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Original Research Article

Integrating Ayurvedic therapies with minoxidil: a randomized, single-blinded, parallel-controlled trial assessing the efficacy and safety of Traya's customized approach for treating male androgenetic alopecia

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ABSTRACT

Background: Male androgenetic alopecia (MAA) is the most common form of hair loss in men, influenced by genetics, hormonal imbalances, nutritional deficiencies, and stress. While treatments like minoxidil address symptoms, they do not target underlying causes. This study compares the effectiveness of a customized regimen versus minoxidil in treating male pattern hair loss (MPHL) in men with MAA stages 2-4.
Methods: A 6-month, single-blinded, randomized, controlled study with 135 adult males (stages 2-4 MAA) was conducted. Participants were assigned to group A (holistic hair treatment regimen), group B (minoxidil), or group C (placebo). Baseline and follow-up assessments (2, 4, and 6 months) included dermatological and Trichoscan® assessments, imaging, and self-assessment questionnaires.
Results: 6 months of TrichoScan® assessment showed a 3.16-fold increase in hair density for group A compared to group B and 5.82-fold compared to group C. Groups A and B showed significant improvements over group C.
Conclusions: The holistic hair treatment regimen proved to be more effective than minoxidil for treating MAA stages 2-4, offering a promising alternative to traditional treatments.

Keywords: Male androgenetic alopecia, Holistic hair treatment regimen, Hair growth

INTRODUCTION

Male androgenetic alopecia (MAA), or male pattern baldness (MPB) or male pattern hair loss is a widespread form of non-scarring alopecia, especially for men. MAA is characterized by progressive, patterned hair loss with a distinctive 'horseshoe' configuration or an 'M' shaped hairline and significant involvement of the temporal and vertex areas but sparing the occipital region.[1] MAA is usually assessed using the Hamilton-Norwood scale (HNS) for males and the Ludwig classification for females.[2]

Predisposing factors for early-onset MAAs are diverse and include genetic liability, nutritional deficiencies (especially biotin, zinc, iron, amino acids, and essential fatty acids), metabolic dysfunction, gastrointestinal dysbiosis, amplified stress levels, compromised sleep-

wake cycles as well as certain medications (oral contraceptives, chemotherapy) components. Furthermore, non-supplementation with certain amino acids (lysine, histidine, isoleucine, leucine, alanine, and asparagine) is linked to MAA and other alopecias. Hormonal factors particularly the activity of the 5α-reductase enzyme and variations in the androgen receptor gene, also contribute significantly to the pathogenesis of MAA.[3,4]

MAA can have a severe psychosocial impact, and there are several therapeutic choices for treatment starting from medical therapy (e.g., topical finasteride, minoxidil, and dutasteride) to classical agents from Ayurveda such as rosemary, Licorice, Brahmi, and Guduchi that are believed to improve hair growth and the condition of hair follicles.[5] However, these treatments primarily target the external aspects of hair loss and tend to overlook the systemic underlying factors.[6] This underscores the need for a more integrated, comprehensive strategy that merges both Ayurvedic and medicinal methods for improved treatment results.

The proposed personalized regimen incorporates Minoxidil, vital hair vitamins, a targeted Hair Ras (to balance pitta dosha and enhance blood flow to the scalp), Defense shampoo, and a customized scalp oil infused with particular booster oils for various concerns. For those facing gastrointestinal problems, supplements such as gutt shuddhi and digest-boost are suggested, while nasal ghrit may help individuals dealing with sleep issues. This all-encompassing treatment strategy merges nutraceuticals, Ayurvedic herbs (including Bhringraj, Ashwagandha, Amla, Brahmi, and Dhamaso), and dietary adjustments alongside minoxidil to promote hair growth. By addressing both external symptoms and internal physiological factors linked to MAA, this regimen seeks to encourage follicular regeneration while also aiding the regulation of digestive and metabolic functions involved in hair loss.

Therefore, the primary objective of the study is to assess the efficacy of the customized regimen, which combines Ayurvedic principles and contemporary pharmacological treatments, in comparison to topical minoxidil alone, in the management of male pattern hair loss (MPHL) in men diagnosed with MAA at stages 2-4.

METHODS

Study design

This randomized, single-blinded, parallel, controlled clinical study was conducted to evaluate the efficacy and safety of a test product for treating male pattern hair loss (androgenetic alopecia). The study spanned 8 months and involved 11 visits per participant.

Study population

The study enrolled 135 healthy male participants aged 18-45 years, accounting for a 10% dropout rate, aiming for 120 evaluable participants by the end of the study and those diagnosed with male pattern hair loss (androgenetic alopecia) at Norwood scale stages 2-4. The inclusion and exclusion criteria were as follows.

Eligibility criteria

The study included male participants aged 18 to 45 years who were diagnosed with male pattern hair loss (Norwood scale stages 2-4) and they were required to provide written informed consent and agree to adhere to all study procedures, including maintaining consistent hair length throughout the study period. Individuals were excluded if they had significant scalp or skin conditions, such as actinic keratosis, seborrheic dermatitis, or psoriasis. Other exclusion criteria included active thyroid disorders, malignancies (including prostate cancer), or hair loss due to non-androgenetic causes such as autoimmune disorders or infections. Additionally, participants who had used anti-androgenic medications, systemic corticosteroids, or anabolic steroids within the past 6 months were excluded. Chronic smokers (defined as those consuming ≥10 cigarettes per day) or individuals with excessive alcohol consumption (≥2 drinks per day) were also excluded, as were those with known hypersensitivity to any ingredients in the test formulations.

Study period

The duration of the study was from August 2023 to November 2024.

Location of data collected

Data was collected from MS Clinical Research.

Study outline

Intervention

A two-week washout period preceded baseline assessments, during which participants discontinued the use of previous hair treatments. Participants then applied the assigned treatment for the entire duration of the study.

Outcome measures

Primary outcomes

The primary endpoint was the improvement in hair density, growth rate, and thickness at months 4 and 8, measured using Trichoscan® imaging in comparison to the placebo and test serum groups.

Secondary outcomes

Reduction of hair thinning, and improvement in hair density, thickness, and softness at months 2, 4, 6, and 8 assessed via dermatological assessments.

Improvements in hair growth, density, A: T ratio, and density of terminal and vellus hairs assessed using Trichoscan®.

Improvement of hair thickness at months 2, 4, 6, and 8 evaluated using the Dino-Lite camera.

Reduction of hair fall and breakage at months 2, 4, 6, and 8 evaluated using the comb test.

Sample size estimation

A total of 35 or more evaluable subjects were estimated to be enrolled in each group with the 16.23 unit of difference between Test products (Group A and Group B) and Placebo (Group C) in 2 months considering Trichoscan hair density assessment assuming Standard Deviation of 24.3 units (calculated using previous clinical studies). Power was set to 80% and level of significance was 5%.

Randomization and grouping

Sequence generation

Computer-generated sequencing (R software: R- ver.3.1.2) was used.

Participants were randomly assigned to one of three groups through dynamic randomization to ensure balance across treatment arms based on baseline characteristics (e.g., the root cause of hair loss, Norwood scale for assessing hair thinning, and hair density i.e. individuals experiencing gastrointestinal (GIT) issues, stress, or a combination of both and healthy individuals).

Group A included customized regimen (including hair growth serum, mild shampoo, vitamins, Ayurvedic herbs, hair oil, and customized booster shots), group B included minoxidil, and group C included placebo.

Implementation

The random allocation sequence was generated by the data science team, participants were enrolled by clinical research coordinators (CRCs), and intervention assignments were performed by clinical research associates (CRAs) at the study site.

Assessments performed

Assessments performed include - baseline (day 0): dermatological evaluations, Trichoscan® imaging (hair density, growth, A: T ratio), and phototrichogram (hair growth in the shaved area), follow-up (months 2, 4, 6, 8): dermatological assessments, Trichoscan® imaging, hair thickness measurements (Dino-Lite camera), comb test (hair fall), and self-assessment questionnaire, and final visit (month 8, day 240): final dermatological assessment, Trichoscan® imaging, and hair thickness measurement.

Safety monitoring

Scalp irritation (erythema, and dryness) was monitored at each visit. Participants documented any adverse events or discomforts in daily diaries, which were reviewed during follow-up visits.

Statistical analysis

Summary statistics (N, Mean, SD) are provided for raw values, change from baseline values by product and timepoint.

For normality checking

The Shapiro-Wilk test was performed on baseline values using R software for each parameter.

For efficacy checking

When the p value is less than 0.05, the data was considered as non-normally distributed data and a non-parametric test i.e., Wilcoxon test was performed to compare each visit with the baseline.

When the p value is more than 0.05, the data was considered as normally distributed data and a parametric test i.e., t-test (paired) was performed to compare each visit with the baseline.

All statistical tests were performed at two-sided 5% level of significance and 95% confidence interval was reported.

Statistical software

The statistical software, R-ver.3.1.2 was used for the analysis of the data and Microsoft Word and Excel have been used to generate graphs, and tables. For each subject, change from baseline (CFB) will be calculated as follows.

$$CFB = Measurement\ at\ timepoint\ (i) - Measurement\ at\ baseline$$

Calculations

$$Change\ from\ baseline\ (CFB) = Time\ point - Baseline$$

$$\%\ Change\ w.r.t.\ Baseline = CFB/Baseline \times 100$$

$$\%\ Change\ w.r.t.\ Placebo = (CFB\ of\ Test\ Product)/(CFB\ of\ Placebo) \times 100$$

RESULTS

Participant flow

Figure 1 is showing participant flow.

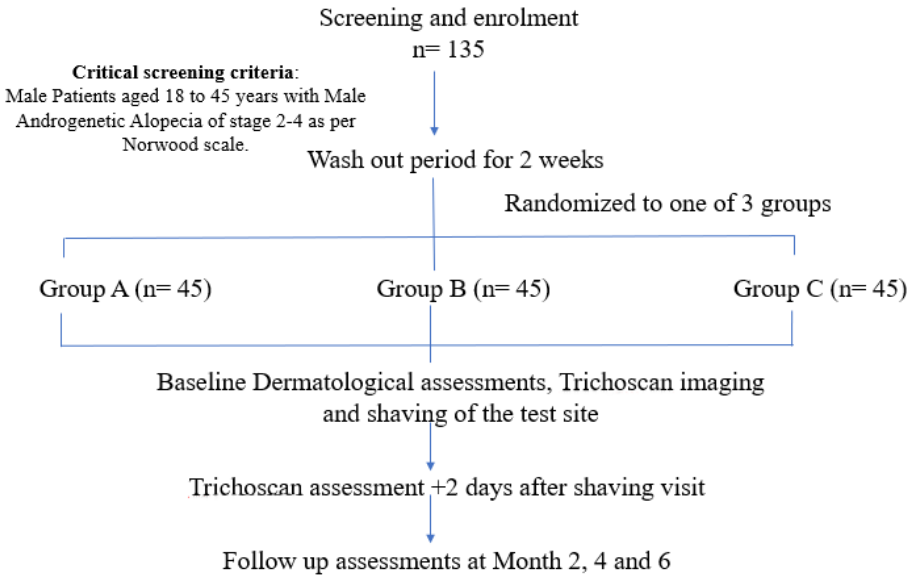

Figure 1: Participant flow.

Table 1: Baseline data.

Test group	Number of subjects completed in the study	Mean age (in years)	Age group	Count	Mean age (in years)
Test regime with serum (Group A)	33	31.36	18-22	8	20.62
			23-27	5	23.60
			28-32	4	29.75
			33-37	6	35.33
			38-42	5	40.00
			43-45	5	44.20
Test serum (Group B)	38	31.73	18-22	8	20.00
			23-27	7	26.00
			28-32	2	29.00
			33-37	11	36.00
			38-42	7	39.42
			43-45	3	44.66
Placebo (Group C)	32	33.06	18-22	7	20.14
			23-27	5	25.00
			28-32	4	30.25
			33-37	2	35.00
			38-42	4	39.75
			43-47	10	44.20

Recruitment

First subject first visit (screening) – 30 August 2023, last subject last visit (study completion date) – 02 August 2024.

Baseline data

Table 1 is showing baseline data.

Data consideration

135 subjects were enrolled and 103 completed subject's data was considered for the statistical analysis.

Test regime with serum: The data from 33 completed subjects was considered for the statistical analysis. Subject number 153 data was noted to be outlier, hence not considered for the Trichoscan assessment data analysis. Therefore, 32 completed subject's data were considered for Trichoscan assessment data analysis.

Test serum: The data of 38 completed subjects were considered for the statistical analysis

Placebo: The data of 32 completed subjects were considered for the statistical analysis.

Number of subjects screened were 162, number of subjects enrolled were 135, completed were 103, withdrawn were 08, lost to follow up were 24, and no. of screen failures were 27.

Outcomes and estimation

Hair fall assessments using comb test (Figure 2).

Hair fall with bulb: Group A showed notable reductions in hair fall with bulb, with a 49.02% decrease at month 4 and a 45.22% decrease at month 6 compared to group B. Compared to group C, group A resulted in a 74.15% reduction in month 4 and a 57.38% reduction in month 6. These differences were statistically significant, indicating that the reduction in hair fall observed in group A was more pronounced than in groups B and C.

Hair fall without bulb: Group A showed a 45.01% reduction at month 6 compared to group B and a 73.52% reduction compared to group C.

Additionally, group A showed significant reduction in hair fall with and without bulb at months 4 and 6 compared to both group B and C.

The regimen achieved reductions of 48.76% and 45.17% in hair fall with and without bulb, respectively, at months 4 and 6 compared to group B. When compared to group C, group A showed reductions exceeding 100% in both categories at these time points.

Hair thinning assessment using

MSCR linear photo numerical scale: The hair thinning (visibility of the scalp) was graded using a 10-point photo numerical linear in-use scale for male subjects on all assessment visits by the dermatologists. The results obtained from group A showed statistically significant reduction in hair thinning at month 4 and 6 compared to baseline (p=0.000) and at month 6 compared to group C (p=0.001) (Figure 3).

Hair quality assessment

Hair smoothness and hair shine: Hair smoothness and shine assessed using a 5-point scale, revealed that group A showed >100% improvement in hair smoothness at month 2, month 4 and, 78.48% at month 6 when compared to group B. Similarly, group A showed >100% improvement in hair smoothness at month-2, month-4 and month-6 when compared to group C (Figure 3).

These results indicate that the regimen not only provides hair growth but is comparatively better in maintaining and improving hair quality with regular use.

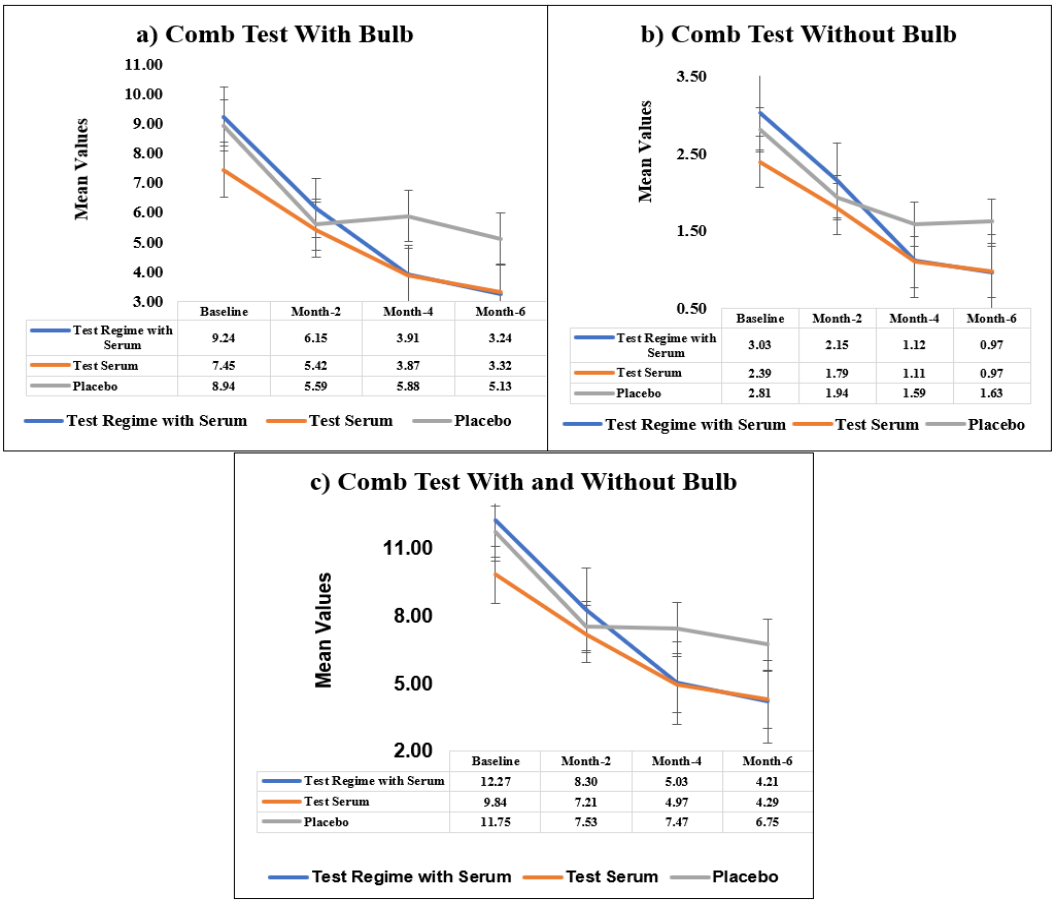

Figure 2 (a-c): Comb test.

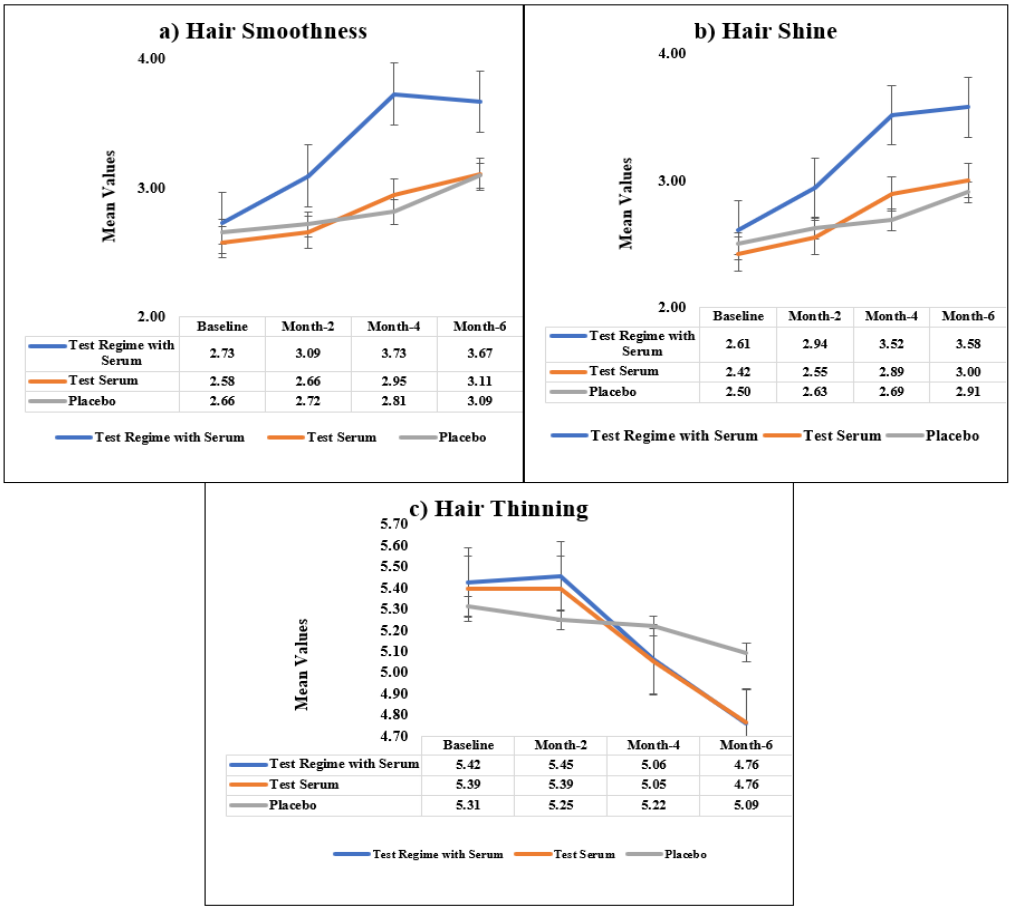

Figure 3 (a-c): Hair shine and smoothness; hair thinning.

Scalp condition

16.5% (n=17) of subjects with normal scalp, 46.6% (n=48) with dry scalp and 36.89% (n=38) with oily scalp condition were distributed across the 3 groups while initiating the study. In group A, 16 subjects were noted to have healthier scalp from dry to normal and 10 subjects' scalp has improved from oily to normal. In group B, 15 subjects' scalp has improved from dry to normal, and 10 subjects' scalp has improved from oily to normal. This indicates that the treatment was efficacious in maintaining a normal healthy scalp and showed an improvement in other two types of scalp condition (dry and oily).

Trichoscan assessment

Hair density per cm^2: At months 2, 4, and 6, both groups A and B exhibited significant improvements in hair density compared to baseline. However, group A demonstrated over 100% improvement in hair density at months 2, 4, and 6 when compared to group C, and 100% improvement at months 4 and 6 when compared to group B (Figure 4-6). Additionally, group A showed significant enhancement in vellus and terminal hair density at months 4 and 6 compared to both group B and C (Figure 6). Similarly, group A showed significant improvement in the Anagen Telogen ratio (A/T ratio) at month 2 when compared to baseline, group B and C (Figure 7).

Hair thickness assessment: Hair thickness assessment was performed using a Dino-lite camera using Caselite software showed group A showed significant improvement in hair thickness at month 2, month 4, and month 6 when compared to baseline. Group A showed significant improvement i.e. more than 100% in hair thickness at month 2, month 4, and month 6 when compared to baseline (Figure 8).

Subject self-assessment

Subject self-assessment provided insight that with regular use of group A, over 80% of the study participants reported a reduction in hair fall count to less than 30 by month 2. At the study's conclusion, 69.7% rated their current hair volume as good or excellent. Additionally, 26 out of 30 subjects reported no hair fall, 72.73% observed rapid hair growth, 66.67% noted increased thickness and volume, and 96.97% found that their hair did not break easily. For group B, more than 85% of participants reported a hair fall count below 30 by month 2. At the study's end, 65.79% rated their hair volume as good or excellent, and 33 out of 36 subjects experienced no hair fall. Furthermore, 68.42% saw rapid hair growth, 76.32% noted thicker and more voluminous hair and 97.37% found their hair resistant to breakage.

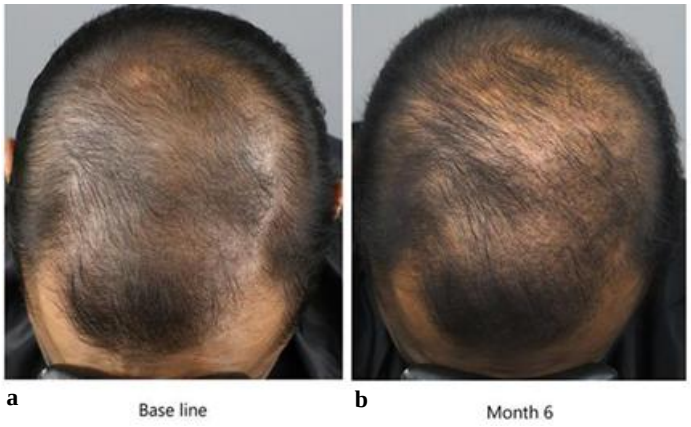

Figure 4 (a and b): Clinical photographs (hair density per cm^2).

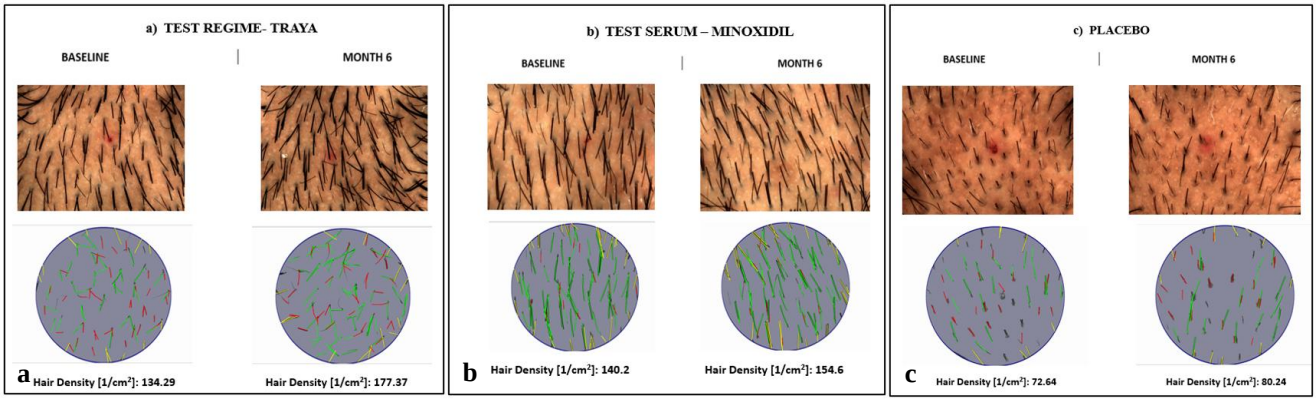

Figure 5: Trichoscan images (a) test regime with serum, (b) test serum, and (c) placebo.

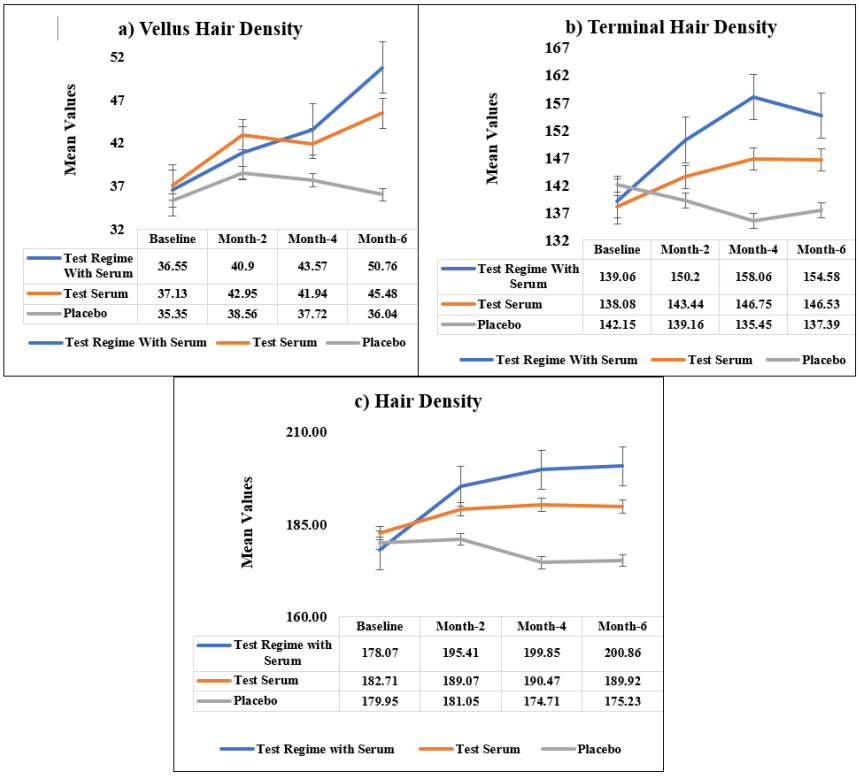

Figure 6: Hair density per cm^2; vellus and terminal hair density.

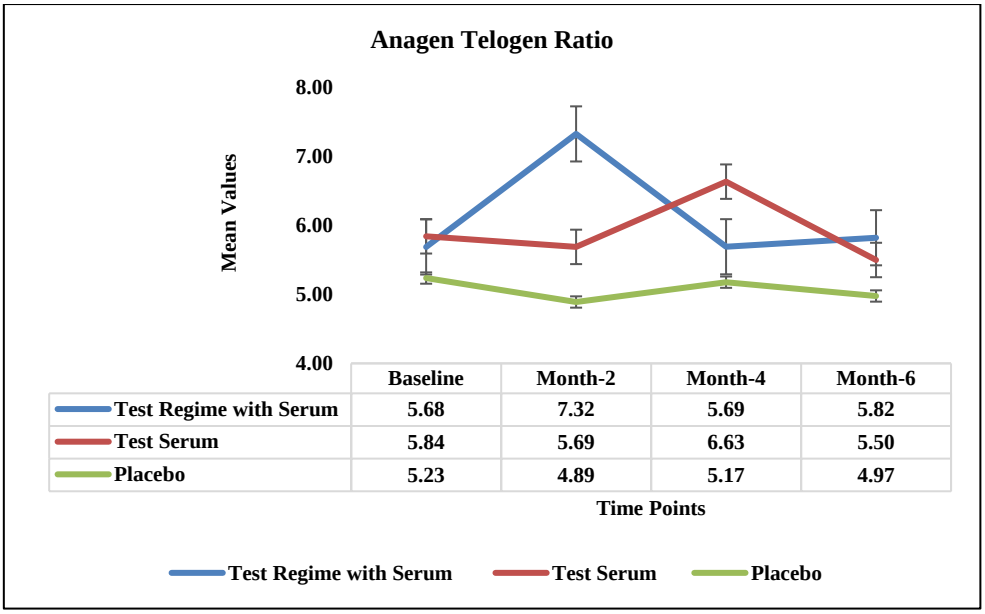

Figure 7: Assessment for anagen and telogen ratio.

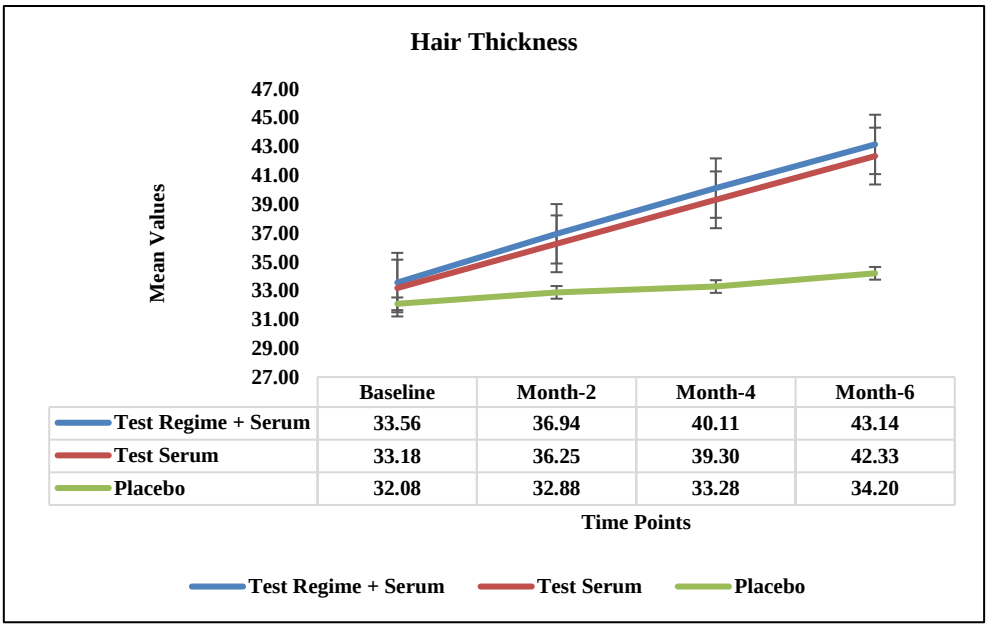

Figure 8: Hair thickness.

Safety assessments

Safety assessments showed that with regular usage of group A, none of the subjects reported irritation, dandruff, boils, erythema, allergic reactions, and folliculitis reactions at the end of the study.

DISCUSSION

Managing androgenetic alopecia is complex because appropriate treatment decisions need evidence-based approaches based on individual patient needs, compliance with the prescribed regimen, extent of baldness, and aesthetic objectives. For individuals experiencing hair loss and thinning, improving their hair growth, density, and thickness is crucial in treating alopecia. These improvements are essential for achieving effective results in their treatment.

Topical minoxidil is one of the only three FDA-approved treatments for male and female pattern hair loss. It was approved specifically for MAA in 1988 as a first-line treatment for men with mild-to-moderate MAA. Minoxidil elicits its greatest effect at the vertex and frontal regions of the scalp where it is known to slow the rate of hair loss by prolonging the anagen phase and promote hair regrowth by increasing both hair diameter and density. Although the efficacy of topical minoxidil is patient-dependent, multiple

studies have demonstrated its effectiveness in promoting hair growth.[7-10]

From the previous literature it is also found that the most serious side effects of minoxidil reported till date are cardiovascular complications, with ischemic heart disease, pericarditis, pericardial effusion and tamponade, pulmonary hypertension, and high output cardiac failure.[11-14]

Alternate to the pharmacological approaches are the Ayurvedic treatments which utilize a variety of herbs to promote hair health and growth while balancing the body's doshas.[15] Key herbs include Bhringraj, known for its ability to strengthen hair follicles and improve circulation; Amla (*Phyllanthus emblica* L.), rich in vitamin C and antioxidants that nourish the scalp; Guduchi or Kari Patta (*Azadirachta indica*), which has antimicrobial properties to combat scalp infections; Ashwagandha (*Withania somnifera*), which helps reduce stress and hormonal imbalances; fenugreek, often used for its ability to strengthen hair and reduce dandruff, which can enhance hair shine and promote growth.[16,17] Additionally, Coconut oil and Sesame oil are commonly used for scalp massages, while Jatamansi (*Nardostachys jatamansi*), Arjuna (*Terminalia arjuna*), Tagara (*Valeriana wallichii*) are valued for their calming effects and ability to promote healthy hair.[18,19]

Phytomedicine that acts against alopecia such as DHT blockers (pumpkin seed, Saw Palmetto), 5 alpha-reductase inhibitors (green tea), and camphor, thyme, and peppermint (*Mentha piperita*) as scalp-improving ingredients are nutritional ingredients that help naturally to reduce the chances of hair loss and treat alopecia.[20-23]

Dietary recommendations often include foods rich in proteins, omega fatty acids, biotin, selenium, vitamin b2 (riboflavin), and vitamin B5 (pantothenic acid) provide essential nutrients to the hair.[24] This holistic approach aims to restore balance and vitality, fostering not just hair growth but overall well-being.

Despite different administration regimens, studies have suggested that a minimum of 6 months is required for a significant cosmetic response which correlates with this study's results as the holistic hair treatment regimen was found to significantly improve patients' hair and scalp health in terms of reduced hair fall, increased hair density, and increased hair thickness over six months of treatment as observed in previous research studies.[25-27] Both statistically significant and clinically important findings were observed. The self-reported outcomes demonstrate that the holistic hair treatment regimen is highly effective, not only in promoting new growth but also in improving hair quality.

Although previous studies employed different methods to enhance hair health, the majority produced results consistent with those of the present study. Specifically, hair fall assessments using the comb test showed a significant reduction in hair loss, both with and without the hair bulb. Additionally, hair thinning assessments revealed substantial improvement, and Trichoscan measurements of hair density, as well as hair quality factors like smoothness and shine, also showed positive changes. Furthermore, the hair growth rate, including Anagen and Telogen percentages, along with Vellus and Terminal hair density, demonstrated notable improvement. Dermatological assessments confirmed these findings, noting significant reductions in hair thinning and improvements in hair quality within the holistic hair treatment regimen group. The combination of follicular and systemic interventions proved particularly effective in enhancing both the cosmetic and structural aspects of hair growth, offering a more comprehensive solution than minoxidil alone. These results are in close agreement with those observed in previous research.[28-31] Moreover, the safety profile of the holistic hair treatment regimen was favorable, with no reports of clinically significant adverse events or scalp-related side effects such as irritation or allergic reactions.

The success of the holistic hair treatment regimen can be attributed to its synergistic approach: while minoxidil directly stimulates hair follicles to promote regrowth, the Ayurvedic components of the regimen address underlying systemic issues that contribute to hair loss, such as nutritional imbalances, digestive disorders, and hormonal dysregulation. By targeting these internal factors, the holistic hair treatment regimen not only promotes new hair growth but also creates a more favourable scalp environment for sustaining long-term hair health. Improvements in scalp condition, including normalization of sebum production and enhanced scalp moisture, were observed, further supporting the regimen's comprehensive therapeutic potential.

The results show that while some participants experienced adverse effects such as dandruff (seborrheic dermatitis) etc., these were effectively managed with the use of antidandruff shampoos. Following this, none of the participants exhibited any clinically significant adverse reactions, and the regimen was well tolerated throughout the study duration. The acceptability of this regimen is further reinforced by the high compliance rates noted during monthly follow-up visits hence creating a setting conducive for successful treatment when compared to minoxidil alone.

Strengths, limitations and generalisability

While the study's strengths lie in its randomized and blinded design, certain limitations must be acknowledged. Despite statistically significant results comparable to or better than MAA in some cases, a visual categoric change on the Norwood scale was not observed within the six-month period for any product. This suggests that while users may experience benefits, a complete reversal of balding is not feasible within this timeframe. Additionally, the long-term sustainability of these effects remains to be

explored, and a longer follow-up may be required to assess the full extent of visible improvements.

CONCLUSION

In conclusion, the holistic hair treatment regimen proved highly effective in improving various aspects of hair health, outperforming the test serum in key areas. The regimen led to a notable reduction in hair loss, along with remarkable improvements in hair thickness and density. Additionally, significant enhancements in hair smoothness and thickness were noted, with the holistic hair treatment regimen consistently delivering superior results compared to other treatments. Subject self-assessments corroborated these findings, reporting reductions in hair fall and increases in volume, thickness, and length.

This holistic hair treatment regimen effectively addresses both internal systemic factors and external manifestations of hair loss, offering a comprehensive treatment option. By targeting the root causes of hair loss, this holistic regimen not only enhances hair density and thickness but also promotes overall scalp health. This approach tackles underlying internal issues like metabolic disorders, and insomnia, ensuring that patients receive support for all contributing factors to hair loss. The findings suggest that this holistic hair treatment regimen with the synergy of Ayurveda and modern science hair actives (minoxidil) is more effective and promising as a therapeutic option for treating stages 2-4 MAA.

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Ethical approval: The study was approved by the Independent Ethics Committee

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