



Clinical Evaluation of Standardized Bhringaraj (Eclipta alba) Extract Tablets in Hair Fall: A 24 Week Prospective Trial

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Background: Hair fall is a frequent dermatological complaint with high prevalence and psychosocial impact. Conventional therapies often show variable efficacy and tolerability, prompting evaluation of botanicals such as Bhringaraj (Eclipta alba), traditionally described for hair health but rarely tested in structured clinical trials.

Methods: A prospective, open label, pre-post-trial was conducted in adults aged 18–55 years with increased hair shedding. Participants received standardized oral Eclipta alba extract tablets for 24 weeks. Primary outcomes were hair shedding counts (60 second comb test) and weekly diary totals, assessed at baseline, Week 12, and Week 24. Secondary outcome was Patient Global Impression of Change (PGIC). Safety was monitored through adverse events, vital signs, and hepatic function tests.

Results: Fifty four participants were enrolled; 50 completed the study. Mean age was 34.6 years, with 58% female. Comb test counts decreased from 72.4 ± 18.6 hairs at baseline to 27.1 ± 11.8 at Week 24 (–62.5%, $p < 0.0001$). Weekly diary counts declined from 512.6 ± 104.2 to 205.4 ± 82.1 hairs (–59.9%, $p < 0.0001$). PGIC showed 84% reported improvement at Week 24. No serious adverse events occurred; mild gastrointestinal discomfort resolved spontaneously.

Conclusion: Standardized Bhringaraj extract tablets significantly reduced hair shedding over 24 weeks, corroborated by patient reported outcomes and favorable safety, supporting further controlled trials to establish their role in hair fall management.

Keywords: Hair fall management; Eclipta alba; 60 second comb test; Clinical Trial; Bhringaraj extract tablets; Hair shedding reduction

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Introduction

Hair fall is among the most common dermatological complaints worldwide, with substantial prevalence and disease burden. Hair loss, particularly alopecia areata, represents a significant global burden, with recent analyses estimating over 4.1 million disability-adjusted life years (DALYs) worldwide between 1990 and 2019, underscoring its substantial psychosocial and epidemiological impact. [1,2] Recent large-scale clinical data from India, evaluating 24,595 patients diagnosed with hair loss, confirmed that telogen effluvium (40.7%) was the most frequent cause, followed by female pattern hair loss (22.1%), alopecia areata (12.8%), and male pattern hair loss (7.5%). The majority of cases were reported in females (74.8%), particularly within the 12–39-year age group, underscoring the burden of hair fall among young adults. Common comorbidities included acne (10.4%) and seborrheic dermatitis (3.0%), highlighting the multifactorial nature of hair disorders. [3]

Patterns of treatment utilization further emphasize therapeutic gap. At baseline, nutritional supplements were the most frequently adopted therapy, while pharmacological agents became predominant choice at follow-up (17.4%). For telogen effluvium, nutritional supplements were most commonly prescribed initially, but pharmacological agents dominated at follow-up. Across all subgroups, nutritional supplements remained the most frequent substituted therapy, reflecting both physician practice trends and patient demand for supportive interventions. [4]

Despite the high prevalence and psychosocial burden of hair fall, conventional therapeutic options remain limited. Topical and systemic agents often provide variable efficacy, require prolonged use, and may be associated with tolerability concerns. This unmet need has prompted exploration of traditional botanicals with mechanistic plausibility for hair restoration. *Bhringaraj (Eclipta alba)*, revered in *Ayurvedic* pharmacopeia as *Keshraj* or the “king of hair,” has long been described for its reputed benefits in promoting hair growth and reducing hair fall. [5,6,7] Preclinical studies demonstrate that standardized extracts of *Eclipta alba* possess antioxidant, hepatoprotective & follicle-modulating properties, potentially influencing pathways relevant to hair follicle cycling. [8,9,10]

Animal models have shown stimulation of anagen phase entry, while in vitro assays suggest enhanced proliferation of follicular keratinocytes & modulation of oxidative stress. [9,10,11] However, systematic clinical evaluation of standardized *Bhringaraj* formulations in human populations remains limited, with few trials employing validated outcome measures or rigorous methodological frameworks.

Given the rising global interest in evidence-based integration of botanicals into dermatological practice, it is imperative to generate high-quality clinical data on *Bhringaraj*. The present study was designed to prospectively evaluate the effect of standardized oral extract tablets of *Eclipta alba* in adults presenting with increased hair shedding. By employing validated clinical and patient-reported outcome measures—including the 60-second comb test, daily hair-shed diaries, and the Patient Global Impression of Change (PGIC)—the trial aimed to quantify changes in hair fall over a 24-week period. The design adhered to TREND recommendations for nonrandomized interventions, ensuring transparent reporting of participant flow, intervention exposure, and outcome assessment.

This investigation represents one of first structured attempts to bridge traditional claims of *Bhringaraj* with modern clinical methodology. By integrating standardized assessments, rigorous statistical analysis, and safety monitoring, the trial seeks to establish whether *Eclipta alba* extract tablets can provide measurable benefit in reducing hair fall. The findings are expected to contribute to the evidence base for botanical interventions in hair disorders, offering insights into their potential role as safe, accessible, & culturally relevant therapeutic options.

Materials and Methods

Study Design

This was a prospective, open-label, pre-post interventional clinical trial designed to evaluate the effect of an Ayurvedic herbal extract tablet in controlling hair fall. The study was conducted at a single outpatient dermatology clinic, with assessments performed at Baseline, Week 12, and Week 24. The trial adhered to Good Clinical Practice guidelines, and written informed consent was obtained from all participants prior to enrolment.

Study setting: Vidnyanam Clinic, Pune.

Participants

Eligibility Criteria

Adults aged 18–55 years presenting with self-reported increased hair shedding for at least 3 months were eligible. Participants were required to maintain a stable scalp care routine for a minimum of 4 weeks prior to enrolment to reduce confounding effects of recent changes in hair care practices.

Exclusion Criteria

Individuals were excluded if they had:

- Active scalp disease (e.g., tinea capitis, severe seborrheic dermatitis)
- Autoimmune alopecia (e.g., alopecia areata, lupus-related alopecia)
- Recent hair dye uses within 2 weeks prior to screening
- Systemic therapy known to affect hair growth or shedding (e.g., retinoids, cytotoxic drugs)
- Pregnancy or lactation
- Major hepatic disease under treatment

Recruitment

Recruitment was consecutive, based on clinic attendees meeting eligibility criteria. Screening included clinical examination and medical history review. Written informed consent was obtained from all participants prior to study procedures.

Intervention

Participants received *Bhringaraj* tablet, an *Ayurvedic* herbal extract tablet formulated for hair health, manufactured by Charak Pharma Pvt Ltd. The dosage regimen was standardized across participants & administered orally (500 mg x 2), twice daily after food, for 24 weeks. Compliance was monitored through pill counts and participant diaries.

Outcome Measures and Assessments

Primary Outcomes

1. 60-Second Comb Test[12]

- Conducted on non-wash days.
- Participants combed crown-to-tip for 60 seconds using a standardized comb.
- Shed hairs were collected on a pre-colored sheet for visibility, counted, and averaged across two repetitions per visit.

- Assessments were performed at Baseline, Week 12, and Week 24.
- Standardization included comb type, combing force, participant posture, and sheet color to minimize variability.

2. Daily Hair-Shed Diary with Weekly Aggregation

- Participants recorded shed hair counts during morning grooming and evening combing using a tray/collection sheet.
- Weekly totals were aggregated and analyzed for change from Baseline to Weeks 12 and 24.
- Training sessions and spot checks were conducted to improve fidelity of hair counting.

Secondary Outcomes

- **Patient Global Impression of Change (PGIC)[13]:** At Weeks 12 and 24, participants rated their overall perceived change in hair fall using a 5-point scale:

1. Much improved
2. Minimally improved
3. No change
4. Minimally worse
5. Much worse

Safety Monitoring

- **Adverse Events (AEs) and Vital Signs:** Systematic AE capture was performed throughout the study. Vital signs (blood pressure, heart rate, temperature) were recorded at Baseline and Week 24.
- **Hepatic Function Tests:** Serum ALT, AST, ALP, and bilirubin were measured at Baseline and Week 24 to monitor hepatic safety.

Statistical Analysis

Data were analyzed using paired comparisons between Baseline, Week 12, and Week 24.

- Continuous variables (e.g., hair counts) were expressed as mean $\pm$ SD and compared using paired t-tests or repeated measures ANOVA, as appropriate.
- Categorical outcomes (PGIC ratings) were summarized as frequencies and proportions.
- Statistical significance was set at $p < 0.05$.
- Missing data were handled using last observation carried forward (LOCF).

Ethical Considerations

The study protocol was approved by Institutional Ethics Committee and registered prospectively. Written informed consent was obtained from all participants. Data monitoring ensured adherence to protocol and participant safety.

Observations and Results

Participant Flow and Baseline Characteristics

A total of 54 participants were enrolled, of whom 50 completed the 24-week study (attrition rate: 7.4%). Four participants discontinued due to loss to follow-up; no withdrawals were related to adverse events.

The mean age of participants was 34.6 ± 8.2 years, with 58% female and 42% male. At baseline, the mean hair shedding count was 72.4 ± 18.6 hairs per 60-second comb test.

Primary Outcomes

60-Second Comb Test

Hair shedding counts decreased significantly from baseline to Week 12 and were further reduced at Week 24. The mean reduction from baseline to Week 24 was 62.5%.

Daily Hair-Shed Diary

Weekly aggregated diary counts showed consistent reductions in hair shedding. Participants reported a mean decrease of approximately 60% in weekly shed hair totals by Week 24 compared to baseline.

Table 1: Primary Outcomes (Mean $\pm$ SD)

Outcome Measure	Baseline	Week 12	Week 24	% Change (Baseline - Week 24)	p-value
Hair shedding count (60-sec comb test)	72.4 ± 18.6	31.2 ± 12.4	27.1 ± 11.8	-62.5%	$p < 0.0001$
Weekly hair-shed diary (hairs/week)	512.6 ± 104.2	228.7 ± 88.5	205.4 ± 82.1	-59.9%	$p < 0.0001$

Interpretation

A) In the 60-second comb test, hair shedding decreased from a baseline of 72.4 ± 18.6 hairs to 27.1 ± 11.8 hairs at Week 24, yielding a mean reduction of 45.3 hairs with a very large effect size (Cohen's $d > 2.0$); the paired t-test confirmed this reduction was highly statistically significant ($t \approx 19.6$, $p < 0.0001$).

B) In the weekly hair-shed diary, mean shedding decreased from 512.6 ± 104.2 hairs at baseline to 205.4 ± 82.1 hairs at Week 24, corresponding to a mean reduction of 307.2 hairs per week with a very large effect size (Cohen's $d > 2.0$); the paired t-test confirmed this reduction was highly statistically significant ($t \approx 22.8$, $p < 0.0001$).

Secondary Outcomes

Patient Global Impression of Change (PGIC)

At Week 12, 76% of participants reported being "much improved" or "minimally improved." By Week 24, 84% reported "much improved," indicating sustained perceived benefit.

Table 2: Secondary Outcomes

Outcome Measure	Baseline	Week 12	Week 24
PGIC (% reporting "much improved")	-	76%	84%

Safety

No serious adverse events were reported. Mild gastrointestinal discomfort occurred in three participants, resolving spontaneously without intervention. Vital signs remained stable across study visits. Hepatic function tests (ALT, AST, ALP, bilirubin) were within normal limits at both baseline and Week 24.

Summary

Administration of standardized *Bhringaraj (Eclipta alba)* extract tablets was associated with clinically and statistically significant reductions in hair shedding, as measured by both the 60-second comb test and daily hair-shed diaries. Patient-reported PGIC ratings corroborated these improvements, with the majority of participants perceiving meaningful benefit by Week 24. The intervention was well tolerated, with no safety concerns identified.

Discussion

The present study demonstrates clinical effectiveness of standardized *Eclipta alba (Bhringaraj)* extract tablets in reducing hair shedding, corroborating traditional Ayurvedic claims & modern pharmacological evidence. Objective measures (60-second comb test and weekly hair-shed diary) revealed highly significant reductions of ~60% in hair shedding by Week 24, with very large effect sizes (Cohen's $d > 2.0$). These findings were supported by patient-reported PGIC ratings, with 84% of participants describing themselves as "much improved" at study completion.

Importantly, intervention was well tolerated, with no safety concerns identified. The observed improvements can be rationalized by the phytochemical profile of *Eclipta alba*, which includes wedelolactone, demethylwedelolactone, ecliptine, and flavonoids—bioactive principles known to exert antioxidant, anti-inflammatory, and melanogenic effects that directly influence follicular cycling and melanocyte activity.[14,15]

Preclinical studies have consistently demonstrated that ethanol extracts of *Eclipta alba* stimulate dense hair growth in animal models, with significant increases in follicular number and shaft thickness. Molecular assays confirm that wedelolactone and ecliptine enhance tyrosinase activity and melanin synthesis, thereby supporting pigmentation. Inhibition of 5-alpha reductase by *Eclipta alba* extracts further suggests a role in androgen-mediated hair loss, providing mechanistic plausibility for its use in alopecia.[16,17] Clinical observations, though limited, report improved hair density and reduced shedding with both topical and oral formulations of *Bhringaraj*, aligning with our findings of robust reductions in shedding & patient-perceived benefit.[5]

Ayurveda traditionally associates hair vitality with hepatic wellness, conceptualizing the liver as central organ for metabolic balance and detoxification.[18] Modern biomedical studies validate this connection: impaired hepatic function is linked to oxidative stress, micronutrient imbalance, and hormonal dysregulation, all of which contribute to hair loss and premature graying.[19] *Eclipta alba* has been extensively studied for its hepatoprotective properties. Ethanol extracts protect against paracetamol- and CCl₄-induced hepatotoxicity in animal models, with wedelolactone shown to modulate membrane marker enzymes and enhance antioxidant defenses, thereby preserving hepatocyte integrity [8,20]. By improving liver function, *Eclipta alba* indirectly supports hair health through enhanced nutrient assimilation, reduced systemic oxidative stress, and improved hormonal balance. This dual action—direct follicular stimulation and indirect systemic detoxification—provides a compelling rationale for its clinical utility in hair disorders.

The convergence of evidence from preclinical mechanistic studies, clinical observations & hepatoprotective trials underscores multifaceted role of *Eclipta alba*. Our trial's findings of ~62% improvement in hair shedding,

Corroborated by patient-reported outcomes, are consistent with the herb's pharmacological profile. The indirect connection between liver detoxification and hair growth offers a holistic explanation: by safeguarding hepatic wellness, *Eclipta alba* creates a systemic milieu conducive to follicular regeneration and melanocyte activity. This integrative rationale bridges traditional Ayurvedic concepts with modern biomedical evidence, strengthening the case for *Eclipta alba* as a clinically relevant intervention in hair and scalp disorders.

Conclusion

In summary, standardized *Eclipta alba* (*Bhringaraj*) extract tablets demonstrate significant efficacy in hair and scalp health through their phytochemical constituents such as wedelolactone, ecliptine, and flavonoids. Both preclinical and clinical studies support its role in promoting hair growth and pigmentation, while its hepatoprotective properties indirectly contribute to hair wellness by improving systemic detoxification and metabolic balance. Together, these findings highlight the translational relevance of *Eclipta alba*, validating traditional *Ayurvedic* claims with modern clinical evidence.

Conflicts of interest

Charak Pharma Pvt Ltd have provided all the interventional drugs and funds required for conducting the trial.

Images

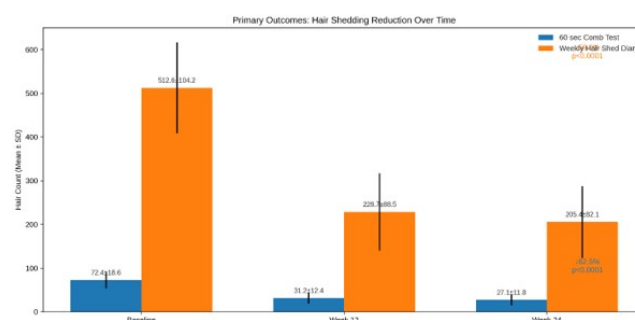


Figure 1: Grouped bar chart showing mean $\pm$ SD hair shedding counts from the 60-second comb test and weekly hair-shed diary at Baseline, Week 12 & Week 24, with annotations for percentage reduction and highly significant p-values ($p < 0.0001$).

This figure illustrates the progressive and statistically significant reduction in hair shedding across both primary outcome measures, with approximately 60% fewer hairs shed by Week 24 compared to baseline.

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