



# COMBINED EFFECT OF MAKKIPOOVADI KASHAYA INTERNALLY AND ARAGVADHADI KSHALANA IN “ATOPIC DERMATITIS”

<sup>1</sup>Dr. Arathi G, <sup>2</sup> Dr. Anilkumar M. V

\*<sup>1</sup> Assistant Professor, Department of Kaumarabhritya, Ahalia Ayurveda Medical College, Palakkad.

\*<sup>2</sup> Professor & head, Department of Kaumarabhritya, Govt Ayurveda College, Trivandrum.

## ABSTRACT

Atopic dermatitis (AD) is an acute, sub acute or chronic relapsing, endogenous eczema, characterized by pruritis, recurrent, symmetric dermatitis lesions. Scratching leads to redness, swelling, cracking, exudation, and crusting. In Ayurveda it was included under spectrum of *kaphapithavisarpa* (type of skin lesion) in the initial stage. *Makkipoovadi Kashaya* is mentioned in the context of *Akakarappan chikitsa* in *Vaidyatharaka* and *Aragvadhalepa* is mentioned in *Chakradatha Kushta chikitsa prakarana*. By considering nature of disease, *lepa yoga* (paste) is modified into *kashaya* (decoction) form for *kshalana* (cleaning) purpose. Children of the age group of 1-6 years with acute stage of Atopic dermatitis attending the OPD of *Kaumarabhritya* (pediatrics), Government Ayurveda College, Thiruvananthapuram were selected for the study by using Hanifin & Rajka's criteria for the diagnosis of Atopic Dermatitis. They were categorized into 2 age groups, 1-3 years and 4-6 years. Orally *Makkipoovadi Kashaya* was given and for cleaning the affected area, *Aragvadhadi kshalana* was advised. Medication was advised for 2 weeks. Changes in the values of SCORAD index were checked before, after treatment and after follow up period of 2 weeks. Comparison of Qualitative variables were analysed using Friedman's Anova and conclusion were drawn. Before treatment- after treatment and after treatment- after follow up comparison was also done using statistical tests like paired t test & wilcoxon signed rank test. Statistically significant responses of the entire variable proved that internal use of *Makkipoovadi Kashaya* and simultaneous external use of *Aragvadhadi kashaya* are found to be effective in acute stage of AD in children.

Keywords: Atopic dermatitis, *Kapha pitha visarpa*, *Makkipoovadi Kashaya*, *Aragvadhadi kshalana*

## I. INTRODUCTION

Skin is the largest organ present in the human body and constantly exposed to external environment. The skin protects us from microbes, helps to regulate body temperature and permits the sensation of touch, heat and cold. It plays an important role in normal well being of a person<sup>[1]</sup>. Any ailment in the skin causes great misery to the person because of its visibility. Atopic dermatitis (AD) is a chronic, highly pruritic inflammatory skin disease, and it is one of the most common skin disorder in children<sup>[2]</sup>. It is a complex disease with a wide spectrum of clinical presentations and combination of symptoms. AD affects up to 10% to 20% of the world's population. Among them it affects 5-15% of school children and 2-10% of adult. It constitutes 28-46% of the total pediatric skin diseases. The current prevalence of AD is estimated to be 10% -15.6%<sup>[3]</sup>.

Current evidence suggests that AD is due to primary skin barrier defect and that facilitates the development of other atopic conditions. In fact, AD is often the first step in “atopic march” (the sequential development of allergic disease manifestations during early childhood), which leads to asthma or allergic rhinitis in the majority of afflicted patients. AD may also consider as a causative factor for the development of food allergy. Newer

insights into AD suggest that both structural abnormalities of the skin as well as immune dysregulation play an important role in the pathophysiology of the disease<sup>[4]</sup>.

Traditionally, Atopic dermatitis was considered as an allergic disease of childhood, but it is now well-established that non-allergic forms of AD also exists and patients have been subdivided into those with atopy and without atopy. Furthermore, genetic research in the field of AD in last decade has led to a paradigm shift in understanding the etiology of atopic dermatitis, from being considered primarily an allergic/immunological disorder to understanding the additional importance of skin barrier dysfunction<sup>[5]</sup>. Therefore, the management of AD requires a multifaceted approach aimed at healing and protecting the skin barrier and addressing the complex immune pathogenesis of the disease

Medicines, commonly used to treat Atopic dermatitis are topical cortico steroids. long-term use of TCSs, particularly those from high potency groups results, side effects such as permanent telangiectasia, skin atrophy, stretch marks, hypertrichosis, depigmentation, perioral dermatitis, acne rosacea, bacterial or fungal infections, withdrawal effects, as well as tachyphylaxis. Longterm application of strong TCSs in children causes undesirable systemic symptoms such as inhibition of the hypothalamic-pituitary-adrenal axis, growth retardation and osteoporosis<sup>[6]</sup>.

It is the need of the hour to standardize and validate the effects of Ayurvedic formulations commonly used in pediatric dermatology practice. *Makkipoovadikashaya* (decoction) and *Aragvadhikashaya kshalana* (cleaning affected area) are the best formulations recommended for both internal and external use. In Ayurveda AD can be included under spectrum of *kaphapitha visarpa* (type of skin disease) in the initial stage<sup>[7]</sup>. In *Arogyakalpadruma* (an authentic Ayurveda text book) “*Karappan*” (type of skin disease) is the term used for *visarpa* in general. *Makkipoovadikashaya* is mentioned for *Akakarappan chikitsa* (pediatric skin disease) in the Malayalam textbook *Vaidyatharaka*<sup>[8]</sup>. Indications of *Makkipoovadikashaya* are *akakarappan*, fever and cough. *Aragvadhilepa* (medicated paste) is mentioned in *Chakradatha* (Ayurvedic textbook) *kushta chikitsa prakarana* (chapter containing treatment of skin disease)<sup>[9]</sup>. By considering nature of disease *lepayoga* (ointment) is modified into *kashaya* (decoction) form for *kshalana* (cleaning) purpose. Drugs contained in these *yogas* (medicines) pacify *kaphapitha* and *kaphavata doshas*. A study was designed with *Makkipoovadi kashaya* internally and *Aragvadhadi kashaya* externally to know its effectiveness in acute stage of Atopic dermatitis.

## II. MATERIAL AND METHODS

### Study design

Interventional model Single group, pre, post and follow up study

### Study setting

OPD of *Kaumarabritya*, Govt Ayurveda college hospital for women and children, Trivandrum

### Study duration

Duration of study was 14 days; follow up was done after 14 days.

### Study period

The duration of entire study including the literary evaluation was 18 months

### Sample size

30 Children affected with atopic dermatitis were selected for the study

### Inclusion Criteria

Children of 1-6 years with clinical signs and symptoms of acute atopic dermatitis irrespective of sex were included in the study.

### Exclusion Criteria

- Chronic cases of atopic dermatitis, with lichenification.
- Have received topical immune modulators, oral corticosteroids, or any other medication 2 weeks prior to study initiation.

- Have presence of major medical illness requiring systemic therapy

### Method of preparation of Drug

#### ▪ *Makkipoovadi Kashaya*

*Makkipoovadi Kashaya* contains following drugs. The Sanskrit names, Botanical name, quantity of drugs in the present study are given in table below.

**Table no: 1 Ingredients of Makkipoovadi Kashaya**

| Sl. No. | Sanskrit Name          | Botanical name                   | Family           | Useful part      | Quantity of drugs |
|---------|------------------------|----------------------------------|------------------|------------------|-------------------|
| 1.      | <i>Makkipoovu</i>      | Artemisia nilagirica             | Asteraceae       | Flowering tops   | 450 gm            |
| 2.      | <i>Maasikka</i>        | Quercus infectoria Oliv          | Fagaceae         | Gall             | 450 gm            |
| 3.      | <i>Malli</i>           | Coriandrum sativum Linn          | Umbelliferae     | Fruits           | 450 gm            |
| 4.      | <i>Jatikka</i>         | Myristica fragrans Houtt         | Myristicaceae    | Seed             | 450 gm            |
| 5.      | <i>Pulladi</i>         | Adiantum lunulatum Burm          | Polypodiaceae    | Whole plant      | 450 gm            |
| 6.      | <i>Katuka</i>          | Picrorhiza kurroa Royle ex Benth | Scrophulariaceae | Root, Rhizome    | 450 gm            |
| 7.      | <i>Tulasipatram</i>    | Ocimum sanctum Linn              | Lamiaceae        | Leaf             | 450 gm            |
| 8.      | <i>Kadukkathodu</i>    | Terminalia Chebula Retz          | Combretaceae     | Dried fruit rind | 450 gm            |
| 9.      | <i>Tippali</i>         | Piper longum Linn                | Piperaceae       | Fruit            | 450 gm            |
| 10.     | <i>Jeeraka</i>         | Cuminum cyminum Linn             | Umbelliferae     | Fruits           | 450 gm            |
| 11.     | <i>Krishna jeeraka</i> | Carum carvi Linn                 | Umbelliferae     | Fruits           | 450 gm            |
| 12.     | <i>Veluthulli</i>      | Allium sativum Linn              | Liliaceae        | Bulb             | 450 gm            |
| 13.     | <i>Plavila njettu</i>  | Artocarpus heterophyllus Lamk    | Moraceae         | Leaves stalk     | 450 gm            |
| 14.     | <i>Mavila njettu</i>   | Mangifera indica Linn            | Anacardaceae     | Leaves stalk     | 450 gm            |

In order to prepare *kashaya* (decoction) coarse powder of ingredients are required. All drugs are taken in the quantity of 450 gram each. Collected drugs were washed, cleaned and dried in sunlight and then powdered well in a micro pulverizer. Final product weighed around 6.5 kg. The powder was packed in a tightly closed container to protect contents from extraneous matter, loss of material, efflorescence, deliquescence and evaporation under normal condition of handling and storage. Powder is packed into 210 gram container for use.

#### ▪ *Aragvadhadi Kshalana*

*Aragvadhadi Kshalana* contains following drugs. The Sanskrit names, Botanical name, Quantity of drugs in the present study are given in table below.

Table no: 2 Ingredients of Aragvadhadi Kshalana

| Sl No | Drug               | Botanical Name        | Family          | Useful part               | Quantity of drugs |
|-------|--------------------|-----------------------|-----------------|---------------------------|-------------------|
| 1     | <i>Aragvada</i>    | Cassia fistula Linn   | Caesalpinoideae | Root bark                 | 2.5 kg            |
| 2     | <i>Chakramarda</i> | Cassia tora Linn      | Caesalpiniaceae | Leaves, Seeds, Root       | 2.5 kg            |
| 3     | <i>Karanja</i>     | Pongamia pinnata Linn | Fabaceae        | Bark                      | 2.5 kg            |
| 4     | <i>Vasa</i>        | Adhatoda vasica Nees  | Acanthaceae     | Leaves, Root, Flower      | 2.5 kg            |
| 5     | <i>Guduchi</i>     | Tinospora cordifolia  | Menispermaceae  | Leaves, Stem, Areal roots | 2.5 kg            |
| 6     | <i>Madanam</i>     | Randia dumetorum      | Rubiaceae       | Fruits                    | 2.5 kg            |
| 7     | <i>Haridra</i>     | Curcuma longa Linn    | Zinzeberceae    | Rhizome                   | 2.5 kg            |

The ingredients like *Aragvadhadi*, *Chakramarda*, *Karanja*, *Vasa*, *Guduchi*, *Madana*, *Haridra* were powdered together in micro pulverizer and sieved to obtain very fine powder. Final product weighed around 17.5 Kg and was packed into 580 gm container for use.

### Research technique and tool

A clinical proforma was designed to collect the details of disease and children suffering from acute stage of atopic dermatitis were selected to the study by using Hanifin & Rajka's criteria for diagnosis of Atopic dermatitis [10]. Assessment scale SCORAD (Scoring Atopic Dermatitis) is used for the clinical assessment of signs and symptoms before treatment, after treatment and after follow up period [11]

### Treatment Schedule

Duration of treatment is 14 days. As per the recommendation of *Acharya sarngadhara* the dose of *Makkipoovadikashaya* was fixed as follows, in the age group 1 – 3 years: 6 ml Bd before food; in the age group 4- 6 years 15 ml Bd before food. Ingredients of *AragvadhadiLepa* are made into *kshalana* (washing) form for cleaning the affected skin region. 48 gram *Aragvadhadi choorna* is boiled in 2 Litres of water and advised to clean the area twice daily morning and evening.

### Assessment criteria

SCORAD INDEX was used as assessment criteria which include data related to skin lesions, its duration, type/nature of lesion (Macule/Papule/Vesicle/Pustule), site of lesions, number of lesions, nature of onset, and its pattern.

### Statistical analysis

- Clinical assessment was done in all the children before, after treatment and after follow up using SCORAD Index.
- After that outcome was statistically analyzed using Fried man Anova test.
- Before, after treatment/ after treatment and after follow up comparison were done with paired t test and wilcoxon signed rank test

### III. OBSERVATION

**Age:** A total of 30 children were included in the study. Age distributions of patients were compared. Study showed that 60 % were belonging to the age group of 1-3 years and 40 % were from 3-6years of age group. As

atopic dermatitis is very common below 5 years of age, the study also showed maximum number of patients in 1-3 years of age group.

The most common question regarding AD is why it is manifesting more in children. Prevalence study proved that AD affects 5% - 15 % in school children and 2- 10 % in adults. Onset of disease is most common by the age of 5 years, with the highest incidence occurring between the ages of 3 to 6 months. Weaning is considered as a risk factor for developing AD. When baby is only a few months old, he or she goes from consuming exclusively breast milk or formula feeds to solid foods. Making the change involves a process called weaning. Weaning is recommended at 4 – 6 months of age. In this study it is clear that peak age for onset of AD is up to 2 years of age. This proved that weaning is a risk factor to develop AD in infants. Baby who had AD in their first 6- 8 months is more likely to have an allergy to one or more foods. As allergy is the most common cause for developing AD, allergic sensitization can occur in infant during period of weaning due to introduction of solid foods. This is the reason for highest incidence of AD in children. Breast feeding has many physiological and psychological benefits in both mother and infant. Exclusive breast feeding for at least 4 – 6 month can prevent allergic diseases and reduces the risk for childhood AD and delays the onset of allergic march. Prolonged breast feeding reduces the risk of developing allergic disease even in the presence of maternal allergy. It is proved that 65% of patient develops symptom in the first year of life and 90% develop symptoms before the age of 5. The present study showed that 66.6% developed the symptom at 0-2 year of age group, 26.6 % developed at 2-4 years and 6.6 % at 4- 6 years of age group which had given the relevance to particular study.

**Allergy** In the study 56.6 % showed no significant past history of allergy, this might be because of small sample size and lack of awareness to know the particular allergen factor. Remaining patients showed specific history to dust, beef, egg, milk products, peanut, sea foods etc. which triggers the skin irritation and worsen the condition. Intake of non congenial diet by mother before conception and during pregnancy increases risk of allergic manifestation in children. Association between maternal food intake before and during pregnancy and childhood asthma and allergy was proved scientifically. Intake of good diet such as cooked / raw green vegetables during pregnancy can reduce the risk of AD in children. Intake of grains, meat during pregnancy increases AD in children. It is clear that diet of mother have important role in allergic manifestation of children.

**Gender:** The study showed slightly high significance among females. Researches supported the data by proving Male to female ratio as 1: 1.4 in Atopic dermatitis.

**Religion:** The dominance of Hindus was remarkably high in present study. Data reflects geographical predominance of Hindus in this particular section.

**Socio economical factors:** In this study it is showed that, 60 % were belonging to the Middle socio economical class. It is because that, patients attending the OPD in this department are maximum of middle class people who are more health conscious and seek the treatment immediately when their children come across the problem.

**Domiciliary:** Urban life style is also considered as a risk factor for the development of the disease. By the intake of unwholesome diet, polluted environment, and climate with low humidity which in turn interrupts the metabolic activity and worsens the disease. Study showed high significance of AD to urban area.

**Diet:** Majority of the patients suffering with AD were belonging to mixed type of diet. This showed that some types of foods had contributed to trigger disease such as sea food, cow's milk and chicken eggs (both egg whites and egg yolks), which contain proteins that have been associated with food allergies. The characteristic of non-vegetarian dietary practices of people of Kerala might have contributed to the increased incidence of AD.

**Aggravating factor:** The aggravating factors were analyzed properly and evaluated their role for exacerbation of the disease. Major aggravating factors are winter, soap, stress and sweating which had an important role in provoking symptoms. Dryness and cool environment increased dryness of the skin and similarly sweating in hot, humid environment increases itching.

**Relieving factors:** The analysis of relieving factors supported the need of *upasaya* (relieving factors) or *pathya* (wholesome) for a particular disease. Proper medication, keeping skin moist and washing with salt water or hot water improved the symptoms. These factors helped to reduce the severity of disease for a certain period of time and 40 % of patients got relief from medication.

**Area of involvement:** In Infantile atopic dermatitis lesions are mainly on face, scalp, and neck while in case of childhood atopic dermatitis it will be more on extremities. Present study showed maximum skin lesions on extremity followed by trunk and face which may be because; maximum numbers of patients were in between 1-3 years of age group than the remaining group.

#### IV. RESULTS

The data on before treatment (BT), after treatment (AT) and after follow up (AF) were collected for various parameters and results were analyzed using Friedman's anova test. BT-AT and AT –AF results were analyzed using statistical tests such as paired t test and wilcoxon signed rank test.

#### Data related to the response to treatment

##### 1) SCORAD

**Table No 3: Effectiveness of treatment on SCORAD Index- BT-AT/ AT- AF/ BT- AF Comparison**

|    | N  | SCORAD score |      | Paired comparison | Paired difference |      | Paired t test |        |
|----|----|--------------|------|-------------------|-------------------|------|---------------|--------|
|    |    | Mean         | Sd   |                   | Mean              | Sd   | T             | P      |
| BT | 30 | 51.40        | 9.34 | BT s AT           | 18.14             | 5.15 | 19.275        | <0.001 |
| AT | 30 | 33.26        | 9.87 | AT vs AF          | 15.42             | 6.03 | 14.002        | <0.001 |
| AF | 30 | 17.84        | 6.40 | BT vs AF          | 33.56             | 7.07 | 26.012        | <0.001 |

**Table No 4: Effectiveness of treatment on SCORAD Index- BT-AT- AF Comparison using Friedman Anova**

| Friedman Test   | Mean Rank |
|-----------------|-----------|
| BT              | 3         |
| AT              | 2         |
| AF              | 1         |
| Test Statistics |           |
| N               | 30        |
| Chi-Square      | 60        |
| Df              | 2         |
| P               | <0.001    |

Scorad index showed a significant response after treatment and after follow up. Since p value <0.001, the effect was highly significant.

##### 2) Area of involvement

**Table No 5: Effectiveness of treatment on area involed - BT-AT/ AT- AF/ BT- AF comparison**

|    | N  | Area of involvement |       | Paired comparison | Paired difference |      | Paired t test |        |
|----|----|---------------------|-------|-------------------|-------------------|------|---------------|--------|
|    |    | Mean                | Sd    |                   | Mean              | Sd   | T             | P      |
| BT | 30 | 30.34               | 10.47 | BT s AT           | 4.39              | 4.22 | 5.689         | <0.001 |
| AT | 30 | 25.95               | 9.05  | AT vs AF          | 5.07              | 4.58 | 6.061         | <0.001 |
| AF | 30 | 20.88               | 8.21  | BT vs AF          | 9.45              | 6.16 | 8.408         | <0.001 |

**Table No: 6 Effectiveness of treatment on area involved - BT-AT- AF comparison using Friedman Anova**

| Friedman Test   | Mean Rank |
|-----------------|-----------|
| BT              | 2.8       |
| AT              | 1.98      |
| AF              | 1.22      |
| Test Statistics |           |
| N               | 30        |
| Chi-Square      | 46.536    |
| Df              | 2         |
| P               | <0.001    |

There was a significant improvement in area affected with AD when the analysis was done after the treatment ( $p<0.001$ ). More over sustained responses are obtained throughout the follow up period as indicated by the p value ( $p<0.001$ ) when the before treatment observations were analyzed with that of observations after follow up.

### 3) Erythema

**Table No7: Effectiveness of treatment on Erythema- BT-AT/ AT- AF/ BT- AF comparison**

| Erythema | BT |      | AT |      | AF |      |
|----------|----|------|----|------|----|------|
|          | N  | %    | N  | %    | N  | %    |
| None     | 0  | 0    | 0  | 0    | 9  | 30   |
| Mild     | 0  | 0    | 14 | 46.7 | 19 | 63.3 |
| Moderate | 17 | 56.7 | 16 | 53.3 | 2  | 6.7  |
| Severe   | 13 | 43.3 | 0  | 0    | 0  | 0    |
| Total    | 30 | 100  | 30 | 100  | 30 | 100  |

| Paired comparison | Wilcoxon signed rank test |        |
|-------------------|---------------------------|--------|
|                   | Z                         | P      |
| BT s AT           | 5.196                     | <0.001 |
| AT vs AF          | 4.6                       | <0.001 |
| BT vs AF          | 4.94                      | <0.001 |

**Table No 8: Effectiveness of treatment on Erythema- BT-AT- AF Comparison using friedmanAnova**

| Friedman Test   | Mean Rank |
|-----------------|-----------|
| BT              | 2.95      |
| AT              | 1.92      |
| AF              | 1.13      |
| Test Statistics |           |
| N               | 30        |
| Chi-Square      | 54.844    |
| Df              | 2         |
| P               | <0.001    |

Erythema was elevated in all the patents included in the study. A dramatic response of the study drug was observed with highest level of significance ( $p<0.001$ ) after the treatment and follow up.

## 4) Edema

Table No: 9 Effectiveness of treatment on Edema - - BT-AT/ AT- AF/ BT- AF comparison

| Edema    | BT |      | AT |      | AF |      |
|----------|----|------|----|------|----|------|
|          | N  | %    | N  | %    | N  | %    |
| None     | 0  | 0    | 6  | 20   | 25 | 83.3 |
| Mild     | 5  | 16.7 | 20 | 66.7 | 4  | 13.3 |
| Moderate | 20 | 66.7 | 4  | 13.3 | 1  | 3.3  |
| Severe   | 5  | 16.7 | 0  | 0    | 0  | 0    |
| Total    | 30 | 100  | 30 | 100  | 30 | 100  |

  

| Paired comparison | Wilcoxon signed rank test |        |
|-------------------|---------------------------|--------|
|                   | Z                         | P      |
| BT s AT           | 5.166                     | <0.001 |
| AT vs AF          | 4.69                      | <0.001 |
| BT vs AF          | 5.031                     | <0.001 |

Table No: 10 Effectiveness of treatment on Edema - BT-AT- AF Comparison using friedmanAnova

| Friedman Test   | Mean Rank |
|-----------------|-----------|
| BT              | 2.98      |
| AT              | 1.88      |
| AF              | 1.13      |
| Test Statistics |           |
| N               | 30        |
| Chi-Square      | 56.162    |
| Df              | 2         |
| P               | <0.001    |

## 5) Oozing

Table No: 11 Effectiveness of treatment on Oozing - BT-AT/ AT- AF/ BT- AF comparison

| Oozing   | BT |      | AT |      | AF |      |
|----------|----|------|----|------|----|------|
|          | N  | %    | N  | %    | n  | %    |
| None     | 2  | 6.7  | 17 | 56.7 | 25 | 83.3 |
| Mild     | 9  | 30   | 11 | 36.7 | 4  | 13.3 |
| Moderate | 17 | 56.7 | 2  | 6.7  | 1  | 3.3  |
| Severe   | 2  | 6.7  | 0  | 0    | 0  | 0    |
| Total    | 30 | 100  | 30 | 100  | 30 | 100  |

  

| Paired comparison | Wilcoxon signed rank test |        |
|-------------------|---------------------------|--------|
|                   | Z                         | P      |
| BT s AT           | 4.919                     | <0.001 |
| AT vs AF          | 3                         | 0.003  |
| BT vs AF          | 4.768                     | <0.001 |

**Table No: 12 Effectiveness of treatment on Oozing -BT-AT-AF Comparison using friedmanAnova**

| Friedman Test   | Mean Rank |
|-----------------|-----------|
| BT              | 2.93      |
| AT              | 1.68      |
| AF              | 1.38      |
| Test Statistics |           |
| N               | 30        |
| Chi-Square      | 52.323    |
| Df              | 2         |
| P               | <0.001    |

Oozing was presented in all the patents included in the study. A dramatic response of the study drug was observed with highest level of significance ( $p<0.001$ ) after the treatment and follow up.

## 6) Excoriation

**Table No: 13 Effectiveness of treatment on Excoriation - BT-AT/ AT- AF/ BT- AF comparison**

| Excoriation | BT |      | AT |      | AF |     |
|-------------|----|------|----|------|----|-----|
|             | N  | %    | N  | %    | N  | %   |
| None        | 0  | 0    | 0  | 0    | 3  | 10  |
| Mild        | 4  | 13.3 | 11 | 36.7 | 21 | 70  |
| Moderate    | 21 | 70   | 16 | 53.3 | 6  | 20  |
| Severe      | 5  | 16.7 | 3  | 10   | 0  | 0   |
| Total       | 30 | 100  | 30 | 100  | 30 | 100 |

| Paired comparison | Wilcoxon signed rank test |        |
|-------------------|---------------------------|--------|
|                   | Z                         | P      |
| BT s AT           | 3                         | 0.003  |
| AT vs AF          | 4.359                     | <0.001 |
| BT vs AF          | 4.939                     | <0.001 |

**Table No: 14 Effectiveness of treatment on Excoriation - BT - AT- AF comparison using FriedmanAnova**

| Friedman Test   | Mean Rank |
|-----------------|-----------|
| BT              | 2.58      |
| AT              | 2.17      |
| AF              | 1.25      |
| Test Statistics |           |
| N               | 30        |
| Chi-Square      | 41.875    |
| Df              | 2         |
| P               | <0.001    |

Excoriation was present in all the patients included in the study. The response of the drug in excoriation after the treatment period and follow up were highly significant ( $p<0.001$ )

## 7) Lichenification

Table No: 15 Effectiveness of treatment on Lichenification

| Lichenification | BT |     | AT |     | AF |     |
|-----------------|----|-----|----|-----|----|-----|
|                 | N  | %   | N  | %   | N  | %   |
| None            | 30 | 100 | 30 | 100 | 30 | 100 |
| Total           | 30 | 100 | 30 | 100 | 30 | 100 |

As lichenification is a exclusion criteria in this study, lichenification was absent in all the patients included in this study.

## 8) Xerosis

Table No: 16 Effectiveness of treatment on Xerosis - BT-AT/ AT- AF/ BT- AF comparison

| Xerosis  | BT |      | AT |      | AF |      |
|----------|----|------|----|------|----|------|
|          | N  | %    | N  | %    | N  | %    |
| None     | 6  | 20   | 8  | 26.7 | 20 | 66.7 |
| Mild     | 10 | 33.3 | 22 | 73.3 | 10 | 33.3 |
| Moderate | 14 | 46.7 | 0  | 0    | 0  | 0    |
| Total    | 30 | 100  | 30 | 100  | 30 | 100  |

| Paired comparison | Wilcoxon signed rank test |        |
|-------------------|---------------------------|--------|
|                   | Z                         | P      |
| BT s AT           | 3.771                     | <0.001 |
| AT vs AF          | 3.464                     | 0.001  |
| BT vs AF          | 4.179                     | <0.001 |

Table No: 17 Effectiveness of treatment on Xerosis - BT-AT- AF Comparison using FriedmanAnova

| Friedman Test   | Mean Rank |
|-----------------|-----------|
| BT              | 2.6       |
| AT              | 1.95      |
| AF              | 1.45      |
| Test Statistics |           |
| N               | 30        |
| Chi-Square      | 34.696    |
| Df              | 2         |
| P               | <0.001    |

The table showed that Xerosis was improved during the course after the treatment and follow up. Since p value<0.001, the effect was highly significant

## 9) Pruritis

Table No: 18 Effectiveness of treatment on Pruritis - BT-AT/ AT- AF/ BT- AF comparison

|    |    | Pruritis score |       | Paired comparison | Wilcoxon signed rank test |        |
|----|----|----------------|-------|-------------------|---------------------------|--------|
|    |    | Median         | IQR   |                   | z                         | P      |
| BT | 30 | 8              | 6 - 8 | BT s AT           | 5.069                     | <0.001 |
| AT | 30 | 5.5            | 4 - 6 | AT vs AF          | 4.813                     | <0.001 |
| AF | 30 | 3              | 2 - 4 | BT vs AF          | 4.852                     | <0.001 |

**Table No: 19 Effectiveness of treatment on Pruritis - BT-AT- AF Comparison using FriedmanAnova**

| Friedman Test   | Mean Rank |
|-----------------|-----------|
| BT              | 3         |
| AT              | 1.98      |
| AF              | 1.02      |
| Test Statistics |           |
| N               | 30        |
| Chi-Square      | 59.513    |
| Df              | 2         |
| P               | <0.001    |

The table showed that Pruritis was reduced after the treatment and follow up. Since p value<0.001, the effect was highly significant.

## 10) Insomnia

**Table No: 20 Effectiveness of treatment on Insomnia- BT-AT/ AT- AF/ BT- AF comparison**

|    |    | Insomnia score |         | Paired comparison | Wilcoxon signed rank test |        |
|----|----|----------------|---------|-------------------|---------------------------|--------|
|    |    | Median         | IQR     |                   | Z                         | P      |
| BT | 30 | 6              | 4.75 -6 | BT s AT           | 4.852                     | <0.001 |
| AT | 30 | 3              | 2 – 4   | AT vs AF          | 4.602                     | <0.001 |
| AF | 30 | 1              | 0 – 2   | BT vs AF          | 4.828                     | <0.001 |

**Table No: 21 Effectiveness of treatment on Insomnia -- BT-AT- AF comparison using FriedmanAnova**

| Friedman Test   | Mean Rank |
|-----------------|-----------|
| BT              | 3         |
| AT              | 1.95      |
| AF              | 1.05      |
| Test Statistics |           |
| N               | 30        |
| Chi-Square      | 58.615    |
| Df              | 2         |
| P               | <0.001    |

The table showed that Insomnia was reduced after the treatment and follow up. Since p value<0.001, the effect was highly significant.

## V. DISCUSSION ON RESULT

SCORAD index, Area of involvement, intensity like erythema, edema, oozing, xerosis, subjective symptoms like pruritis and insomnia were showed a significant response after treatment and after follow up since p value is < 0.001

High significant response was noted in reduction of SCORAD score after treatment and after follow up. This proved that the selected drugs were very effective in reducing SCORAD score after treatment and even after follow up by sustained action.

Remarkable improvement in reducing erythema was noticed after treatment. Erythema was severe in almost all of the patients before treatment. After treatment severity was changed to moderate level and which further changed to mild level after follow up. Most of the drugs present in *Makkipoovadikashaya* are having *setavirya* (cold potency), *pithahara* (reduces *pitha* dosha), *dahahara* (reduces burning sensation), *raktaprasadhana* (blood purifier), *varnya* (improves complexion) and *kushtaghna* (alleviates skin diseases) action<sup>[12]</sup>. This helped to reduce erythema in patients. *Aragvadhakishalana* also helped to reduce erythema due to *varnya*, *tvakdoshahara* (reduces abnormalities of skin) property of most of the drugs in it<sup>[13]</sup>.

Itching is the common irritating symptom in most of the patients. A statistically significant value proved the efficacy of selected drugs for reducing itching. These drugs were having dominant sustained action after follow up period to reduce itching. *Makkipoovadikashaya* and *Aragvadhadiikshalana* showed combined effect to reduce itching by *kandughna* (anti pruritic) and *krimighna* (anti helminthic) properties.

Study drugs showed significant response to reduce insomnia after treatment and after follow up. This is due to the effect of drugs to reduce itching and associated symptoms and which leads to extended period of sleep.

Both the drugs were effective in reducing edema and excoriation. This showed statistically significant value after treatment and after follow up. As selected patients were devoid of lichenification, combined effect of drugs for lichenification was not assessed. As some of the drugs in *makkipoovadikashaya* are having *snigda* (unctuous), *ushnaguna* (hot potency) it helped to reduce dryness to some extent.

## V. CONCLUSION

The clinical study intended to evaluate the efficacy of *Makkipoovadikashaya* and *Aragvadhadiikshalana* in Atopic Dermatitis has provided the following conclusions.

- The trial drug *Makkipoovadikashaya* and *Aragvadhadiikshalana* was effective in reducing SCORAD score which was the main tool to assess the severity index of Atopic dermatitis. This showed significant effectiveness on erythema, edema and xerosis in children affected with acute Atopic dermatitis.
- *Makkipoovadikashaya* and *Aragvadhadiikshalana* were successful in improving other graded subjective parameters such as itching and sleeploss.
- Strict dietary regimen played a major role in improving the clinical condition.
- The action of *Makkipoovadikashaya* and *Aragvadhadiikshalana* showed sustained effect even after the follow up period of 2 weeks.

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