“Management of Indralupta (Alopecia Areata) with Prachchhana Karma and Bibhitaka Lepa- An Open Labelled Single Arm Clinical Trial”

Shital K. Baraiya¹*, Bhakti Chhaya², Mehul Gohil³, Khyati Bhupta⁴ Sejal Gamit⁵

Abstract
There are 8 branches of Ayurveda Shalakya Tantra is one of them. Acharya Sushruta has mentioned 11 types of Shiro Roga and Acharya Vagbhatta described 10 types of Shiro Roga and he also described 9 types of Shirokapalgata Roga. In Ayurvedic approach, loss of hair is coined out as in term of ‘Indralupta’ under the broad heading of Kshudra Roga except Vagabhatta who has mentioned it under Kapala Roga. According to Acharya Sushruta and Vagabhatta Vata Dosha along with Pitta Dosha resides in Romkooopa (hair root) results in hair fall (Keshapatan). After then Kapha Dosha along with Rakta Dosha block Romkooopa (hair root) so no more hair produce on that place, its results in Indralupta. Indralupta occurs due to Rakta Dushhti and treatment of Indralupta, Prachchhana karma is stated by major Acharya. Now a days many Ayurvedic practitioners used Bibhitakaa Lepa as a Keshya but we need to prove it scientifically so Bibhitaka has been selected in form of Lepa. Bibhitaka is Keshya so keep in mind above reference we select the treatment Prachchhana is as Shodhan therapy and Lepan as a Shaman therapy. For evidence database these both treatments are selected. Total 32 patients were registered, in which 30 patients were continued their therapy. Prachchhana Karma was done in one sitting followed by Bibhitaka Lepa for 21 days. The effect of therapy was assessed by a specially prepared proforma. The data obtained in clinical study was analysed by using Paired ‘t’ test.

Keywords: Shiro Roga, Indralupta, Prachchhana, Bibhitaka Lepa, Keshya

INTRODUCTION
The Word Ayurveda is from the Sanskrit Language and composed of two parts: Ayush means life, Veda means knowledge, wisdom and science. Thus, the term meaning can be translated as a science of life. There are 8 branches of Ayurveda [1]. Shalakya Tantra is one of them [2]. The branch which deals with diseases of upper clavicular region and its management is called Shalakya Tantra [3]. According to Acharya Charak, Sirah is the part of body where life along with sense faculties resides. Acharya Sushruta has mentioned 11 types of Shiro Roga [4] and Acharya Vagabhatta described 10 types of Shiro Roga [5] and he also described 9 types of Shirokapalgata Roga [6].

In Ayurvedic approach, loss of hair is coined out as in term of ‘Indralupta’ under the broad heading
of Kshudra Roga [7] except Vagabhatta who has mentioned it under Kapala Roga [8]. According to Acharya Sushruta and Vagbhatta Vata Dosha along with Pitta Dosha resides in Romkoopa (hair root) results in hair fall (Keshapatan). After then Kapha Dosha along with Rakta Dosha block Romkoopa (hair root) so no more hair produce on that place, its results in Indralupta [9]. According to Acharya Kartikeya hair loss of beard and mustache is called Indralupta. According to Ayurvedic fundamentals Kesha is Mala of Asthi Dhatu [10].

According to modern, Alopecia types are Alopecia Areata, Alopecia Totalis, Alopecia Universalis, Androgenic alopecia, Traction alopecia, Scarring Alopecia but as per symptoms of Indralupta, It can correlate with Alopecia Areata. Alopecia Areata is the general medical term for patchy hair loss. It is most common disease in all age group. In modern medical science topical steroids, topical immunotherapy, topical minoxidil, oral corticosteroids are used for treatment but it’s not a permanent treatment, after sometimes symptoms of Alopecia areata reappears.

Early hairfall has been attributed to be the result of varied factors like hormonal imbalance, faulty hair care, pollution, cosmetic, junk food etc. To solve the above query and to find out promising remedy the present study ‘Indralupta’ (Alopecia Areata) has been undertaken.

Indralupta occurs due to Rakta Dushhti [11] and treatment of Indralupta, Prachchhana karma is stated by major Acharya. For the treatment of vitiated Rakta, Raktanokshana is the line of treatment [12]. Prachchhana Karma is one among Rakt Moksha [13]. Acharya Sushruta and Acharya Vagbhatta both described Prachchhana Karma as a treatment of Indralupta [14].

There are many formulations for Indralupta is mentioned for local use in various texts of Ayurveda which has no systemic effects. Lepa which is made by compound of drugs is not effective like single drug therapy because it not justifies its effect properly.

According to Acharya Bhavprakash Bibhitaka having a Kesha property [15]. Now a days many Ayurvedic practitioners used Bibhitaka Lepa as a Kesha but we need to prove it scientifically so Bibhitaka has been selected in form of Lepa.

Bibhitaka is Kesha so keep in mind above reference we select the treatment Prachchhana is as Shodhan therapy and Lepan as a Shaman therapy. For evidence database these both treatments are selected.

HYPOTHESIS
- H0: Prachchhana karma followed by Bibhitaka Lepa is not effective in management of Indralupta (Alopecia Areata)
- H1: Prachchhana Karma followed by Bibhitaka Lepa is effective in management of Indralupta (Alopecia Areata)

AIMS AND OBJECTIVES
To evaluate the efficacy of Prachchhana Karma followed by Bibhitaka Lepa in management of Indralupta (Alopecia Areata).

MATERIAL AND METHODS
In present study, with the above mentioned aims and objectives, the clinical study progressed utilizing the clinical material as under:
- Selection of Patients: 32 patients attended the O.P.D. of Govt. Akhandananand Ayurveda College and Hospital, Ahmedabad, who were fulfilling the criteria of the disease were selected.
- Sampling Technique: The patients were selected irrespective of their age, sex, religion, occupation etc. and simple random sampling technique was followed.
DIAGNOSTIC CRITERIA
The patients with the complaints of Indralupta as well as Alopecia Areata were selected for the study. For the purpose of perfect diagnosis and assessment a special research Performa was designed.

Inclusion Criteria
Patients having age between 18 to 60 years. Patients having symptoms of Indralupta and as well as Alopecia Areata have been selected irrespective of any bar of caste, gender, religion and occupation.

Exclusion Criteria
- Patients whose age was less than 18 and above 60 years. A person who has ongoing treatment of Indralupta will be excluded.
- Patients who have been diagnosed to have local disease like Androgenetic Alopecia, Alopecia Totalis, Alopecia Universalis, Scarring hair loss, Tinea capitis, Traction Alopecia, Scalp psoriasis, Seborrheic dermatitis, Contact dermatitis, Patients with furuncles, pustules, oozing skin lesion over scalp were excluded
- Patient suffering from any severe systemic disease was excluded.

MANAGEMENT OF PATIENTS
- Patients included in the present study randomly selected for treatment.
- **Group A: Prachchhana Karma followed by Bibhitaka Lepa**
  - *Prachchhana Karma with surgical blade no.11* in one sitting after that *Bibhitaka Lepa* was applied.
  - *Matra (Dose) of Lepa:* as per size and no of patches Thickness of Lepa: 1/4th Angul (4-5 mm)
  - Duration of Lepa: once in a day up to 3 week.

FOLLOW UP
Follow up will be done upto 15 days after completion of therapy. Patient will be assessed every 7 days for 15 days.

CRITERIA FOR ASSESSMENT
Patients will be assessed before, during and after for the efficacy the trial treatment by following parameters:

- According to size of patches: *S=* size of patch
  - Grade S0: No patches
  - Grade S1: 0-1 cm
  - Grade S2: 1-2 cm
  - Grade S3: 2-3 cm
  - Grade S4: 3-4 cm
  - Grade S5: 4-5 cm
  - More than 5 cm size was excluded

- According to no. Of patches: *N=*/ no of patches
  - Grade N0: No patches
  - Grade N1: 1-2 patches
  - Grade N2: 3-4 patches
  - Grade N3: 5-6 patches
  - Grade N4: 7-8 patches
  - Grade N5: 9-10 patches
  - More than 10 patches were excluded

GRADATION OF HAIR FALLING

- Symptoms Gradation
  - Absent 0
  - Mild (hair fall on washing) 1
  - Moderate (hair fall on combing) 2
  - Severe (hair fall on simple strengthening) 3

For other associated symptoms like Darunaka, Sirah Kandu, Kesha Tanutva etc. The same scoring pattern is accepted.
Objective Parameters
Comparing diagnostic test report and grading pattern.

STATISTICAL ANALYSIS
The data generated in the clinical study will be analyzed by applying paired “t” test statistical method.

OVERALL EFFECT OF THERAPY
Overall effect of the therapy was assessed in by adopting the following criteria (Table 1).

Table 1. Overall effect of therapy.

<table>
<thead>
<tr>
<th>1. Cured</th>
<th>100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Markedly Improved</td>
<td>&gt;75 % to 100%</td>
</tr>
<tr>
<td>3. Moderate Improved</td>
<td>&gt;50 % to 75%</td>
</tr>
<tr>
<td>4. Mild Improvement</td>
<td>&gt;25 % to 50%</td>
</tr>
<tr>
<td>5. Unchanged</td>
<td>0 to 25%</td>
</tr>
</tbody>
</table>

RESULT OF THERAPY
Effect of Therapy on Subjective Criteria of Indralupta (Table 2 and Table 3)
- **Ekdeshiya Keshpatan (Patchy Hair loss):** As per Table 2, before treatment mean score was 2.167 which reduced to 1.000 after the treatment. This relief (53.85%) was highly significant (P< 0.001).
- **Keshpatan (Hair fall):** The mean score was 0.800 before treatment which reduced to 0.567 after the treatment. This reduction of 29.17% was significant (P<0.05) (Table 3).
- **Darunaka (Dandruff):** The mean score was 0.367 before treatment which reduced to 0.233 after the treatment. This reduction of 36.4% was significant (P<0.05) (Table 3).
- **ShirahKandu (Itching on Scalp):** The initial mean score was 0.367 which was reduced to 0.200 after the therapy. This 45.45% relief was significant (P<0.05) (Table 3).
- **Palitya (Graying of Hair):** Before treatment mean score was 0.0625, which remain unchanged after treatment showing 0% i.e. no relief, which was statistically insignificant (P>0.05) (Table 3).

Table 2. Effect of Therapy on Chief complaint of *Indralupta*.

<table>
<thead>
<tr>
<th>Chief Complaints</th>
<th>Mean Score</th>
<th>Diff</th>
<th>%age</th>
<th>SD</th>
<th>SE</th>
<th>“t” Value</th>
<th>“p” Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ekdeshiya Keshpatan</td>
<td>2.167</td>
<td>1.000</td>
<td>1.167</td>
<td>0.592</td>
<td>0.108</td>
<td>10.79</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Table 3. Effect of therapy on associated symptoms of *Indralupta*.

<table>
<thead>
<tr>
<th>Associated Symptoms</th>
<th>Mean Score</th>
<th>DIFF</th>
<th>%</th>
<th>SD</th>
<th>SE</th>
<th>“t” Value</th>
<th>“p” Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Keshpatan</td>
<td>0.800</td>
<td>0.567</td>
<td>0.233</td>
<td>0.430</td>
<td>0.0785</td>
<td>2.971</td>
<td>0.006</td>
</tr>
<tr>
<td>Darunaka</td>
<td>0.367</td>
<td>0.233</td>
<td>0.133</td>
<td>0.346</td>
<td>0.0631</td>
<td>2.112</td>
<td>0.043</td>
</tr>
<tr>
<td>ShirahKandu</td>
<td>0.367</td>
<td>0.200</td>
<td>0.167</td>
<td>0.379</td>
<td>0.0692</td>
<td>2.408</td>
<td>0.023</td>
</tr>
<tr>
<td>Palitya</td>
<td>0.0625</td>
<td>0.0625</td>
<td>0.000</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>1.000</td>
</tr>
<tr>
<td>Kesh Tanatva</td>
<td>0.219</td>
<td>0.188</td>
<td>0.031</td>
<td>0.177</td>
<td>0.0312</td>
<td>1.00</td>
<td>0.325</td>
</tr>
<tr>
<td>Kesh Rakshita</td>
<td>0.161</td>
<td>0.129</td>
<td>0.032</td>
<td>0.180</td>
<td>0.0323</td>
<td>1.00</td>
<td>0.325</td>
</tr>
</tbody>
</table>
• **Kesha-Tanutva (Thinness of Hair):** The initial mean score was 0.219, which reduced to 0.188 with the therapy. This 14.29% relief was statistically insignificant (P> 0.05) (Table 3).

• **Kesha-Rukshata (Dryness of Hair):** The mean score of Kesha- Rukshata was 0.161 before treatment which decreased to 0.129 after treatment showing 20% relief. Statistically this result was insignificant (P>0.05) (Table 3).

### EFFECT OF THERAPY ON OBJECTIVE CRITERIA OF INDRALUPTA

- **No. of patches:** The mean score of total no of patches of 30 patient was 1.733 before treatment which reduced to 0.900 after the treatment. This reduction of 48.08% was highly significant (P<0.001) (Table 4).

- **Size of patches:** The mean score of total size of patches of 52 patches of 30 patient was 2.712 before treatment which reduced to 1.115 after the treatment. This reduction of 58.87% was highly significant (P<0.001) (Table 4).

- **Grade 1 patches:** The mean score of grade 1 size of 8 patches of 30 patients was 1.000 before treatment which reduced to 0.125 after the treatment. This reduction of 87.5% was very highly significant (P<0.001) (Table 5).

- **Grade 2 patches:** The mean score of grade 2 size of 19 patches of 30 patients was 2.000 before treatment which reduced to 0.316 after the treatment. This reduction of 84.21% was very highly significant (P<0.001) (Table 5).

- **Grade 3 patches:** The mean score of grade 3 size of 11 patches of 30 patients was 3.000 before treatment which reduced to 0.727 after the treatment. This reduction of 75.8% was very highly significant (P<0.001) (Table 5).

- **Grade 4 patches:** The mean score of grade 4 size of 8 patches of 30 patients was 4.000 before treatment which reduced to 1.250 after the treatment. This reduction of 31.3% was highly significant (P<0.01).

- **Grade 5 patches:** The mean score of grade 5 size of 6 patches of 30 patients was 5.000 before treatment which reduced to 1.500 after the treatment. This reduction of 70% was highly significant (P<0.01).

#### Table 4. Effect of therapy on no and size of Patches of total 30 patients of Indralupta.

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>No. of total 30pts</th>
<th>Mean Score</th>
<th>Paired t Test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B.T.</td>
<td>A.T.</td>
<td>Diff.</td>
</tr>
<tr>
<td>NO. of patches</td>
<td>52</td>
<td>1.733</td>
<td>0.900</td>
</tr>
<tr>
<td>SIZE of patches</td>
<td>141</td>
<td>2.712</td>
<td>1.115</td>
</tr>
</tbody>
</table>

#### Table 5. Effect of therapy on gradation wise size of Patches of total 30 patients of Indralupta.

<table>
<thead>
<tr>
<th>Grade</th>
<th>No of Patches</th>
<th>Mean Score</th>
<th>Paired T Test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B.T.</td>
<td>A.T.</td>
<td>Diff.</td>
</tr>
<tr>
<td>1</td>
<td>8</td>
<td>1.000</td>
<td>0.125</td>
</tr>
<tr>
<td>2</td>
<td>19</td>
<td>2.000</td>
<td>0.316</td>
</tr>
<tr>
<td>3</td>
<td>11</td>
<td>3.000</td>
<td>0.727</td>
</tr>
<tr>
<td>4</td>
<td>8</td>
<td>4.000</td>
<td>2.750</td>
</tr>
<tr>
<td>5</td>
<td>6</td>
<td>5.000</td>
<td>3.500</td>
</tr>
</tbody>
</table>

### OVERAL EFFECT OF THERAPY (TABLE 6)

**Group A:** Overall effect of Therapy- 40% patients had complete remission moderate improvement; while 36.66% patients had mild improvement; 16.66% patients remained unchanged and 6.66% had moderate improvement. While evaluating the overall effect of therapy, it was observed that none of the patients marked improvement (Table 6) (Figure 1).
DISCUSSION

In this clinical study among the type of Raktamokshana, Prachchhana Karma with surgical blade no 11 had been selected. Prachchhana is indicated in Uttana Rakta, Ek Desha and Pindit Rakta. Probably in Indralupta also the Sthiti of Dushita Rakta is Pindit and ekdeshiya. Hence, Prachchhaana type of Raktamokshana may be more appropriate for the Raktamokshana in Indralupta. Due to hard surface of Scalp and for convenient use here surgical blade no 11 had selected for Prachcchana Karma.

After Prachchhana Karma, Lepa with Bibhitaki Churna had been selected. Lepa which is made by compound of drugs is not effective like single drug therapy because it not justifies its effect proper. Because Bibhitaki having Keshya property, had been selected for this study.

Probable Mode of action of the Procedure and Drug

- Probable mode of action of Prachchhana Karma
  - In present clinical study Raktamokshana of Dushita Rakta was done by the Prachchhana with surgical blade no.11.
  - Removal of vitiated Rakta may happens after Prachchhana, due to deprivation of Ushnata and Tikshnata of Pitta and Rakta (Flowchart 1).
  - After removal of vitiated Rakta, obstructed Romakoopa were released and after that new hair may growth (Flowchart 1).
- Probable mode of action of Lepa with Bibhitaki Churna:
  - Here for the Lepa, Bibhitaki churna was selected.
  - By the Lepa Karma, the Bibhitaki churna enters into the Romakoopa and further gets absorbed through Swedavahi Srotas and Siramukh leading to quicker absorption of medicament (Flowchart 2)
  - After absorption, Tridoshshamak and Keshya Guna of Bibhitaki may cause hair growth (Flowchart 2)
OVERALL EFFECT OF THERAPY (TABLE 6)

In present clinical study, out of 30 patients 12(40%) number of the patients were cured. 11(36.66%) number of the patients showed mild improvement. 2(6.66%) number of patients showed moderate improvement and 5(16.66%) number of patients showed very less improvement or remained unchanged (Table 6).

The mild improvement may be shown due to low level of Pathya Palana and Hair care in that patients. Also, due some patients job and study, Viharaja Nidana Sevana was continuously acquired by them. Moderate improvement probably due less upgradation in hair care methods in some patients. No or very less improvement due to more chronicity and Apathya Palana was continuously acquired by them.

CONCLUSION OF ALL OVER STUDY
1. At the end of this study, following conclusions can be drawn on the basis of observations made and results obtained.
   - Acharya Vagbhatta was the first to differentiate Indralupta and Khalitya. Kartika – the commentator of Madhava Nidana has differentiated Khalitya, Ruhya and Indralupta.
   - Hormonal imbalance plays important role in hair fall. Stress induced by diseases, surgery or emotional crisis disturbs the protein synthesis in hair follicle and as a result of it large numbers
of hairs of Anagen phase enters in Telogen (dying) phase. Consequently, massive hair loss is evident.

- In etiopathological study Lavana, Katu and Kshara Pradhana Dravya, Guru, Snigdha and Ushna Guna, Raja and Atapa Sevana, Prajagarana, Divaswapa, Chinta and Krodha are the responsible etiopathological factors for the development of Samprapti of Indralupta.

**Indralupta** is not a Kulaj Vikar according to Ayurveda. But modern science considers genetic predisposing factor. family history

- In clinical study, **Prachchhana Karma** is effective in relieve obstruction of Romakoopa by pacify Rakta Dushti and then Bibhitaka lepa promotes hair growth through its Tridoshshamak and Keshya Property.

- Also, the patients who followed the instructions regarding Pathyapalana respond better as compared to other patients who didn’t follow.

- Therefore, at the end of this study, it can be concluded that null hypothesis (H0) is rejected and alternative hypothesis (H1) is accepted. (statistically)

**Null Hypothesis (H0)**

“**Prachchhana Karma followed by Bibhitaka Lepa** is not effective in management of **Indralupta** (Alopecia Areata)

**Alternative Hypothesis (H1)**

“**Prachchhana Karma followed by Bibhitaka Lepa** is effective in management of **Indralupta** (Alopecia Areata)

**REFERENCES**


© STM Journals 2021. All Rights Reserved
15. Bhvaprakasha Nighantu by Prof Krushna Chanda Chunekara, chaukhmabha- bharati Academy Varanasi- 2010, Nidanstan-1/37, page 9