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Efficacy of 'Romasanjanana Lepa' (Karanja, Kasisa, Kapittha, Hastidant Mashi and Rarikela Taila) in Regeneration of Hair in 'Indralupta' (Alopecia)

Dr. Deodatta Bhadlikar

Abstract: ***Introduction 'Ayurveda' is one of the oldest documented systems of healthcare which deals elaborately with measures for healthy living. Ayurveda thus is knowledge of life and encompasses both preventive and curative aspects towards restoration of healthy life. It describes the basic and applied aspect of life process, health, disease and its management in terms of its own principles and approaches In Ayurvedic texts, there are four types of Ayu. Among these, Sukhayu is most important.1 Sukhayu deals with life, which is without physical and mental disorders and which is having qualities like Bala (strength), Virya (vitality), Parakrama (courage) and Soundarya (beauty). According to the famous quotation, "A thing of beauty is joy forever.'' So, the concept of beauty (Soundarya) is gaining more and more attention globally and hair play an important role in it, as it has been said that hair is a barometer of one's beauty. Healthy, beautiful, long and attractive hairs add 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. Hair loss is silent but devasting problem which may occur to a healthy person also. It has been regarded as geriatric physiological phenomena, generally after the midforties. 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. Hair is a major factor of appearance and a part of physical attraction. Therefore Alopecia has been found to have 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. Alopecia areata (AA) is a common form of non-scarring alopecia.***

Keywords: Ayurveda

1. Introduction

'Ayurveda' is one of the oldest documented systems of healthcare which deals elaborately with measures for healthy living. Ayurveda thus is knowledge of life and encompasses both preventive and curative aspects towards restoration of healthy life. It describes the basic and applied aspect of life process, health, disease and its management in terms of its own principles and approaches In Ayurvedic texts, there are four types of Ayu. Among these, Sukhayu is most important.1 Sukhayu deals with life, which is without physical and mental disorders and which is having qualities like Bala (strength), Virya (vitality), Parakrama (courage) and Soundarya (beauty).

According to the famous quotation, "A thing of beauty is joy forever.'' So, the concept of beauty (Soundarya) is gaining more and more attention globally and hair play an important role in it, as it has been said that hair is a barometer of one's beauty. Healthy, beautiful, long and attractive hairs add 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.

Hair loss is silent but devasting problem which may occur to a healthy person also. It has been regarded as geriatric physiological phenomena, generally after the midforties. 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. Hair is a major factor of appearance and a part of physical attraction. Therefore Alopecia has been found to have 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.

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.2 It was first described by Cornelius Celsus, and the term AA was coined by Sauvages in 1760.3 It accounts for 2-3% of the new dermatology cases in UK and USA, 3.8% in China, and 0.7% in India.(3-5) In general population, the prevalence was estimated at 0.1-0.2% with a lifetime risk of 1.7%. Both males and females are equally affected, 6 but some studies reported male preponderance. (3, 5, 7, 8) It can occur at any age. The youngest was 4-months-old, and the oldest was in late seventies.9 Twenty percent of cases were children, and 60% of AA patients had their first patch before 20 years of age.6 Highest prevalence was between 30-59 years of age.1 Family members are affected in 8.7-20% of cases.(3,9)

In Ayurvedic approach, loss of hair is coined out as in term of 'Indralupta' under the broad heading of Kshudra Rogas10 except Vagbhata who has mentioned it under Kapala Rogas.11 Indralupta can be compared with Alopecia Areata in modern medicine. Alopecia Areata (AA) is the common form of hair loss affecting the quality of life of many patients.

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.

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'Acharya Sushruta' is known as Father of Surgery. Even though Sushruta was an expert surgeon he advised surgery only when utmost necessary. This is evident by the fact that in 'Ṣhashti Upakrama'.12 'Acharya Sushruta' has preferred upakrama like application of 'lepa' etc. thus avoiding surgery. 'Indralupta' (Alopecia) is one such disorder where 'lepa' has been advocated.13

Even though the 'Ayurvedic' texts have documented time tested remedies that can be made known to society only with scientific validation.

1.1 Purpose of the Study

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. 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. This study was an extension of post graduate

The study topic "Efficacy of 'Romasanjanan Lepa' (Karanja, kasisa, kapittha)" in'Indralupta' (Alopecia).14 Combination of Ayurvedic substances viz 'Karanja', 'Kasisa', 'Kapittha' (Romasanjanan Lepa) was employed on 'Indralupta' for 42 days patch to find out their effect in revitalizing the hair growth.15

From the study the following conclusions were drawn:-
1) The drug combination is safe & effective.
2) The drug combination has ability to lower the patches.
3) The drug combination stimulates the hair growth.

From the previous study it was observed that this Ayurvedic formulation is effective in 'Indralupta', hence it was decided to take a same topic by adding 'Hastidanta mashi' and 'Narikel Tel' which are said to be the best 'keshya drayva' for further study. (16,17)

1.2 Hypothesis

A) Null Hypothesis (Ho): 'Romasanjanana lepa' application has no significant role in 'Indralupta' (Alopecia).
B) Alternate Hypothesis (H1): 'Romasanjanana lepa' application has significant role in 'Indralupta' (Alopecia).

1.3 Research Question

Is the application of 'Romasanjanana lepa' statistically & clinically significant in patients suffering from 'Indralupta' (Alopecia) with subjective variables as: a) 'Ruksha' (Dryness) b) 'Pandu' (Pallor) c) 'Daha' (Burning) d) 'Rakta' (Redness) e) 'Snigdha '(unctuousness) f) 'Paka '(Suppuration) g) 'Sannipataja' (all) h) 'Kandu' (Itching) & objective variables as: a) decrease in area of patch b) number of patches c) regeneration of hair ?

2. Aims & Objectives

2.1 Aim

To assess the efficacy of 'Romasanjanana Lepa' in 'Indralupta'(Alopecia)

2.2 Objectives

1) To prepare and standardize the Romasanjanana Lepa formulation
2) To study the phytochemical characterization of raw material used in formulations
3) To study the efficacy of the formulation 'Romasanjanana Lepa' on Alopecia through clinical study

3. Review of Literature

1) Ayurvedic Literature
Acharya Charaka mentions that Tejas by involving Vatadi Dosha when reaches the scalp, it results in Khalitya (Indralupta). According to Chakrapani word Tejas here denots Deha Ushma as well as Pitta Dosha

Chikitsa Siddhanta
Specific line of treatment has been adopted for all disease in ancient Ayurvedic texts, especially in Charaka Samhita. Such a line of treatment for a disease is also called Chikitsa Siddhanta.

The line of treatment Indralupta mentioned by different Acharya is as under. Acharya Sushrut mentioned Samshodhana (snehan & shodhan) along with Nasya, Head massage of oil, Raktamokshan and Shirolepa. Acharya Charaka says that after adequate Samshodhana patient of Hair loss should be subjected to Nasya, massage of oil and Shirolepa.

2) Modern Literature
Sushruta Samhita: Pitta along with Vata by involving the roots of hair (Romakoopa) causes fall of hairs and thereafter Shleshma along with Shonita obstructs the channel of Romakoopa leading to the stoppage of the regeneration of Hair and this condition is known as Indralupta, Khalitya or Ruhya.

Alopecia areata (AA) is probably the third most common form of hair loss dermatologists see, after androgenetic alopecia and telogen effluvium. The lifetime risk for AA is nearly 2%. It is not contagious. Researchers believe AA is an autoimmune disease For whatever reason, the immune system is inappropriately activated and attacks hair follicles. Research using several disease models shows certain types of lymphocytes play a primary role in the hair loss. It often appears as well-defined circular bald patches on the scalp. Many people will get just one or two patches, but for some the hair loss can be extensive. Hair loss that spreads to cover the entire scalp is called alopecia totalis. If it spreads over the entire body affecting scalp, eyebrows, lashes, beard, pubic hair, and everything else, then the condition is called alopecia universalis. If the alopecia is just limited to the beard area in men, it is called alopecia barbae.

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4. Drug Review

S.O.P of Romasanjanan Lepa

Sr. No.	*Name of ingredients*	*Used Parts*
1	'Hastidanta'.	Mashi
2	'Kasisa'– Ferrous sulphate Feso4 7 H2O	Purified Kasisa
3	'Karanja – Pongamia glabra	'Patra' (Leaf) 4
4	'Kapittha' – Feroniael ephantum	Pulp of ripe fruit
5	'Narikela'	Tail (oil)

Kasisa purchased from local market was subjected to Shodhana as per classical references.

Materials used for Kasisa Shodhan-

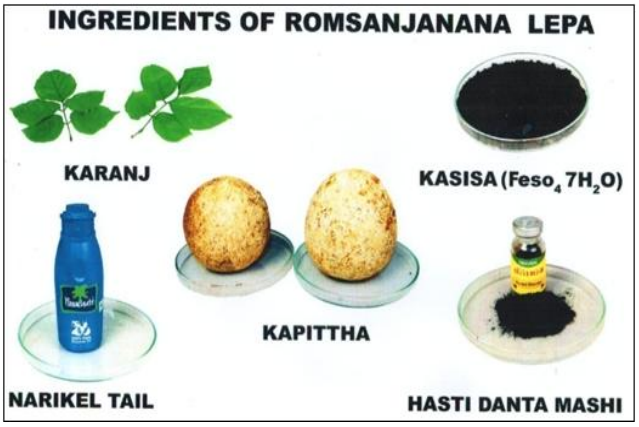
- 'Ashuddha Kasisa'
- 'Bhringaraja Swaras' (juice of 'Eclipta alba')

Procedure for Shodhan of Kasisa

- 'Ashuddha Kasisa was converted to powder form.
- It was subjected to 'Svedan' into 'Dolayantra' containing 'Bhringaraja Swarasa'
- The 'Swedan' was done for 72 minutes i.e. 3 'Ghatika'.
- At the end of process Shuddha Kasisa in dry state was obtained.

Procedure for the preparation of Romasanjanan Lepa'

- Equal quantity of Shuddha Kasisa'& 'Karanja Patra' were triturated in 'Khalvayantra' till homogeneous mixture i.e. 'Kalka' was formed.
- Swaras (Fruit pulp juice) of ripen 'Kapittha' was added to above 'Kalka' and triturated well till it dried completely.
- 'Hastidanta Mashi' was added to this dried powder and mixed in 'Khalvayantra' till a homogeneous mixture is obtained.
- This powder was then stored in air tight container and named as 'Romasanjanana Lepa'.



Analytical Study

1) **Total phenolic content:**
The maximum concentration of the total phenolic was found to be in distilled water 21.66±0.32 mg/ml whereas the minimum concentration was observed in ethanol 4.80±1.60 mg/ml. Distilled water formulation is the better solvent for phenolic content estimation because water molecules can retain the phenolic compounds for a longer period of time. 3
2) **DPPH assay (Antioxidant activity):**
The highest antioxidant capacity of formulation was observed in the distilled water 85.24±0.30 mg/ml and the lowest activity was observed in ethanol 70.89±0.05 mg/ml. Thus the phenolic and polyphenolic compounds are natural antioxidants which enhance the free radical scavenging activity4
3) **FRAP assay (Antioxidant activity):**
Ferric reducing antioxidant power was found maximum in methanol 0.017±0.02 mg/ml and minimum in distilled water 0.011±0.01 mg/ml.

Probable Mode of Action of Romasanjanan Lepa

Constituents	Rasa	Virya	Vipaka	Guna	Karma	Active Principles
Bhringaraja	Katu, Tikta	Ushna	Katu	Ushna, Tikshna	Kaphavatahara, Kesharanjan Keshavardhana, Twachya ,Vishahara	Alkaloids, Ecliptine and Nicotine.
Narikel Tel	Tikta, Madhura	Sheeta	Madhura	Guru, Snigdha	Vata-Pittahara, Keshya, Balya, Bhruhaniya	Fixed Oil lauric acid,
Hastidanta Mashi						CaO , P (Phosphorus) Al2O3 , MgO

Clinical Study:

Materials:
Patients attending the O.P.D. of Seth Tarachand Hospital, Rasta Peth, Pune fulfilling
the criteria of the disease were randomly selected and 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

Informed Consent: The patients undergoing treatment were informed about the same and written consent for each was taken.

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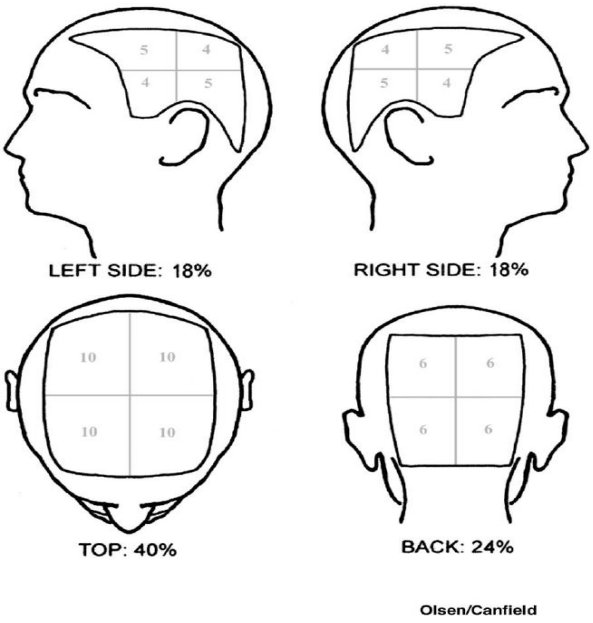
Drug: 'Romasanjanana Lepa' was prepared by mixing 'churna' with 'Narikela tail'

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 for continuous 18 months.

Duration of Treatment: 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.

1) Assessment of Symptoms:
   a) '*Ruksa*' (Dryness) b) '*Pandu* '(Pallor) c) 'Daha' (Burning) d) 'Rakta' (Redness) e) 'Snigdha '(unctuousness) any other major/minor symptom or sign.
2) **No. of Patches**
3) **Percent scalp hair loss:** This takes into account the percent of the scalp surface with no hair.
4) **Hair regrowth:** Regrowth of hair was assessed on initial day, on every follow up of 3 months, at the end of 18th month.
5) **Assessment of Adverse Drug reactions (**if any)



Assessment Of Effect Of Therapy:
- Cured: 100% relief, from all the signs & symptoms, was considered as totally cured.
- Markedly Improved: 50% to 99% relief from, the signs & Symptoms, was considered as markedly improved.
- Improved: 25% to 49% relief, from the signs & symptoms was, considered as improved.
- Unchanged: Less than 25% or no relief, from the signs & Symptoms, was considered as unchanged.

Statistical Analysis
A) For objective Parameters (Quantitative Data) (i.e. Improvement in Physical Parameters & Improvement in Hematological parameters) parametric test was applied: **Paired ' t ' test**
B) For subjective Parameters (Qualitative Data) (Relief in Symptoms) Non - Parametric test was applied: **Wilcoxon matched pairs test**

5. Observations and Results

5.1 Analytical Study

1) Total phenolic content:
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3) FRAP assay (Antioxidant activity):
Ferric reducing antioxidant power was found maximum in methanol 0.017±0.02 mg/ml and minimum in distilled water 0.011±0.01 mg/ml.

4) Flavonoids estimation:
Flavonoid content was observed maximum in methanol content 0.72±0.02 mg/ml and minimum in ethanol content 0.51±0.02 mg/ml.

5) RP-HPLC
The RP-HPLC results was observed maximum in ethanol formulation were cathechol was observed to be 50.701 ppm and caeffic acid 1.923 ppm. Caeffic acid and vanillin in methanol formulation was observed to be 8.066 and 0.605 respectively.

6) Heavy metal analysis by XRF method:
Not a single heavy metals like Chromium (Cr), Cadmium (Cd), Lead (Pb), Barium (Ba), Arsenic (As), Antimony (Sb), Selenium (Se), Mercury (Hg) detected from fruit *Ferronia elephuntum* (*Kapittha*), Sample B = *Hasthidant* Powder (Burnt *Mashi* of Ivory), Sample C = Ferrous Sulphate FeSO4.7H2O (*Kasisa*) .

Clinical Study:
- During this clinical study, it was observed that out of 30 sample size 24(80%) Patients were form Hindu religion and only 3 (10%) patients were from Muslim and Sikh Religions each.
- Out of 30 Patients enrolled in the trial, 24(80%) were males and 6(20%) from female gender.
- Most common age group was in 41 years to 50 years of age (12 patients -40 %).
- Regarding Socio-economic status and occupational status, it was observed that 26 (86.67%) patients were

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from middle class whereas 4 (16.33%) were businessmen i. e. from higher socio-economic class.

- Out of 30 patients studied in this study, 24 (80%) patients were from '*Vata-Pitta prakruti*', 4 (13.33%) patients had '*vata-kaphajprakruti'* and 2 (6.67%) patients were of '*pitta-kaphajPrakruti'*. Observations show that maximum persons possessed *Vata-pitta Prakruti*.
- During the evaluation, it was observed that 17 (56.66%) patients had history Of *Indralupta* from '*pitrujkula'*, 01 (3.33%) Patient had history of *Indralupta* from '*matrujkula'* and there were 12 (40%) patients found without any family history.

Out of Thirty (30) patients, 09 (30.0%) patients had the history of disease up to 4 yrs, 20(66.67%) patients were having the 04 years to 08 years of duration and 01 (3.33%) Patient had the duration of disease for more than 8 years.

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Sr.no	Symptoms	BT	AT	Difference	Percentage
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	Snigdhata	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%

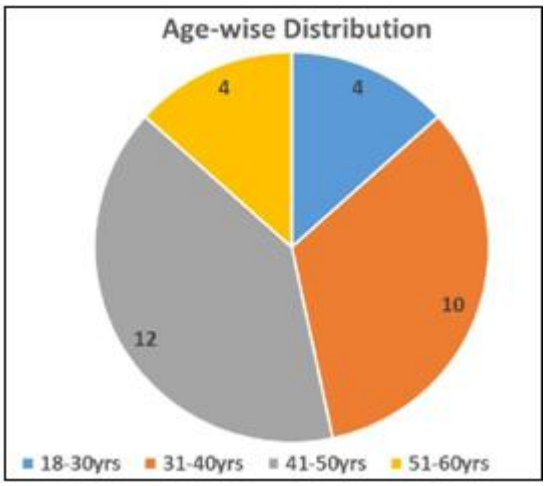
Sr.No	Symptom	Statistical Significance
1	Ruksha (Dryness)	p <0.0001 Highly Significant
2	Pandu (Pallor)	p <0.0001 Highly Significant
3	Daha (Burning)	p <0.0001 Highly Significant
4	Rakta (Redness)	p <0.0001 Highly Significant
5	Snigdha (Unctousness)	p <0.0001 Highly Significant

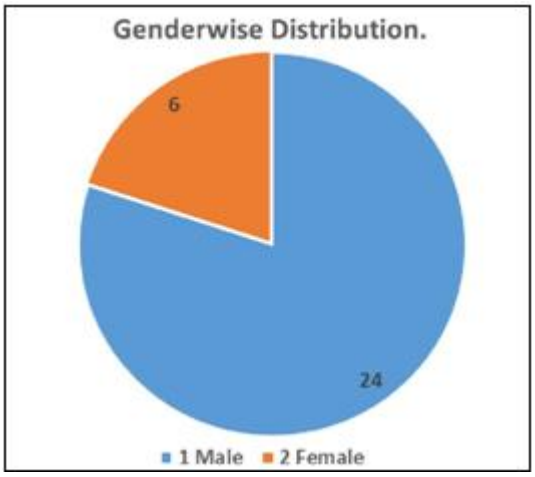
Sr. No.	Physical Parameters	Statistical Significance
1	Percent Hair Loss	p < 0.0001, Extremely Significant
2	No. of Patches	p < 0.0001, Extremely Significant
3	Regeneration of Hair	p < 0.0001, Extremely Significant

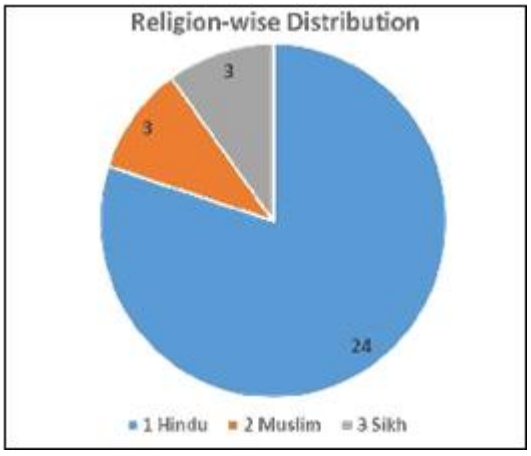
*For all the above parameters, initially paired t test was used but since the data did not pass the normality test, the Wilcoxon matched pairs test was applied. (Graphpad Software was used for statistical analysis)

S. 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

Demographic Details- Graphs







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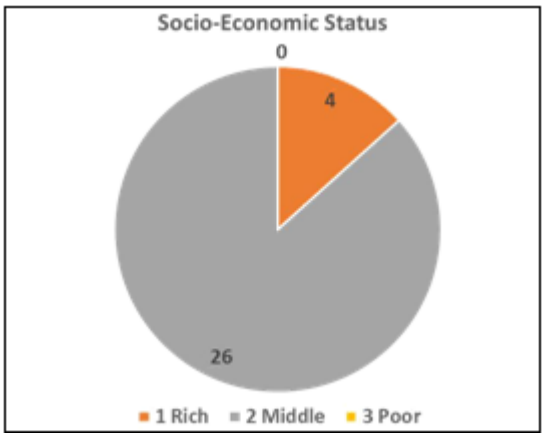

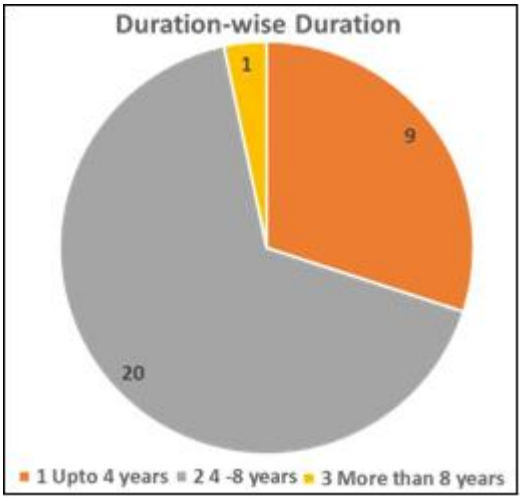

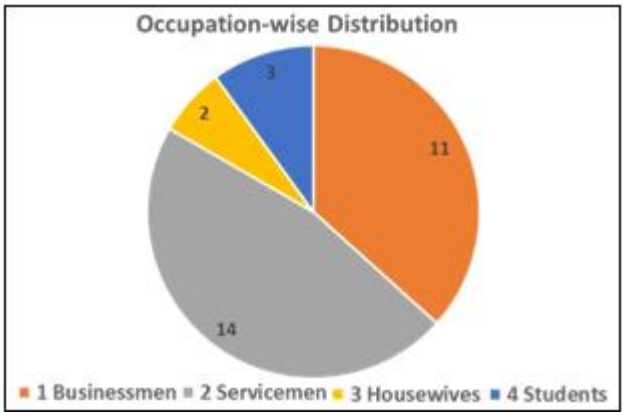

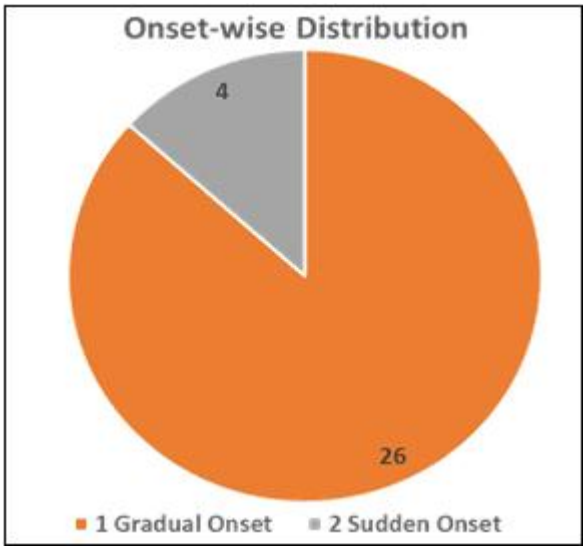

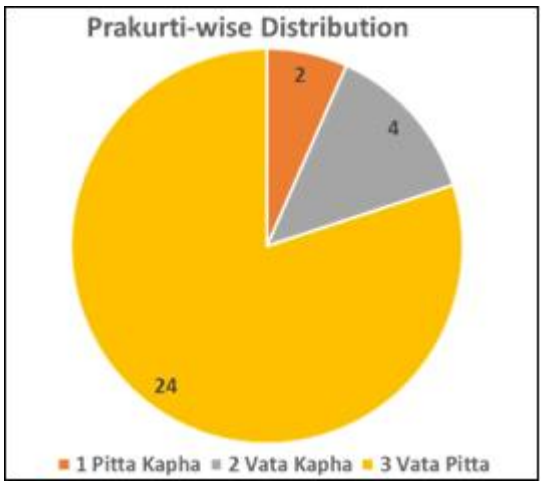

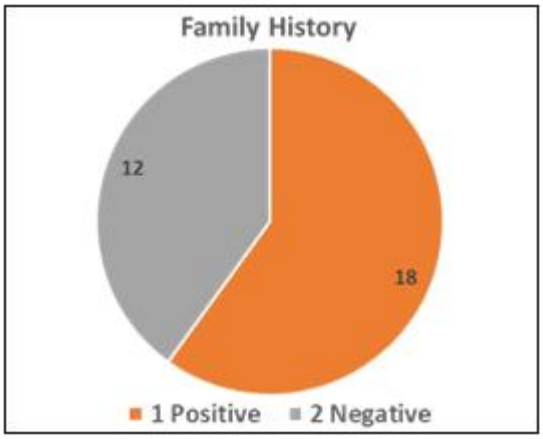

Photographic representation of different cases of Indralupta

BEFORE TREATMENT AFTER TREATMENT

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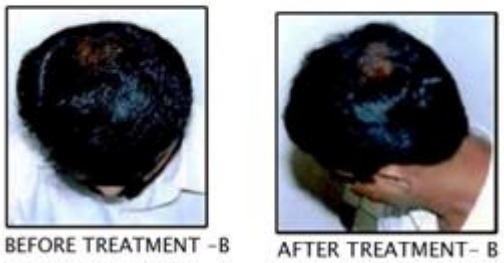

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6. Discussion

Science is a gradual evolution; it is not a sudden invention. Ayurveda as a science is not an exception for it. The imperishable fundamentals of Ayurveda, which were laid down by the great sages of the olden days are still applicable because of their scientific background.

According to ancient research methodology before establishing any theory, Upanaya (Discussion) is the prior step to Nigamana (conclusion). Upanaya is a process of re-examining oneself. It forms a base for Nigamana. In spite of detailed classical study and experimentation in various ways, a theory is accepted only after the proper reasoning of observation.

Discussion is the process of examining the facts through their merits and demerits to obtain proper knowledge about facts. To reach up to the depth of the knowledge it is the important step which helps in understanding the subject and guides to conclusive judgment. Before establishment of truth as conclusion, discussion is mandatory. It is the process of re-examining the whole work. It can either support the hypothesis or it can help in amendment or it may revolutionize the concept totally. Our body processes a unique capacity of perpetuating a healthy state amidst various disturbing factors. On account of our faulty habits as well as changed environmental conditions. The inherent capacity of the body to cope with these changes turns out short.

'Indralupta' (Alopecia) i.e. patchy hair loss is a common disease all over the world. Hair is the main part of personality and has always remained the center of attraction and everybody is extra conscious about hairs.The pathogenesis of Indralupta according to Ayurveda, Mithya Ahara and Vihara, Manoabhighata like mental stress, fright, anger, shock etc. may collectively increase the Pitta and Vata Dosha. The Ushna and Tikshna properties of Pitta get augmented whereas the Vata suffers aggravation in Ruksha, Khara and Chala properties. Here the aggravated Pitta (Bhrajaka Pitta) supported by the vitiated Dehoshma burns the Keshabhoomi whereas an increased Vata gives rise to more frequent and comparatively prolonged Shira Sankocha by its Ruksha and Khara Guna. The Snigdhatva and the Pichchhilatva of the normal Kapha Dosha is prevalent throughout the pores of the skin so as to keep it soft and moist. By the augmentation of the Ushna, Tikshna, Ruksha and Khara properties of Pitta and Vata Doshas respectively, the Sneha and the Pichchhilatva of the Kapha Dosha are dried up within the pores of the skin of the scalp thus, obstructing the growth of new hairs, causing Indralupta.

In Modern Medicine, lot of remedies are available for 'Indralupta' which are in the form of Steroid with toxic side effects, skin irritant, less effective and recurrence of disease is common. Hair transplantation is a modern surgical management for Alopecia, but this is less effective and with post-operative complications. So, there are number of prescriptions and surgical treatment for Alopecia but they have their own complications and limitations.

In general, in day to day life 'Indralupta' (Alopecia) is commonly treated. The treatment at these conditions is a late sequel and is difficult to get complete cure. Ayurveda has typically conservative management with a different regimen of Lepa for'Indralupta', and one of them is 'Romasanjanana Lepa' (which consists of Hastidanta Mashi, Karanja, Kasisa, Kapittha and Narikel Taila).

7. Analytical Study

Plants produce various antioxidant compounds to combat reactive oxygen species posing an oxidative stress. Antioxidant activity is strongly dependent on the solven due to the different antioxidant potentials of phytochemical compounds with distinct polarities and extractability. Antioxidant properties of single compounds within groupcan vary remarkably, so that the same levels of phenolics do not necessarily correspond to the same antioxidant responses. Lipid peroxidation is caused due to reactive oxygen species (ROS) which is responsible for the deterioration of food by leading the formation of potential toxic compounds. The concentration of peroxide decreases with the increase in the antioxidant activity, while the absorbance values are much smaller with higher antioxidant activities of the samples. The TBA assay is not specific formalondialdehyde (MDA)

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which is one of the breakdown products of lipid peroxidation. The nonspecificity probably results from the acid eating step of the TBA assay that causes the formation of artificial TBA/MDA-like derivatives. The DPPH scavenging activity was found to be in agreement with the % protection activity of the extracts. Phytochemicals such as phenolics, anthocyanins and other flavonoids contributes antioxidant activities in plants. Correlation analysis clearly determine that assay such as total phenol content, DPPH radical scavenging activity and lipid peroxidation correlates with each other. But total flavonoid content has negative correlation with total phenols and lipid peroxidation1,2.

Total phenolic content:
The maximum concentration of the total phenolic was found to be in distilled water 21.66±0.32 mg/ml whereas the minimum concentration was observed in ethanol 4.80±1.60 mg/ml. Distilled water formulation is the better solvent for phenolicontent estimation because water molecules can retain the phenolic compounds for a longer period of time.

DPPH assay (Antioxidant activity):
The highest antioxidant capacity of formulation was observed in the distilled water 85.24±0.30 mg/ml and the lowest activity was observed in ethanol 70.89±0.05 mg/ml. Thus the phenolic and polyphenolic compounds are natural antioxidants which enhance the free radical scavenging activity.

FRAP assay (Antioxidant activity):
Ferric reducing antioxidant power was found maximum in methanol 0.017±0.02 mg/ml and minimum in distilled water 0.011±0.01 mg/ml.

Flavonoids estimation:
Flavonoid content was observed maximum in methanol content 0.72±0.02 mg/ml and minimum in ethanol content 0.51±0.02 mg/ml.

RP-HPLC:
The RP-HPLC results was observed maximum in ethanol formulation were cathechol was observed to be 50.701 ppm and caeffic acid 1.923 ppm. Caeffic acid and in methanol formulation was observed to be 8.066 and 0.605 respectively.

Heavy metal analysis by XRF method:
Not a single heavy metals like Chromium (Cr), Cadmium (Cd), Lead (Pb), Barium (Ba), Arsenic (As), Antimony (Sb), Selenium (Se), Mercury (Hg) detected from fruit Ferronia elephuntum (Kapittha), Sample B = Hasthidant Powder (Burnt Mashi of Ivory), Sample C = Ferrous Sulphate FeSO4.7H2O (Kasisa) .

Clinical Study:
The present clinical study analyzed with the aims to evaluate the efficacy, Specificity, Limitations and Scope of the 'RomasanjananaLepa' in re-generation of the hair in 'Indralupta' (Alopecia).

8. Assessment of Observed Parameters

1) During this clinical study, it was observed that out of 30 sample size 24(80%) Patients were form Hindu religion and only 3 (10%) patients were from Muslim and Sikh Religions each. These results are insignificant to draw any conclusion because the study centre was located in a Hindu dominant area.
2) Out of 30 Patients enrolled in the trial, 24(80%) were males and 6(20%) from female gender. More Prevalence of Alopecia in males can be due to hormonal factor. Males are prone to get androgenic alopecia. The reason behind this may be that male is more prone towards stress and environment hazards. Androgenic alopecia, commonly called male or female pattern baldness, was caused by the predominance of the male sex hormone, testosterone, which women also have in trace amounts under normal conditions. The hormonal process of testosterone converting to DHT, which then harms hair follicles, happens in both men and women.
3) Most common age group was in 41 years to 50 years of age (12 patients -40 %). According to Sushruta, individuals are in a state of Parihani. 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.
4) Regarding Socio-economic status and occupational status, it was observed that 26 (86.67%) patients were from middle class whereas 4 (16.33%) were businessmen i. e. from higher socio-economic class. Data is insufficient to draw any conclusion as the patients coming to hospital were mostly from middle socio-economic status.
5) Out of 30 patients studied in this study, 24 (80%) patients were from 'Vata-Pitta prakruti', 4 (13.33%) patients had 'vata-kaphajprakruti' and 2 (6.67%) patients were of 'pitta-kaphajPrakruti'. Observations show that maximum persons possessed Vata-pitta Prakruti. Keeping this fact in mind, one can say that all the three Doshas viz. Vata, Pitta and Kapha are involved in the Samprapti of Indralupta. But there is obvious dominancy of Vata-pitta Dosha.
6) During the evaluation, it was observed that 17 (56.66%) patients had history of Indralupta from 'pitrujkula', 01 (3.33%) Patient had history of Indralupta from 'matrujkula' and there were 12 (40%) patients found without any family history. 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.
7) Out of Thirty (30) patients, 09 (30.0%) patients had the history of disease up to 4 yrs, 20(66.67%) patients were having the 04 years to 08 years of duration and 01 (3.33%) Patient had the duration of disease for more than 8 years.
8) 26 (86.67%) patients had gradual hair loss and 4 (13.33%) patients had sudden onset of disease. In most of

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the cases, Alopecia is a gradual hair loss which evokes patient for treatment.

9) 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. It can be said that non-vegetarian food causes aggravation of doshas as well as vitiation of Raktadhatu which leads to hair loss.

9. Assessment of clinical efficacy:

Clinical assessment of symptoms:

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 Rukshata (Dryness) was 52.75% in total 30 patients over a period of 18 months. Rukshata (Dryness) got reduced due to Vatahara properties of the formulation.

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. Varnapasadana effect of the formulation can be observed through this result.

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. Snigdhata (Unctuousness):
Here was significant relief in Snigdhata (Unctuousness) after completion of trial. The 'p' value comes less than 0.0001 which is statistically extremely significant. Increase in Snigdhata (Unctuousness) was 40% in total 30 patients over a period of 18 months. Local action of Narikela taila can be seen through this result.

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.

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.

Hair Regrowth
There was significant regrowth of hair after completion of trial. The ' p ' value comes less than 0.0001 which is statistically extremely significant. Regrowth of hair was observed by 50.83% in total 30 patients over a period of 18 months. There was a significant decrease in number of patches and percent scalp hair loss. Significant hair growth also took place. These results could be enhanced by regular use of formulation over along period of time.

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.

Probable action of drug:
In Indralupta, derranged 'Pitta' in hair follicle along with derranged 'VataDosha' acts upon the shaft of hair upon its tip as well as on the root and damages it. As a result of which hair falls. Derranged 'Pitta' in turn leads to derrangement of 'Rakta-dhatu' and 'KaphaDosha'. The ingredients of 'Romasanjanana Lepa' are of 'Amla, Kaṭu, Kashaya rasa', Ushna and shitavirya, Tridoshaghna in Doshaghnata and hence they reduce 'Kapha' in Romakupa and help in opening the hair follicle. Along with that, the formulation also clears the vitiations of 'Pitta and Vata Dosha' resulting in further normal regrowth of hair, reduction in number of patches and percentage loss of hair at significant level along with significant changes in all parameters like Ruksha, Pandu, daha, Raktata, Snigdhata.

During the present clinical study it has been observed that 'Romasanjanana Lepa' reduces the size of 'Indralupta' patches as well as significantly cures without any potential complications such as Hypersensitivity, dermatitis, Skin exfoliation. Thus this formulation is found to be safe in patients for topical application over a long period of time. Even though the Ayurvedic texts have documented time-tested remedies they can be popularized only with scientific validation. And for same more extensive study needs to be done on more number of cases with specific objectives and objective parameters to explore the details.

10. Summary and Conclusion

Alopecia has many significant deleterious effects like social anxiety, increased selfconsciousness, low self-esteem, embarrassment and depression impairing psychological well being thus affecting mental and social status of person. 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. This study was an extension of post graduate study topic entitled "Efficacy of 'Romasanjanan Lepa' (Karanja, kasisa, kapittha)" in 'Indralupta' (Alopecia). Lepa prepared with 'leaf of Karanja', 'Kasisa' and 'Kapittha fruit' was applied on clinically diagnosed patients of 'Indralupta' for 42 days to find out their effect in revitalizing the hair growth. From the previous study it was observed that this Ayurvedic formulation is effective in 'Indralupta'. In

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'Sushruta Samhita' it is mentioned that both 'Hastidanta mashi' & 'Rasanjana' in equal quantity are taken & mixed with 'Ajakshira' in case of ''Indralupta''. Its effect has been exemplified stating that hair grow even on palms and feet if used properly. Narikela Tail is reported as Keshya and being in used since time immortal. Hence present study entitled "Efficacy of Romasanjanana Lepa (Karanja, Kasisa, Kapittha, Hastidant Mashi and Narikela Tail) in regeneration of Hair in 'Indralupta' (Alopecia)" study was taken by adding Narikel tail and Hastidanta mashi in previously studied 'Romasanjanana Lepa'. Study was planned with the following aims and objectives.

10.1 Aims and Objectives:

Aim:
To assess the efficacy of 'Romasanjanana lepa' in 'Indralupta'(Alopecia)

Objectives:
1. To prepare and standardize the Romasanjanana lepa formulation
2. To study the phytochemical characterization of raw material used in formulations
3. To study the efficacy of the formulation 'Romasanjanana lepa' on Alopecia through clinical study

10.2 Plan of Study

The study was carried out in three phases, i.e.
1. Review of literature
2. Analytical study
3. Clinical study

10.2.1 Review of Literature
It embraces;
- Ayurvedic as well as modern view on Anatomy and physiology of Kesha (Hair):
- Disease review: It include Ayurvedic view regarding Nidanapanchaka & treatment of Indralupta given in various Ayurvedic treatises. This chapter also contains etiopathogenesis & various treatment modalities of Alopecia given in modern texts.
- Review about the concept of lepa
- Drug review: It includes details review of the ingredient of Romasanjanana Lepa. Drug review encompasses review of Karanja, Kasisa, Bhrungaraj (used for Kasisa shodhana) Kapittha, Hastidant Mashi and Narikela Taila

10.2.2 Analytical Study
Romasanjana lepa consist leaves of Karanja, fruit of Kapittha, Kasisa, Narikela tail and Hastidant mashi. Ingredient of Romasanjanana lepa and compound formulation were subjected to certain analytical study to evaluate the antioxidant activity of the sample. Ten grams of each sample were suspended in 60mL of different solvent systems viz; distilled water, methanol, ethanol and kept overnight. These extract were used for further analytical study Total phenolic content by Folin's reagent:, Antioxidant by DPPH(1,1-diphenyl-2-picrylhydrazyl), Antioxidant by FRAP (ferric reducing antioxidant power), total flavonoid content, and assessment of phenolic compound by HPLC method were carried out on ingredients of Romasanjanana lepa as well as on compound formulation. Whereas lipid peroxidation by TBARS was carried out on ingredient only. Heavy metal analysis was carried out using XRF method on three samples Fruit Ferronia elephuntum (Kapittha); Hasthidant Powder (Burnt Mashi of Ivory) and **Ferrous Sulphate FeSO4.7H2O (Kasisa).**

- Maximum (80.86 ± 1.07) total phenolic compound was observed in Bhrungaraj Leaves in methanol extract, whereas in formulated sample it was highest (21.66±0.32) in distilled water extract.
- Antioxidant by DPPH method, maximum value (96.99 ± 0.50) was observed in leaves of Karanja in methanol extract whereas in formulated sample it was highest (85.24±0.30) in distilled water extract.
- Antioxidant activity by using FRAP assay, maximum value 0.015 ± 0.0017 was observed in methanol extract of leaves of Bhrungaraja, whereas in formulated sample it was maximum (0.017±0.02) in methanolic extract.
- Total Flavonoids was maximum (0.356 ± 0.010) in methanol extract of Bhrungaraj leaves, it was highest (0.72±0.02) in methanolic extract of formulation.
- Lipid peroxidation using TBARS assay, maximum percentage protection (86.11%) was observed in methanol extract of fruit of Kapittha.
- Gallic acid (25.80 ppm), catechu (23.22ppm) was found highest in ethanol extract of Karanja leaves. Caffic acid (62.30) and Ferullic acid (104.64) was maximum in distilled water extract of fruit of Kapittha. Whereas in compound formulation, Catechol (50.701 ppm) and Vanillin (0.760) was maximum in ethanolic extract, whereas caffic acid was maximum 8.066 ppm in methanolic extract.
- None of the studied sample shows presence of heavy metal in Heavy Metals in formulated sample using XRF.

10.2.3 Clinical 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.
- During this clinical study, it was observed that out of 30 sample size maximum patients belonged to Hindu religion (80%), most of them were males (80%) and in 41 years to 50 years of age group (40 %).
- Regarding Socio-economic status & occupational status, it was observed that 26 (86.67%) patients were from middle class whereas 4 (16.33%) were businessmen i. e. from higher socio-economic class.
- Out of 30 patients studied in this study, 24 (80%) patients were from 'Vata-Pitta prakruti', 4 (13.33%) patients had 'vata-kaphaj prakruti' and 2 (6.67%) patients were of 'pitta-kaphaj Prakruti'.
- 56.66% patients had history of Indralupta from 'pitruj kula', 01 (3.33%) Patient had history of Indralupta from 'matruj kula' and there were 12 (40%) patients found without any family history.
- Out of Thirty (30) patients, 09 (30.0%) patients had the history of disease up to 4 yrs, 20(66.67%) patients were having the 04 years to 08 years of duration and 01 (3.33%) Patient had the duration of disease for more than

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8 years. 26 (86.67%) patients had gradual hair loss and 4 (13.33%) patients had sudden onset of disease.

- 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.
- There were significant changes in the symptoms such as Rukshata (Dryness), Pandu (Pallor), Daha (Burning), Raktata (Redness) and Snigdhata (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.
- 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 Snigdhata.
- No patient showed untoward reaction on use of drug. It proved the safety of the present formulation over a long period of time.
- Thus, 'Romasanjanana Lepa' proved its efficacy and safety for topical Application.

11. Conclusion

1) Indralupa is considered under Kshudraroga by most of the authors of classical texts. Acharya Vagbhata was the first to differentiate Indralupta and Khalitya.
2) Indralupta is Sannipatika Vyadhi with predominance of Pitta and VatDosha.
3) Indralupta can be compared with Alopecia Areata in modern medicine. Alopecia areata (AA) is an autoimmune inflammatory disease, considered as third most common form of hair loss.
4) Lepa cikitsa' is one of Shashti-upakrama given by acharya Sushrut. Lepa is external application of medicinal dugs (Bahirparimarjana Chikitsa).
5) 5.Acharya Sushrut has mentioned that Kasisa and tender leaves of Karanja pounded with Kapittha is useful in Romasanjanana.
6) Romasanjanana Lepa includes Kasisa, Karanja Patra and fruit of Kapittha along with Narikela Taila and Hastidant mashi.
7) Total phenolic compound and antioxidant property by DPPH was maximum in distilled water extract. Antioxidant by FRAP method and total falvaonoid was maximum in methanol extract. HPLC method reveals that, Catechol and Vanillin was maximum in ethanolic extract, whereas caffic acid was maximum in methanolic extract. Thus Romasanjana Lepa possess antioxidant activity.
8) None of the studied sample shows presence of heavy metal in Heavy Metals in formulated sample using XRF.
9) 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.
10) Romasanjanana Lepa reduced the size of patches, and percentage hair loss on local application. On regular use of Romasanjanana Lepa, regenaration of hair was also observed to significant level.
11) Significant change was also observed in symptoms such as Rukshata (Dryness), Pandu (Pallor), Daha (Burning), Raktata (Redness) and Snigdhata (Unctuousness). Thus, 'Romasanjanana Lepa' proved its efficacy and safety for topical Application.

12. Limitations of the Present Study

1) Small sample size
2) Single group study (No comparator used)
3) Use of Simple efficacy parameters
4) Short duration of study

13. Future Scope

1) Large sample size
2) Controlled study can be carried out with oral medications
3) Use of advanced efficacy parameters
4) Longer duration of study

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