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A prospective study in the treatment of androgenic alopecia using combination of procapil, capixyl, redensyl

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Cover Page Footnote

I would like to convey my thanks to my departmental faculty during my study

Original Article

A prospective study in the treatment of androgenic alopecia using combination of procapil, capixyl, redensyl

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Abstract

Background: Androgenic alopecia is characterized by its diffuse loss and the miniaturization of the hair. The study aimed to assess the safety and efficacy of procapil, redensyl, capixyl, bicapil, and anagain in topical hair growth serum in androgenic alopecia.
Methods: A prospective study was conducted on 110 healthy subjects aged 18-60 with androgenic alopecia in the Department of Dermatology, Tundla, Etmadhpur. Each subject applied 1 ml of serum on a dry scalp and was followed up on the 4th, 8th, 12th, and 16th week. Mean, median, and standard deviation were calculated. A repeated measure of the ANOVA test followed by post-hoc pairwise comparison using the Bonferroni test was applied. JAMOVI® (Sydney, Australia) software, was used for the statistical analysis.
Results: Seventy subjects completed the four follow-ups. Post hoc pair-wise comparison showed that each pair differed significantly, and an increased mean score was observed between the initial and follow-up assessments for the mean Anagen:Telogen (A:T) ratio and mean hair diameter [76.84 µm vs 77.77µm, 76.84µm vs 80.03 µm, 76.84 µm vs 82.33 µm; $p<0.05$]. A significant difference was found in hair density between baseline and 16th week [76.84 vs 84.60; $p=0.002$]. No adverse effects were observed.
Conclusion: This study's results suggest that after 120 days of treatment with hair serum, it is safe and effective, improving the A:T ratio, hair density, and hair thickness and hence reducing hair fall.

Keywords: *anagain, androgenetic alopecia, capixyl, procapil, redensyl*

Background

Androgenic alopecia (AGA) is a psychologically distressing disorder where there is a recession of the hairline secondary to diffuse loss of hair along with hair miniaturization. Alopecia can begin in the late teens and may progress to complete baldness by the age of 60. It is a non-scarring type of alopecia.[1] In males, the mid-frontal scalps, vertex, and temporal area are affected whereas in females, the frontal and parietal scalp are affected. This pattern of hair loss in males is caused by the 5-alpha reductase enzyme, which leads to androgen-dependent hair follicle miniaturization.[2]

Familial susceptibility, drugs, circulating androgens, deficiencies of certain vitamins and minerals, and stress are some of the factors that contribute to early alopecia. The defect in the autosomal dominant gene with polygenetic inheritance causing baldness.[3]

The United States Food and Drug Administration (FDA) has approved topical minoxidil and oral finasteride for treating androgenic alopecia. The efficacy of topical minoxidil is around 40%, with a response declines after 16 weeks of continuous usage.[4] Topical minoxidil works by opening potassium channels and reducing intracellular calcium reducing intracellular calcium, which stimulates the epidermal growth factor-mediated growth of hair roots. In alcohol bases, it causes dryness, burning, and local irritation in the form of irritant dermatitis. Also, hypertrichosis and headaches are reported.[5] Finasteride is an inhibitor of the 5-alpha-reductase enzyme that causes an

increase in the production of dihydrotestosterone hormone, leading to miniaturization of hair follicles.[6] Oral finasteride causes side effects like orthostatic hypotension, gynecomastia, testicular pain, hypersensitivity reactions, impaired sexual function (loss of libido in males about 2.1% to 3.8%), and the risk of feminization of a male fetus (pregnancy category C).[7]

Oral dutasteride is recognized as more effective than finasteride in inhibiting dihydrotestosterone (DHT) and hence enhancing hair growth.[8] Having such potential side effects and understanding the truth that hair fall treatment needs a long time, the drug should be safer, effective, mild, cost-effective, and give sustained results for a long time without a rebound hair fall. These days, the market is flooded with hair serums of herbal origin which are as effective as conventional treatments with the fewest side effects. This study aimed to assess the safety and efficacy of procapil, redensyl, capixyl, bicapil and anagain in topical hair growth serum in male pattern hair loss (MPHL) and female pattern hair loss (FPHL).

Methods

An open-label single-arm prospective study was conducted on 110 healthy subjects aged 18-60 years on healthy males and females to evaluate the safety and efficacy of hair serum having MPHL and FPHL in the Department of Dermatology from 20th December 2023 to 21st June 2024. All the patients who consented to participate were evaluated using the inclusion and exclusion criteria. The evaluation was done based on clinical, instrumental, and questionnaires. The adverse effects were monitored. This study was approved by the Institutional of Ethics Committee of F.H. Medical College, Tundla, Agra with ethical clearance number FHMC/IEC/R.Cell/2023/31.

Inclusion criteria

Healthy female and male subjects aged 18–60 years with MPHL and FPHL were enrolled in this study. The Norwood scale or Hamilton-Norwood scale II to IV classification was for males, while the Ludwig scale I to II was for females enrolled in this study, as per the classification. Participants were instructed not to use any hair serum or minoxidil solution other than the test product. Female subjects of childbearing potential were required to have a negative urine pregnancy test at the screening visit. A routine blood test for a hemogram and a thyroid profile was done. Subjects willing to allow photographs of affected areas during the study were included.

Exclusion criteria

The following subjects were excluded: history of any skin dermatoses in the scalp hair other than hair loss; local application or oral medication of any hair growth serum or any drug that the observer thinks influence the growth of hair growth for at least 90 days before the start of study, any surgical or non-surgical procedures like platelet-rich plasma (PRP), hair transplant, weaving, or laser, etc., any shaving of scalp hair, an allergic reaction to any of the component of hair serum; any systemic and long-standing disease.

Test product

The test product hair serum contained 3% of capixyl, 3% of redensyl, 3% of procapil, 3% of anagain, 3% of baicapil (brands used: Trichodense, Pilodil HS, Kerascalp marketed by Fuchan (India), Solderma (India), and Ipca (India) respectively was applied by 110 subjects for 120 days. Each subject applied the hair serum with a dropper, about 1 ml twice a day, in the morning and evening, on the hairless areas of the dry scalp, gently massaged the product with their fingertips for 2 minutes and then washed their hands with soap and water. The subjects were asked to use a regular shampoo three times a week and not oil their hair.

Evaluation

The evaluation of subjects was done at baseline (i.e., on the first day of the visit) and then on the 4th week, 8th week, 12th, and 16th week in the Department of Dermatology.

Subject self-evaluation

At each visit, the subjects were asked to complete a case record form which included the four-point questionnaire, where the subject assessed their density, hair growth, length, the shrinking of the bald area, and satisfaction after every four weeks. A Likert scale, ranging scores from 1 to 5 was used for assessment of the self-evaluation of the patients in terms of questions. A maximum score of 20 indicated the worst outcome, while a minimum score of 4 indicated a positive result. The scores were recorded in case-related form (CRF). Any side effects associated with the topical preparation were also documented, as shown in Table 1.

Researcher evaluation

A “hair pull test” was done to assess the strength of hair. Using trichoscopy, by Folliculoscope® (LeadM

Corporation, Seoul, Korea), a microscopic evaluation of hair was done to estimate the number and the proportion of hair in the different phases of the hair cycle, hair thickness, and hair density. An observer-standardized rating scale for the assessment of the subjects was used in terms of scores +3 (improved), +2 (moderately improved), +1 (slightly improved), 0 (no change), -1 (slightly decreased), -2 (moderately decreased), and -3 (decreased). The scores were recorded in CRF (case related form). The modified global photographic assessment score (MGPA) was 1 (significant disease progression), 2 (moderate disease progression), 3 (slight disease progression), 4 (no change), 5 (slight improvement), 6 (moderate improvement), 7 (significant improvement).

Statistical analysis

Mean, median, standard deviation and quartiles were measured as statistical descriptive measures. All statistical tests of the recorded data were done using JAMOVI® (Sydney, Australia) statistical software. A repeated measure ANOVA test and Bonferroni test were used to evaluate continuous variables and compare baseline to post-treatment data. Friedman and Wilcoxon signed-rank tests were used for ordinal variables, to calculate within-treatment analysis and to compare baseline to post-treatment analysis.

Results

Of the 149 subjects, 110 completed the study, and 39 were lost to follow-up. Several subjects were lost to follow up due to live in a nearby village and couldn't come monthly for four months. Additionally, some patients had improvement so they could have stopped coming for follow-up. Telephonic follow-up was attempted, but physical examination and documentation couldn't be done unless the patient visited the department**.** Of the 110 subjects, 59 were males and 51 were females. The mean age was 39.05 (S.D-10.84).

The efficacy of hair serum was assessed by measuring the Anagen:Telogen (A:T) ratio, hair growth, hair density, and hair diameter. The average A:T ratio at baseline was 52.24±16.36 which increased to 53.34±16.21 at 4th week (2.10 % change), 54.73±16.43 at 8th week (4.77 % change from baseline), 55.96±16.42 at 12th week (7.12% change from baseline), and 57.18±16.40 at 16th week (9.46% change from baseline). This depicts the increase in the hair growth.

Table 1. Self-Evaluation Form of The Patient

No	Question	Grade	Score
1.	My bald area shrank	Strongly agree	1
		Agree	2
		No idea	3
		Disagree	4
		Strongly disagree	5
2.	New hair growth	Perfectly increased	1
		Moderately increased	2
		Not changed	3
		Moderately decreased	4
		Clearly decreased	5
3	The view of my hair after treatment	Much better	1
		Better	2
		Same	3
		Worse	4
		Much worse	5
4.	Satisfaction with the look of my hair		
	Frontal	Very satisfactory	1
		Satisfactory	2
	Vertex	Average	3
		Not satisfactory	4

Table 2. Comparison of Mean Difference for Parameters at Different Time Points

Variables	Comparison of Mean at different time points					*f* - value	*p-value*
	Baseline	4th Week	8th week	12th week	16th week		
A:T ratio	52.24±16.36	53.34±16.21	54.73±16.43	55.96±16.42	57.18±16.40	564.27	<0.01
Hair Density	76.79±24.00	77.72±16.00	79.97±15.89	82.25±15.90	84.51±15.92	13.20	<0.01
Hair Diameter	38.73±3.00	39.51±3.09	40.15±3.19	40.92±3.25	41.73±3.28	349.33	<0.01

A:T: Anagen:Telogen; F: Fisher's Test; P: Probability Test

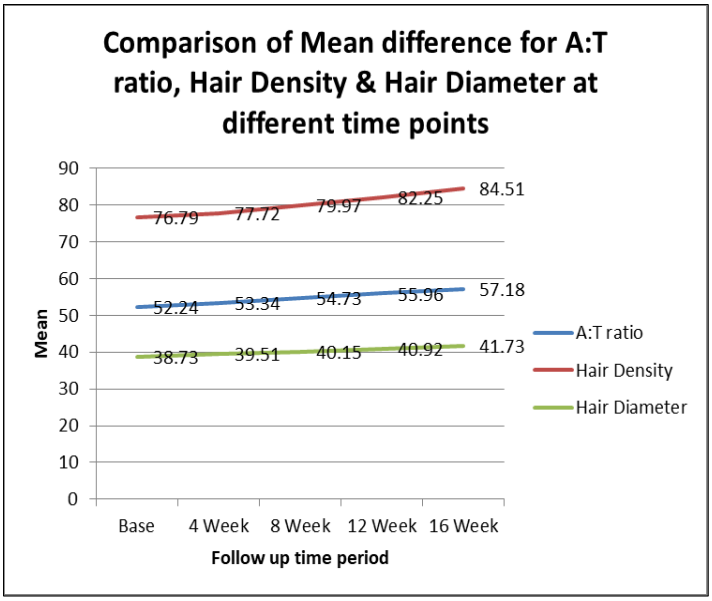

Figure 1. Trichoscopy Assessment.
*A:T ratio = anagen:telogen

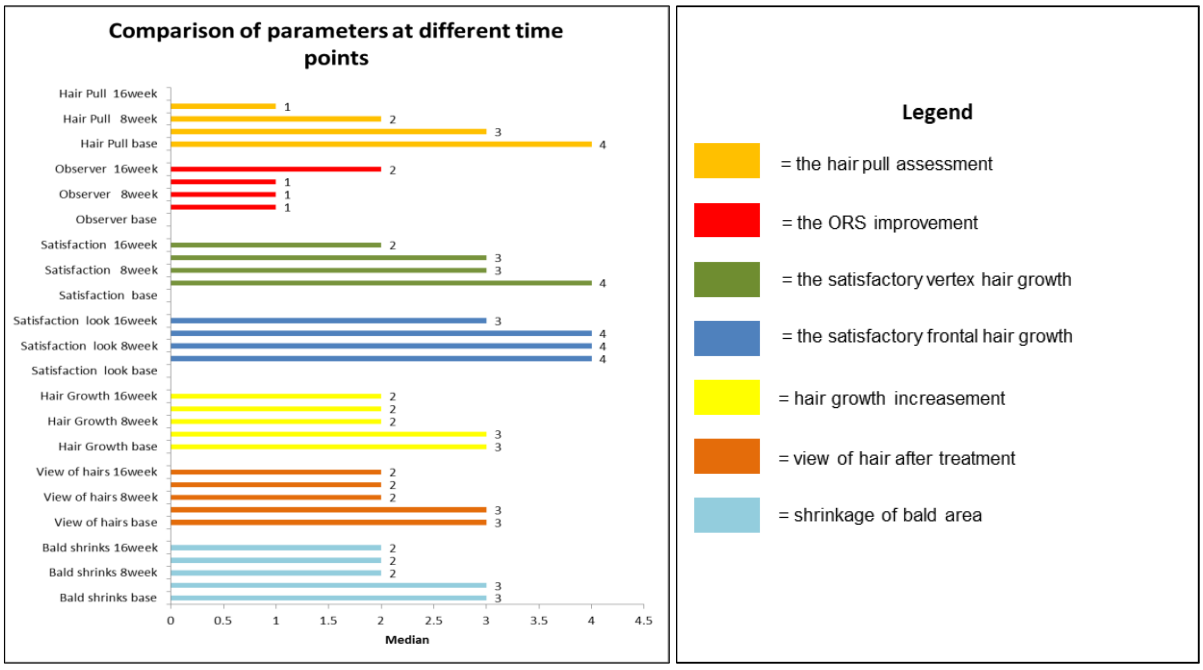

Figure 2. Assessment of Patient's Questionnaire and Observer Rating Scale (ORS) Score.

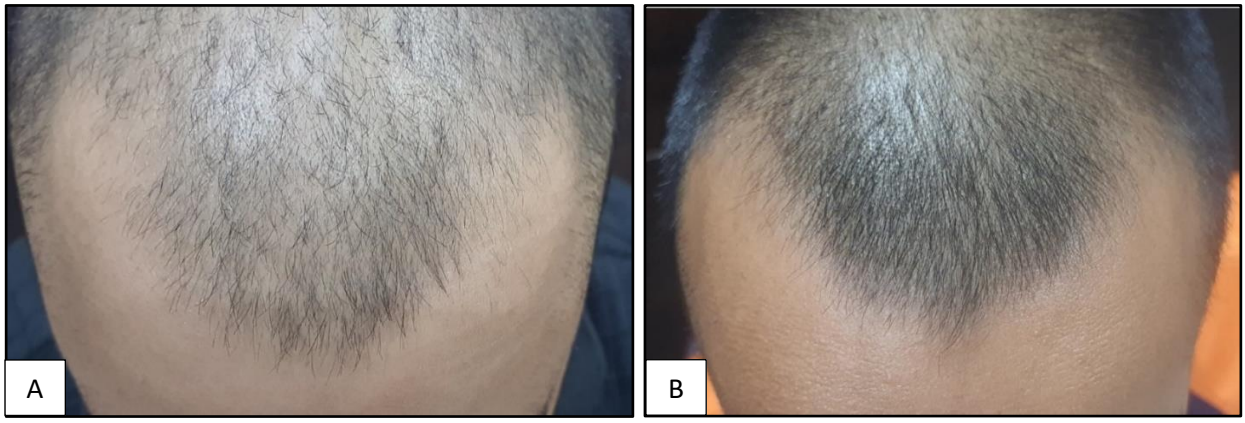

Figure 3. Androgenic Alopecia of a 35-Year-Old Man**.**
A. Showing Sparse Hair at The First Visit (Frontal View). B. After Using Hair Serum Showing Hair Growth at the 16th Week (Frontal View).

Observed hair density at baseline was 76.79±24.00 which significantly increased to 77.72±16.00 in the 4th week (1.21 % change), 79.97±15.89 in the 8th week (4.15 % change from baseline), 82.25±15.90 at 12th week (7.12% change from baseline), and 84.51±15.92 at 16th week (10.05 % change from baseline). Hair diameter at baseline was 38.73 ±3.00 µm which significantly increased to 39.51±3.09 µm at 4th week (2.0 % change), 40.15±3.19 µm at 8th week (3.67 % change from baseline), 40.92±3.25 µm at 12th week (5.64% change from baseline), 41.73±3.28 µm at 16th week (7.75 % change from baseline) in Table 2.

The trichoscopy findings showed an increase in the mean difference in A: T ratio, hair density, and hair thickness was statistically significant (p≤0.05) shown below in Figure 1. Upon analyzing the subject self-evaluation questionnaire (Figure 2). The subjects were satisfied with the efficacy of hair serum in terms of “shrinking of my bald area,” better look in “the view of my hair,” increase in “the new hair growth,” and “satisfactory improvement in the vertical and frontal look of my hair”. The observer assessment score which can be shown in Figure 2, improved from a median of 0 at baseline to a median of 2 at the 16th week. The “hair pull” test also showed a reduction, suggesting better hair anchorage (Figure 2).

The Figure 2 described from down – upward shows depict the subject’s self-evaluation questionnaire. The blue bar shows the reduction in shrinkage of the bald area from a median baseline of 3 to a median of 2 at the 16th week. The dark orange bar shows the “view of hair after treatment” from median of 3 at baseline to median of 2 at 16th week. The yellow bar shows the increase in hair growth from median of 3 to median of 2 at 16th week. The dark blue bar shows satisfactory look of frontal hair growth on from median of 4 at base to median of 3 at 16th week. The green bar shows the satisfactory look on vertex hair from median of 4 at baseline to median of 2 at 16th week. The red bar shows the improvement in observer rating scale scoring from median 1 at baseline to median of 2 at 16th week. The orange bar shows the hair pull assessment which shows reduction from a median of 4 at baseline to median of 1 at 16th week. The MGPA (mean global photographic assessment) score showed that the median (50th percentile) increased from 0 at the first visit to 6.0 at the 16th week, which was statistically significant (p≤0.01) shown in Figures 3A and 3B.

Discussion

Androgenic alopecia is a difficult condition to treat, as the etiology of hair fall is multifactorial. It can start as early as in teenagers. Nutritional deficiency can be corrected by appropriate supplementation, but genetic predisposition cannot be. Since the cause of AGA is multifactorial so multimodal treatment should be given which gives sustained results and the rebound hair fall should be delayed. After the termination of minoxidil use, rebound hair fall is expected within 12-24 weeks. Minoxidil is often combined with oral or topical finasteride or dutasteride to give thicker hair growth.[9]

Therefore a hair growth product should be safe, non-irritant, enhance quick hair growth, and prevent rebound hair fall. The vasodilator property of certain ingredients extracted from plants like propanil, baicapil, redensyl, capixyl, caffeine, sinapic acid, and shikimic acid, rosemary oil,[10,11,12] hibiscus flowers, grape seed, and sage has been

found to enhance hair growth. The DHT blockers like ginkgo, green tea extract, and emu oil alopecia act on the 5α enzyme thereby decreasing DHT.[13] A combination of botanical ingredients containing dihydro quercetin glucoside (DHQG: 0.005%), epigallocatechin gallate glucoside (EGCG2: 0.0009%), glycine (0.005%), zinc chloride (0.002%), metabisulfite (0.015%), and glycerin (50%) results in the formation of redensyl.[14] Zinc facilitates the binding of cysteine to keratin-associated proteins (KAP).[15] Procapil is comprised of oleanolic acid (derived from olive tree-leaves vasodilator, DHT blocker), *apigenin* (extracted from citrus peel-vasodilator), *biotinyl-GHK* (a vitamin-carrying peptide) is formed from biotin (vitamin H).[16]

Capixyl is a biomimetic peptide complex comprising 4 amino acids and an extract of Trifolium pratense. This extract is rich in biochanin A, an important inhibitor of enzymes 5-alpha reductase I and II. It helps synthesize extra-cellular matrix proteins, enhancing the synthesis of ECM (extracellular matrix) I, III, VII, and increasing the hair follicle's size and hence better anchorage. Baicapil, a synergistic combination of *Scutellaria baicalensis*, soy, and wheat sprouts. Anagain is an extract prepared from edible organic pea sprouts *(Pisum sativum L.).*[17] Pea sprouts are rich in biotin, L-arginine, and isoflavones, which has been found to enhance hair growth in experimental models. The later two plant-based extracts: Baicapil and anagain are antioxidants and prevent premature termination of the anagen phase by inhibiting the release of pro-inflammatory cytokines such as IL-1 (interleukin-1) and TNF-α (tumor necrosis factor) that bring about apoptosis and follicular atrophy.[18]

In addition, it directly affects hair growth by stimulating the expression of genes FGF-7 (fibroblast growth factor) and noggin. Apart from the above treatment options, other promising treatments are hair restoration surgery which includes either scalp reduction surgery, hair transplantation, or a combination of both for severe grades of AGA. A few minimally invasive treatments are platelet-rich plasma (PRP), mesotherapy[19,] and microneedling[20] with various hair booster serums that can be complemented to enhance the results. Common side effects include bruising, pain, and folliculitis. Non-invasive methods like low laser light therapy (LLLT) with wavelength 600-100 nm can be used as home-use devices in the form of combs, helmets, and caps which enhance hair growth stimulation.[21] Permanent hair camouflaging options include micropigmentation and hair transplantation.[22,23] Our study showed an improvement in hair fall after using the hair serum for 120 days. The evaluation score showed an improvement in the A:T ratio, hair density, and hair diameter from the baseline to the 16th week ($p<0.01$). The observer's evaluation scores showed an improvement from a median score of 0 at the 50th percentile to a score of 2 at the 16th week. The mean A:T ratio increased from 52.24 at baseline to 57.18 at the 16th week. ($p<0.01$). The mean difference in hair density improved from 76.79 to 84.51 in the 16th week. ($p<0.01$). The mean difference of hair diameter increased from 38.73 µm at baseline to 41.73 µm at the 16th week. The hair pull score with median, at the 50th percentile, decreased from 4 at baseline to 0 at the 16th week ($p<0.05$).

The subject's self-evaluation score also showed an improvement in the "satisfactory looks of frontal and vertex hair", a reduction in the baldness of hair, a better look of hair growth, and an increase in hair growth. These results were similar to a study in 2020 by Katoulis, et al.[24] The mean global photographic assessment with the median score at the 50th percentile revealed an improvement of 0 at baseline to 6 at the 16th week. In another study by Karaca N, Akpolat ND,[25] the RCP (redensyl, capixyl, procapil) group was compared with the 5% minoxidil group, which showed 1.5 times greater improvement in the RCP group than the minoxidil group confirming the researcher evaluation score.[26] In a study by Eslahi, et al.[13] RCP solution such as trust tonic group was compared with 5% minoxidil. A 64% improvement in hair growth and density was found in RCP group and 36% in minoxidil group. The observer assessment scores were 60% and 30%, and the photographic score method was 57% and 8% respectively, for the RCP and minoxidil group ($p<0.05$).

Karaca N and Alkpolat[15] conducted a study, where the RCP group was compared with the 5% minoxidil group for androgenic alopecia. The results showed that hair growth was 2.54 times higher in the RCP group than in the minoxidil group, at the end of 24 weeks ($p\leq0.05$). The global photographic evaluation also revealed statistically significant improvement in the RCP group at 88.9% and 60% in the 5% minoxidil group ($p<0.05$). In a study by Kohli M, et al.[27] RCP hair serum was applied to thirty subjects for alopecia in males, for a period of 90 days. It was observed that statistically significant ($p<0.0001$) improvement was observed in the A:T ratio, hair density, hair thickness, hair strength, and also a significant reduction ($p<0.0001$) in hair fall. No irritant local reaction or any side effects were observed during the study period justifying the safety of products. The limitation of this study is that it is neither randomized nor compared with a controlled

population, limited sample size, and a short follow-up has been done during the study. Comparative studies should be done with the conventional treatment with long-term follow-up to further support the findings of RCP hair serum.

Conclusion

In this present prospective study, the use of a photo-ingredient-based solution containing procapil, capixyl, redensyl, bicapnil, and anagain applied at a dose of 1 ml twice daily, was found to be effective and safe as monotherapy for the long-term management of MPHL and FPHL. It enhanced the appearance of scalp hair by improving hair density, strength, and thickness, without any adverse effects. Hence, it can be used as monotherapy or an adjuvant to conventional treatment.

Acknowledgments

I would like to convey my thanks to my departmental faculty during my study.

Author Contributions

All the authors conceived the review and approved the final manuscript. GB and RB participated in conceptualization, investigation, and resources. GB and RB participated in the methodology, formal analysis, validation, review, and editing of the manuscript. GB and RB made the original draft of the manuscript and visualization. All authors read and approved the final manuscript.

Conflicts of Interest

None.

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