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

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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 Vagbhatta Vata Doṣha along with Pitta Doṣha resides in Romkoopa (hair root) results in hair fall (Keshapatan). After then Kapha Doṣha along with Rakta Doṣha block Romkoopa (hair root) so no more hair produce on that place, its results in Indralupta. Indralupta occurs due to Rakta Dushti 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 Prahcchhana 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*

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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 Vagbhatta* 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 Doṣha* along with *Pitta Doṣha* resides in *Romkoopa* (hair root) results in hair fall (*Keshapatan*). After then *Kapha Doṣha* along with *Rakta Doṣha* 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 fundaments Kesha is Mala of Asthi Dhatu [10].*

According to modern, Alopecia types are Alopecia Areata, Alopecia Totalis, Alopecia Universalis, Androgenic alopecia, Traction alopecia, Scaring Alopecia but as per symptoms of *Indralupta,* Itcan 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, pol1lution, 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 Dushti [11] and treatment of Indralupta, Prachchhana karma* is stated by major *Acharya.* For the treatment of vitiated *Rakta*, *Raktamokshana* is the line of treatment [12]. *Prachchhana Karma* is one among *Rakt Mokshaṇa* [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 *Keshya* property [15]. Now a days many *Ayurvedic* practitioners used *Bibhitaka 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 *Prahcchhana* 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:** 32patients attended the O.P.D. of Govt. *Akhandanand 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 between18 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 Bibhitka 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: $1/4^{th}$ 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: 0-1cm, Grade S2: 1-2 cm, Grade S3: 2-3 cm, Grade S4: 3-4cm, Grade S5:4-5cm
  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.

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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.

1.	Cured	100%
2.	Markedly Improved	>75 % to 100%
3.	Moderate Improved	>50 % to 75%
4.	Mild Improvement	>25 % to 50%
5.	Unchanged	0 to 25%

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 2.167which 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 0.567after 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 0.233after 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).

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

Chief Complaints								
Chief Complaints	*Mean Score*		*Diff.*	*%age*	*SD*	*SE*	*"t" Value*	*"P" Value*
	BT	*AT*						
Ekdeshiya Keshpatan	2.167	1.000	1.167	53.85%	0.592	0.108	10.79	<0.001

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

Associated Symptoms								
Symptoms	**Mean Score**		**DIFF**	**%**	**SD**	**SE**	**"t" Value**	**"p" Value**
	B.T.	**AT**						
Keshpatan	0.800	0.567	0.233	29.17%	0.430	0.0785	2.971	0.006
Darunaka	0.367	0.233	0.133	36.4%	0.346	0.0631	2.112	0.043
ShirahKandu	0.367	0.200	0.167	45.45%	0.379	0.0692	2.408	0.023
Palitya	0.0625	0.0625	0.000	00	00	00	00	1.000
Kesh Tanutva	0.219	0.188	0.031	14.29%	0.177	0.0312	1.00	0.325
Kesh Rukshta	0.161	0.129	0.032	20%	0.180	0.0323	1.00	0.325

- *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).

- *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 0.900after 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 0.125after 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 0.316after 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 0.727after 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 1.250after 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 1.500after the treatment. This reduction of 30% was highly significant (P<0.01).

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

Symptoms	No. of total 30pts	Mean Score				Paired t Test			
		B.T.	**A.T.**	**Diff.**	**%**	**SD**	**SE**	**"t" value**	**"P" value**
NO. of patches	52	1.733	0.900	0.833	48.08%	0.791	0.145	5.767	<0.001
SIZE of patches	141	2.712	1.115	1.596	58.87%	0.799	0.111	14.414	<0.001

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

Grade	No of Patches	Mean Score		Diff.	%	Paired T test			
		B.T.	**A.T.**			**SD**	**SE**	**"t" value**	**"p" value**
1	8	1.000	0.125	0.875	87.5%	0.354	0.125	7.000	<0.001
2	19	2.000	0.316	1.684	84.21%	0.478	0.110	15.372	<0.001
3	11	3.000	0.727	2.273	75.8%	0.0786	0.237	9.587	<0.001
4	8	4.000	2.750	1.250	31.3%	0.886	0.313	3.989	0.005
5	6	5.000	3.500	1.500	30%	1.049	0.428	3.503	0.01

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).

Table 6. Overall effect of therapy on 30 patients of *Indralupta.*

Results	Group A	
	No.	%
Complete remission (100%)	12	40%
Marked improvement (76-99%)	0	00
Moderate improvement (51-75%)	02	6.66%
Mild improvement (26-50%)	11	36.66%
Unchanged (= and < 25%)	05	16.66%
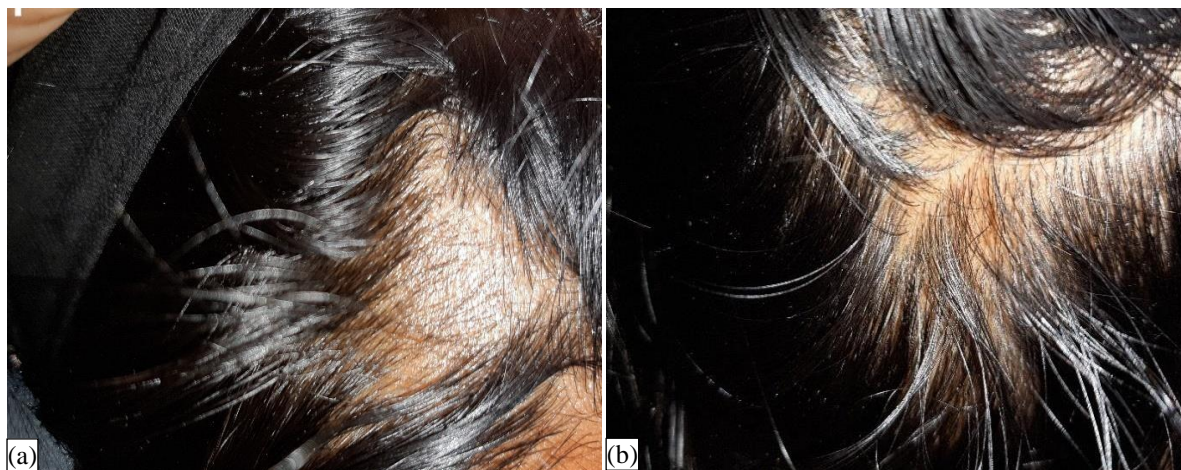
Figure 1. Patient's photograph of patch on scalp. (a) Before treatment, (b) After treatment.

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*
  o In present clinical study *Raktamokshana* of *Dushita Rakta* was done by the *Prachchhana* with surgical blade no.11.
  o Removal of vitiated *Rakta* may happens after *Prachchana*, due to deprivement of *Ushnata* and *Tikshnata* of *Pitta* and *Rakta* (Flowchart 1).
  o 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*:
  o Here for the *Lepa, Bibhitaki churna* was selected.
  o 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)
  o After absorption, *Tridoshshamak* and *Keshya Guna* of *Bibhitaki* may cause hair growth (Flowchart 2)

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Removal of vitiated *Rakta* and *Pitta* (*Ushnta*, *Tikshnata* decreased) and also *Aavaran* of *Kapha*

↓

Suddhi of *sthanastha Rakta* along with Kapha

↓

Release the obstruction of *Romakoopa*

↓

May hair growth occur

Flowchart 1. Probable mode of action of Prachchhan Karma.

Bibhitaki Churna Lepa

↓

Enters in the *Romakoopa* and gets absorbed through *Swedwahi Strotas* and *Siramukh*

↓

By *Tridoshshamaka* and *Keshya Guna* of *Bibhitaki*

↓

May Hair Growth occur
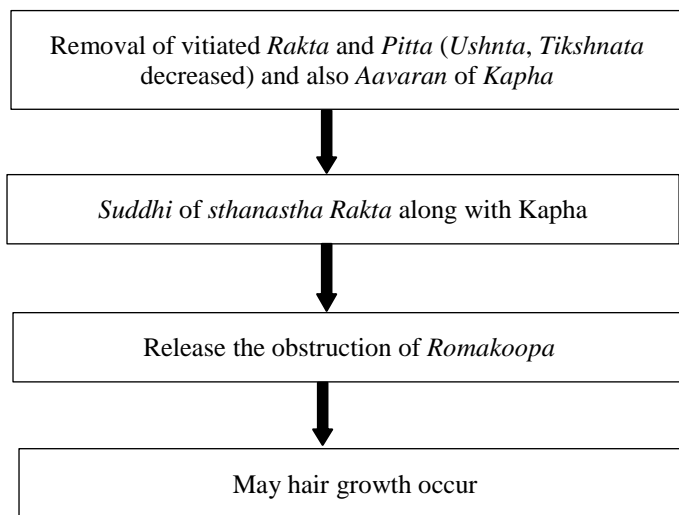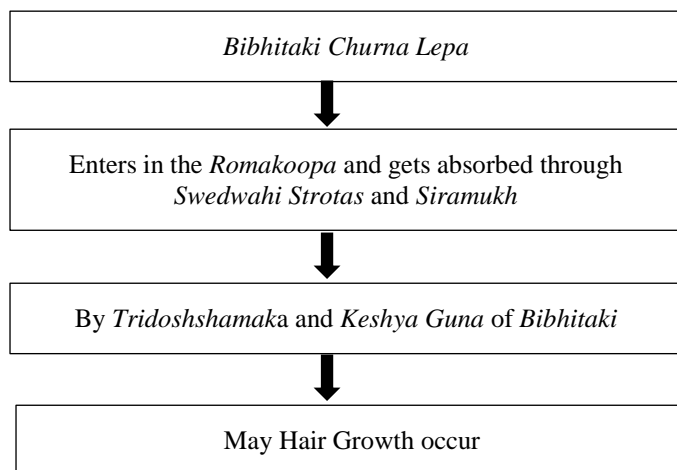
Flowchart 2. Probable mode of action of Lepa with bibhitaki churna.

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 *UshnaGuna, 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)

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