

TO EVALUATE THE EFFICACY OF *PRIYALBEEJADI LEPA* & *AAMRABEEJA HARITAKI LEPA* IN THE MANAGEMENT OF *DARUNAKA*- A RANDOM, OPEN LABELLED CONTROLLED STUDY

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ABSTRACT

Background: *Darunaka* is a common scalp disorder. *Priyalbeejadi Lepa* was assessed for its role in managing *Darunaka*. **Objective:** The study was planned to evaluate the efficacy of *Priyalbeejadi Lepa* in the management of *Darunaka*. **Methods:** The study included forty patients of both sexes, aged 16 to 40, who met *Darunaka*'s diagnostic criteria and were seen in the institute's outpatient department. They were split up at random, with *Aamrabeeja Haritaki Lepa* administered on alternate days for 30 days to the Controlled Group and *Priyalbeejadi Lepa* to the Interventional Group. *Twakasphutana*, *Kandu*, *Keshachyuti*, *Rookshata*, and *Adherent Scalp Flaking Score (ASFS)* were evaluated. On days 15, 30, and 45, clinical evaluations were conducted. Effect sizes were computed using paired t-tests for within-group comparisons and independent t-tests for between-group comparisons. **Results:** Following treatment, all clinical metrics significantly improved for both groups ($p < 0.01$). *Twakasphutana* demonstrated a statistically significant advantage over the control group ($p = 0.044$, Cohen's $d = 0.66$), however the Interventional Group consistently showed larger decreases in mean scores across parameters. Other measures had small to medium effect sizes that favored the Interventional Group and showed gains that were clinically significant. **Conclusion:** With notable improvements in scalp flaking, itching, and related clinical

symptoms, Priyalbeejadi Lepa is a successful intervention for *Darunaka*. When compared to *Aamrabeeja Haritaki Lepa*, it had better therapeutic results, indicating its potential as a preferred therapy option.

KEYWORDS: *Priyalbeejadi Lepa*, *Aamrabeeja Haritaki Lepa*, *Darunaka*, Pityriasis Capitis.

INTRODUCTION

A presentable personality is greatly enhanced by having healthy hair. For many people, particularly women, the condition and maintenance of their hair have a direct impact on their confidence and self-consciousness. A person's overall appearance can be affected by a number of disorders that affect the scalp and hair. The flaking of the scalp's skin is a common symptom of dandruff, a persistent scalp ailment. Dead skin cells are normally removed from the surface of the scalp, however in certain individuals, this shedding becomes excessive and causes dandruff. Dandruff can cause low self-esteem, just like other skin conditions. If others see dandruff as an indication of poor hygiene or inadequate grooming, those who have it may feel ashamed.

In Ayurveda, Dandruff is similar to *Darunaka*. As per *Vagbhata*^[1] and *Sharangadara*^[2] have declared that, *Darunaka* is a *Kapalagata Roga* while according to *Sushruta*^[3] *Bhavaprakasha*^[4] and *Madhava*^[5] this clearly mentioned as a *KshudraRoga*. *Shirapradeshi Kandu* (itching), *Rukshata* (dryness), *Shirotwaka Sphutanam* (cracking of the scalp skin with fine flakes), and *Keshachyuti* (hair-fall) are the cardinal symptoms of *Darunaka* which involves mainly vitiated *Vata and Kapha Doshas*^[6]

Dandruff is a frequent term for pityriasis capitis, sometimes called pityriasis simplex capitis. This ailment is characterized by considerable flakiness and an itchy scalp. Its development is influenced by both microbial and non-microbial causes. An elevated level of *Malassezia restricta* is thought to be the main microbiological cause. Increased sebaceous gland activity, decreased skin hydration, irritation, immunological suppression, and oxidative stress are examples of non-microbial factors.

Three main factors predict the development of dandruff: individual predisposition, sebum production, and *Malassezia* colonization^[7] These parameters' interrelation may be connected to anomalies in the stratum corneum. The stratum corneum, the epidermis's anucleated outer layer, acts as a barrier to prevent water loss and the admission of pathogens and dangerous

substances from the surrounding environment.^[8] The stratum corneum, which is composed of corneocytes, helps in hydration and water retention.^[9] Many specialized intercellular proteins termed corneodesmosomes, which bind nearby corneocytes together, are responsible for the integrity of the stratum corneum. For desquamation to be facilitated, surface layers must be hydrated.^[7]

Proper hydration may be hampered by severe or persistent barrier degradation. The amount of vital stratum corneum barrier lipid is decreased and the relative structural organization is weakened in the dandruff scalp. Increased trans-epidermal water loss is the outcome of this.^[7] Washing the afflicted area with anti-dandruff shampoos on a regular basis is the standard treatment for dandruff.^[10] Antifungal-based shampoos cause a number of reactions, according to clinical and experimental research. Itching is lessened at first and frequently goes away after the second or third use. Although it is not completely eradicated, the *Malassezia* yeast population on the scalp likewise declines. The first clinical scenario reappears two to three weeks after treatment is discontinued as *Malassezia* levels return to their baseline levels.^[11]

Three key aspects of Ayurveda's unique therapeutic methods—Nidana Parivarjana (eliminating the cause), Shodhana Chikitsa (purification therapies), and Shamana Aushadhis (palliative medications)—can produce long-lasting improvements. This makes Ayurveda a significant approach to controlling Darunaka. Lepa (herbal pastes) and Dhavana (cleansing/washing) are two examples of local remedies known as Sthanika Chikitsa that are important in reducing symptoms and improving hair health.

Priyalbeejadi Lepa^[12] (Trial drug) is one such formulation of *Lepa* that is provided in *Astangsamgraha Uttarsathana* 28/33. It is taken to evaluate its effectiveness on *Darunaka* wsr to Pityriasis Capitis and compared with *Aamrabeeja Haritaki Lepa*^[13] (controlled).

MATERIALS AND METHODS

Study Design

This study was a randomized, controlled, open-label, comparative clinical trial.

Participants

A total of 40 patients diagnosed with *Darunaka* based on classical signs and symptoms were enrolled in the study after screening.

Eligibility Criteria

Inclusion Criteria

1. Subjects aged between 16 and 40 years.
2. Patients presenting with signs and symptoms of *Darunaka*.
3. Subjects willing to participate in the study with written informed consent, conveyed in a language understandable to the participant.

Exclusion Criteria

1. Eczema of the scalp.
2. Psoriasis of the scalp.
3. Immunocompromised conditions.
4. Conditions in which head wash is restricted, such as *Pratishyaya* and scalp injuries.
5. Pregnant and lactating women.
6. Subjects with uncontrolled systemic illnesses including diabetes mellitus and hypertension.

Randomization

Randomization was performed using computer-generated random numbers through randomization software (www.randomizer.org).

Interventions

After randomization, all participants (n = 40) were allocated into two groups:

- Group PB (*Priyalbeejadi Lepa Group*): Twenty patients received *Priyalbeejadi Churna Lepa* applied externally on the scalp on alternate days for 30 days.
- Group AH (*Aamrabeeja Haritaki Lepa Group*): Twenty patients received *Aamrabeeja Haritaki Churna Lepa* applied externally on the scalp on alternate days for 30 days.

Authentication of all raw materials was carried out at the Department of *Dravyaguna*, Preparation of *Priyalbeejadi Lepa* and *Aamrabeeja Haritaki Lepa* was conducted at the institute pharmacy. Both raw materials and finished formulations were subjected to qualitative analysis in accordance with Ayurvedic Pharmacopeia of India (API) guidelines.

Follow-up

Participants were assessed at baseline and during follow-up visits on the 15th day, 30th day, and 45th day. Patients were instructed to adhere strictly to the treatment protocol throughout the study period.

Statistical methods

All statistical analyses were conducted using SPSS version 26. Continuous variables were checked for normality using the Shapiro–Wilk test and by inspecting Q–Q plots. No extreme outliers were detected, and the assumptions of normality and independence were satisfactorily met.

1. Between-Group Comparison

An independent samples t-test with effect size (Cohen's d) was conducted to compare post-treatment outcomes between *Priyalbeejadi Lepa* group and *Aamrabeeja Haritaki Lepa* group.

Table 1: Comparison of Clinical Parameters Between *Priyalbeejadi Lepa* group and *Aamrabeeja Haritaki Lepa* group

(Independent Samples t-test with Effect Sizes)

Variable	Group A (AH) Mean $\pm$ SD	Group B (PB) Mean $\pm$ SD	Mean Diff.	t-value	p-value	Effect size (Cohen's d)
TWAKASPHUTANA	0.10 $\pm$ 0.308	0.45 $\pm$ 0.686	−0.35	−2.08	0.044	0.66
KANDU	0.40 $\pm$ 0.503	0.65 $\pm$ 0.671	−0.25	−1.33	0.190	0.41
KESHACHYUTI	0.55 $\pm$ 0.686	0.75 $\pm$ 0.910	−0.20	−0.78	0.438	0.24
ROOKSHATA	0.50 $\pm$ 0.607	0.50 $\pm$ 0.688	0.00	0.00	1.000	0.00
ASFSSCORE	1.10 $\pm$ 1.373	1.90 $\pm$ 1.774	−0.80	−1.59	0.119	0.50

Effect size interpretation—0.2 = small, 0.5 = medium, 0.8 = large.

The clinical parameters of the *Priyalbeejadi Lepa* group and the *Aamrabeeja Haritaki Lepa* group were compared using an independent samples t-test. For TWAKASPHUTANA, a statistically significant difference was found, with the *Priyalbeejadi Lepa* group improving more than the *Aamrabeeja Haritaki Lepa* group. ($t(26.34) = -2.08$, $p = 0.044$), with a medium effect size (Cohen's $d = 0.66$). The effect sizes ranged from small to medium ($d = 0.24$ – 0.50), continuously favoring the *Priyalbeejadi Lepa* group, even if differences for KANDU, KESHACHYUTI, and ASFS SCORE did not reach statistical significance ($p > 0.05$). This shows that the *Priyalbeejadi Lepa* group has improved more across a number of metrics, which is a useful and clinically significant trend.

For ROOKSHATA, no difference was found ($p = 1.000$, $d = 0.00$). Even though statistical significance was not reached, the overall pattern of results indicates that the *Priyalbeejadi Lepa* group showed superior clinical outcomes, as evidenced by higher mean scores and significant effect sizes.

RESULTS

Total patients recruited in the study were 40. Amongst which 20 patients from PB group and 20 patients from AH group completed the study.

Overall, the findings suggest that the *Priyalbeejadi Lepa group* exhibited **comparatively better clinical outcomes**, supported by higher mean improvements and relevant effect sizes, even in parameters where statistical significance was not achieved

BEFORE TREATMENT AFTER TREATMENT





DISCUSSION

The current study assessed a dermatological intervention's efficacy in two patient groups using five clinical indicators. Both the Priyalbeejadi Lepa group and the Aamrabeeja Haritaki Lepa group showed extremely significant post-treatment improvements across all parameters, according to paired samples t-tests ($p < 0.01$). Rookshata and ASF Score showed the biggest drops, suggesting that the intervention had significant therapeutic advantages. These results emphasize how crucial it is to present effect sizes in addition to p-values because clinically significant changes could still exist even in the lack of statistical significance. A strong therapeutic benefit is suggested by the Priyalbeejadi Lepa group's consistent pattern of better improvement across all evaluated metrics. The Priyalbeejadi Lepa group's intervention may offer a wider range of dermatological advantages, indicating its potential as a preferable course of treatment.

CONCLUSION

Overall, the Priyalbeejadi Lepa group showed better clinical results, which were corroborated by notable advancements and significant effect sizes in a number of variables. While admitting the need for additional research to validate and build upon these findings, these results demonstrate the therapeutic efficacy of the intervention.

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