Original Article

Role of *Haratala Shodhana* in the therapeutic efficacy of *Rasamanikya* along with *Guduchi Ghana* in the treatment of *Ekakushtha* (psoriasis): A double-blind randomised clinical trial

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Abstract

Introduction: *Rasamanikya* (RM) and *Guduchi Ghana* (GG) are well-known formulations for treating skin disorders in *Ayurveda*. The drug RM is prepared from *Shuddha Haratala* (processed orpiment) as a single ingredient. In the present study, RM was prepared from the *Haratala*, which was *Shodhita*, with two different media, viz., *Kushmanda Swarasa* and *Churnodaka*. In the classics, the preparation of RM is mentioned in the *Kushmanda Shodhita Haratala*. However, the availability and cost of *Kushmanda* are the main points of concern in the present era. *Shodhana* of *Haratala* by *Churnodaka* is more cost-effective than *Kushmanda Swarasa*. **Aim:** The aim of this study is to evaluate the comparative efficacy of RM prepared by *Churnodaka Shodhita Haratala* (CSHRM) and RM prepared by *Kushmanda Shodhita Haratala* (KSHRM) with GG in *Ekakustha* (psoriasis). **Materials and methods:** The study was a randomized double-blind study involving 76 patients with *Ekakushtha* that were randomly divided into two groups. Patients registered in group A (n = 37) were treated with CSHRM with GG (125 mg + 375 mg) and group B (n = 36) with KSHRM with GG (125 mg + 375 mg) for 8 weeks. The Wilcoxon signed rank test and paired t-test were applied to evaluate the effect of therapy in the individual group for subjective criteria like the PASI score, *Matsyashakalopamam* (looks like the scales of a fish), *Rukshata* (dryness), *Aswedanam* (anhydrosis), *Daha* (burning), *Strava* (discharge), *Unnati* (raised patches), *Kandu* (itching), *Mahavastu* (broad-based), and *Vaivarnya* (discoloration), while the comparison of results between the groups for the same was done by applying the Coefficient of Variation (CV). **Result:** CSHRM with GG showed better results in all signs and symptoms except *Matsyaskalopamam*, *Aswedanam*, *Strava*, *Mahavastu*, *Nindra* and DLQI in terms of the coefficient of variation. In both groups, statistically highly significant (P > 0.001) improvement was found in the signs and symptoms of *Ekakushtha*. However, the difference between the groups was statistically nonsignificant. **Conclusion:** *Rasamanikya* prepared with both media *Shodhita Haratala* along with *Guduchi Ghana* was discovered to be a safe and effective psoriasis treatment.

Keywords: *Ekakushtha, Guduchi Ghana, Haratala,* orpiment, psoriasis, *Rasamanikya*

Introduction

Rasamanikya (RM) is one of the familiar medicaments used by Ayurvedic physicians to treat various disorders such as *Jwara* (fever), *Kasa* (cough), *Shwasa* (dyspnea), *Arsha* (haemorrhoids), *Bhagandara* (fistula-in-ano), and *Kushtha* (integumentary disease).[1] *Shuddha Haratala* (processed orpiment) is the only component of RM. Processed orpiment has *Katu* (bitter) and *Kashaya* (astringent) *Rasa* (taste), *Ushna Veerya* (hot in potency), and *Katu Vipaka* (biotransformed in bitter taste). It possesses a *Snigdha* (slimy) property and is used for *Rasayana* (rejuvenation).[2] *Ekakushtha* is classified under *Kshudra Kushtha* by all the Acharyas of Ayurveda. According to Ayurveda, it is *Vata Kapha Dosha Pradhana Vyadhi*. It

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Quick Response Code:

Website: www.ayujournal.org

DOI: 10.4103/ayu.ayu_292_21

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How to cite this article: Parekh DN, Bopaliya D, Prajapati D, Bedarkar P, Patgiri BJ. Role of *Haratala Shodhana* in the therapeutic efficacy of *Rasamanikya* along with *Guduchi Ghana* in the treatment of *Ekakushtha* (psoriasis): A double-blind randomised clinical trial. AYU 2021;42:76-86.

Submitted: 31-Aug-2021 **Revised:** 27-Jul-2022
Accepted: 07-Oct-2022 **Published:** 16-Mar-2023

has been correlated with psoriasis by previous researchers.[3] Psoriasis is defined as an autoimmune, chronic inflammatory disease of the skin. The worldwide prevalence of psoriasis is estimated to be approximately 2–3%.[4] Modern medical science treats psoriasis with psoralen plus ultraviolet (UV)-A radiation treatment and corticosteroids. However, the therapy has serious side effects, such as liver and kidney failure and bone marrow depletion.[5] Hence, it is time to find a safe and effective medicine for psoriasis, and here comes the role of Ayurveda. Previously, pharmaceutical studies[6] on RM and various clinical studies on *Ekakushtha* have been carried out in various institutes.[7] Till date, no research has been carried out to find out the efficacy of RM along with *Guduchi Ghana* (GG) in psoriasis or the role of *Shodhana* media in the preparation of RM. Therefore, an attempt has been made to find out the results of these drugs.

Materials and methods

The study was approved by the institutional ethics committee (7-A/Ethics/2017-18/2069/2.10, dated November 21, 2017) and registered with the clinical trial registry of India, ICMR, New Delhi (see Registration No. CTRI/2018/01/011151 dated January 5, 2018) and conducted at IPGT and RA, GAU, Jamnagar, India. The study was randomised and double-blind, involving 76 patients with psoriasis who fulfilled the inclusion criteria. Each patient was examined in detail. Relevant pathological (total leukocyte count [TLC], differential leukocyte count [DLC], hemoglobin [Hb], erythrocyte sedimentation rate[ESR], total red blood cell [T- RBC], absolute eosinophil count [AEC] etc.) and biochemical investigations (fasting blood sugar [FBS], Serum glutaminic-oxaloacetic transaminase [SGOT], Serum glutamic pyruvic transaminase [SGPT], and alkaline phosphate, serum creatinine, and blood urea etc.) were done before and after treatment to assess the disease condition and to exclude any other pathology. Informed consent was taken from all the patients before they were included in the trial.

Inclusion criteria

Patients having classical signs and symptoms of *Ekakushtha* (psoriasis) like *Aswedanam* (anhydrosis), *Mahavastu* (broad based), and *Matsyashakalopamam* (which looks like the scales of a fish) were included in the study.[8] Patients having an age range between 18 to 60 years, irrespective of gender, and a chronicity of upto 10 years were included.

Exclusion criteria

Patients who have had a chronic illness for more than ten years, patients with cardiac, renal, and hepatic diseases, and patients with other conditions such as insulin-dependent diabetes mellitus (IDDM), non-IDDM, pregnant and lactating women, and women of reproductive age planning to conceive within the next three months were unfitted for trial. *Sarva Linga Yukta* (having all the symptoms of *Kustha*), *Trushna* (thirsty), *Daha* (burning sensation), *Shantagni* (satiated digestive power), and *Jantubhijdham* (worm-eaten) were all the symptoms ruled out.[9]

Method of preparation of trial drug

The *Kacha Kupi* (glass bottle) was filled with powder (#40) of processed orpiment (*Shuddha Haratala*) after three layers of clay & cotton cloth (*Kapadmitti*) smear on a glass bottle. A filled glass bottle was kept in the EMF. The temperature of the EMF was settled at 400 °C. EMF was turned off once the orpiment had completely melted. After self-cooling, the final product was collected from the bottom of the glass.[6] *Guduchi Kwatha* is prepared from fresh *Guduchi*, and after that, it is again boiled to a semi-solid consistency. Then it was dried under sunlight and the powder was prepared.[10] Then the *Rasamanikya* and *Guduchi Ghana* were mixed properly, and the capsules were filled.

Posology and revealing the blinding

There were 76 registered patients in the study. Eighty participants were randomly divided into blocks of 40:40. To replicate this plan, use seed 30 (created on July 6, 2018, at 7:01 p.m. from http://www.randomization.com). Both groups were treated with capsules prepared with 125 mg RM and 375 mg GG. Patients have to open that capsule and take it with honey and *Goghrita* twice a day. The treatment protocol was followed for 8 weeks, with a follow-up of 4 weeks. Other medicines were stopped, and dietary restrictions had been advised in both groups, as stated in the classics. Patients were treated with the internal administration of trial drugs A and B in groups A (n = 37) and B (n = 36), respectively. The blinding was unveiled after a complete statistical analysis of the obtained data. After revealing the blinding, drug A was found to be RM prepared with *Churnodaka Shodhita Haratala* (CSH) with GG, and drug B was RM prepared with *Kushmanda Swarasa Shodhita Haratala* (KSH) with GG.

Criteria for assessment

Subjective criteria involved the chief complaints such as *Matsyashakalopamam* (looks like the scales of a fish), *Rukshata* (dryness), *Aswedanam* (anhydrosis), *Daha* (burning), *Strava* (discharge), *Unnati* (raised patches), *Kandu* (itching), *Mahavastu* (broad based), *Vaivarnya* (discoloration), and associated complaints such as *Jwara* (fever), *Nindra* (sleep), *Sandhishoola* (joint pain), and *Nakhadushti* (involvement of nails). The candle grease sign and Auspitz sign were also evaluated for the assessment.[11] Special psoriasis area and severity index PASI)[12] scores and dermatology life quality index (DLQI)[13] scoring patterns were adopted for scrutinizing the symptomology. [Table 1] PASI is a quantitative rating score for measuring the severity of psoriatic lesions based on area coverage and plaque appearance. For assessment of the involvement of the body area, the rule of nine[14] used to calculate the percentage of the burn was considered with certain modifications. The whole body was scored but, looking into the nature of the disease, the score was further specified to the organs.

Table 1: Scoring pattern of sign and symptoms

Symptoms	Score	Symptoms	Score
Matsyashakalopamam (looks like the scales of a fish)		*Rukshata* (dryness)	
No scaling	0	No line on scrubbing with nail	0
Mild scaling by rubbing/by itching (scaling from <30% lesions)	1	Faint line on scrubbing by nails	1
Moderate scaling by rubbing/by itching (from >70% lesions)	2	Lining and even words can be written on scrubbing a nail	2
Severe scaling by rubbing/by itching (from >70% lesions)	3	Excessive *Rukshata* leading to *Kandu*	3
Scaling without rubbing/by itching (from >70% lesions)	4	*Rukshat*a leading to crack formation	4
Aswedanam (anhydrosis)		*Nindra* (sleep)	
Not present	0	Sound sleep	0
Present in few lesions	1	Sleep sound when interrupted can sleep again	1
Present in all lesions	2	Sleep sound when interrupted can't again	2
Aswedanam in the psoriatic lesion and uninvolved skin	3	Disturbed sleep but can sleep for few hours	3
Daha (burning sensation)		*Strava* (discharge)	
No burning	0	No *Strava*	0
Mild/occasional burning	1	Mild *Strava* in <70% lesions	1
Moderate (tolerable) infrequent	2	Mild *Strava* in >70% lesions	2
Severe burning frequently	3	Moderate *Strava* in <70% lesions	3
Very severe burning disturbing sleep and other activities	4	Moderate *Strava* in >70% lesions	4
Unnati (raised patches)		*Kandu* (itching)	
No raised patches	0	No itching	0
Slight raised patches that cannot be felt	1	Mild/occasional itching	1
Raised patches can be felt but depressed in middle	2	Moderate (tolerable) infrequent	2
Raised patches in all lesions but soft	3	Severe itching frequently	3
Raised patches in all lesions and hard	4	Very severe itching disturbing sleep and other activities	4
Mahavastu (broad based)		*Vaivarnya* (discoloration)	
No lesions on *Mahasthanam*	0	Normal coloration	0
Lesion on partial part of hand, leg, neck, scalp, hand, back	1	Near to normal which looks like normal color to distant observer	1
Lesions on most part of hand, leg, neck, scalp, trunk, back	2	Reddish coloration	2
Lesions on whole part of *Mahasthanam*	3	Slight black reddish discoloration	3
Lesions on whole body	4	*Krishna Arunavarna* (deep black reddish discoloration)	4
Jwara (fever)		*Sandhishoola* (joint pain)	
No fever	0	No joint pain	0
Occasional fever subsides by itself	1	Slight pain	1
Occasional fever subsides by drug	2	Pain present but do not hinder activity	2
Remittent fever	3	Pain with deformity	3
Continuous fever	4	Pain with deformity affecting activity and sleep	4
Nakhadushti (involvement of nails)			
No nail involvement	0		
1-5 nail's involvement of any extremities	1		
5-10 nail's involvement of any extremities	2		
10-15 nail's involvement of any extremities	3		
15-20 nail's involvement of any extremities	4		
Candle grease sign		Auspitz sign	
Absent	0	Absent	0
Improvement	1	Improvement	1
Present	2	Present	2
DLQI (Dermatology Life Quality Index)		PASI (Psoriasis Area Severity Index)	
No effect	0-1	Mild	1-10
Small	2-5	Moderate	11-20
Moderate	6-10	Severe	>21
Very large	11-20		
Extremely large	21-30		

Gradation for improvement

1. Complete remission: 100%
2. Markedly improved: In between 76% and 99%
3. Moderately improved : In between 51% and 75%
4. Mildly improved: In between 26% and 50%
5. Unchanged: <25%.

Statistical analysis

The percentage of improvement in each parameter in both treated groups was calculated. The paired 't'test and the wilcoxon signed-rank test were used to assess the effect of therapy on subjective criteria in the individual group. The unpaired 't'test and coefficient of variation (CV) were applied to the statistical data for evaluating the differences in the effects of the two therapies in two ways: subjective and objective criteria. The overall effect of therapy on each scale was calculated with reference to the percentage improvement in all symptoms. Finally, the overall effect of therapy was evaluated by enumerating the number of patients in each improvement category.

Results

In the present clinical study, a total of 85 subjects were assessed for eligibility criteria. Among them, 76 subjects with *Ekakushtha* (psoriasis) were enumerated for management. From them, 73 subjects finished the full duration of treatment, while three patients left the treatment against medical advice at different stages. Two patients were shifted to another place, whereas one patient left the course of treatment for personal reasons. [Chart 1] Differnts signs and symptoms, involvement of body surface area and *Nidana Sevena* (causative factor) the subjects were showed in Charts 2-4 respectively. Other observations in the patients were tabulated in the Table 2.

Table 3 shows highly significant ($P < 0.001$) difference between two groups in eosinophil count and MCV% whereas significant difference ($P < 0.05$) seen in monocytes. All other parameters of hematocrit show an nonsignificant difference ($P > 0.05$). Table 4 shows a significant difference ($P < 0.05$) seen in FBS, S. triglycerides, and S. calcium. All other parameters of biochemistry show an nonsignificant difference ($P > 0.05$). All changes were within normal biological ranges in the combination of two therapies.

A comparison of the effect of treatment within the same group (paired 't' test) showed that both groups exhibited highly significant ($P < 0.001$) improvement in the chief complaints of *Ekakushutha* in the patients. There was a statistically significant difference (unpaired 't' test) ($P > 0.05$) in the effect of treatment between two groups on the parameters *Daha* and *Kandu* in the chief complaints. The CSHRM along with the GG-treated group was seen to provide better results in percentage change on *Unnati*, *Kandu*, *Vaivarnya,* the candle grease sign, the Auspitz sign, PASI, and DLQI scores. KSHRM along with the GG-treated group showed better results on *Matsyasakalopamam*, *Aswedanam*, *Daha*, *Strava,* and *Mahavastu*. [Table 5]

Table 2: Demographic data of 76 patients of psoriasis

Observations	Parameters	Maximum %
Age	50-60 years	27.63
Occupation	Housewife	31.58
Onset	Gradual	88.15
Type of psoriatic patches	Plaque	73.68
Chronicity wise distribution (years)	<1	06.58
	1-5	48.68
	5-10	44.74
Condition of patches in last 2 months	Increasing	69.73
Aggravating factor	Sunlight and dust	43.42
	Season (winter)	63.16
Medicinal history	Ayurvedic + allopathic	43.42
Site of involvement	Hands	64.47
	Legs	43.42
	Whole-body	30.26
	Back	19.74
	Face	18.42
	Trunk	18.42
Area wise distribution	Anterior	75.00
	Posterior	57.89
Pattern wise distribution	Symmetrical	57.89
Color wise distribution	Silvery shiny	82.89

Table 3: Comparative effect of therapies on haematological parameters

Parameter	Group A ($n=37$)	Group B ($n=36$)	*t*	*P*	S
TLC (count/mm^3)	2.90↓	1.097↓	0.32	>0.05	NS****
Neutrophil (%)	0.65↑	2.55↑	0.51	>0.05	NS****
Lymphocyte (%)	4.23↓	3.09↓	0.27	>0.05	NS****
Eosinophil (%)	10.75↓	23.67↓	-3.97	<0.001	HS***
Monocyte (%)	4.83↑	15.08↓	-1.98	<0.05	S**
Haemoglobin (g/dL)	1.15↓	0.27↑	1.07	>0.05	NS****
PCV (%)	0.79↓	0.93↑	1.33	>0.05	NS****
ESR (mm/h)	14.56↓	24.93↓	-0.56	>0.05	NS****
T-RBC (10^6/µL)	0.35↓	0.29↑	0.51	>0.05	NS****
Platelet (10^6/ml)	2.40↓	0.11↓	0.72	>0.05	NS****
MCV (fl/cell)	1.98↓	0.59↑	-34.65	<0.001	HS***
MCH (pg/cell)	0.71↑	0.53↓	-0.93	>0.05	NS****
MCHC (g/dL)	0.14↓	0.61↑	0.98	>0.05	NS****
AEC (cells/mcL)	27.92↓	22.59↓	0.41	>0.05	NS****

NS****: Nonsignificnat, HS***: Highy significant, S**: Significant, ↓ : Decrease; ↑: Increase

At the end of the treatment duration, the PASI score of all the subjects was calculated, and subjects were divided as per chronicity. There was a statistically significant ($P < 0.05$) and highly significant ($P < 0.001$) reduction in score noted in chronicity <1 year and chronicity >1 year to 10 year respectively in both the groups. There was better result found in CSHRM with GG treated group (88.46%, $P < 0.01$) in all patients who completed the treatment. It

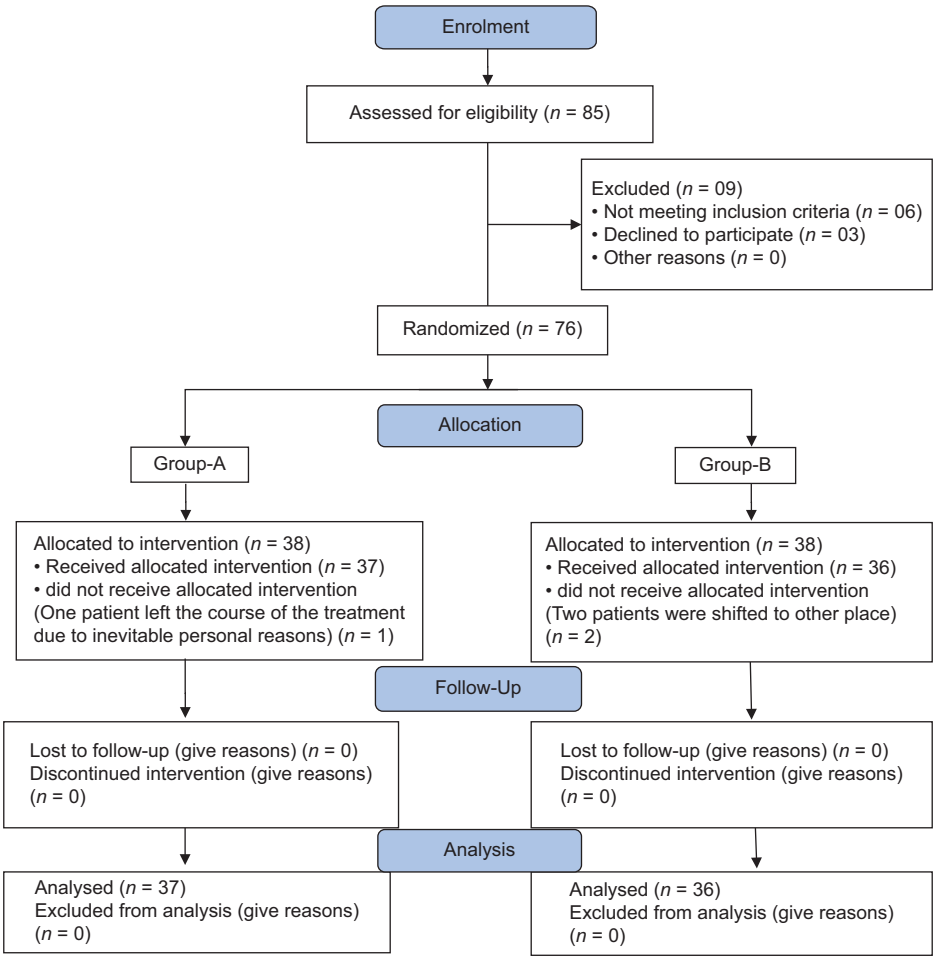

Chart 1: CONSORT diagram

Table 4: Comparative effect of therapies on Biochemical parameters

Parameter	Group A (*n*=37) % change	Group B (*n*=36) % change	*t*	*P*	S
FBS (mg/dL)	4.44↑	0.57↓	-2.047	<0.05	S**
S. Cholesterol (mg/dL)	2.89↑	2.12↑	-0.203	>0.05	NS****
S. Triglyceride (mg/dL)	5.93↓	6.41↓	0.165	<0.05	S**
HDL-cholesterol (mg/dL)	1.62↑	3.70↑	0.429	>0.05	NS****
LDL - cholesterol (mg/dL)	6.35↑	5.46↑	0.123	>0.05	NS****
S.Urea (mg/dL)	4.54↓	4.34↑	1.378	>0.05	NS****
S.Creatinine (mg/dL)	4.21↓	5.11↓	0.112	>0.05	NS****
Uric acid (mg/dL)	3.91↓	1.84↓	0.566	>0.05	NS****
Total billirubin (mg/dL)	5.26↓	0.36↓	0.909	>0.05	NS****
Direct billirubin (mg/dL)	3.96↓	54.46↓	0.943	>0.05	NS****
SGPT (IU/L)	16.62↓	09.80↓	-0.0027	>0.05	NS****
SGOT (IU/L)	0.00	09.12↓	0.512	>0.05	NS****
S. Alkaline Phosphate (IU/L)	0.17↑	02.40↓	0.725	>0.05	NS****
Total Proteins (g/dL)	1.61↓	1.39↓	0.115	>0.05	NS****
S. Albumin (g/dL)	0.00	4.07↓	-1.508	>0.05	NS****
S. Globulin (g/dL)	4.01↓	2.38↓	0.564	>0.05	NS****
A: G Ratio	2.31↑	5.70↑	0.803	>0.05	NS****
S Calcium (mg/dL)	3.05↑	1.65↓	2.056	<0.05	S**

NS****: Nonsignificnat, S**: Significant, ↓: Decrease, ↑: Increase

was also discovered that there was no statistically significant difference in the reduction of PASI score among subgroups of patients with varying chronicity.Patients with higher chronicity (6-10 years) have similar results (reduction of

PASI score) as patients with 1 year chronicity and chronicity 1 to 5 years.This suggests that patients with more chronic disease who are resistant to treatment and have poor clinical outcomes in the later stages of the disease are frequently associated with complications such as psoriatic arthritis, etc. Hence, a similar improvement and reduction in PASI score in patients with a higher chronicity of 6–10 years is of great clinical significance. [Table 6]

A comparison of the effect of treatment on PASI score before the treatment and after the follow-up period with varying chronicity suggests that there was no significant reduction in the observed effect of drug treatment (which was achieved after 2 months of treatment) on PASI score after the follow-up period (even after the discontinuation of drug treatment for 1 month). The decrease in PASI score observed after follow-up in all patients with varying chronicity did not show many variations within them (as chronicity changed). PASI score reductions after follow up period were greater in the group treated with KSHRM "(79.08%, $P < 0.001$)" along with GG than in the CSHRM along with GG receiving group. Even in patients with chronicity of 6-10 years, the persistence of effect at the end of follow-up was clinically more significant, as the prognosis of psoriasis worsens with chronicity, along with the evolution and progression of chronicity and a reduction in the positive response to therapy. [Table 7]

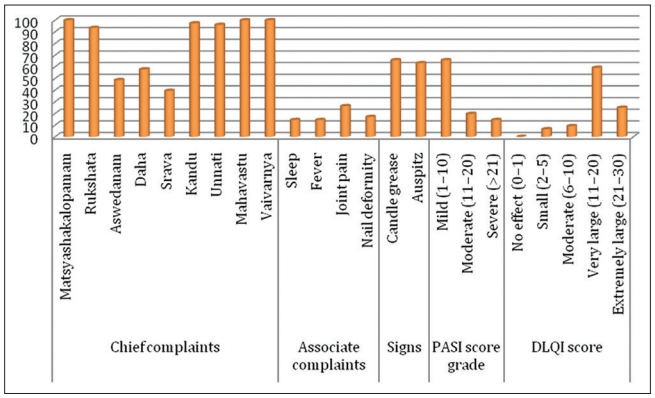

Chart 2: Demographic data of 76 patients – signs and symptoms of psoriasis

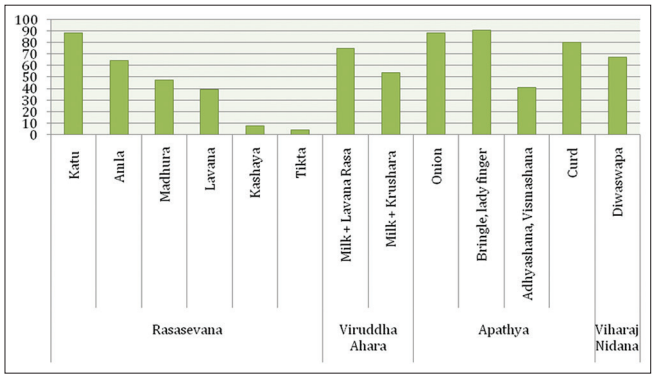

Chart 4: Demographic data of 76 patients – *Ahara viharaj Nidana*

On applying a CV, CSHRM along with GG showed better and more consistent results except in the symptoms, i.e., *Matsyaskalopamam*, *Aswedanam,* and *Strava*. The major difference was found in the *Daha* symptom (CV of group A: 38.99, CV of group B: 58.29). [Table 8] In the overall effect of therapy, CSHRM along with GG group has shown better results than group B. These data are mentioned in Chart 5.

Discussion

In this clinical trial, the maximum number of patients (i.e., 27.63%) with psoriasis were found in the age group of 50–60 years; this showed that the disease can occur at any stage of life. One study reported that the onset of psoriasis was bimodal, with two peaks of the disease: the first between 16 and 22 years of age and the second between 57 and 60 years of age.[15] As the sample size was too small in the present study to draw any concrete conclusion, one cannot say that the disease is more prevalent at an older age. The maximum number of patients, i.e., 31.58%, were housewives. The course of psoriasis is inconsistent or inpredicatable, and the variations are numerous.[16] In the present study 88.15% patients having gradual onset of disease. *Ekakushtha* is a disease characterised by *Vata-Kapha* dominance.[17] As a result, the disease's

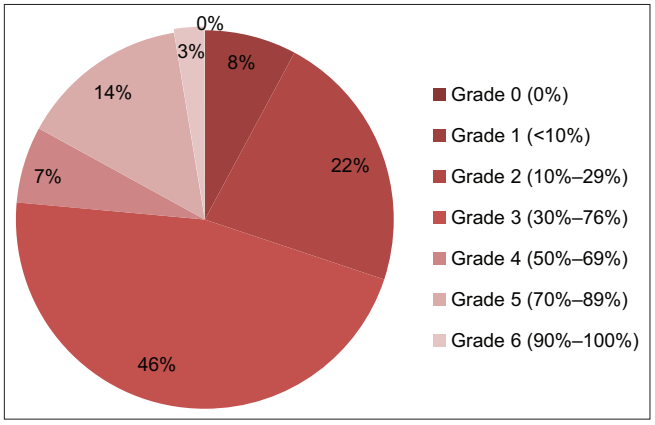

Chart 3 : Demographic data of 76 patients – involvement of body surface area

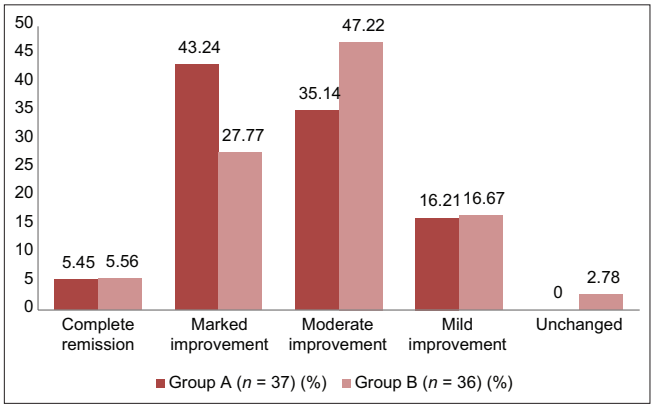

Chart 5 : Overall effect of therapy on 73 patients of *Ekakushtha* on subjective criteria

Table 5: Effect of both trial drug on signs and symptoms of *Ekakushtha*

Symptoms	Group A				Group B				Between the groups		
	n	% change	*P*	S	*n*	% change	*P*	S	*t*	*P*	S
Chief complaints											
Matsyasakalopamam (looks like the scales of a fish)	37	74.74↓	<0.001	HS***	36	75.00↓	<0.001	HS***	0.84	>0.05	NS****
Rukshata (dryness)	35	71.43↓	<0.001	HS***	36	74.73↓	<0.001	HS***	0.15	>0.05	NS****
Aswedanam (anhydrosis)	16	65.71↓	<0.001	HS***	21	80.85↓	<0.001	HS***	1.37	>0.05	NS****
Daha (burning)	19	75.00↓	<0.001	HS***	25	79.54↓	<0.001	HS***	2.17	<0.05	S**
Strava (discharge)	17	94.44↓	<0.001	HS***	13	96.29↓	<0.001	HS***	0.00	>0.05	NS****
Unnati (raised patches)	37	66.67↓	<0.001	HS***	36	63.63↓	<0.001	HS***	0.88	>0.05	NS****
Kandu (itching)	35	76.00↓	<0.001	HS***	35	71.05↓	<0.001	HS***	2.24	<0.05	S**
Mahavastu (broad based)	37	42.19↓	<0.001	HS***	36	47.27↓	<0.001	HS***	0.037	>0.05	NS****
Vaivarnya (discoloration)	37	54.12↓	<0.001	HS***	36	49.42↓	<0.001	HS***	0.26	>0.05	NS****
Candle grease sign	28	87.5↓	<0.001	HS***	22	85.71↓	<0.001	HS***	0.78	>0.05	NS****
Auspitz sign	26	88.46↓	<0.001	HS***	22	85.71↓	<0.001	HS***	0.90	>0.05	NS****
PASI score	37	87.70↓	<0.001	HS***	36	77.53↓	<0.001	HS***	1.51	>0.05	NS****
DLQI score	37	81.75↓	<0.001	HS***	36	75.30↓	<0.001	HS***	0.33	>0.05	NS****
Associated complaints											
Nindra (Sleep)	06	75.00↓	>0.05	NS****	05	71.42↓	>0.05	NS****	0.00	>0.05	NS****
Jwara (fever)	06	90.00↓	>0.05	NS****	05	66.66↓	>0.05	NS****	1.67	>0.05	NS****
Sandhi Shoola (joint pain)	12	75.00↓	<0.001	HS***	12	75.00↓	<0.001	HS***	1.67	>0.05	NS****
Nakha Dushti (involvement of nail)	08	0.00	>0.05	NS****	08	0.00	>0.05	NS****	0.00	>0.05	NS****

PASI: Psoriasis area and severity index, DLQI : Dermetology life quality index, NS**** : nonsignificnat, HS***:Highy significant, S** : significant, ↓: Decrease

Table 6: Compression of PASI score as per isolated chronicity of the diseases statistically (effect before treatment and after treatment)*

Group/ chronicity	<1 year-10 years (*n*=73)			<1 year (*n*=4)			1-5 years (*n*=35)			6-10 years (*n*=34)		
	P	% change	S	*P*	% change	S	*P*	% change	S	*P*	% change	S
A (*n*=37)	<0.001	88.46↓	HS***	<0.05	76.63↓	S**	<0.001	78.57↓	HS***	<0.001	76.14↓	HS***
B (*n*=36)	<0.001	85.71↓	HS***	<0.05	77.97↓	S**	<0.001	78.87↓	HS***	<0.001	69.12↓	HS***

*Wilcoxon signed rank test within group before treatment after treatment. ↓: Decrease, PASI: Psoriasis area and severity index, HS***: Highy significant, S**: Significant

progression may have been gradual. The most common type of psoriasis found in patients is plaque psoriasis.[18] In the present study, 73.68% patients found that most common type and this support the same statement.

Psoriasis is a life-long disorder subject to unpredictable remissions and relapses. Single episodes are uncommon, and in them, there is frequent variety. An episode in the teenage years is followed by a series of attacks, each lasting a week or months, in the succeeding years.[19] It is clear from the data of the chronicity-wise distribution of *Ekakushtha* patients that the maximum number of patients, i.e., 90.78%, had a chronic disease (>1 year), and 9.22% of patients were suffering from an acute disease (1 year). 48.68% of patients had a duration of 1–5 years, while 44.74% had a duration of 5–10 years. Acharya Charaka has considered *Kushtha* a chronic skin disease.[20]

Patients, i.e., 43.42%, reported sunlight and dust as aggravating factors. 63.16 percent of patients had symptom aggravation during the winter season. In some studies, it is reported that the patients' skin lesions worsened during the winter.[21,22] Studies have also indicated that cold weather may be a predisposing factor or trigger for psoriasis, in contrast to the hot and sunny climate that appears to be beneficial.[23] *Sheeta* and *Ruksha Guna* are aggravated by the cold, and it may cause aggravation of *Vata Dosha* and disease in the winter season.[24] 43.42% of patients were taking allopathic and ayurvedic medications simultaneously; this suggests a major trend in the choice of treatment line in this local area.

The dominance of *Rasa* (taste) in the diet of the patients was in the order of *Katu* (pungent -88.16%) > *Amla* (sour - 64.47%) > *Madhura* (sweet - 47.37%) > *Lavana* (salt -39.47%) > *Kashaya* (astrigent -7.89%) > *Tikta* (bitter - 03.95%). As per the classical text of Ayurveda, an excessive proportion of *Katu Rasa* in the diet causes an increase in *Vata Dosha*, *Amla Rasa* causes vitiation of *Rakta Dosha*, *Madhura Rasa* causes *Shleshma Roga*, and *Lavana Rasa* causes versatility for *Kushtha*.[25] 40.78% of patients were practising

Table 7: Compression PASI score as per isolated chronicity of the diseases statistically (effect before treatment and end of follow up of 1 month)*

Group/ chronicity	<1 year-10 years (*n*=73)			<1 year (*n*=4)			1-5 years (*n*=35)			6-10 years (*n*=34)		
	P	% change	S	*P*	% change	S	*P*	% change	S	*P*	% change	S
A (*n*=37)	<0.001	77.40↓	HS***	<0.05	76.15↓	S**	<0.001	77.94↓	HS***	<0.001	76.71↓	HS***
B (*n*=36)	<0.001	79.08↓	HS***	<0.05	69.12↓	S**	<0.001	81.06↓	HS***	<0.001	79.49↓	HS***

*Wilcoxon signed rank test within group before treatment after treatment. ↓: Decrease. PASI: Psoriasis area and severity index, HS***: Highy significant, S**: Significant

Table 8: Comparison of results on cardinal symptoms between the groups by applying coefficient of variation

Symptoms	G	*n*	Mean difference	SD	CV (%)	Better group
Matsyasakalopamam (looks like the scales of a fish)	A	37	2.00	0.913	45.65	B
	B	36	1.83	0.775	42.34	
Rukshata (dryness)	A	37	1.86	0.879	47.25	A
	B	36	1.89	0.919	48.62	
Aswedanam (anhydrosis)	A	16	1.44	0.814	56.52	B
	B	21	1.81	0.814	44.97	
Daha (burning)	A	19	1.89	0.737	38.99	A
	B	25	1.40	0.816	58.29	
Strava (discharge)	A	17	2.00	0.935	46.75	B
	B	13	2.00	0.707	35.35	
Unnati (raised patches)	A	37	1.57	1.068	68.03	A
	B	36	1.36	0.931	68.46	
Kandu (itching)	A	35	2.17	0.985	45.39	A
	B	35	1.54	1.336	86.75	
Mahavastu (broad based)	A	37	0.92	0.845	91.84	B
	B	36	0.72	0.815	88.34	
Vaivarnya (discoloration)	A	37	1.24	0.683	55.08	A
	B	36	1.19	0.707	59.41	
Nindra (sleep)	A	6	1.00	0.889	88.9	B
	B	5	1.00	0.707	70.7	
Jwara (fever)	A	6	1.50	0.816	54.40	A
	B	5	0.80	0.447	55.88	
Sandhi shoola (joint pain)	A	12	1.00	0.603	60.30	A
	B	8	1.13	0.835	73.89	
Nakhadusti (involvement of nails)	A	8	0.00	0.00	0.00	-
	B	5	0.00	0.00	0.00	
Candle grease sign	A	28	1.75	0.441	25.2	A
	B	22	1.63	0.581	35.64	
Auspitz sign	A	26	1.76	0.430	24.57	A
	B	22	1.63	0.581	35.64	
PASI Score	A	37	6.97	5.633	80.81	A
	B	36	6.52	5.979	91.70	
DLQI score	A	37	13.56	4.676	34.48	B
	B	36	12.03	3.960	32.92	

PASI: Psoriasis area and severity index, DLQI: Dermatology life quality index, SD: Standard deviation, CV: Coefficient of variation

Vishamashana (food irregularity) and *Adhyashana* (eating excess food). *Vishamashana* causes *Vata Prakopa* and the aggravation of disease conditions.[26]

75.00% of patients were taking milk and *Lavana* (salt taste), while 53.95% of patients were taking milk and *Krushara* (thick gruel) together. *Viruddha Aahara* (incompatible food) may aggravate the symptoms of the disease due to the increased involvement of vitiated *Dosha*. Undigested food produces free radicals, as they can damage skin tissue and decrease the body's production of cyclic AMP.[27] Research shows that 60% of people with psoriasis also have disorders of carbohydrate metabolism. Toxic substances produced by faulty digestion include polyamines, which prevent the body from making cyclic adenosine monophosphate [AMP], a regulator of metabolism in the cells.[31] *Viruddha Ahara* can be considered *Nidana* (causative factor) only when a patient has a history of

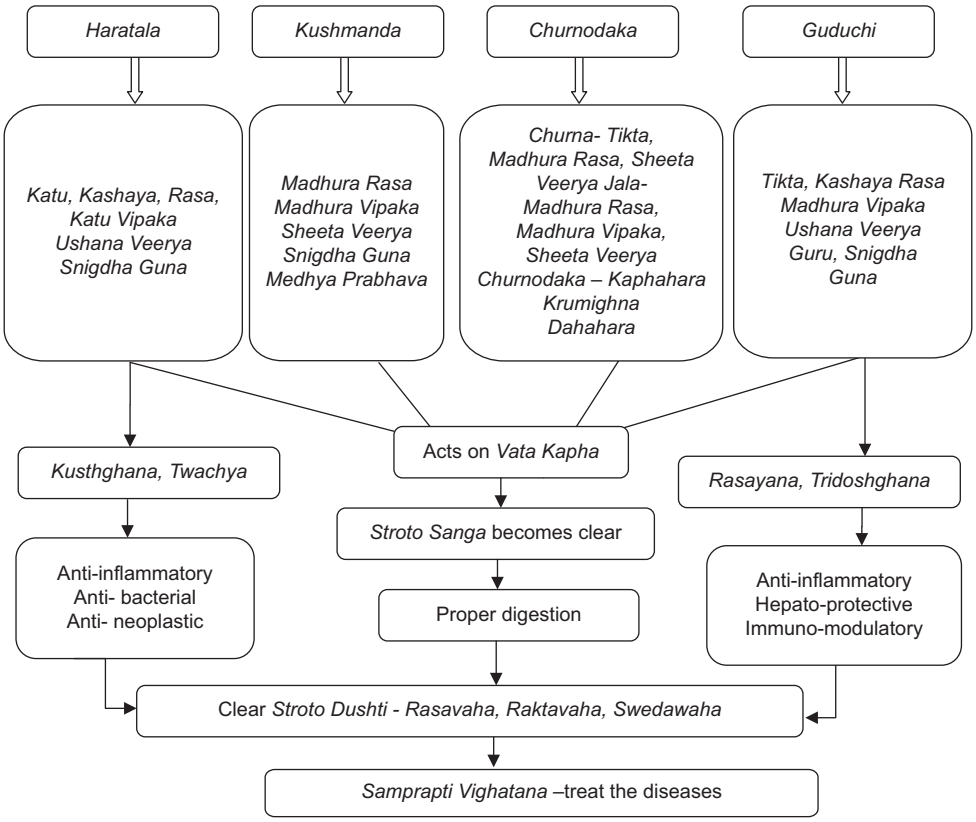

Chart 6: Probable mode of action of *Rasamanikya* and *Guduchi Ghana* in *Ekakushtha*[28-30]

regular consumption for a longer duration and it causes the *Nindita Vyadhis* like *Kushtha* and *Shwitra* (leucoderma).[32]

67.10% of patients had a history of *Diwaswapa,* which is a cause of *Pitta* and *Kapha Dosha* vitiation and also cause for *Kotha* (wheal like skin eruptions) & *Kandu* (itching) like skin disorders.[33] The most common sites affected by the lesion of psoriasis reported by the patients were the hands (64.47%), legs (43.42%), the whole body (30.26%), the back (19.74%), and the face and trunk (18.42% each). These findings are also supported by modern medical texts. Prediction sites are the extensor surfaces (especially elbows and knees), trunk, and scalp.[34] One study reported that approximately 20% of patients with plaque psoriasis present with the facial manifestations of the disease. Facial psoriasis is more frequently observed in patients with a longer disease duration, a family history of psoriasis, and more severe psoriasis. The face seems to be a less affected area. It is still not established whether this is due to the effect of sunlight or whether the facial skin itself is less susceptible to psoriasis.[35] A maximum of 57.89% of patients had symmetrical patterns. Normally, the site of psoriasis is bilateral, often symmetrical. A well-demarcated border is an important feature for diagnosis in flexures and glans, where other features like scaling may be absent.[36]

The persistence of the treatment's effect even after a one-month follow-up period suggests that the action of drugs is more than just an instant and or fast acting action or instant symptomatic relief in nature, such as instant anti-inflammatory, anti-allergic, antihistaminic, and photosensitizer (improving UV A absorption), but it may also have a long-term effect, such as long-term immunomodulation, persistent anti-inflammatory action, and because arsenicals are both local and systemic photosensitizers,[37] and they have a significantly prolonged half-life in biological systems, their lipophilicity results in target deposition in fats, subcutaneous fat, whose excretion may be from hair follicles, hair openings, sebaceous secretions,[38] and so on, affecting the dermal layers where the rate of proliferation is increased, which is one of the key pathological events of psoriasis. Lipophilicity with a long half-life and subcutaneous deposition increase and prolong photosensitivity, UV-A absorption, local and systemic immune suppression, and so on [Chart 6].[39]

Vata and *Pitta Doshas Sthana* is *Twak* (skin).[40] *Ekakushtha* has predominant features of scaling, dryness, cracks (the Auspitz sign), and impairment of the skin, suggesting the predominant involvement of *Vata Dosha* where there are complications such as the ageing of the skin, hyperpigmentation and or hypopigmentation, skin sensitization, and chronic inflammation.[41] By default, the generalised treatment of *Vata Dosha* is the application and administration of *Taila*, or *Sneha*. Arsenicals, owing to their lipophilicity, have a tendency to get deposited in subcutaneous fat along with bone (marrow, fats), the brain, the nerves and, of course, the kidneys and liver as major sites of deposition. Skin appendages (skin, hair and nails) are among the excretory pathways of arsenicals; hence,

they may be a judicious choice in treating dermal affections like psoriasis. Although *Kushtha* is a chronic skin disease, its chronicity and prognosis are most often evident in the case of *Ekakushtha*, as advocated by Acharya Charaka to add *Rasayana* therapy to all chronic diseases.[42] The drugs that are to be given for prolonged periods of time, often for a long time, especially in cases of psoriasis in the paediatric age group, must be safer. However, the results can be revalidated by a well-designed clinical trial with a larger sample size.

Adverse Drug Reaction

No adverse drug reactions were observed in any of the patients.

Conclusion

In the present study, statistically highly significant ($P < 0.001$) results were found in both the groups on the cardinal symptoms of *Ekakushtha* and parameters of assessment (PASI score and DLQI) after treatment, and there was the persistence of the effect of treatment on PASI score in both the groups with an insignificant reduction even till the end of the follow-up of one month without any medicine. *Rasamanikya* prepared with both the media *Shodhita Haratala* and *Guduchi Ghana* were discovered to be safe and effective psoriasis treatments.

Acknoweldgement

The author would like to thank Dr. Swpnil Chaudhari, for their guidance to prepare this manuscript. The author would like to thank Dr. Sarika Makwana, and Dr. Om Pandey for helping throughout the study.

Financial support and sponsorship

Institute for teaching and research in Ayurved., Jamanagar.

Conflicts of interest

There are no conflicts of interest.

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