

EFFICACY OF 'ROMASANJANAN LEPA' (KARANJA, KASISA, KAPITTHA, HASTIDANT MASHI AND NARIKELA TAILA) IN 'INDRALUPTA' (ALOPECIA)

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ABSTRACT

Indralupta (Alopecia) has many significant deleterious effects like social anxiety, increased self-consciousness, low self-esteem, embarrassment and depression impairing psychological well-being thus affecting mental and social status of person. *Indralupta* is considered under *Kshudraroga* by most of the authors of classical Ayurvedic texts. Acharya Vagbhata was the first to differentiate *Indralupta* and *Khalitya*. The risk of allopathic treatment outweighs their benefits. '*Lepa cikitsa*' in the treatment of Alopecia as given by 'Acharya Sushruta' is cost-effective, non-toxic, and easily available. Efficacy of *Romasanjanana Lepa* (*Karanja, Kasisa, Kapittha, Hastidant Mashi and Narikela Tail*) in regeneration of Hair in '*Indralupta*' (Alopecia) is assessed through present study. Prospective open randomized single-arm clinical trial was carried out on 30 patients showing classical symptoms of *Indralupta*. The '*Romasanjanana Lepa*' was given for local application twice a day over a period of 18 months. *Indralupta* was found to be more prevalent in males and in the age group of 41-50 years. Intake of *Amla, Katu* and *Lavana Rasa*, non-vegetarian diet, stress factor and use of cosmetic could be considered as etiological factors of *Indralupta*. *Romasanjanana Lepa* reduced the size of patches, and percentage hair loss on local application. On regular use of *Romasanjanana Lepa*, regeneration of hair was also observed to significant level. Significant change was also observed in symptoms such as *Rukshata* (Dryness), *Pandu* (Pallor), *Daha* (Burning), *Raktata* (Redness) and *Snigdghata* (Unctuousness). Thus, '*Romasanjanana Lepa*' proved its efficacy and safety for topical Application.

Keywords: Alopecia, *Indralupta*, *Romasanjanana Lepa*

INTRODUCTION

It has been said that hair is a barometer of one's beauty. Healthy, beautiful, long and attractive hair adds charm to the personality. So, it has a great aesthetic value and it is the crowning glory of any person. Therefore to keep the healthy hair in healthy state is entirely the duty of human beings, because just like face hair is also a mirror of healthy state of

the body. Early hair fall has been attributed to be the result of varied factors like hormonal imbalance, faulty hair care, pollution etc. Alopecia is essentially a cosmetic disorder. Alopecia areata (AA) is a common form of non-scarring alopecia involving the scalp and/or body, characterized by hair loss without any clinical inflammatory signs. It is one of the

most common forms of hair loss seen by dermatologists and accounts for 25% of all the alopecia cases.¹ It was first described by Cornelius Celsus, and the term AA was coined by Sauvages in 1760.² It accounts for 2-3% of the new dermatology cases in UK and USA, 3.8% in China, and 0.7% in India.⁽²⁻⁴⁾ In Ayurvedic approach, loss of hair is coined out as in term of 'Indralupta' under the broad heading of *Kshudra Roga*⁵ except Vagbhata who has mentioned it under *Kapala Rogas*.⁶ *Indralupta* can be compared with Alopecia Areata in modern medicine. There are certain limitations for the treatment of Alopecia in modern medicine. There may be recovery in milder cases but usually severe cases progress to extreme baldness. These treatments which are available in modern medicine have side effects too. 'Acharya Sushruta', the Father of Surgery, has preferred *upakrama* like application of 'lepa' etc. in some cases thus avoiding surgery. 'Indralupta' (Alopecia) is one such disorder where 'lepa' has been advocated.⁷ Combination of Ayurvedic substances viz 'Karanja', 'kasisa', 'kapittha' (*Romasanjanana Lepa*) was advised for 'Indralupta' in Ayurvedic text. 'Hastidanta mashhi' and 'Narikela Taila' which are said to be the best 'keshya dravya' were added to this formulation and its efficacy was observed on patients of *Indralupta* (Alopecia).^(8,9)

AIMS AND OBJECTIVES:

- To study the efficacy of the formulation 'Romasanjanana lepa' on Alopecia through clinical study

MATERIALS AND METHODS: 30 patients attending the O.P.D. of Seth Tarachand Hospital, Rasta Peth, Pune fulfilling the criteria of the disease *Indralupta* were randomly selected irrespective of their age, sex, religion etc.

Study design: Prospective Randomized Non-comparative (Single group) clinical trial

Sample Size: 30 patients

Inclusion Criteria – Thirty patients of either sex with age group between 18-60 years complaining of classical signs of 'Indralupta' like round or oval shaped smooth patchy areas devoid of hair were selected at random for the study.

Exclusion criteria -

1. Patients below 18 years and above 60 years of age
2. Patients diagnosed with common systemic diseases like T.B. Diabetes, AIDS, and Leprosy etc.
3. Alopecia resultant of burns, acids, radiation hazards, chemicals, caustics, wounds, and drug induced neoplasms
4. Congenital ectodermal defects and congenital disorders
5. Alopecia caused by alteration in endocrinal system e.g. raised testosterone levels

Diagnosis of the patients:

I. Clinical diagnosis-was done based on symptoms and signs of patient which were examined by classical methods of examination of patient i.e. by Inspection (*Darshana*), Palpation (*Sparshana*) and interrogation (*Prashna*) method. The change in the following signs and symptoms was taken into consideration and were entered in C.R.F. a) 'Ruksha' (Dryness) b) 'Pandu' (Pallor) c) 'Daha' (Burning) d) 'Rakta' (Redness) e) 'Snigdha' (unctuousness) or any other major/minor symptom or sign. Details of personal data, previous medical history and follow up every 3 months to 18 months were recorded in C.R.F. Any major or minor signs or symptoms other than initially present

were recorded. Signs and symptoms were graded on the 5 point scale i.e. 0-4 in C.R.F.

II. Laboratory diagnosis

- a) Haemogram
- b) Testosterone and Hormonal level. (if required clinically)

The above laboratory examinations were done to see causative factors of diseases. Ethical clearance was taken from the Institutional Ethics Committee. (STH/PG/IEC/303A/2010) All the patients were registered after obtaining

voluntary informed consent.

A special proforma (C. R. F.) was designed for detailed history taking and examination of the patient incorporating all the signs and symptoms of the disease as per Ayurvedic texts.

Drug:

'Romasanjanana

Lepa' was prepared by mixing 'churna' with 'Narikela taila

Mode of administration: Topical application of 1/4 'Anguli' thick lepa was applied on affected area. Lepa was applied on the affected part twice a day i.e. in the morning and evening till it dries off. **Total duration of treatment was 18 Months.** Follow up was taken every 3 months till 18 months to notice the changes.

Criteria for assessment: To facilitate the statistical analysis of the effect of

therapy, scoring system was adopted. Each patient was screened on 1st day, every 3 months to 18 months. Overall assessment of therapeutic effect was made on the 5 point scale on the conclusion of the trial.

Assessment of Symptoms:

- a) 'Ruksha' (Dryness)
- b) 'Pandu' (Pallor)
- c) 'Daha' (Burning)
- d) 'Rakta' (Redness)
- e) 'Snigdha' (unctuousness) any other major/minor symptom or sign.

➤ No. of Patches:

➤ Percent scalp hair loss:

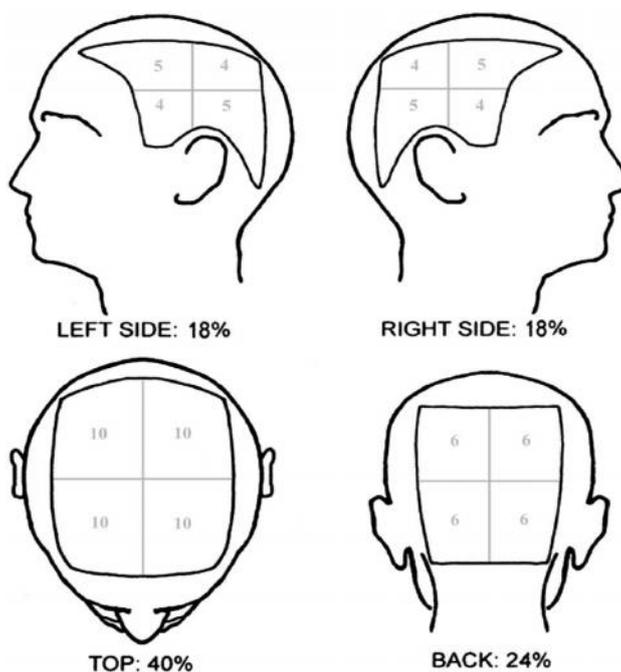
This takes into account the percent of the scalp surface with no hair.

➤ Hair regrowth:

Regrowth of hair was assessed on a four point scale on initial day, on every follow up of 3 months, at

the end of 18th month.

Tolerability was assessed by monitoring base line symptoms. Other signs and symptoms developing in the course of treatment were recorded with reference to their nature, duration and severity to find out any untoward effect of the formulation. Any premature discontinuation of trial treatment either due to early cure on medical advice or without medical advice due to unsatisfactory therapeutic effect or poor tolerability was recorded individually. The effect of the therapy was assessed in



terms of cured (100% relief), markedly improved (50% to 99% relief), improved (25% to 49% relief) and unchanged (less than 25% or no relief) from all the signs & symptoms.

Statistical Analysis:

Appropriate statistical tests were applied to the collected data.

For Quantitative data: Parametric tests were applied – paired t test

For Categorical data: Non-Parametric test was applied – Wilcoxon Rank sign test.

The obtained data were analysed statistically using **Graph Pad InStat 3 version**. A level of P value <0.05 was considered as statistically significant, P < 0.01 or P < 0.001 were considered as highly significant.

OBSERVATIONS AND RESULTS:

Total 30 patients were registered under study. Most of the patients i. e. 12 patients were from the age group 41 years to 50 years of age (40 %). Out of 30 patients of *Indralupta*, 24 were males (80%) and 06 patients were Females (20%). Most of the patients i. e. 26(86.67%) were belonging to middle socio-economic class. Out of 30 patients studied in this study, 24(80%) patients were from '*Vata-Pitta prakruti*', 4 (3.33%) patients had '*vata-kaphajprakruti*' and 2 (6.67%) patients were of '*pitta-kaphajPrakruti*'. 17 (56.66%) patients had history of *Indralupta* from '*pitrujkula*'. 20(66.67%) patients were having the 04 years to 08 years of duration. 26 (86.67%) patients had gradual hair loss. During the clinical evaluation, it was observed that '*Indralupta*' (Alopecia) is very common in Mixed diet Patients. 22 (73.33%) out of 30 patients of '*Indralupta*' had history of mixed diet whereas 8 patients (26.67%) were vegetarians.

Clinical Assessment of Patients of *Indralupta*: (Table No. 1 and 2)

A. *Rukshata* (Dryness): There was significant relief in ***Rukshata* (Dryness)** after completion of trial. The 'p' value comes less than 0.0001 which is statistically extremely significant. Relief in ***Ruksata* (Dryness)** was 52.75% in total 30 patients over a period of 18 months.

B. *Pandu* (Pallor): There was significant relief in ***Pandu* (Pallor)** after completion of trial. The 'p' value comes less than 0.0001 which is statistically extremely significant. Relief in ***Pandu* (Pallor)** was 51.43% in total 30 patients over a period of 18 months.

C. *Daha* (Burning): There was significant relief in ***Daha* (Burning)** after completion of trial. The 'p' value comes less than 0.0001 which is statistically extremely significant. Relief in ***Daha* (Burning)** was 54.43% in total 30 patients over a period of 18 months.

D. *Raktata* (Redness): There was significant relief in ***Raktata* (Redness)** after completion of trial. The 'p' value comes less than 0.0001 which is statistically extremely significant. Relief in ***Raktata* (Redness)** was 65% in total 30 patients over a period of 18 months.

E. *Snigdhatta* (Unctuousness): There was significant relief in ***Snigdhatta* (Unctuousness)** after completion of trial. The 'p' value comes less than 0.0001 which is statistically extremely significant. Relief in ***Snigdhatta* (Unctuousness)** was 40% in total 30 patients over a period of 18 months.

➤ **No. of Patches:** There was significant relief in **Number of Patches** after completion of trial. The 'p' value comes less than 0.0001 which is statistically extremely significant. Number of patches was reduced by 72.97% in total 30 patients over a period of 18 months. (Table No. 3)

- **Percent Scalp Hair Loss:** There was significant relief in **Percent Scalp Hair Loss** after completion of trial. The ' p ' value comes less than 0.0001 which is statistically extremely significant. Reduction in **Percent Scalp Hair Loss** was by 46.27% in total 30 patients over a period of 18 months. (Table No. 3)
- **Hair Regrowth:** There was significant Re-growth of hair after completion of trial. The ' p ' value comes less than 0.0001 which is statistically extremely significant. Re-growth of hair was observed by 50.83% in total 30 patients over a period of 18 months. (Table No. 3)
- **Total Effect Of Therapy:** Out of the 30 patients included in this trial in which 'Romasanjanana Lepa' was administered for 18 months, none patient showed total relief (100%) in symptoms, 20 (66.67%) patients were markedly improved (50-99% relief) while 10 (33.33%) patients showed improvement (25-49% relief). No one patient remained unchanged. (Table No. 4)

DISCUSSION

Indralupta (Alopecia) is common in males and in middle age group (41-50 years of age). As there is predominance of Vata and Pitta dosha in *Indralupta*, it occurs mainly in people with *Vata-Pitta prakruti*. Most common age group was in 41 years to 50 years of age. According to Sushruta, individuals are in a state of *Parihani* in this age group. Hormonal disturbance, emotional ups and downs are common in this age group. Uses of shampoo, colour, hair conditioner which are harmful to hair are frequent in this age group causing hair loss. Dietetic habit, Sleep patterns and Life style are also improper in this Age group. Many patients had history of *Indralupta* from

'*pitrujkula*'. These results indicate that *Indralupta* is a hereditary disease with Y-linked characters. Male pattern baldness sufferer inherits hair follicle which is genetically sensitive to Dihydrotestosterone (DHT). Those who develop their first patch of alopecia areata before the age of thirty have a higher possibility that other family members will also have it. In most of the cases, Alopecia is a gradual hair loss which evokes patient for treatment. '*Indralupta*' (Alopecia) is found to be very common in mixed diet patients. It can be said that non-vegetarian food causes aggravation of *doshas* as well as vitiation of *Raktadhatu* which leads to hair loss. There were significant changes in the symptoms such as *Rukshata* (Dryness), *Pandu* (Pallor), *Daha* (Burning), *Raktata* (Redness) and *Snigdhatu* (Unctuousness). There were statistically significant reduction in number of patches and percentage loss of hair. Regrowth of hair was also observed to a significant level at the end of 18 months of treatment.

Out of the 30, patients included in this trial in which 'Romasanjanana Lepa' was administered for 18 months, none patient showed total relief (100%) in symptoms, 20 (66.67%) patients were markedly improved (50-99% relief) while 10 (33.33%) patients showed improvement (25-49% relief). No one patient remained unchanged. No patient showed untoward reaction on use of drug. It proved the safety of the present formulation over a long period of time. The ingredients of '*Romasanjanana Lepa*' reduce '*Kapha*' in *Romakupa* and help in opening the hair follicle. Along with that, the formulation also clears the vitiations of '*Pitta & Vata Dosha*' resulting in further normal regrowth of hair, reduction in number of patches & percentage loss of

hair at significant level along with significant changes in all parameters like Ruksha, Pandu, Daha, Raktata and Snigdghata. Thus, 'Romasanjanana Lepa' proved its efficacy and safety for topical Application.

CONCLUSION

Indralupta was found to be more prevalent in males and in the age group of 41-50 years. Intake of Amla, Katu and Lavana Rasa, non-vegetarian diet, stress factor and use of cosmetic could be considered as etiological factors of Indralupta. Romasanjanana Lepa reduced the size of patches, and percentage hair loss on local application. On regular use of Romasanjanana Lepa, regeneration of hair was also observed to significant level. Significant change was also observed in symptoms such as Rukshata (Dryness), Pandu (Pallor), Daha (Burning), Raktata (Redness) and Snigdghata (Unctuousness). Thus, 'Romasanjanana Lepa' proved its efficacy and safety for topical Application. Small sample size, single group (no comparator used), use of simple efficacy parameters and short duration of study were the limitations of the present study. The same study can be carried out with large sample size, controlled study with oral medications, use of advanced efficacy parameters and with longer duration.

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Tables:

Table No. - 1 Showing Effect on General Symptoms Score of Patients of Indralupta

Sr. No	Symptom	Assessment of Parameters			
		BT	AT	Difference	Percentage of Relief

1	Rukshata	91	44	48	52.75%
2	Panduta	70	34	36	51.43%
3	Daha	79	36	43	54.43%
4	Raktata	80	28	52	65%
5	Snigdghata	27	75	-48	40%
6	Percent hair Loss	518	140	378	72.97%
7	No. of Patches	67	36	31	46.27%
8	Regeneration of Hair	11	72	-61	50.83%

Table No. 2 showing statistical analysis of symptoms of 30 patients

Sr. No.	Symptom		Mean	SD	SE	Sum of all Signed Ranks (W)	No. of Pairs	P value
1.	Ruksha (Dryness)	BT	3.03	0.32	0.06	465	30	<0.0001 Highly Significant
		AT	0.57	0.68	0.13			
		Difference	2.47	0.77	0.14			
2.	Pandua (Pallor)	BT	2.37	0.93	0.17	406	28	<0.0001 Highly Significant
		AT	0.4	0.5	0.09			
		Difference	1.97	1	0.18			
3.	Daha (Burning)	BT	2.63	0.72	0.13	435	29	<0.0001 Highly Significant
		AT	0.27	0.45	0.08			
		Difference	2.37	0.97	0.17			
4	Rakta (Redness)	BT	2.63	0.89	0.17	406	28	<0.0001 Highly Significant
		AT	0.2	0.41	0.08			
		Difference	2.43	1	0.18			
5.	Snigdgha	BT	3.03	0.49	0.09	465	30	<0.0001 Highly Significant
		AT	0.9	0.48	0.09			
		Difference	2.13	0.59	0.1			

Table No. 3 showing statistical analysis of physical parameters of 30 patients

FACTORS		MEA N	S.D.	S.E.	Sum of all ranks	No. of pairs	P – value
Percent hair loss	BT	17.267	11.809	2.156	W = 465	30	p < 0.0001 Extremely Significant
	AT	4.6667	5.4223	0.99	T+ = 465		
	Difference	12.6	8.7832	1.6036	T- = 0		
No. of patches	BT	2.2333	0.7279	0.1329	W = 231	21	p < 0.0001 Extremely

	AT	1.2	0.55	0.10	T+ = 231		Significant
	Difference	1.0333	0.8087	0.1477	T- = 0		
Regeneration of hair	BT	0.3667	0.4901	0.0895	W = -465	30	p < 0.0001 Extremely Significant
	AT	2.4	0.4983	0.091	T+ = 0		
	Difference	-2.0333	0.4138	0.0756	T- = -465		

Table no 4: showing the total effect of therapy on 30 patients

Sr. No.	Total Effect of Therapy	No. of Patients	Percentage
1.	Cured (100%)	0	0
2.	Markedly Improved (50-99%)	20	66.67%
3.	Improved (25-49%)	10	33.33%
4.	Unchanged (0-24%)	0	0
	Total	30	100

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Source of support: Nil
Conflict of interest: None Declared