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Developing Topical Gel Formulation of Erandakarkati (*Carica papaya* Linn.) Latex for Managing Indralupta: A Preliminary Study

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ABSTRACT

Introduction: *Indralupta*, a *tridosha-raktaja vyadhi*, is marked by patchy hair loss caused by blocked hair follicles due to aggravated *Rakta* and *Kapha doshas*. This blockage disrupts nutrient flow to the follicles, resulting in hair fall and bald patches. Ayurveda recommends dietary changes, oral medications, and *Panchakarma* therapies for restoring *dosha* balance. *Carica papaya* (*Erandakarkati*) is known for its medicinal properties, especially in its latex, which contains enzymes like papain and chymopapain with anti-inflammatory and antioxidant effects.

Methods: This pilot study aimed to evaluate the efficacy of a topical *C. papaya* latex gel for treating *Indralupta*. Thirteen participants aged 20–60 years were selected from the outpatient department of *Dravyaguna* at Vaidyaratnam Ayurveda College. A pre-post interventional design was used, assessing subjective and objective parameters at baseline, and on the 7th, 14th, 21st, and 28th days. The gel was prepared using Carbopol 934 and triethanolamine and applied daily for 10 min over 28 days. Safety was ensured through a patch test on healthy volunteers.

Results: By the end of the 28-day treatment, nine participants showed no hair fall, and eleven exhibited hair growth in previously bald areas. However, the bald patch size did not significantly change. No participants reported itching, and the gel was confirmed safe by the patch test. Demographic analysis showed that most participants were male, married, educated, and middle-class, with a preference for non-vegetarian diets and spicy foods. The onset of *Indralupta* was mostly sudden.

Discussion: The *C. papaya* latex gel showed promise in reducing hair fall and promoting hair regrowth in *Indralupta* patients over a 28-day period. However, the lack of significant change in bald patch size suggests the need for longer treatment or additional interventions. The small sample size and short treatment duration limit the generalizability of the results.

Conclusion: *C. papaya* latex gel may be effective in treating *Indralupta*, but further research with larger sample sizes and longer treatment durations is needed to validate these findings.

1. INTRODUCTION

Hair plays a crucial role in protecting the scalp, as well as in regulating body temperature and detecting environmental shifts. In addition, hair functions as a sensory organ. Through sensitive nerve endings at the base of hair follicles, hair detects subtle changes in the environment, such as the touch of wind, adding another layer of

sensory awareness to the body. Beyond these physiological roles, hair significantly influences psychological well-being, impacting self-esteem and confidence. Its association with identity and beauty makes hair loss a distressing experience for many, highlighting its influence on mental and emotional health.^[1] These protective, sensory, and psychological roles underscore the multifaceted importance of hair in human physiology and psychology, illustrating that its value is far greater than its surface-level appearance. In Ayurveda, hair loss is not only a physical issue but often reflects an underlying imbalance within the body's *doshas* (energetic principles), particularly when linked to a condition like *Indralupta*. *Indralupta* is categorized as a

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Tridosha-raktaja vyadhi, a disorder involving the combined imbalance of the three *doshas*.^[2,3] These aggravated factors are believed to block hair follicles, impeding nutrient supply to the follicles and causing hair to fall out in clumps, ultimately leading to bald patches. Unlike other forms of alopecia, *Indralupta* often prevents the natural regrowth of hair unless the underlying imbalances are addressed. Ayurvedic treatments for *Indralupta* involve dietary modifications, lifestyle changes, oral medications, and *Panchakarma* procedures aimed at *dosha* balance, improving digestion, removing toxins, and nourishing hair follicles. These therapeutic approaches support the Ayurvedic view of promoting overall health to address hair loss holistically. *Carica papaya*, known as *Erandakarkati* in Ayurveda, is widely grown across India and is recognized for its medicinal properties, particularly in the latex extracted from the unripe fruit.^[4] Conventionally used in Ayurvedic treatments for skin diseases and as an anthelmintic (worm expeller), *Erandakarkati* has a longstanding place in herbal medicine. The latex contains bioactive compounds such as papain, chymopapain, and caricain, which exhibit anti-inflammatory, antioxidant, and wound-healing properties.^[5,6] These attributes have potential therapeutic benefits in managing conditions like *Indralupta*, where inflammation and oxidative stress are contributing factors to hair loss. Recent studies further highlight *C. papaya*'s potential in stimulating hair growth, with bioactive compounds promoting cell regeneration and reducing scalp inflammation, making it a promising candidate for treating hair loss.^[7-11]

In Kerala, Ayurvedic practitioners have traditionally used *Erandakarkati* latex in treating *Indralupta*. Empirical observations suggest that this latex encourages hair growth and aids in filling bald patches associated with this condition. This pilot study aims to evaluate the effect of a topical gel prepared from *C. papaya* latex on clinical symptoms of *Indralupta*. Given that *Papaya* latex has demonstrated wound-healing and skin-beneficial properties, formulating it as a gel offers practical advantages such as easy application, targeted delivery, and potentially improved absorption of active compounds. If effective, this study would validate the traditional Ayurvedic use of *Erandakarkati* latex in *Indralupta* treatment, offering a safe, accessible, and cost-effective approach. Such findings could reinforce evidence-based practices within Ayurveda and support the wider acceptance of Ayurvedic solutions for hair loss conditions.

2. MATERIALS AND METHODS

2.1. Study Setting

Outpatient department (OPD), Department of *Dravyaguna Vijnanam*, Vaidyaratnam Ayurveda College, Ollur, Thrissur, Kerala, and CAREKERALA, Koratty, Thrissur, Kerala.

2.2. Study Materials

2.2.1. Collection of fresh latex

Fresh latex from the unripe fruit of *C. papaya* was collected by making 7–8 longitudinal incisions on the fruit. The latex was dried and stored in air-tight containers.

2.2.2. Excipients

Carbopol 934 (gelling agent), Triethanolamine (TEA) (emulsifying agent), and methylparaben (preservative) were of analytical grade.

2.3. Preparation of Gel

0.5 g of Carbopol 934 was dispersed into 98.5 mL of distilled water in a beaker. The mixture was stirred continuously for about 30 min to ensure full dispersion, then allowed to hydrate for 3 h.

Subsequently, 1 g of *Papaya* latex was gradually added to the hydrated Carbopol solution, with continuous stirring to ensure even dispersion. The pH was adjusted to approximately 6.5–7.0 by adding TEA drop by drop while stirring until the gel thickened. Methylparaben was incorporated to extend the gel's shelf life. The mixture was continuously stirred until the gel achieved a uniform consistency, then it was transferred to clean, sterilized containers and labeled appropriately.

2.4. Physicochemical Characterization

The physical parameters such as color and appearance were observed. The presence of any aggregate and homogeneity of the gel was visually inspected. The pH of the gel was measured using an electrode-type pH meter. The viscosity of the gel was measured using a Brookfield viscometer. To determine the spreadability, an excess amount of the sample was applied between two glass slides and compressed with a 1,000 g weight for 5 min. A 50 g weight was then added to the pan. The time taken for the two slides to separate, indicated by the upper glass slide moving over the lower plate, and was recorded as the measure of spreadability.

2.5. Study Design

This study was conducted as a pre-post interventional study.

2.6. Inclusion Criteria

Individuals aged 20–60 years, irrespective of gender, presenting in the *Dravyaguna* department OPD with patchy hair loss on any area of the scalp. Only those willing to participate in the study and able to provide informed consent were recruited.

2.7. Exclusion Criteria

- Patients diagnosed with other forms of alopecia areata, such as alopecia totalis and alopecia universalis
- Patients with associated complications, such as *Dustavruna*
- Individuals with severe systemic illnesses
- Patients with hair loss due to other scalp disorders, including Tinea capitis, Trichotillomania, and traumatic alopecia or psoriasis
- Pregnant and lactating women.

2.8. Sample Size

15.

2.9. Sampling Methods

Consecutive.

2.10. Ethical Considerations

Institutional Ethics Committee clearance was obtained before the commencement of the research, and all procedures adhered to the guidelines set forth by the committee. Informed consent was secured from all participants, ensuring their understanding of the study's purpose, procedures, and potential risks.

2.11. Study Procedure: Assessment Criteria

2.11.1. Objective criteria

1. Size of patch

The size of each hair loss patch was measured using blotting paper and graded as follows:

- Grade 0: No patch
- Grade 1: 0.5–1 cm
- Grade 2: 1–2 cm
- Grade 3: 2–3 cm
- Grade 4: Greater than 3 cm

2. Number of patches

The total number of patches on the scalp was recorded and categorized as follows:

- Grade 0: None
- Grade 1: 1–2 patches
- Grade 2: 2–3 patches
- Grade 3: 3–4 patches
- Grade 4: More than 4 patches

2.11.2. Subjective parameter

- Itching
 - Grade 0: No itching
 - Grade 1: Itching present.

2.12. Intervention

Participants for the pilot study were recruited according to the predefined inclusion and exclusion criteria. Each participant underwent an initial assessment to determine the severity of their condition based on both subjective and objective criteria.

The study participants received a gel formulated from the latex of *C. papaya*, provided in 10 g tubes. Participants were instructed to clean the affected area thoroughly, dry it with a cotton cloth, and then apply a sufficient quantity of the gel to the affected area. The application was to be performed daily for 10 min over 28 consecutive days. To facilitate adherence to the treatment regimen, a chart was provided for participants to record their daily gel application. Follow-up assessments were conducted every 7th day throughout the treatment period, during which both subjective and objective parameters were re-evaluated to monitor progress and treatment effectiveness.

3. RESULTS OF PHYSICOCHEMICAL ANALYSIS

Physicochemical characterization is essential in ensuring product quality, stability, and performance. The color, appearance, and homogeneity were visually inspected:

In the present study, 15 patients who met the inclusion and exclusion criteria were selected for participation. Out of these, 13 patients completed the study, while 2 withdrew from the trial. All participants were examined both before and after the treatment according to the established case pro forma. Observations were systematically recorded on a weekly basis, allowing for a comprehensive comparison of conditions. The collected data were subsequently analyzed and interpreted to assess the treatment outcomes [Table 1].

3.1. Assessment of Growth of Hair in 13 Cases of Indralupta (Alopecia Areata)

Cochran Q test was done for comparing the presence of hair growth in different weeks, results shows that there exists a significant difference in the cases having the presence of hair growth throughout the period. Initially, hair fall was absent in all cases. As the week's progresses, number of cases having hair growth also increases and on week 4, 11 cases have hair growth [Table 2].

3.2. Assessment of Hair Fall in 13 Cases of Indralupta (Alopecia Areata)

Freidman's test was done for comparing hair all in different weeks. Results show that P -value is very <0.01 which indicates that the test statistic is significant. Hence, reject the null hypothesis that there is a change in hair fall between the weeks. Thus, it can be concluded that there is no significant difference in the size of patch throughout the study period. Results of pair-wise comparison of week in terms of hair fall is given in Tables 3 and 4.

3.3. Assessment of Size of Patch in 13 Cases of Indralupta (Alopecia Areata) during the Study Period

Freidman's test was done for comparing size of patch in different weeks. Results show that P -value is >0.05 which indicates that the test statistic is non-significant. Hence, accept the null hypothesis that there is no change in size of patch. Thus, it can be concluded that there is no significant difference in the size of patch throughout the study period [Table 5].

3.4. Results of Pair Wise Comparison of Hair Fall between Different Periods

Week 3 and 4 is significantly different from week 0 and week 1. All other weeks show no significant difference between each other. As per the results given in Table 4, all cases have hair fall in week 0 and week 1 and 5 cases in both weeks have a moderate level of hair fall and one case has severe hair fall. From week 2 onward, slight changes were observed, but it was not statistically significant. In week 3, 6 cases have no hair fall, and in week 4, 9 cases have no hair fall. These results show that there is a significant reduction in hair fall using this treatment.

3.5. Assessment of Itching in 13 Cases of Indralupta (Alopecia Areata)

No participants reported itching throughout the study period [Table 6].

3.6. Assessment of Number of Patch in 13 Cases of Indralupta (Alopecia Areata)

No significant [Table 7] reduction in bald patch size was observed ($P > 0.05$).

4. DISCUSSION

Indralupta is a condition characterized by sudden, patchy hair loss, primarily affecting the scalp. This condition is attributed to the imbalance of *Tridoshas* – *Vata*, *Pitta*, and *Kapha* – along with *Rakta* (blood).^[12-14] The blockage of hair follicles due to aggravated *Rakta* and *Kapha* leads to hair loss and prevents regrowth, resulting in bald patches.^[15] The present study aimed to formulate and evaluate a topical gel of *Erandakarkati* (*C. papaya* Linn.) latex for the management of *Indralupta*. The gel was prepared using Carbopol 934 as a gelling agent and TEA to adjust the pH.

Physicochemical characterization was done to ensure product quality, stability, and performance. The *Erandakarkati* (*C. papaya* Linn.) latex gel is a dull white, translucent substance with good homogeneity, a skin-friendly pH, and a high viscosity of 9988 cps, ensuring it stays in place upon application. Its moderate spreadability of 21.75 g cm/sec and uniform distribution of ingredients make it effective.

The study found a significant reduction in hair fall among participants over the 28-day treatment period. By the end of the study, nine out of 13 participants reported no hair fall, a marked improvement

from the baseline. The statistical significance ($P < 0.001$) of these results underscores the potential of *C. papaya* latex gel in effectively managing hair fall associated with *Indralupta*.

A notable outcome was the significant increase in hair growth observed in participants. Initially, none of the participants showed hair growth in the affected patches. However, by the 4th week, 11 out of 13 participants exhibited new hair growth. This improvement, also statistically significant ($P < 0.001$), suggests that the gel formulation not only prevents further hair loss but also actively stimulates the regrowth of hair in bald patches.

Despite the positive outcomes in hair fall reduction and hair growth, the study noted no significant change in the size of the bald patches. The Friedman test results indicated that the patch size remained relatively constant throughout the study period ($P > 0.05$). This finding suggests that while the treatment is effective in initiating hair regrowth and reducing hair fall, it may require a longer duration or additional therapeutic interventions to significantly alter the size of existing bald patches.

Demographically, the majority of participants were male, married, and from middle-class backgrounds, with a preference for non-vegetarian diets. The study highlighted the need for larger sample sizes and longer follow-up periods to generalize the findings and evaluate the sustained efficacy of the treatment. Further research is suggested to explore alternative formulations and analyze the active phytoconstituents of the *C. papaya* latex gel.

5. CONCLUSION

The study demonstrates that *C. papaya* latex gel significantly reduces hair fall and promotes hair regrowth in *Indralupta* cases. However, its effect on patch size reduction remains inconclusive within the 28-day period. Longer treatment duration or complementary therapies may enhance outcomes. This was a pilot study limited to 13 samples only. It has to be conducted in a large sample size to get more precise clinical evaluations. Further analysis of the formulation may be carried out to find out the presence of phytoconstituents responsible for the action. Considering alternative formulations, such as ointments, could be explored to see if they potentially enhance the therapeutic outcomes.

6. ACKNOWLEDGMENTS

Nil.

7. AUTHORS' CONTRIBUTIONS

All the authors contributed equally in the design and execution of the article.

8. FUNDING

Nil.

9. ETHICAL APPROVALS

This study is approved by Institutional Ethical Committee.

10. CONFLICTS OF INTEREST

Nil.

11. DATA AVAILABILITY

This is an original manuscript and all data are available for only review purposes from principal investigators.

12. PUBLISHERS NOTE

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Table 1: Physicochemical characterization of Erandakarkati gel

Sl. no.	Characterization	Results
1	Color	Dull white
2	Appearance	Clumpy translucent
3	Homogeneity	Good
4	pH	6.6
5	Viscosity	9988 cps
6	Spreadability	21.75 g cm/sec

Table 2: Assessment of growth of hair in 13 cases of Indralupta (Alopecia areata)

Sr. no.	Hair growth	No. of cases				
		Week 0	Week 1	Week 2	Week 3	Week 4
1.	Absent	13	09	08	06	02
2.	Present	00	04	05	07	11

Chi-square=26.080; $P=0.001$ **Table 3:** Assessment of hair fall in 13 cases of Indralupta (Alopecia areata)

Sr. no.	Hair fall	No. of cases				
		Week 0	Week 1	Week 2	Week 3	Week 4
1.	Absent	00	00	04	06	09
2.	Mild (hair fall on Washing)	07	07	05	04	02
3.	Moderate (hair fall on combing)	05	05	03	02	01
4.	Severe (hair fall on simple strengthening)	01	01	01	01	01

Table 4: Results of pair-wise comparison hair fall between different period

Period of comparison	P-value
Week 0 versus week 1	1.00 ^{ns}
Week 0 versus week 2	0.082 ^{ns}
Week 0 versus week 3	0.008 ^{**}
Week 0 versus week 4	<0.001 ^{**}
Week 1 versus week 2	0.082 ^{ns}
Week 1 versus week 3	0.008 ^{**}
Week 1 versus week 4	<0.001 ^{**}
Week 2 versus week 3	0.352 ^{ns}
Week 2 versus week 4	0.055 ^{ns}
Week 3 versus week 4	0.321

ns- not significant, meaning the difference between the compared weeks was not statistically significant - that is, $P>0.05$; **-the difference is statistically significant, usually at the level of: $P<0.01$ (highly significant)

Table 5: Assessment of size of patch in 13 cases of Indralupta (Alopecia areata)

Sr. no.	Size of patch	No. of cases				
		Week 0	Week 1	Week 2	Week 3	Week 4
1.	Grade 0 (no patch)	00	00	00	00	00
2.	Grade 1 (0.5–1 cm)	03	03	03	04	05
3.	Grade 2 (1–2 cm)	09	09	09	08	08
4.	Grade 3 (2–3 cm)	01	01	01	01	00
5.	Grade 4 (>3 cm)	00	00	00	00	00

Chi-square=6.400ns; $P=0.171$ **Table 6:** Assessment of Itching in 13 Cases of Indralupta (Alopecia Areata)

Sr. no.	Itching	No of cases				
		Week 0	Week 1	Week 2	Week 3	Week 4
1.	Grade 0	13	13	13	13	13
2.	Grade 1	00	00	00	00	00

Table 7: Assessment of Number of Patch in 13 Cases of Indralupta (Alopecia Areata)

Sr. no.	No of patch	No of cases	Percentage of cases
1.	Grade 0	00	0
2.	Grade 1	06	46.15
3.	Grade 2	03	23.08
4.	Grade 3	02	15.38
5.	Grade 4	02	15.38