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The effect of *Kustahara Kashaya* with *Durvadya* Tail and Hydroxyzine HCl with Clobetasol propionate in Management of Atopic Dermatitis in Children- A Randomized Comparative Clinical Study

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ABSTRACT

BACKGROUND AND OBJECTIVES:

Atopic dermatitis is the most common chronic relapsing skin disease seen in children. It affects 10- 30% of children worldwide and frequently occurs in families with other atopic disease such as asthma, allergic rhinitis and food allergy.

Objective of the present study was to evaluate the effect of *Kustaharakashaya* tablet and *Durvadya* tail and comparing *Kustaharakashaya* Tablet and *Durvadyataila* with Hydroxyzine HCl with Clobetasol propionate.

METHODOLOGY:

40 patients fulfilling the inclusion criteria of atopic dermatitis were randomly selected and divided into two groups each group contains 20 patients, namely **Group A**-*Kustaharakashaya* tablet and *Durvadyatail*, **Group B** -Hydroxyzine HCl syrup and Clobetasol propionate ointment.

SOURCE OF THE DATA: Patients were randomly selected from outdoor patients of SJG AMC& Hospital, Koppal.

Clinical signs and symptoms were given suitable scores according to their severity and were assessed based on pre and post test data gathered through predesigned clinical research proforma. The results having 'p' value <0.05 were considered to be statistically significant in this study.



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RESULTS: Complete or Marked relief was not observed in any of the groups. Moderate response, 60% was noticed in Group A, where as in 57% was seen in Group B.

CONCLUSION: Based on observation and results concluded as trial drug i.e. *Kustaharakashaya Tablet with DurvadyaTaila* has a positive role in the management of Atopic Dermatitis in Children.

KEYWORDS

Atopic dermatitis, Kustahara kashaya tablets, Durvadyataila



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INTRODUCTION

Allergic dermatitis usually begins in infancy approximately 50% patients experiences symptoms in the 1st year of life and in additional 30% are diagnosed between 1 to 5 years of age. Children with Atopic dermatitis are predisposed to develop the subsequent allergic rhinitis and asthma later in childhood and this process is called 'The Atopic March'/Allergic March Which is common in genetically susceptible children for allergy. Scratching and excoriation cause increased skin inflammation that contributes to the development of more pronounced eczematous skin lesions, which may lead to lichenification¹. Hence it may cause hardship to the child and family in terms of disfiguration and with sever itching, lichenification. As skin of the child differs greatly from adult skin which is tender, delicate and easily susceptible to infections as they are *sukumara* [delicate body parts] and also will have *asthiradhatus*[immature tissues]², hence they are more susceptible to allergy and infection because of that there is a need of early intervention to prevent the further progression of pathological conditions. There is no complete treatment available in allopathic science and symptomatically child may be treated with like hydrating the skin, anti inflammatory

topical corticosteroids along with oral administration of antihistamines, which may give short relief but recurrence may not be prevented and also may have some side effects. Hence there is need of research on the atopic for the study. Atopic dermatitis can be compared with *Vicharchika*, which is mentioned in *Ayurvedic* Classics. As clinical features of Atopic Dermatitis is more or less similar to that of *vicharchika*³ of *kustaprakarana*. Various treatments are mentioned in the *Ayurveda* in the form of *shodana* and *shamana* for *vicharchika* in *kustaprakarana*. Among various *shamanaoushadha* available in *Ayurvedic* Classics, in which *Kustaharakashaya* as an internal medication from *sahasrayoga*⁴ and *Dhurvadi tail* as an external application from *bhaisajyaratnavali*⁵ are selected to prove its effect on atopic dermatitis and for control group hydroxyzine as internal and Clobetolol propionate as external application are given. Hence an attempt made to evaluate the effect of *kustaharakashaya* and *dhurvadi tail* in the management of atopic dermatitis.

OBJECTIVES

1. To evaluate the effect of *Kustaharakashaya Tablet* and *DurvadyaTaila* in the management of Atopic Dermatitis in children.
2. To compare efficacy of



Kustaharakashaya Tablet and *DurvadyaTaila* with Hydroxyzine hydrochloride with Clobetasol propionate.

METHODOLOGY

STUDY DESIGN

(Table 1) Diagnosed 40 children's with atopic dermatitis were selected and divided into two groups randomly.

Table 1 Distribution of divided groups

Trial Group (Group A)	<i>Kustahara kashaya</i> tablet with <i>Durvadya taila</i> for 10 days.
Control Group (Group B)	Hydroxyzine HCl syrup with Clobetasol propionate ointment f or 10 days.

INCLUSION CRITERIA

1. Patients between the age of 1 year to 16 years of either sex are included.
2. Patients with clinical features of Atopic dermatitis.

EXCLUSION CRITERIA.

1. Atopic Dermatitis with other skin diseases like infective origin and autoimmune disorders like Psoriasis, Vitiligo and Pemphigus.

Table 2 Ingredients of *Kustahara Kashaya* Tablets

Sl no	Name	Botanical name	Quantity
1	Patola	Tricosanthes dioica	1 part
2	Triphala	Haritaki	Terminalia chebula
		Bibitaki	Terminalia bellerica
		Amalaki	Emblica officinalis
3	Nimba	Azadirachta indica	1 part
4	Guduchi	Tinospora cordifolia	1 part
5	Khadira	Acacia catechu	1 part
6	Vasa	Adhathoda vasica	1 part
7	Karanja	Pongamia pinnata	1 part

2. The drugs were mixed properly to get homogeneous mixture.

2. Patient with acute and chronic systemic disorders.

ASSESSMENT CRITERIA:

- A scoring schedule was prepared based on intensity of itching, intensity of redness, swelling, intensity of dryness, intensity of oozing, intensity of scratch mark, intensity of skin thickening and scoring was given initially and each successive visit.
- Scoring was given based on visual analogue scale that is SCORAD scale before treatment and also during and after treatment to see the outcome.

METHOD OF PREPARATION OF DRUG

METHOD OF PREPARATION OF KUSTAHARA KASHAYA:

1. Ingredients of *Kustaharakashaya* (Table-2 contains the ingredients of *kustaharakashaya*) were taken in equal quantity and made into coarse powder (*yavakutachurna*).

3. 8 parts of water was added in above mentioned coarse powder mixture and



boiled on mild fire & reduced it to 1/8th part and filtered to obtain *kashaya*.

4. The filtered *kashaya* was reheated on mild fire for 3 to 4 minutes till to get thread consistency as to prepare in the tablet form.

DURVADYA TAILA:

1. PREPARATION OF MURCHITA TILA TAILA⁷

➤ Raw drugs (Table 3) were taken and made in to coarse powder then soaked in the water and made into a kalk form.

Table 3 Drugs Used for Preparation of *Murchana* of *Tila Taila* are

Drugs	Composition
1 Haritaki	1/16 th part
2 Manjista	1/16 th part
3 Vibhitaki	1/16 th part
4 Amalaki	1/16 th part
5 Mustha	1/16 th part
6 Haridra	1/16 th part
7 Lodra	1/16 th part
8 Vtankura	1/16 th part
9 Harivera	1/16 th part
10 Nalika	1/16 th part
11 Ketakipushpa	1/16 th part
12 Tila taila	1 part
13 Jala	4 parts

➤ One part of *tilataila* was taken in a wide mouthed vessel and kept on a mandagni, then 4 parts of jala (water) and 4 parts of *kalka* were added one by one and cooked till *tailapakalakshana* were attained and finally prepared tail was filtered for usage.

2. PREPARATION OF DURVADYA TAILA⁸

In this process first prepared *murchita tila taila* was taken then *durva kalka*, *durva swarsa*, and water were added one by one in prescribed quantity (Table - 4) then it

was kept for boiling on mild to moderate fire untill *sneha siddalakshnas* obtained .

Then prepared *Durvadi Tail* was collected into clean and sterile container for dispense.

Table 4 Ingredients of *Durvadya Taila*

Sl no	Name	Quantity
1	Murchita tila taila	1 lit
2	Durva swarasa	4 lit
3	Water	4 lit
4	Durva kalka	250 mg

METHOD OF STUDY:

Fourty patients between the age group of 1-16yrs who have attended the *kaumarabhritya* OPD and IPD and during *Swarna prasana* of *Kaumarabhritya* Department, SJGAMC and Hospital, Koppal. With complaints of atopic dermatitis were selected for the study after following the criteria laid as above. Their age, sex, religion, socioeconomic status, food habits family history, *prakruthi* were noted.

Total 40 patients were taken for the study, complete history and clinical examination of all these patients were carried out and recorded in a specially designed proforma.

MODE OF ADMINISTRATION OF DRUG:

All patients were administered the drugs as follows,

GROUP A- 20 Children with Atopic Dermatitis were received trail drug (Table 5 contains internal and external medication its Age, Dosage, Anupana of drug).



GROUP B - 20 Children with Atopic Dermatitis received control drug (Table-6 contains internal and external medication its dosage).

Table 5 "Group A" Received Internal and External Medications

Sl no	Drugs	Age	Dosage
1	Kustahara kashaya tablet	1-5yrs	250mg tds
		6-10yrs	500mg tds
		11-16yrs	1gm tds
	Oushada kala Anupana		After food Madhu (quantity required)
	Durvadya taila		As quantity required, depending upon area of lesions. Twice a day.

Table 6 "Group B" Received Internal and External Medications.

Sl no	Drugs	Dosage
1	Hydroxyzine HCl	2mg/kg/day (after food)
2	Clobetasol propionate ointment	As quantity required, depending upon area of lesions,twice a day.

DURATION OF THE STUDY:

Treatment duration- 10 days

Follow up duration- 20 days after treatment.

Total study duration- 30 days.

ASSESSMENT OF RESULTS

Subjective parameters were assessed First day (base line), 10th day (end of treatment) and 30th day(i.e. on follow up) and data

obtained data was statistically tested by using Wilcoxon signed ranks test within the group and, Mann-Whitney U test between the groups.

SUBJECTIVE PARAMETERS

Scorad {scoring atopic dermatitis}⁹

INTENSITY (Figure 1) It contains symptoms of Atopic Dermatitis with grading.)



Figure 1 Symptoms of Atopic Dermatitis with their Grading.



A representative area of eczema is selected. In this area, the intensity of each of the following signs is assessed as none (0), mild (1), moderate (2) or severe (3).

- Redness
- Swelling
- Oozing
- Scratch marks
- Skin thickening
- Dryness
- Itching

RESULTS

Table 7 Effect of Treatment on Symptoms in each Group

Symptoms	Mean score					
	Group A			Group B		
	BT	AT	AF	BT	AT	AF
Itching	1.95	0.50	1.20	2.00	0.55	1.30
Redness	1.80	0.70	1.30	1.55	0.50	0.95
Dryness	1.85	1.05	1.40	1.75	0.65	1.10
Swelling	1.35	0.65	0.95	1.15	0.50	0.70
Oozing	1.00	0.35	0.50	0.90	0.55	0.75
Scratch mark	1.10	0.40	0.55	1.05	0.50	0.80
Skin thickening	1.15	0.40	0.60	1.50	0.50	0.80

[BT: BEFORE TREATMENT,AT: AFTER TREATMENT,AF: AFTER FOLLOW UP]

Table 8 Comparison of Symptoms between the Group

Symptoms	Mean score			
	Group A		Group B	
	AT	AF	AT	AF
Itching	0.50	1.20	0.55	1.30
Redness	0.70	1.30	0.50	0.95
Dryness	1.05	1.40	0.65	1.10
Swelling	0.65	0.95	0.50	0.70
Oozing	0.35	0.50	0.55	0.75
Scratch mark	0.40	0.55	0.50	0.80
Skin Thickening	0.40	0.60	0.50	0.80

In Group A 60 % moderate response was seen and In Group B 57% of moderate response was found ,which was not much significant statistically .

TABLE 7: EFFECT OF TREATMENT ON SYMPTOMS IN EACH GROUP

TABLE 8: COMPARISON OF SYMPTOMS BETWEEN THE GROUP

After the 10 days of treatment with *Kustaharakashaya* tablet internally and *Durvadyataila* externally there was considerable improvement was observed in the following clinical features like itching, redness, dryness, oozing ,scratch mark, skin thickening but recurrence was seen in some cases may be due to short duration of treatment.

DISCUSSION

There is significant reduction in the above symptoms like itching, redness, swelling,



dryness, oozing, scratch mark, skin thickening, after the treatment but reoccurrence of the above symptoms seen during the follow up period.

1) **KUSTAHARA KASHAYA TABLET:**

The formulation comprises of *Patola*, *Nimba*, *Khadira*, *Karanja*, *Triphala*, *Vasa*, *Guduchi*. As the *samprapti* tells about *agimandya & amotpatti* for that *deepana - pachana* drugs like *Nimba*, *Patola*, *Guduchi* would be beneficial and also by its *Tikta-Katurasa*, *ushnaveerya* properties will helps in removing the *ama* & thereby it removes *srotoavarodha*. Since *Kaphadosha* is responsible for itching, and here drugs like *kadhira*, *karanja*, *nimba* by its *kandughna*, *kaphagna*, *katu-tiktarasa*, *ushnavirya* properties they are best in *kanduhara* and *kaphahara* hence may be reduction in itching was seen in trail group. *Vaasa* is having *kashaya rasa*, which is responsible for *kledashoshaka* (hygroscopic nature) & enhances *rookshata* because of these properties oozing may be subsided. *Patola* is best *rechaka* and *sodhaka* may be helpful in expelling of morbid *doshas*.

Guduchi, *haritaki*, *amalaki* are known for its *Rasayana* property there by it boosts the immune system through which the immunity of the child can be improved & hence attack of disease can be reduced. *Haritaki* & *patola* are having *mrudu*

rechaka property which leads to reduction in inflammation, erythema because of elimination of *vitiated pitta*. By its anti-inflammatory property of *patola*, *nimba*, *guduchi*, *amalaki* may reduces the inflammation. In the past research Antioxidant¹⁰ property of *nimba*, *guduchi*, *amalaki* were proved that, these drugs prevent the oxidative stress within the cell and there by reduction in inflammatory process which leads reduction in pain ,itching .

Anti allergic¹¹ property of *guduchi* was proved its inhibitory activity on arachidonic acid metabolism as it was the triggering factor for mast cell stimulation during allergen exposure.

2. **DURVADYA TAILA**

Application of *taila* on lesions is *stanika chikitsa* and its effectiveness lies in the facts that it helps in *lakshana upashamana* and also external application is always convenient for children. The topical application of tail has the advantage of targeting drug on local tissues. There is high drug concentration near the tissue and high flux through the membrane is thus achieved. Application of *tail* on wound helps the medicine to remain at the site for a longer period for better actions. It performs the action with the help of the drug's use in the preparations of *tail*. It diminishes the chances of infections ad it is



vrunaropaka and used for *snehanartha* of the lesion.

For this reason as external application of *durvadyataila* is selected. *Durvadyataila* contains *murchitatilataila*, *durvaswarasa*, *durvakalka*, among the ingredients *durva* is having *kashaya*, *madhurarasa*, *madhuravipaka* that provides nourishment to skin and also possesses *vrunaropana* & *vishaghna*, *dahaprashamana* properties. By *stambana*, *raktashodaka* stops oozing and also acts on *pitta* as disease is predominated with *pitta*. *Madura rasa*, *sheetavirya*, *pitta shamaka*, *reducesdaha*, *raga*, and increases the skin complexions. By its *kashaya rasa sheetavirya acts on kaphapittashamaka* which leads to reduction in it. *Durva* enhances immune system it contains CPDF (Cynodon Dactylon Protein fraction) which exert immunomodulatory activity that helps in optimizing the immune system by its anti inflammatory & antiseptic agent widely used to reduce itching, redness in atopic dermatitis. *Tila taila* by its *vatahara*, *vrunashodana*, *lekhaniya* property removes cell debris at local site improves cell granulations.

CONCLUSION

Though Atopic Dermatitis is a chronic relapsing condition, here early reduction in

clinical features were seen after the treatment but recurrence of symptoms were observed in many cases may be due short duration. Finally it can be concluded that *Kustahara Kashaya tablet with Durvadya Taila* will be safe and had a positive role in the management of atopic dermatitis in children.



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