ROLE OF ARKA TAILA AND BAAKUCHIKADYAM CHURNA ON VICHARCHIKA: A RANDOMIZED CONTROL TRIAL

Sheetal Yadav1*, Anita Sharma2, Dinesh C. Chouhan3

1P.G. Scholar, 2Professor and Head of Department, Department of Agad Tantra, National Institute of Ayurveda, Jaipur.
3Assistant Professor, Department of Sharir Kriya, Mahatma Jyotiba Fule Ayurved Mahavidhyalaya, Chomu, Jaipur, India.

ABSTRACT
In the present era skin diseases like atopic dermatitis/eczema get a suitable atmosphere especially in developing countries like India, due to unhygienic living condition, disturbed lifestyle, polluted environment and repeated use of chemical additives. This type of diseases make a person feels much more humiliation in society because no one wants to touch them, forbidden by everyone, in that condition person leads to lack of confidence and feels underestimated mentally as well as physically. Due to this life disturbing condition this disease was chosen for the study.

The study was conducted in 30 clinically diagnosed patients of Vicharchika (Atopic Dermatitis) and randomly divided into two groups, namely group A and group B. Each group has 15 number of patients. Group A is treated with Arka Taila (external application) used twice in a day for 45 days along with Baakuchikadyam Churna for internal consumption (3-6 grams). Group B is treated with Cutis Capsule (2 Capsules) twice a day orally along with external application of Cutis Cream as required for 45 days.

KEYWORDS: Vicharchika, Atopic dermatitis and Arka Taila, Baakuchikadyam Churna.

INTRODUCTION
Ayurveda describes the triple support of life that are ingestion of right food, adequate sleep and observance of celibacy. But in today's era drastic changes in the food habits like Viruddha Ahara, Mithya Ahara, sedentary life style and avoiding of physical exertion are consumed frequently by majority of people. All these drastic changes of life style are taking us away from the nature and we trapped in various disorders including a large number of skin disorders.

Skin is the first organ of the body which interacting with the environmental agents like physical, chemical & biological agents. Interaction with such factors skin should be leads to specific reaction pattern, producing characteristic skin lesions in different parts of the body. Skin is a mirror that reflects internal & external pathology & thus helps in diagnosis of diseases. Skin ailments effects all ages from the neonates to the elderly & cause harm in a number of ways, such as discomfort, disfigurement, disability, etc. Biologically, cosmetically and socially the color of the skin is important factor. The unbroken skin is the nature's effective barrier against the entry of diseases. It acts as a dressing over the body.

According to contemporary science, Vicharchika can be considered as Eczema[1]. Ayurvedic texts, there are so many special procedures and hundreds of medicaments as a successful and safer remedy for the chronic derma problems including Vicharchika[2].

The clinical presentation of Vicharchika is considered with symptoms like itching, discharge, Pustules, Scrapes, Pain and Discoloration of skin etc[3]. According to Tridosha theory of Ayurveda Vicharchika shows pathology with vitiation of Tridosha along with Pitta & Kapha vitiation majorly. The Rakta and Twak is considerably included in pathology as Dushya in Vicharchika[4]. In Ayurveda there is an elaborated description available regarding the treatment of Vicharchika, which includes both Shodhana[5] and Shamana Chikitsa[6]. In the present study the management of Vicharchika was planned by Baakuchikadyam Churna[7] for internal use and Arka Taila[8] for external use.
The above selected trail drugs help in breaking the pathology of *Vicharchika* by internal and external application. In both the formulation most of the drugs are having *Deepana*, *Pachana*, *Srotoshodhana*, *Raphaghnâ*, *Kandughna*, *Kushtghna*, *Raktaprasadaka*, *Vranashodhaka* and *Rasayana* properties. According to modern pharmacology these drugs possess Anti-inflammatory, Anti-oxidant, Anti-allergic, Mast cell stabilizer, Anti-histaminic, Antibacterial, Antifungal, Blood purifier and Immuno-modulator properties which helps in breaking the pathogenesis of *Vicharchika*.[9]

So, in the present study "Role of *Arka Taila* and *Baakuchikadyam Churna* to A randomized control trial" was planned & carried out.

**Aims and Objectives of the Study**
- To study the disease *Vicharchika* clinically & comprehensively in the light of the description available in Ayurveda & modern science for Eczema.
- Clinical evaluation of the safety and efficacy of *Baakuchikadyam Churna* and *Arka Taila* for local application in the management of *Vicharchika*.
- Clinical evaluation of the safety and efficacy of Cutis Capsule (Oral), and Cutis cream for local application in the management of *Vicharchika*.
- Compare the efficacy of study group and control group.

**MATERIAL AND METHOD**

**a. Source of Data** - Subjects was randomly selected irrespective of age, sex, religion, education, socio economic status & occupation from OPD of NIA hospital.

**b. Study Design** - Open labeled randomized clinical trial.

**c. Sample size** - 30 clinically diagnosed patients were randomly selected into two groups. Namely group A and B. Each group has 15 patients.

- **Group A**: *Arka Taila* (external application) as required twice daily for 45 days along with *Baakuchikadyam Churna* (3-6 grams) orally twice daily for 45 days.
- **Group B**: Cutis Cream (external application) as required twice daily for 45 days along with Cutis Capsule (2 capsules) twice a day orally for 45 days.

**d. Drugs**
- **1. Study Drug**: *Arka Taila*[8] (external application) and *Baakuchikadyam Churna*[7] (orally) were prepared in the Pharmacy of National Institute of Ayurveda, Jaipur.
- **2. Control Drug**: Cutis cream (external application) as required and cutis capsule for internal uptake were purchased from Vasu Healthcare Pvt. Ltd. Pharmaceuticals.

**e. Dose**
1. *Arka Taila* (external application) as required and *Baakuchikadyam Churna* (3-6 grams) orally twice daily for 45 days.
2. Cutis cream (external application) as required twice daily for 45 days along with cutis capsule (2 capsules) twice a day for internal consumption for 45 days.

**f. Time period of Clinical trial** - Total duration of clinical trial was 45 days.

**g. Follow up** - Follow-up of patient was done on 15th and 30th days of treatment. Improvement in the symptoms if any and other effects were noted down.

The collected data will be analyzed statistically.

**Ethical Clearance**: This study was approved by Institutional Ethical committee (IEC) of National Institute of Ayurveda, Jaipur letter no. IEC/ACA/2017/05; dated 26/04/2017 and also registered in Clinical trial registry - India CTRI/2018/11/016438 before staring the clinical trial on patients of *Vicharchika* (Atopic dermatitis).

**Inclusion Criteria**
- Patient willing for trial.
- The patients of age group between 16-70 years.
- The patients having clinical signs and symptoms of *Vicharchika*.
- Either sex.

**Exclusion Criteria**
- Patient below 16 years & above 70 years of age.
- Patients with long term Steroid and cytotoxic treatment.
- Systemic illness like HTN; DM, HIV, Venereal disease, TB and other bleeding disorders.

**Withdrawal Criteria**
- Occurrence of any serious events.
- Patient has become uncooperative.
- The patient is not willing to continue the trial.

**Criteria for Assessment**
- Classical signs & symptoms of *Vicharchika* (Atopic Dermatitis) according to Ayurveda and Modern system of medicine.
- A special Performa was prepared incorporating all the signs & symptoms of *Vicharchika* and Atopic dermatitis as well as the *Duṣṭi Laksana* of *Doṣa*, *Dosya*, *Srotas*, *Agni* etc. On the basis of the Performa, all the patients of the present study were examined in detail.

**Subjective Criteria**: Scoring criteria for assessing *Vicharchika*.

Available online at: [http://ijapr.in](http://ijapr.in)
1. **Kaṇḍu** (pruritis)
   - 0 - No itching
   - 1 - Mild itching not disturbing normal activity
   - 2 - Occasional itching disturbs normal activity
   - 3 - Itching present continuously & even disturbing sleep

2. **Daha** (burning)
   - 0 - No burning sensation
   - 1 - Mild type of burning not disturbing normal activity
   - 2 - Occasionally burning disturbing normal activity
   - 3 - Burning present continuously & even disturbing sleep

3. **Srava** (Oozing)
   - 0 - No discharge
   - 1 - Occasional discharge after itching
   - 2 - Occasional oozing without itching
   - 3 - Excessive oozing making clothes wet

4. **Rukṣha** (Dryness)
   - 0 - No dryness
   - 1 - Dryness with rough skin (**Ruksha**)
   - 2 - Dryness with scaling (**Khara**)

**Area of involvement**

| 0 | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|
| No eruption | < 10% | 10-29% | 30-49% | 50-69% | 70-89% | 90-100% |

5. **Pidikotpatti** (Eruption)
   - 0 - No eruption in the lesion
   - 1 - Scanty eruptions in few lesions
   - 2 - Scanty eruptions in at least half of the lesion
   - 3 - All the lesions full of eruption

6. **Vaivarnyata** (Discolouration)
   - 0 - Nearly normal skin colour
   - 1 - Brownish red discoloration
   - 2 - Blackish red discoloration
   - 3 - Blackish discoloration

7. **Raji** (Thickening of skin)
   - 0 - No thickening of skin
   - 1 - Thickening of skin but no crisscross marking
   - 2 - Thickening with crisscross marking
   - 3 - Severe Lichenfication

**EASI (Eczema Area and Severity Index) score:** The intensity of redness (**erythema**), thickness (**infiltration, population, and edema**), scratching (**excoriation**) and Lichenfication (**lined skin**) of the eczema is assessed as none (0), mild (1), moderate (2) and severe (3). Half scores are allowed.

**Showing subjective Criteria of Vicharchika (Atopic dermatitis)**

| Erythema | Infiltration/population | Excoriation | Lichenfication |
|----------|-------------------------|-------------|---------------|
| 0        | None                    | None        | None          |
| 1-Mild   | Faintly detectable erythema: very light pink | Barely perceptible elevation | Slight thickening of the skin dissemble only by touch and with skin marking minimally exaggerated |
| 2- Moderate | Dull red clearly distinguishable | Clearly perceptible elevation but not extensive | Define thickening of the skin with skin marking exaggerated so that they form a Crisscross pattern |
| 3-Severe | Deep/ dark red | Marked and extensive elevation | May erosive or crustily lesion |
|          |                        |             |               |
| 0        | None                    | None        | None          |
| 1-Mild   | Scant evidence of excoriation with no sign of deeper skin damage (erosion, crust) | Severe linear marks of skin with showing evidence of deeper skin injury (erosion, crust) | Thickenened indurated skin with skin marking visibly portraying an exaggerated Crisscross pattern |
| 2- Moderate | Severe linear marks of skin with showing evidence of deeper skin injury (erosion, crust) | May erosive or crustily lesion |               |
| 3-Severe | May erosive or crustily lesion | Thickenened indurated skin with skin marking visibly portraying an exaggerated Crisscross pattern |               |
|          |                        |             |               |
RESULTS
All the Results are calculated by using Software: In Stat Graph Pad 3.
- For Nonparametric Data Wilcoxon matched-pairs signed ranks test is used and results Calculated in each group.
- For calculating the Intergroup comparison, Mann-Whitney Test was used. Results showing effect of therapy in subjective parameters.

Showing effect of therapy on subjective parameters (wilcoxon matched pairs single ranked test)

| Variable | Gr. | Mean | Mean | % Relief | SD± | SE± | p value | S |
|----------|-----|------|------|----------|-----|-----|---------|---|
| Kandu    | Gr. A | 2.53 | 1.87 | 0.67    | 26.32 | 0.62 | 0.16    | VS |
|          | Gr. B | 2.67 | 2.20 | 0.47    | 17.50 | 0.52 | 0.13    | S  |
| Daha     | Gr. A | 2.40 | 2.00 | 0.40    | 16.67 | 0.51 | 0.13    | S  |
|          | Gr. B | 1.53 | 0.93 | 0.60    | 39.21 | 0.63 | 0.16    | S  |
| Srava    | Gr. A | 1.60 | 0.93 | 0.67    | 41.67 | 0.62 | 0.16    | VS |
|          | Gr. B | 1.73 | 1.27 | 0.47    | 26.92 | 0.52 | 0.13    | S  |
| Rukshata | Gr. A | 1.80 | 0.93 | 0.87    | 48.33 | 0.83 | 0.22    | S  |
|          | Gr. B | 1.87 | 1.20 | 0.67    | 35.71 | 0.82 | 0.21    | S  |
| Pidika   | Gr. A | 1.53 | 1.00 | 0.53    | 34.78 | 0.64 | 0.17    | S  |
|          | Gr. B | 1.40 | 1.00 | 0.40    | 28.57 | 0.51 | 0.13    | S  |
| Vaivaranyata | Gr. A | 1.53 | 0.87 | 0.67    | 43.48 | 0.82 | 0.21    | S  |
|          | Gr. B | 1.93 | 1.20 | 0.73    | 37.93 | 0.70 | 0.18    | S  |
| Raji     | Gr. A | 1.00 | 0.47 | 0.53    | 53.33 | 0.52 | 0.13    | S  |
|          | Gr. B | 1.93 | 0.73 | 1.20    | 62.07 | 1.08 | 0.28    | ES |
| EASI Score | Gr. A | 5.79 | 2.67 | 3.12    | 53.92 | 3.33 | 0.86    | S  |
|          | Gr. B | 7.72 | 3.73 | 3.99    | 51.73 | 3.34 | 0.86    | ES |

Intergroup Comparison
To access the efficacy of two therapies intergroup comparison was done. As the variables are nonparametric Mann-Whitney Test was used for statistical analysis. The results are as follows:

Intergroup Comparison in Subjective Parameters of Group A & B (Mann-Whitney Test)

| Variable | Gr. | Mean | Mean | % Relief | SD± | SE± | p value | S |
|----------|-----|------|------|----------|-----|-----|---------|---|
| Kandu    | Gr. A | 2.53 | 1.87 | 0.67    | 26.32 | 0.62 | 0.16    | VS |
|          | Gr. B | 2.67 | 2.20 | 0.47    | 17.50 | 0.52 | 0.13    | S  |
| Daha     | Gr. A | 2.40 | 2.00 | 0.40    | 16.67 | 0.51 | 0.13    | S  |
|          | Gr. B | 1.53 | 0.93 | 0.60    | 39.21 | 0.63 | 0.16    | S  |
| Srava    | Gr. A | 1.60 | 0.93 | 0.67    | 41.67 | 0.62 | 0.16    | VS |
|          | Gr. B | 1.73 | 1.27 | 0.47    | 26.92 | 0.52 | 0.13    | S  |
| Rukshata | Gr. A | 1.80 | 0.93 | 0.87    | 48.33 | 0.83 | 0.22    | S  |
|          | Gr. B | 1.87 | 1.20 | 0.67    | 35.71 | 0.82 | 0.21    | S  |
| Pidika   | Gr. A | 1.53 | 1.00 | 0.53    | 34.78 | 0.64 | 0.17    | S  |
|          | Gr. B | 1.40 | 1.00 | 0.40    | 28.57 | 0.51 | 0.13    | S  |
| Vaivaranyata | Gr. A | 1.53 | 0.87 | 0.67    | 43.48 | 0.82 | 0.21    | S  |
|          | Gr. B | 1.93 | 1.20 | 0.73    | 37.93 | 0.70 | 0.18    | S  |
| Raji     | Gr. A | 1.00 | 0.47 | 0.53    | 53.33 | 0.52 | 0.13    | S  |
|          | Gr. B | 1.93 | 0.73 | 1.20    | 62.07 | 1.08 | 0.28    | ES |
| EASI Score | Gr. A | 5.79 | 2.67 | 3.12    | 53.92 | 3.33 | 0.86    | S  |
|          | Gr. B | 7.72 | 3.73 | 3.99    | 51.73 | 3.34 | 0.86    | ES |

(VS: Very Significant; S: Significant; NS: Non Significant)
Follow-Up Study
Regular follow up during the trial & after 45 days of successful completion of trial was done. Regular follow up after trial was done after 15 days & 30days.

Showing Percentage of Improvement of Therapy on Subjective Parameters

| Subjective Parameters | % Relief in Group A | % Relief in Group B |
|-----------------------|---------------------|---------------------|
| Kandu                 | 26.32 %             | 17.50 %             |
| Daha                  | 16.67 %             | 39.13 %             |
| Srava                 | 41.67 %             | 26.92 %             |
| Rukshata              | 48.15               | 35.71               |
| Pidika                | 34.78               | 28.57               |
| Vaivaranya            | 43.48               | 37.93               |
| Rajii                 | 53.33               | 62.07               |
| EASI Score            | 53.92               | 51.73               |

DISCUSSION
Probable Modes of Actions of the Drug
Selection of trial drug is milestone in any research project because success of the project is totally depends on that. Selection of drugs was the most difficult job in this trial. While selecting the trial the following points was taken into consideration.

- Trial drug should be effective, safe & economic & easily available.
- As recurrence is the most serious problem so it must have some property to check the relapse of disease.
- Drug should be easy for administration.

Baakuchikadyam Churna
Considering all above things in mind trial drug *Baakuchikadyam Churna*, was selected for this study. It was prepared in Pharmacy of NIA, Jaipur by the method mentioned in *Bharat Bhaishajya Ratnakara*.

- *Baakuchikadyam Churna* containing drugs Baakuchi[^10], Haritaki[^11], Bibhitaki[^12], Amlaki[^13], Chitrak[^14], Bhallataka[^15], Shatavari[^16], Nirgundi[^17], Ashwagandha[^18], Nimba[^19].
- All drugs containing in *Baakuchikadyam Churna* having predominantly Katu-Tikta-Kasaya in Rasa, Laghu-Ruksha in Guna, Ushna Virya and Madhura in Vipaka.
Due to all above mention properties presents 
Baakuchikadyam Churna, the drug act as Bhedana, Deepana, Krimighna, Sophahara, Vatahara, Vranahara, Vishaghna, Kushtaghana and Kandughna etc.

**Arka Tail**

Considering all above things in mind trial drug Arka Tail, was selected for this study. In the original form drug is described as a Tail Kalpana was prepared by the method mentioned in Sharangadhar Samhita, was made in Rasayanshala, Pharmacy of NIA, Jaipur.

**Arka Tail** containing drug Arka, Haridra, Sarshapatail.

**Arka**[20] has Katu-Tikta Rasa, Laghu-Ruksha-Tikshna Guna, Ushna Veerya, it act as Bhedana, Deepana, Krimighna, Sophahara, Vatahara, Vranahara, Vishaghna, Kushtaghana, Kandughna.

**Haridra**[21] has Katu-Tikta Rasa, Laghu-Ruksha Guna, Ushna Veerya, it act as Kushtagha, Kandughna, Raktaprasadana, Raktavardhaka, Vishaghna, Anulomana, Shothahara, Varnya.

**Sarshapa Tail**[22] has Katu-Tikta Rasa, Tikshna, Snigdha Guna, Ushna Veerya, it act as Lekhana, Varnya, Krimighna, Jantughna, Kushtaghana.

**Probable Mode of Action of Tail**

**Pilosebaceous Uptake**

When a Tail is applied over the surface of skin opposite to the direction of hairs on it, through a proper base, the active principles of the ingredients of Tail are released into that base. After that, this combination enters the Romkooopa and further gets absorbed through the Swedavahi Srotas and Siramukhi.[23] However, it should be kept in mind that the pilosebaceous uptake i.e. absorption of Tail differs as per the site variation, skin condition & more important is the base through which it is applied.

**CONCLUSION**

Vicharchika being a Kshudra Kushta has Kapha dominance & even involvement of Tridosha can be evident from its signs & symptoms. Vicharchika in modern parlance has similarity with Eczema & its types. Administration of Arka Taila and internal administration of Baakuchikadyam Churna can be used as safe and effective therapeutic agent in the management of Vicharchika. Medicine was well tolerated by all the patients no unwanted/ side effects were seen in any patients.

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*Address for correspondence
Dr. Sheetal Yadav
P.G. Scholar,
Department of Agad Tantra,
National Institute of Ayurveda,
Amer Road, Jaipur, Rajasthan, India.
Email: drsheetalyadav0201@gmail.com

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