this study, maximum patients were married 32 (80%) as shown in table no.11, belonged to the Middle Class (60%) as shown in table no.12, and had a Positive Family History as shown in table no.13. It was prevalent in *Vata-Kapha Prakriti* (62.5%) as shown in table no 14, Farmers (37.5%) as shown in table no 15, and having a habit of Smoking, Tobacco, and Tea shown in table no 16. The majority of patients (60%) had Disturbed Sleep shown in table no 17, and a majority (62.5%) were suffering from Stress shown in table no 18. Most females (80%) have the aggravation of symptoms during the menstrual period as shown in table no 19. Aggravation of symptoms noted during *Varsha Ritu* (57.5%), in patients using bore water (47.5%) for bath and after excessive exposure to Sunlight (60%) as shown in table no 20.

Table 21: Showing Comparison of *Kandu*/ Pruritis at day 0,15thand day 30 in two groups			
***Kandu*/ Pruritis**	**Baseline**	**Day 15**	**Day 30**
Group A			
Present	20(100%)	6(30%)	4(20%)
Absent	0(0%)	14(70%)	16(80%)
Comparison with baseline in group A			
X 2-value	-	21.54 P=0.0001, S	26.67 P=0.0001, S
Group B			
Present	13(65%)	10(50%)	3(15%)
Absent	7(35%)	10(50%)	17(85%)
Comparison with baseline in group B			
X 2-value	-	0.92 P=0.33, NS	10.42 P=0.0012, S
Comparison between group A and group B			
X 2-value	8.48 P=0.003, S	1.66 P=0.19, NS	0.17 P=0.67, NS

In Group A - X 2-26.67 and p value (P=0.0001)
In Group B - X 2-10.42 and p value (P=0.0012)
Comparison of both groups - X 2-0.17and p value (P=0.67). p<0.05 is considered as level of significance.



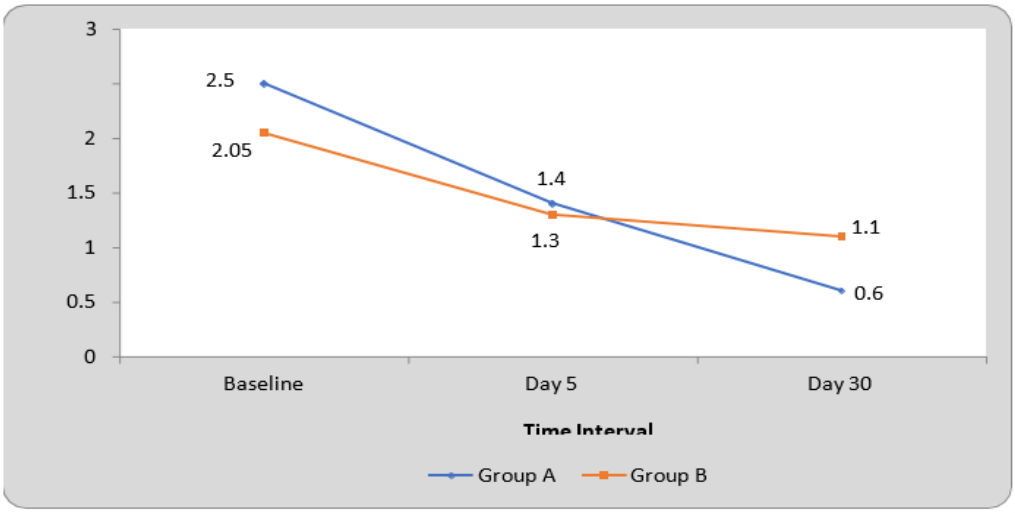
Kandu/ Purities

Graph 1: - Distribution of patients according to *kandu*/ purities in between two groups

Table 22 Showing Comparison of PASI Score at day 0,15th and day 30 in two groups

PASI score	Baseline	Day 15	Day 30
Group A			
Mean ± SD	2.50±0.60	1.40±0.75	0.60±0.88
Comparison with baseline in group A			
Z-value		11 P=0.0001, S	13.26 P=0.0001, S
Group B			
Mean ± SD	2.05±0.75	1.30±0.80	1.10±0.91
Comparison with baseline in group B			
Z-value		7.55 P=0.0001, S	7.02 P=0.0001, S
Comparison between group A and group B			
Z-value	2.07 P=0.045, S	0.40 P=0.68, NS	1.76 P=0.08, NS

In Group A -Z-13.26 and p value (P=0.0001), In Group B - Z-7.02 and p value (P=0.0001)
Comparison of both groups - Z-0.76 and p value (P=0.08)
p<0.05 is considered as level of significance.



Graph 2:- distribution of patients according to PASI score in two groups

6. EXPLANATION

In group A, before treatment 20(100%) patients had *Kandu*. During first follow up it was present in 6 (30%) patients and after completion of treatment only 4(20%) patients had *Kandu*. Thus, complete improvement was observed in 16 (80%) patients with statistical significance (p = 0.0001, S) as shown in table 21 and graph no.1. In group B, before treatment 13(65%) patients had *Kandu*. During first follow up, it was present in 10 (50%) patients and after completion of treatment, *Kandu* was present only in 3(15%) patients thus improvement was observed in 10 (50%) patients with statistical significance (p = 0.0012, S.) as shown in table 21 and graph no.1. When comparing both groups, they were having no statistical significance during follow up and after completion of treatment (p =0.19, NS) and 0. P=0.67, NS respectively as shown in table 21 and graph no.1. In group A mean of PASI score before treatment was 2.50±0.60 that reduced to 1.40±0.75 and 0.60±0.88 during first follow up and after completion of treatment respectively which was statistically significant with p=0.0001, S as shown in table 22 and graph no.2. In group B mean of PASI score before treatment was 2.05±0.75 that reduced to 1.30±0.80 and 1.10±0.91during first follow up and after completion of treatment respectively which was statistically significant with p=0.0001, S as shown in table 22 and graph no.2. Comparison of both groups A and B was statistically not significant with p=0.08, NS as shown in table 22 and graph no.2. Significant improvement was observed in *Kandu* and PASI scores in both groups after treatment. The improvement in all subjective and objective variables was statistically insignificant when compared. That is both groups are equally effective in reducing itching and PASI score, but based on p-value, group A showed more results than group B, and improvement in *Kandu* was observed in more number patients in the group treated with internal *Kushthadi* capsule than group B treated with placebo internally

Showing Comparison of PASI Score at day 0,15thand day 30 in two groups			
PASI score	Baseline	Day 15	Day 30
Group A			
Mean ± SD	2.50±0.60	1.40±0.75	0.60±0.88
Comparison with baseline in group A			
Z-value		11 P=0.0001, S	13.26 P=0.0001, S
Group B			

7. DISCUSSION

7.1 Mode of Action of Kushthadicapsule

*Kushthadi*yoga is described in *Charaka Samhita* for the management of *Ekakustha* which is used in the form of a capsule in this study. It contains *Chakavada* (*Cassia tora* Linn.), Vidanga (*Embelia ribes* Burm.F.), and *Aragvadha* (*Cassia fistula* Linn.) as shown in table no. 2. It was given 500mg twice a day as shown in table no. 1. *Kushthadi*capsule has *Tikta Madhur* (bitter, sweet) *taste, Laghu*(light), *Ruksha*(dry), properties, *Ushnavirya* (hot potency) and *Katuvipaka*(Pungent after digestion). It possesses *Kushthaghna, Kandughna, Krumighna, Tridoshshamaka, Raktavikarnashak* and*Virechaka* properties. *Tridoshashamak* property help in alleviating aggravated *Doshas*, *Kandughna* property help in reducing *Kandu*. *Kushthaghna* property helps in correction of vitiated *Doshas* and *Dushyas* like *Rasa, Rakta, Mamsa,* and *Lasika* at affected area thus helps in breaking *Samprapti.*

7.2 Probable Mode of Action of Chakramarda

Chakramarda has *Katu*, *Tikta (pungent, bitter)* taste, *Laghu*(light), *Ruksha*(dry), *Tikshna*(penetrating)properties, *Ushnavirya* (hot potency) and *Katuvipaka*(Pungent after digestion). *Chakramarda* has *Tej*, *Vayu* &*Akash Mahabhuta.* It possesses

Tridoshashamaka, Kushthaghna, Kandughna, Vishahar, and *Krumighna* properties. Due to all these properties, it is indicated in *Kushtha.*[22]The *Ushnavirya* causes pacification of aggravated *Kapha* and *Vata*. Due to its hot, penetrating, & minute properties, it acts on *Swedavahisrotas*and causes the elimination of local toxins through the sweat, and helps in clearing out the microchannels. Thus, it helps in breaking *Samprapti* and reduces symptoms of *Ekakushtha*. *Tiktarasa* has *Kushthaghna* property and it acts on the skin hence mostly indicated in skin disorders like *Ekakustha*. Animal studies conducted on *Cassia tora* proved its anti-psoriatic, anti-pruritic, anti-fungal, anti-helminthic, anti-bacterial, anti-oxidant, and anti-inflammatory properties. These pharmacological properties are helpful in the management of skin disorders like psoriasis. The research studies conducted on *Chakramarda* in other types of *Kushtha* like *Dadru*, *vicharchika* proved its anti-pruritic activity[23].

7.3 Probable Mode of Action of Aragvadha

Aragvadha has *Tikta* (pungent, bitter) taste*, Laghu*(light), *Ruksha*(dry), *Tikshna*(penetrating) properties*,* and *Sheetvirya*(cold potency).It has *Tridoshashamaka*, *Kushtasudana*, *Krimighna*, *Raktashodhak, Vranashodhana, and Anulomaka* properties. *Tridoshashamaka* property helps in alleviating aggravated *doshas*[24]. *Anulomana* property helps in the elimination of aggravated doshas from the body thus help in breaking the *Samprapti* of *Ekakushtha*. *Kushtasudana* and *Krimighna* properties help in the alleviation of vitiated *dosha* and *dushya*. Thus, it helps in breaking *Samprapti* and reducing symptoms. Anthraquinones, flavonoids, flavon-3-of derivatives, alkaloid, glycosides, tannin, saponin, terpenoids, reducing sugar, and steroids were discovered in the Cassia fistula fruit. Anti-pruritic, anti-inflammatory, antioxidant, hepato protective, antibacterial, wound healing, and antiulcer are only a few of the therapeutic effects of these phytochemicals[25].

7.4 Probable Mode of Action of Vidanga

Vidanga possess *Katu*(pungent), *Kashay* (astringent) *tasteLaghu*(light), *Ruksha*(dry), *Tikshna*(penetrating) properties*, Usnavirya* (hot potency) and *Katuvipaka*(Pungent after digestion).. *Vidanga* has *Kapha-Pittahar*, *Krimighna, Kusthaghna,* and *Virechaka* properties[26]. *Krimi* is a causative factor of *Kushtha*. It is indicated in *Kandu* and *kushtha*. It causes *Kapha-Pitta Shamana* and also helps in the elimination of aggravated *doshas* and *dushya*. In Samhitas repeated *Shodhan* is advice in the management of *Ekakustha* due to its *bahudosha avastha.*[27] In this study *Aragvadha* and *Vidanga* acts as *Krumighna* as well as *Nityavirechak*, which helps in the elimination of aggravated *doshas*.

7.5 Probable Mode of Action of Kushthadi Ointment

*Kushthadi*yoga is used in the form of Ointment for external use in this study. It contains *Chakavada* (*Cassia tora*Linn.), *Vidanga* (*Embelia ribes* Burm.F.), and *Aragvadha* (*Cassia fistula* Linn.) as shown in as shown in table no. 3. Acharya *Sushruta* has mentioned *Lepa* (local application) in the *Kushtha*, as one of the types of *Shodhana* (purification).[28] Acharya *Charaka* has described *Lepa* (paste) as "*Sadyah Siddhi Karaka* (providing instant effect)" which means showing immediate effects.[29] It enters into *romakupa* (hair follicle) and further gets absorbed through *svedavahisrotasa* (channels of sweat) and *siramukha* (opening the skin pores). *Lepa* (paste) pacifies provoked local *dosha* on local application and helps in eliminating aggravated *doshas* locally. *Chakramarda* has *Katurasa*, *Rukshaguna* and, *Ushna* virya which act locally and helps in reducing symptoms. It has *Sukshma* Guna which helps in its penetration to micro-channels of skin & enhances the action of *Chakramarda*. *Aragvadha* has *Kushthagna*, *Kandughna*, *Kriminashaka,* and *Rakta Shodhak* properties which help in reducing symptoms when applied locally. *Snigdha guna* helps in reducing scaling and dryness. Due to its antibacterial, antifungal, and anti-itching activities it is indicated in various skin disorders. *Tilataila* is used in the preparation of *Kushthadi* Ointment which possesses *Tridoshashamaka* and *Twachya* properties.[30]Thus, topically applied *Kushthadi* Ointment helps in reducing symptoms of *Ekakushtha*.

7.6 Probable Mode of Action of Placebo Capsule

In the present study, the Starch powder was used as the Placebo in the form of a Capsule (as shown in table no. 4along with *Kushthadi* Ointment. Starches are polysaccharides, composed of some glucose molecules. Placebo is an inert substance having no therapeutic value but placebo shows effect or response. The exact mechanism of action of placebo is not understood but has psychological and neurobiological effects. *Psychoneuroimmunology* studies the relationship between the emotional state, nervous system function, and the immune system. The body's immune system is capable of combating sickness that is intimately tied to a person's psyche. Research has shown that symptoms can be reduced in a significant way by getting an inert medication. Neurochemicals record thoughts and moods, causing the production of hormones that interact with disease-fighting cells. Stress factors and immunity have major contribution in the causation of Psoriasis. The extent of the placebo effect on itch in clinical trials involving patients with persistent itch related to Atopic Dermatitis, Psoriasis, or Chronic Idiopathic Urticaria was extensively evaluated in the meta-analysis. They found a significant decrease in itch with Placebo treatment as compared with baseline itch, demonstrating that placebo effects play a significant role in the treatment of these individuals.[31] Various research studies conducted using placebo in Psoriasis showed a significant reduction in *Kandu* and PASI scale which is similar to this study[32]. The Group A treated with *Kushthadi* Ointment and *Kushthadi* Capsule and group B treated with *Kushthadi* Ointment and Placebo Capsule showed significant relief in *Kandu* and PASI score as shown table no. 7 and 8. The comparison of each group was statistically Non significant that is both groups are equally effective in reducing symptoms.

8. CONCLUSION

Statistically, significant improvement was observed in *Kandu* and PASI scores in both groups. When compared the efficacy of drugs in both parameters like subjective as well as objective, it was statistically insignificant that is both groups are equally effective in reducing all symptoms. Comparison of overall improvement in group A treated with *Kushthadi* capsule *and Kushthadi* Ointment showed better improvement in a greater number of patients than group B treated with Placebo Capsuleand *Kushthadi* Ointment.From this conclusion can be drawn that *Kushthadi Yoga* is effective in reducing symptoms of *Ekakushtha.* Also, if it is given internally as well as externally then it shows better results. No adverse effects of *Kushthadi Yoga* and placebo were observed in the study.

9. AUTHORS CONTRIBUTION STATEMENT

Dr. Ashish Nimbhorkar collected the data related to this study and conducted the study under the guidance of Dr. Sadhana Misar Wajpeyi, who gave the necessary inputs towards the designing of the manuscript and contributed to the final manuscript.

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12. CONFLICT OF INTEREST

Conflict of interest declared none.

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