

## RANDOMIZED CONTROLLED CLINICAL STUDY TO EVALUATE THE EFFICACY OF PUGADI KSHEERA SEKA IN VATAJA CHARMADALA W.S.R TO ATOPIC DERMATITIS IN CHILDREN

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### ABSTRACT

**Introduction:** In Ayurveda all kinds of skin diseases are mentioned under the heading of Kushta. *Charmadala* is one among *Kshudra kushtas* by most of the Acharyas. *Kashyapokta Charmadala* is a *Vata Pradana Tvak Vikara* and it is commonly seen in children as they are *Sukumara* and have *Asthira dhatus*. Based on its symptoms, *Charmadala* can be correlated with Atopic dermatitis (AD). The prevalence of AD has increased in recent years, yet conventional treatments, such as topical steroids, often lead to skin sensitivity. Therefore, there is a need for alternative treatments. This study aims to evaluate the effectiveness of *Pugadi Ksheera Seka* and *Panchatikta Ghrita Lepa* in treating *Vataja Charmadala*, which is clinically comparable to Atopic dermatitis in children. **Methods:** In this study, 40 subjects diagnosed with *Vataja Charmadala* were randomly selected and assigned in to two groups, with 20 subjects in each groups. Group A (trial group) was administered with *Pugadi Ksheeraseka* and Group B (control group) was given with *Panchatiktaghrita Lepa*. Intervention was given for 7 days and study period was of 21 days. Assessment was

done on 0th day, 7th day, 14th day and 21st day based on Ayurvedic parameters and SCORAD index of Atopic dermatitis. The data obtained was statistically analysed by using Paired and Unpaired t –test and the results were represented in the forms of tables and graphs.

**Results:** Both treatments showed a statistically significant reduction in symptoms of Vataja Charmadala (AD) within each group. However, between the two groups, *Panchatikta Ghrita Lepa* demonstrated better results. This may be attributed to the lipophilic nature of *Panchatikta Ghrita*, which enhances physical occlusion and improves the absorption of active ingredients into the skin. *Pugadi Ksheera Seka*, which contains *Vatahara* drugs in a liquid medium, also contributed to symptom reduction, though it was less effective compared to the *Ghrita*-based formulation. **Interpretation and Conclusion:** *Pugadi Ksheera Seka*, containing *Vatahara* herbs in a liquid medium, helped in reducing *Vata* and alleviating the symptoms of *Vataja Charmadala*. *Panchatikta Ghrita*, known for its *Kushtaghna* properties and lipid base, was more effective due to its superior ability to occlude the skin and enhance absorption of active compounds. Both treatments were effective in managing *Vataja Charmadala*, but *Panchatikta Ghrita Lepa* showed better results overall. Thus, both therapies can be considered viable options for treating atopic dermatitis in children, with *Panchatikta Ghrita Lepa* being more efficacious.

**KEYWORDS:** *Vataja charmdala*; *Pugadi Ksheera Seka*; *Seka*; *Panchatikta Ghrita*; *Lepa*; Atopic dermatitis (AD).

## INTRODUCTION

The skin, the body's largest organ, protects internal organs and structures from the environment. The skin in children is physiologically different in terms of structure, composition and functions.<sup>[1]</sup> Skin barrier in children is less permeable and mature than that of adult skin which makes it more vulnerable to the environment along with their developing immune system. Their skin is more prone to dryness and there is a greater chance of developing irritations and infections. In pediatric practice, about one-third of patients present with skin conditions, with Atopic dermatitis being the most common, affecting 15-20% of children.<sup>[2]</sup> This chronic relapsing and highly pruritic dermatitis typically emerges in early childhood and is marked by decreased skin barrier dysfunction. Its prevalence has been rising in both developing countries, including India.<sup>[3]</sup> Treatment often involves moisturizers, topical corticosteroids, and systemic immunosuppressants, but these options can be complex and have limitations in efficacy and safety. Atopic dermatitis significantly impacts the quality

of life for patients and families, affecting physical, mental, and social well-being, highlighting the need for effective management strategies.<sup>[4]</sup>

Based on the signs and symptoms, Atopic dermatitis can be correlated to *Kashyapokta Charmadala* which is commonly seen in children. In Ayurveda all kinds of skin diseases are mentioned under the heading of *Kushta*. It is considered as one among the *Mahagadas* and when left untreated causes disfigurement of the body. *Kushta* is broadly classified into *Mahakushta* and *Kshudrakushta*, where *Charmadala* is classified under *Kshudra kushta* by most of the *Acharyas*. *Charmadala* mentioned by *Acharya Kashyapa* is a *Vata Pradana Tvak Vikara* and it is commonly seen in *Ksheerada* and *Ksheerannada Bala* as they are *Sukumara* and have *Asthira dhatus*. He has dedicated a whole chapter for the disease *Charmadala* where he explains about *Nidana panchaka* which is very specific to childhood age group. It features *Charmavadarana* (cracking) due to predominant *Vata dosha* and is categorized into four types: *Vataja*, *Pittaja*, *Kaphaja*, and *Sannipataja*. *Vataja Charmadala* presents with skin lesions like cracking, roughness, and discoloration, accompanied by itching. Contributing factors include vitiated breast milk, friction, exposure to heat, lack of cleanliness, and familial tendencies.<sup>[5]</sup> These aspects resemble the acute and subacute phases of Atopic dermatitis. Various treatments for *Charmadala* include *Pradeha*, *Lepa*, *Seka*, and *Abhyanga*. The effect of *Lepa* has been studied extensively, with *Pugadi Ksheera Seka* being noted for *Vataja Charmadala* treatment. This involves ingredients like *Puga*, *Patali*, *Palasha*, and *Rasna*, prepared as *Ksheerapaka*. *Seka*, a form of *Swedana*,<sup>[6]</sup> uses warm medicated liquids to induce perspiration. Studies show that external applications, especially *Ghrita Lepa* like *Panchatiktaka ghrita*, are effective in treating *Charmadala*.<sup>[7]</sup> This study aims to assess the efficacy of *Pugadi Ksheera* and *Panchatiktaka ghrita Lepa* in *Vataja Charmadala*.

## OBJECTIVES

- To evaluate the efficacy of *Pugadi Ksheera Seka* in *Vataja Charmadala* w.s.r to Atopic dermatitis.
- To re-evaluate the efficacy of *Panchatiktaka Ghrita Lepa* in *Vataja Charmadala* w.s.r to Atopic dermatitis.
- To compare the efficacy of *Pugadi Ksheera Seka* and *Panchatiktaka Ghrita Lepa* in *Vataja Charmadala* w.s.r to Atopic dermatitis.

## HYPOTHESIS

### Null hypothesis

(H<sub>0</sub>) -*Pugadi Ksheera Seka* and *Panchatiktaka Ghrita Lepa* are equally effective in *Vataja Charmadala* w. s. r to Atopic dermatitis.

### Alternate hypothesis

(H<sub>1</sub>)- *Pugadi Ksheera Seka* is more effective than *Panchatiktaka Ghrita Lepa* in *Vataja Charmadala* w. s. r to Atopic dermatitis.

(H<sub>2</sub>)-*Panchatiktaka Ghrita Lepa* is more effective than *Pugadi Ksheera Seka* in *Vataja Charmadala* w. s. r to Atopic dermatitis.

## MATERIALS AND METHODS

### • Source of data

#### a) Literary

Data was collected from Samhitas, contemporary modern texts, reputed journals, research articles, web sources and related works from different Universities.

#### b) Sample

40 subjects visiting OPD and IPD of Sri Sri College of Ayurvedic Science and Research Hospital, Bengaluru fulfilling the inclusion criteria and whose parents were willing to give consent were selected for the study.

#### c) Drug source

- Drugs were collected from Kerala and Gujarat (16/12/2019, 20/12/2019) and was identified and approved by Department of Dravyaguna, Sri Sri College of Ayurvedic Science and Research Hospital, Bengaluru.
- Research Design: Randomized controlled clinical study.
- Randomization – Lottery method

## DIAGNOSTIC CRITERIA<sup>[8,9]</sup>

Diagnosis was made based on *Vataja charmadala Lakshanas* that is

- *Sphutana* (Cracking)
- *Parushata* (Dryness)
- *Shyavata* (Blackish discolouration)
- *Kandu* (Itching) at the site of lesion

- Based on signs & symptoms of acute & sub-acute types of Atopic dermatitis
- Acute Atopic dermatitis –Red Papules, Vesicles Exudation, Erythema, Exfoliation, Erosion
- Sub Acute Atopic dermatitis Erythema, Exfoliation, Exhudation, Scaling etc

### INCLUSION CRITERIA

1. Subjects of age group 1 year to 5 years were included irrespective of religion, gender and socio-economic status.
2. Subjects diagnosed with *Lakshanas* of *Vataja Charmadala* were included for the study.
3. Subjects having the clinical features of Acute & Sub-acute Atopic dermatitis were included.

### EXCLUSION CRITERIA

1. Subjects below the age of 1 year and above the age of 5 years were excluded.
2. Chronic Atopic dermatitis (more than 1 year duration) was excluded.
3. Atopic dermatitis associated with secondary bacterial infection, Lichenification, oozing from the site of lesions were excluded.
4. Subjects presenting associated systemic symptoms like diarrhoea, acute respiratory infections, and acute febrile conditions were excluded.

### GROUPING

40 Subjects fulfilling the inclusion criteria were randomly selected and assigned in to two groups.

Group A (20) - *Pugadi Ksheera Seka*

Group B (20) – *Panchatiktaka Ghrita Lepa*

**Table 1: METHODOLOGY.**

	Group A	Group A
Intervention	<i>Pugadi Ksheera Seka</i> <sup>[10]</sup>	<i>Panchatiktaka Ghrita Lepa</i> <sup>[12]</sup>
No of subjects	20	20
Route of Administration	<i>Bahya Marga</i> (External application)	<i>Bahya Marga</i> (External application)
Ingredients	<i>Puga</i> ( <i>Areca catechu</i> Linn.) <i>Palasha</i> ( <i>Butea monosperma</i> Roxb.) <i>Patala</i> ( <i>Stereospermum suaveolens</i> Roxb.) <i>Rasna</i> ( <i>Pluchea lanceolata</i> (DC.) C.B. Clarke)	<i>Nimba</i> ( <i>Azardacta indica</i> A. Juss) <i>Patola</i> ( <i>Trichosanthus dioica</i> Roxb.) <i>Vyaghri</i> ( <i>Solanum surtense</i> Burm.F.) <i>Guduchi</i> ( <i>Tinospora cordifolia</i> (Willd.) Miers) <i>Vasa</i> ( <i>Adathoda vasica</i> Nees) Go Ghrita
Preparation	1 part each of <i>Puga</i> , <i>Palasha</i> , <i>Patala</i>	Medicine was collected from GMP

	and <i>Rasna</i> were taken and crushed in a <i>Khalva yantra</i> . 8 parts of milk was taken in a vessel and 32 parts of water was added to it. The mixture of crushed medicine was added to the solution of milk and water, and then boiled and reduced to 8 parts <sup>[11]</sup>	certified pharmacy
Method of administration	Subjects were made to lie down on the <i>Abhyanga</i> table and the <i>Ksheerapaka</i> which is instantly prepared (Luke warm ~ 38 C) was poured over the affected areas till the subject develops the signs of proper <i>Swedana</i> .	Instructions were given to the parents regarding the procedure of application of the medicine at home. Parents were asked to clean the affected area with luke warm water and make it dry and apply <i>Pancha tiktaka ghrita</i> over the affected areas as a thin layer (1/4th angula~0.48cm) with the help of a sterile cotton and kept for 30 minutes and then to wash with luke warm water.
Duration of treatment-	7 days	7 days
Duration of Study	21 days	21 days
Follow up	14th day and 21st day	14th day and 21st day

**DIET REGIMEN** -In children who are still receiving the breastfeeding, instructions were given to the mother regarding diet and regimen.

**ETHICAL CLEARANCE** -For starting the study ethical clearance was obtained from Sri Sri Institutional Ethical Committee.

**CTRI REGISTRATION**- Before commencing the study CTRI registration was done. [Registration No. CTRI/2020/04/024429]

#### ASSESSMENT CRITERIA

Assessment was done based on *Vataja Charmadala Lakhshanas* and SCORAD INDEX. *Vataja Charmadala* was assessed based on the following Subjective and objective criteria.

**Table 2: Subjective criteria.**

	Parameter	score
<i>Kandu</i> (Itching)	No Itching	0
	Mild Itching (Present rarely/Episodic)	1
	Moderate Itching (Frequent itching or Disturbing patient's attention)	2
	Severe Itching (Continuous Itching or Disturbing patient's sleep)	3

Table 3: Objective criteria.

	Parameter	score
<i>Sphutana</i> (cracking)	No cracking of skin	0
	Mild cracking of skin (superficial skin cracking)	1
	Moderate cracking of skin (Superficial & deep skin cracking)	2
	Severe cracking of skin (Dominated by deep cracks)	3
<i>Parushata</i> (dryness)	No dryness /smooth	0
	Mild dryness (Slightly dry skin ,occasional scaling)	1
	Moderate dryness (fairly and uniformly distributed scaling)	2
	Severe dryness (pronounced scaling visible with naked eye)	3
<i>Syavatha</i> (blackish discolouration)	Normal skin colour	0
	Brownish red discolouration	1
	Blackish red discolouration	2
	Blackish discolouration	3

Figure 1: SCORAD Index. [13]

The figure displays the SCORAD Index assessment form. It includes two body diagrams for extent evaluation, a table for criteria and intensity, and visual analog scales for pruritus and sleep loss.

Figures in parenthesis for children under two years

A: EXTENT Please indicate the area involved

B: INTENSITY

C: SUBJECTIVE SYMPTOMS PRURITUS + SLEEP LOSS

**A/5 + 7B/2 + C**

CRITERIA	INTENSITY
Erythema	
Oedema/Papulation	
Oozing/crust	
Excoriation	
Lichenification	
Dryness*	

\* Dryness is evaluated on uninvolved areas

MEANS OF CALCULATION  
INTENSITY ITEMS (average representative area)  
0 = absence  
1 = mild  
2 = moderate  
3 = severe

Visual analog scale (average for the last 3 days or nights)

PRURITUS (0 to 10)  0 10

SLEEP LOSS (0 to 10)  0 10

## STATISTICAL ANALYSIS

Data from both groups were recorded on assessment and follow-up days. Statistical analysis was performed using SPSS version 20, with paired t-tests for within-group comparisons and unpaired t-tests for between-group comparisons. Results were interpreted based on mean values and p-values, with a significance level of  $p < 0.05$ .

## OBSERVATIONS

In the present study 5% of subjects were *Annada* and 25% *Ksheerannada*. The higher incidence in *Annada Avastha* may be due to more outdoor exposure, sensitive skin, and less immune development. *Ksheerannada* children have lower incidence likely due to less exposure and better skin care. The most common sites of involvement were *Hasta* (77.5%), *Pada* (70%), *Mukha* (50%), *Anga sandhi* (40%), *Kati* (32.5%), and *Gala* (2.5%). No subjects had *Vrushanantara* involvement. The distribution of the lesions depend on the age of presentation. Since most of the subjects enrolled in the study were in childhood phase of AD, most of the lesions were observed on the flexors of elbows and knees and extremities. 85% had a history of recurrent upper respiratory infections, 45% recurrent skin diseases, and 12.5% recurrent lower respiratory infections. 47.5% had a positive family history of asthma, 37.5% allergic rhinitis, and 15% persistent dermatitis. Asthma, Allergic rhinitis and AD are the heterogenous presentations of the same allergic disease and are categorized as atopic diseases. They run in families and has been rightly identified as *Kulaja Nidana* for *Charmadala* by *Acharya Kashyapa*. *Beejabhaga Avayava Dushti* of *Rasa Dhatu* and *Rasatmaka Ojus* combinely pre disposed the individuals to *Tamaka Shwasa*, *Vataja Pratishtyaya* and *Charmadala* like conditions. *Vataja Stanyadushti* was observed in all mothers (100%) of *Ksheerannada Balaka*. *Jala Pareeksha* of *Stanya* showed the scattering of *Stanya* over the surface of water. In the present study, 72.5 % of subjects were having disturbed sleep, 27.5 % of subjects were having a sound sleep pattern. Intense pruritis was observed in 72.5% of subjects, which increased during night leading to sleep disturbances. 27.5% subjects had mild pruritis and thus had no sleep disturbances.

## RESULTS

**Table 4: Comparison of Parameters within the groups.**

Parameter	Group	N	Mean B.T	Mean 7 <sup>th</sup> day	S.D	P value	Mean 14 <sup>th</sup> day	S.D	P value	Mean 21 <sup>st</sup> day	S.D	P value
Parushata	A	20	2.85	1.95	0.30	0.001	1.25	0.50	0.001	0.90	0.68	0.001
	B	20	2.95	1.90	0.22	0.001	1.15	0.52	0.001	0.65	0.47	0.001
Kandu	A	20	2.60	1.65	0.224	0.001	1.3	0.470	0.001	0.50	0.44	0.001
	B	20	2.55	1.50	0.224	0.001	1.6	0.598	0.001	0.20	0.48	0.001
Insomnia	A	20	2.85	2.10	0.71	0.001	1.25	1.536	0.001	2.85	1.97	0.001
	B	20	2.35	1.40	0.88	0.001	0.85	1.357	0.001	2.35	1.98	0.001
Sphutana	A	20	1.80	0.95	0.36	0.001	0.55	0.55	0.001	1.80	0.73	0.001
	B	20	2.50	1.45	0.22	0.001	0.80	0.57	0.001	2.50	0.63	0.001
Excoriation	A	20	1.80	0.95	0.36	0.001	0.55	0.55	0.001	0.10	0.73	0.001
	B	20	2.50	1.45	0.22	0.001	0.80	0.57	0.001	0.25	0.63	0.001
Shyavata	A	20	2.45	1.60	0.36	0.001	0.95	0.51	0.001	0.50	0.51	0.001

	B	20	2.30	1.50	0.41	0.001	0.80	0.51	0.001	0.20	0.55	0.001
Extent	A	20	8.67	6.94	2.44	0.005	3.94	4.28	0.001	1.54	5.51	0.001
	B	20	6.89	5.27	1.81	0.001	3.79	3.40	0.001	0.94	4.59	0.001
SCORAD Index score	A	20	34.10	23.76	3.11	0.001	14.29	6.18	0.001	6.54	8.32	0.001
	B	20	34.81	22.92	3.06	0.001	12.66	5.51	0.001	5.04	7.67	0.001

Table 5: Comparison of parameters between the group.

Parameter	Group	N	BT	SD	P value	Mean-7 <sup>th</sup> day	SD	P value	Mean-14 <sup>th</sup> day	SD	P value	Mean-21 <sup>st</sup> day	SD	P value
Parushata	A	20	2.85	0.36	0.034	1.95	0.39	0.91	1.25	0.44	0.70	0.90	0.55	0.33
	B	20	2.95	0.22	0.034	1.90	0.30	0.91	1.15	0.48	0.70	0.65	0.48	0.33
Kandu	A	20	2.60	0.50	0.55	1.65	0.58	0.71	1.30	0.67	0.00	0.50	0.60	0.004
	B	20	2.55	0.51	0.55	1.50	0.51	0.71	0.95	0.22	0.00	0.20	0.41	0.004
Insomnia	A	20	2.85	2.58	0.79	2.10	2.10	0.32	1.25	1.41	0.32	0.60	1.09	0.026
	B	20	2.47	2.24	0.79	1.40	1.53	0.32	0.85	1.13	0.32	0.20	0.52	0.026
Sphutana	A	20	1.80	0.76	0.87	0.95	0.68	0.31	0.55	0.51	0.20	0.10	0.30	0.012
	B	20	2.50	0.68	0.87	1.45	0.68	0.31	0.80	0.52	0.20	0.25	0.44	0.012
Excoriation	A	20	1.80	0.76	0.87	0.95	0.68	0.31	0.55	0.51	0.20	0.10	0.30	0.012
	B	20	2.50	0.68	0.87	1.45	0.68	0.31	0.80	0.52	0.20	0.25	0.44	0.01
Shyavata	A	20	2.45	0.51	0.93	1.60	0.50	0.37	0.95	0.51	0.74	0.50	0.51	0.002
	B	20	2.30	0.57	0.93	1.50	0.51	0.37	0.80	0.41	0.74	0.20	0.41	0.02
Extent	A	20	8.67	5.97	0.44	6.94	4.15	0.62	3.94	2.50	0.65	1.54	1.77	0.29
	B	20	6.89	4.97	0.44	5.27	3.75	0.62	3.05	2.59	0.65	0.94	1.54	0.29
SCORAD Index score	A	20	34.10	10.99	0.11	23.76	9.66	0.04	14.2	6.86	0.32	6.94	5.99	0.27
	B	20	34.81	10.99	0.11	23.76	9.66	0.04	14.29	6.86	0.32	5.04	3.95	0.27

## DISCUSSION

**Effect of Pugadi Ksheerapaka and Panchatiktaka Ghrita on Dryness** -Both *Pugadi Ksheerapaka* and *Panchatiktaka Ghrita* significantly reduced skin dryness in both groups on the 7th, 14th, and 21st days (P value 0.001). In atopic dermatitis, skin dryness occurs due to reduced hydration and lipids, particularly ceramides. In the trial group, the *Snigda Guna* of *Palasha* and *Ksheera* helped restore skin hydration by improving lipid function and reducing water loss. In the control group, *Guduchi's Snigda Guna* maintained skin integrity. The effect was more sustained in group B, as the *Ghrita*-based preparation had longer contact with the skin and is considered more nourishing than *Ksheera*.

### *Parushata*

Within group A and group B there was statistically highly significant reduction in *Parushata* with P value 0.001. *Twak Parushata*, caused by dryness and buildup of dead skin cells, is alleviated by moisturizing and gentle exfoliating treatments. *Pugadi Ksheera*, with *Rasna* and *Patala* for inflammation reduction and *Puga* and *Palasha* for wound healing, likely exfoliates and restores moisture through the *Snigda Guna* of *Ksheera*. *Panchatiktaka Ghrita*, with its

*Vranahara* herbs in a *Ghrita* base, provides mild exfoliation and nourishment, reducing roughness. Both preparations effectively reduce dryness and roughness, counteracting the Vata dosha's qualities with *Snigdhatta* and *Shlakshnata*.

### **Kandu / Pruritis**

Both *Pugadi Ksheerapaka* and *Panchatiktaka Ghrita* significantly reduced *Kandu* in the study, with a highly significant P value of 0.001. Pruritis in Atopic Dermatitis is linked to nerve sensitization and inflammation. The lipid-based formulations, rich in ceramides, help improve skin barrier function and reduce irritation. *Pugadi Ksheerapaka*, with its *Shothahara* and *Vranahara* properties, effectively suppresses inflammation, while *Panchatiktaka Ghrita*, containing similar anti-inflammatory ingredients, also reduces pruritis.

### **Insomnia**

Both *Pugadi Ksheerapaka* and *Panchatiktaka Ghrita* showed a statistically significant reduction in insomnia (P value 0.001), indicating their effectiveness in improving sleep. In Atopic Dermatitis, Insomnia severity is closely linked to pruritis, and the reduction in pruritis in both groups led to improved sleep. Group B, which received *Panchatiktaka Ghrita*, showed better results in reducing insomnia due to the prolonged contact time of the formulation on the skin, providing continued relief from pruritis.

### **Sphutana / Excoriation**

Both groups showed a statistically significant reduction in *Sphutana*/Excoriation (P value 0.001), indicating their effectiveness in healing excoriations due to their *Vranahara* properties. The effective control of pruritis also helped prevent the appearance of new excoriations. When comparing the two groups, Group A showed more significant results in reducing *Sphutana*. In *Pugadi Ksheerapaka*, *Puga*, *Patala* and *Rasna* due to its *Ruksha guna*, *Palasha* due to its *Vranahara*, *Krimihara*, *Kushtaghna* and *Sandhana* properties, has helped in the fast healing of the excoriations by enhancing granulation process and wound contraction. Probably *Seka* as a procedure had better effect on regeneration of *Twak* as compared to *Lepa*.

### **Shyavata**

Within group A and group B there was statistically highly significant reduction in *Shyavata* on 7th day, 14th day and 21st day with P value 0.001. The hyperpigmentations observed at the sites of skin lesions were mostly *Shyava* and *Aruna Varna*. They are post inflammatory

hyper pigmentations occurring as a result of damage to the epidermis and deposition of melanin within the keratinocytes.

Both *Pugadi Ksheera* and *Panchatikta Ghrita* were effective in reducing *Shyavata* and *Aruna Varna* as they were able to suppress the *Prakupita Vata* and *Pitta*. In Group A, *Ksheera* had *Varnya* property and in Group B, *Patola* and *Ghrita* both had *Varnya* properties, also *Panchatikta Ghrita* was used as *Lepa*, *Lepana* having a greater effect on pigmentation. Thus Group B was more effective in establishing normal pigmentation than Group A. Of course, both the groups could suppress the underlying inflammatory process effectively and thereby prevent melanosis.

**Extent of the skin lesions-** Extent of the skin lesions were assessed based on the rule of nine in the SCORAD index. The extent of the lesions shows the parts of the body involved and not the size of the lesions. There was statistically significant reduction in extent within group A and group B with p value 0.005. On comparing both the groups, there was similar effect on extent of lesions, where in fading up of lesions and reduction in the number of lesions was observed. But the area wise complete disappearance of lesions was not observed. This shows that both the groups initiated the anti inflammatory response but required more than 21 days for complete healing of the lesions.

**Effect on SCORAD index-** There was statistically highly significant reduction in total SCORAD Score in both the groups with a P value of 0.001 which indicates that both interventions were effective in reducing the clinical features of AD and related to *Vataja Charmala*. SCORAD index includes extent and intensity of lesions along with Subjective symptoms like Pruritis and Insomnia. Though both the groups had similar effect on extent of lesions, Group B fared well in reducing the intensity of lesions and subjective symptoms. Intensity of the lesions like erythema, papules, excoriations and dryness reduced in both groups as both groups had a lipid medium suppressing inflammation. Group B has *Ghrita* which is *Uttama Sneha* as compared to *Ksheera*. Also *Ghrita* has a special property of acquiring the properties of drugs with which it is processed without losing its own properties. With all these properties *Panchatikta ghrita* was more effective in establishing the lost lipid matrix in skin, preventing transepidermal water loss and finally re establishing the skin integrity as compared to *Pugadi Ksheerapaka*. The *Snigda Guna*, *Varnya*, *Twachya* properties of *Ghrita* were enhanced by the drugs with which it was processed. The subjective symptoms

i.e pruritis and insomnia were relative symptoms, the reduction in intensity of lesions had a direct bearing on reduction of pruritis and insomnia and was better seen in group B subjects.

### **Propable mode of action of *Seka* and *Lepa***

*Seka* and *Lepa* are categorized under *Bahya Parimarjana Chikitsa*, the route of administration being the *Twak*. The medicaments administered through *Twak* are subjected to *Paka* by *Bhrajaka Pitta* present in *Avabhasini* layer of *Twak* i.e the most superficial layer of skin.<sup>[14]</sup> Further these drugs are absorbed in to circulation by the *Tiryakgata Dhamanis* which are situated under the skin.<sup>[15]</sup> Drugs administered through this route do not undergo *Avasthapaka*, but are subjected to *Dhatvagnipaka*. Thus *Guna* and *Prabhava* of the drugs play an important role in these modalities of treatment.

*Seka*, one of the *Bahya Chikitsas* has both *Snehana* and *Swedana Karma* when it is performed with *Ksheera*, *Taila* etc *Dravyas*.

*Snehana* is achieved by the lipid base of medicament used for the procedure and *Swedana* is achieved by the method of doing the procedure. Extent of *Snehana* achieved depends upon the concentration and type of lipids present in the drug. The medicament is taken in the *Sukhoshna* form and dropped over the skin with a particular technique. *Seka* has a good *Swedana* effect. The *Swedavaha Sroto Dushti* involves *Aswedana* and *Parushya* which are well evident in *Vataja Charmadala*. *Swedana* procedure has helped in relieving the *Sanga* of *Swedavaha Srotas*, increasing *Swedana* there by bringing *Kledata* and *Mardavata* of *Twak*. This helped in *Deepana* of *Bhrajaka Pitta* and enhancing *Pachana Karma*. It also helped in enhancing the absorption of drug by *Twakgata Dhamanis* by doing *Srotoshodhana*. Thus *Ksheera* as a medium, with drugs processed in it and *Seka* as a procedure collectively helped in doing *Twak Shodhana*, *Ropana* and *Prasadana*.

The stratum corneum acts as a barrier to drug penetration, with tightly packed hydrophilic and lipophilic layers. After application, active molecules must partition and diffuse through it, choosing intercellular, intracellular, or transappendageal pathways based on their characteristics. Stratum corneum being lipid rich in nature, the drug with lipophilic character is easily absorbed through intercellular pathway which is the main pathway for any molecule. Thus Panchatiktaka Ghrita, being lipophilic due to its Ghrita content, helps active molecules penetrate the stratum corneum more easily. The lipophilic components form an occlusive

layer on the skin, preventing water loss and enhancing the hydration of the stratum corneum, which in turn improves the penetration of active substances.<sup>[16]</sup>

In this study, both Pugadi Ksheera Seka and Pancha Tiktaka Ghrita Lepa, using a lipid-based medium, increased stratum corneum hydration by restoring the altered lipid mechanisms involved in Atopic dermatitis. They also improved the barrier lamellar lipid content in the epidermis and may support the natural moisturizing factor, which helps retain water in corneocytes and prevent trans epidermal water loss, thereby enhancing skin barrier integrity.

The combination of drugs in both treatments effectively reduced the vitiated *Vata Dosha*, alleviating symptoms of *Vataja Charmadala*.

## CONCLUSION

The present clinical study was aimed to evaluate the effect of *Pugadi Ksheera Seka* and *Panchatiktaka Ghrita* in the management of *Vataja Charamadala* w.s.r to Atopic dermatitis in children of 1-5 years. *Charmadala* is explained by *Kashyapa* in detail with the specific *Nidana Panchaka* is a separate chapter unlike the other Samhitas which enumerate it under *Kshudra kushta*. *Kashyapokta charmadala* is typical to the childhood age, is an *Utapata roga*, *Stanya dushti* is the important cause along with other environmental factors which present with clinical features similar to allergic manifestations of skin. Thus *Kashyapokta Charmadala* was compared to Atopic dermatitis. clinical features of *Vataja Charmadala* closely resembles the features of Sub acute AD and to some extent the acute AD.

*Bahihparimarjana Chikitsa* plays an important role in the treatment of *Twak Vikaras*. In *Vataja Twak Vikaras*, procedures which have *Snehana Swedana* and *Ropana* action are most preferred. *Lepa* and *Seka* are 2 such procedures which fulfil these criteria. When the *Ropana* drugs are taken in a *Snigdha* form like *Ghrita* or *Ksheera* and the procedures are carried out for a prescribed time, due to the effect of the drugs, the medium and the method of the treatment they collectively alleviate *Vataja Twak Vikara*. *Pugadi Ksheera* was used in the form of *Seka* and *Panchatiktaka Ghrita* in the form of *Lepa* and it was effective in reducing the symptoms of *Charmadala*. *Pugadi Ksheera* was more effective in reducing *Sphutana* of *Twak* and Size of the lesions, *Panchatiktaka Ghrita* was rather effective in reducing *Rookshata*, *Kandu*, *Anidra* and *Shyava Varna* of *Twak*. Both groups were equally effective in reducing *Parushata*. With respect to SCORAD Index, both groups were equally effective in reducing the extent of lesions, Group B showed better results in reducing the intensity of

lesions like dryness, erythema, papules and excoriation and Subjective symptoms like pruritis and insomnia. On comparing both the groups, *Panchatikta ghrita lepa* showed statistically better results in reducing the symptoms of *Vataja Charmdala* than *Pugadi Ksheera*. *Panchatikta ghrita* has a lipid base when used in the form of *Lepa* due to its lipophilic nature and the ability to produce Physical occlusion has given better results when comparing to *Seka*. In this study, Null hypothesis is rejected and alternative hypothesis (H2) is accepted- ***Panchatiktaka Ghrita Lepa is more effective than Pugadi Ksheera Seka in Vataja Charmadala w. s. r to Atopic dermatitis.***

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