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Original Research Article

A Comparative Study of the Efficacy and Safety of 5% Minoxidil and 1 Mg Finasteride in Male Androgenetic Alopecia Patients at a Tertiary Centre in Bihar

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Conflict of interest: Nil

Abstract

Background: Androgenetic alopecia (AGA) is responsible for 95% of hair loss in males over 50. However, AGA is far less frequent in women, with around 40% of women experiencing some degree of hair loss, particularly after menopause. In a gradual process, alopecia is caused by the 5-reductase enzyme converting testosterone to dihydrotestosterone (DHT), which causes hair follicles to shrink.

Aims and Objectives: A comparative study of the efficacy and safety of 5% minoxidil and 1 mg finasteride in male androgenetic alopecia patients.

Material and methods: Ninety males with Androgenetic Alopecia were included in this analysis. There were two Categories of patients. The total number of patients in each Category was 45. Patients in Category I were prescribed 1 ml of a 5% minoxidil topical solution twice daily, while those in Category II were given a 1 mg finasteride pill once daily. Hair was evaluated using a 7-point scale (-3 for significantly reduced, -2 for moderately reduced, -1 for slightly reduced, 0 for no change, +1 for slightly increased, +2 for moderately increased, +3 for significantly increased) applied to before- and after-treatment images.

Results: The average pre-treatment hair density of the scalp in Category 1 was 95.85 hairs/cm2, whereas that of Category 2 was 97.68 hairs/cm2. After treatment, the average number of scalp hairs in Category I was 118.58 per square centimetre, whereas in Category II it was 108.96. There was a statistically significant split (P 0.05). Table 3 reveals that score -1 was seen in 3 in Category 2, 0 in Category 1 , 22 in Category 1 and 15 in Category 2, 1 in 9 in Category1 and 7 in Category 2, 2 in 7 in Category 1 and 8 in Category 2 and 3 in 7 in Category 1 and 11 in Category 2. The difference was significant (P< 0.05).

Conclusion: The treatment of Androgenetic Alopecia with oral 1 mg finasteride was shown to be more successful than that with topical 5% minoxidil.

Keywords: Androgenetic Alopecia, Dihydrotestosterone, Scalp.

Introduction

Androgenetic alopecia (AGA) is responsible for 95% of hair loss in males over 50.1 However, AGA is far less frequent in women, with around 40% of women experiencing some degree of hair loss, particularly after menopause. In a gradual process, alopecia is caused by the 5-reductase enzyme converting testosterone to dihydrotestosterone (DHT), which causes hair follicles to shrink. Recent evidence suggests a role for dihydrotestosterone (DHT) in the aetiology of androgenetic alopecia (AGA) in males who have a hereditary deficit of the enzyme 5-alpha-reductase (5-AR) type II, which transforms testosterone. Androgenetic alopecia (AGA), telogen effluvium, and alopecia areata are the three most frequent kinds of non-scarring alopecia that affect men.[1] The condition causes hair loss in the fronto-temporal and vertex areas of the scalp and varies in severity from mild to severe. AGA causes patterned hair loss that begins with bitemporal recession of the frontal hair line and progresses to diffuse thinning over the vertex.[1] A model for the pathogenesis of AGA must account for the aforementioned histological features, in particular the miniaturisation of the hair follicle and an increase in the ratio of telogen to anagen hairs, as well as the local and systemic effects of androgens in aggravating the condition and the familial tendency. Although a polygenic inheritance has been ruled out, the complicated genetics of AGA suggest that it is produced by an autosomal dominant gene with variable penetrance. The genes responsible for both androgen synthesis and the subsequent conversion to dihydrotestosterone (DHT) are prime candidates.[2,3] Due to the high incidence of AGA, with 50% of men experiencing hair loss, several therapies have been developed to combat this condition, including topical solutions, oral medications, surgical hair replacement, etc. However, the FDA has only authorised two medications, topical Minoxidil and oral Finasteride, for the treatment of AGA in males. Pharmacodynamic studies have shown that an increase in testosterone by 5-alpha-reductase to DHT results in hair loss due to the miniaturisation of scalp hair follicles. Minoxidil has been shown to aid in enhancing hair growth by vasodilation by providing nutrients to the hair follicles and thus direct stimulation of the hair follicle cells.[4,5] To prevent hair follicles from becoming too small, finasteride acts as a 5-reductase inhibitor in the human body. Female breast development, feminization, and erectile dysfunction have all been linked to oral Finasteride.3 Oral Finasteride at 1mg/day and topical Minoxidil at 5% were reported to be safe and effective. Patients with moderate to severe AGA benefited more from oral Finasteride than Minoxidil in a randomised controlled trial.[6] Patients who used both topical Minoxidil and oral Finasteride saw greater improvement than those who used either drug alone, suggesting a synergistic effect.[7-9] Unfortunately, a topical formulation of Finasteride is not currently on the market. We've created a lipid-based topical formulation of Minoxidil and Finasteride (MorrF) to provide patients more options for therapy. Since patients wouldn't have to take separate medications at the same time, adherence rates would increase, and the accelerated rate at which hair regrowth would improve from the combination of two molecules working on the same condition would also be a bonus. People who are worried about the potential adverse effects of oral Finasteride would benefit greatly from this treatment option.

Aims and Objectives: A comparative study of the efficacy and safety of 5% minoxidil and 1 mg finasteride in male androgenetic alopecia patients

Material and Methods

The present prospective cross-sectional study comprised 110 male patients with Androgenetic Alopecia. Out of 110

patients, 15 did not meet the inclusion and exclusion criteria. Hence, 95 patients were enrolled. But 5 patients were lost to follow-up. The final analysis was done on 90 males with Androgenetic Alopecia patients. It was a hospital-based interventional study at the Bhagwan Mahavir Institute of Medical Science, Pawapuri, Bihar, India, in the Department of Pharmacology, in collaboration with the Department of Skin & VD, Bhagwan Mahavir Institute of Medical Science, Pawapuri, Nalanda, Bihar (India). The institutional ethical committee gave its clearance before the study could be carried out. The research was conducted from July 2022 to December 2022. All patients attending the Skin & VD, OPD were informed regarding the study, and their written permission was acquired from everyone who participated in the research after they were given all of the relevant information. People's names, ages, and other information were taken down. There were two groups of patients. The total number of patients in each group was 45. Patients in Category I were prescribed 1 ml of a 5% minoxidil topical solution twice daily, while those in Category II were given a 1 mg finasteride pill once daily. Hair was evaluated using a 7-point scale (-3 for significantly reduced, -2 for moderately reduced, -1 for slightly reduced, 0 for no change, +1 for slightly increased, +2 for moderately increased, +3 for significantly increased) applied to before- and after-treatment images.

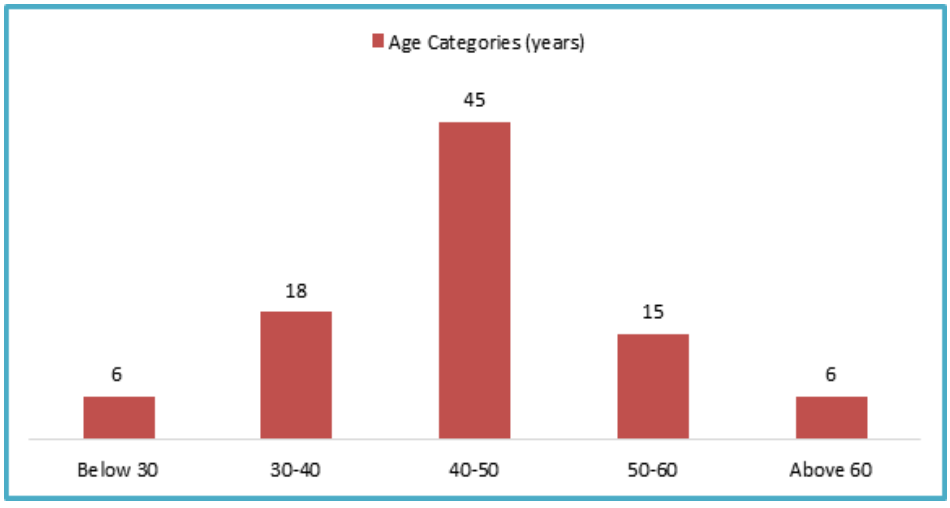
Statistical analysis

Results thus obtained were subjected to statistical analysis with the help of Microsoft Excel 15 and SPSS Version 22 software. Given that the data were parametric, we ran an unpaired t-test for headache frequency to determine whether there was any significant baseline difference between groups that was statistically significant. A P value less than 0.05 was considered significant.

Results

Table 1: Distribution of patients

Age Categories (years)	Number=90	%
Below 30	6	6.67
30-40	18	20
40-50	45	50
50-60	15	16.67
Above 60	6	6.67

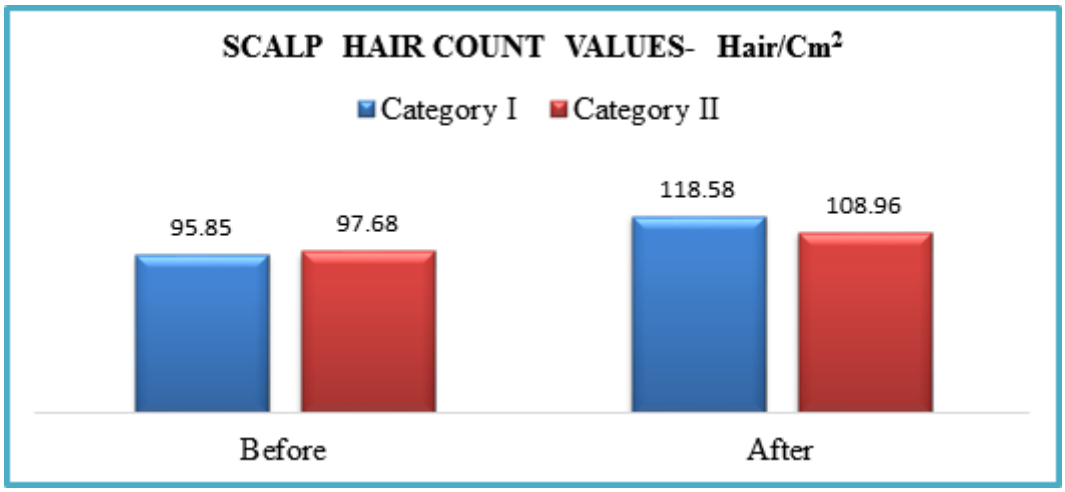


Graph I: Distribution of patients.

Table I and Graph I shows that most of the patients from the age Category 40-50 years followed by 30-40 years, 50-60 years, below 30 and above 60.

Table 2: Scalp hair count values before and after treatment

Period	Category 1(Hair/cm^2)	Category 2 (Hair/cm2)	P value
Before	95.85	97.68	0.56
After	118.58	108.96	0.05



Graph 2: Scalp hair count values before and after treatment

Table II and Graph II shows the average pre-treatment hair density of the scalp in Category 1 was 95.85 hairs/cm2, whereas that of Category 2 was 97.68 hairs/cm2. These data are shown in Graph I of Table 2.

After treatment, the average number of scalp hairs in Category I was 118.58 per square centimeter, whereas in Category II it was 108.96. There was a statistically significant split (P <0.05).

Table 3: Global photographic assessment in both Categories

Score	Category 1	Category 2	P value
-1	0	4	0.69
0	22	15	0.05
1	9	7	0.74
2	7	8	0.69
3	7	11	0.05

Table 3 reveals that score -1 was seen in 4 in Category 2, 0 in Category 1, 22 in Category 1 and 15 in Category 2, 1 in 9 in Category 1 and 7 in Category 2, 2 in 7 in Category 1 and 8 in Category 2 and 3 in 7 in Category 1 and 11 in Category 2. The difference was significant (P< 0.05).

Discussion

30% to 50% of men over the age of 50 and up to 80% of men over the age of 70 suffer from androgenetic alopecia (AGA), the most common form of male hair loss.[10] AGA is characterized by the gradual transformation of terminal hair (pigmented, thick, visible) into fine, nonpigmented vellus hair due to the decreasing activity and size of scalp hair follicles.[11] This results in a receding hair line and balding at the top of the head The current research evaluated the effectiveness and safety of 5% minoxidil and 1 mg finasteride in male patients with Androgenetic Alopecia.[12-15] The initial effects of therapy may be anticipated roughly 6-8 weeks following treatment commencement, with clinically noticeable results at 3-4 months.[16,17]

Most of the patients from the age Category 40-50 years followed by 30-40 years, 50-60 years, below 30 and above 60. The effectiveness and safety of oral minoxidil for the treatment of male androgenetic alopecia were analyzed by Panchaprateep et al. [18] Oral minoxidil 5 mg once day for 24 weeks was used to treat 30 males aged 24-59 years with AGA types III vertex to V. Methods including manual hair counting, manual measurement of hair diameter, photographic analysis, and a self-administered questionnaire were used to determine effectiveness. Physical exams and lab tests were used to ensure the therapy was safe. Total hair counts increased significantly from baseline by week 12 (mean change + 26, range 182.5-208.5 hairs/cm2) and again by week 24 (mean change + 35.1, range 182.5-217.6 hairs/cm2) (both p = 0.007). Expert photographic evaluation of the cranial tip found complete resolution of symptoms in every case (score > + 1), with 43 percent of patients displaying good resolution (score +3, 71-100% increase). The frontal region also responded significantly, but not as much as the apex. Hypertrichosis was seen in 94% of patients, while pedal oedema showed up in 9%. There were no major adverse cardiovascular events or abnormal laboratory results.

Table 3 reveals that score -1 was seen in 3 in Category 2, 0 in Category 1 , 22 in Category 1 and 15 in Category 2, 1 in 9 in Category1 and 7 in Category 2, 2 in 7 in Category 1 and 8 in Category 2 and 3 in 7 in Category 1 and 11 in Category 2. The difference was significant (P< 0.05).

After two years of therapy with 5% topical minoxidil and oral finasteride for alopecia areata (AGA), Chandrashekar et al. [19] evaluated the effectiveness of sustaining hair growth with 5% topical minoxidil supplemented with 0.1% finasteride in patients. Fifty male patients with AGA, aged 20-40, were evaluated retrospectively. Patients were given a combination of topical minoxidil and oral finasteride for two years, and then switched to topical minoxidil boosted with finasteride. Of the 50 patients, 5 had stopped therapy for 8-12 months before starting again on topical minoxidil with finasteride. The effectiveness of the minoxidil-finasteride combination was evaluated by the assessment of patient case sheets and images by separate reviewers. Topical minoxidil-finasteride combination was effective in maintaining hair density for 88.89% of 45 individuals undergoing continuous therapy for AGA. Four out of the five patients who had stopped taking oral finasteride for 8-12 months responded well to resuming therapy with a topical minoxidil-finasteride formulation.[20]

The results of two years of oral finasteride therapy and one year of treatment discontinuation were analyzed by Kaufman et al.[20]. In contrast to the placebo group, those taking oral finasteride had an increase in hair density, and this increase was reversed when treatment with the drug was discontinued. It was because after finasteride was discontinued, DHT levels rise.

Limitations of study

The limitations of the present study are that the number of subjects is small, and the study duration is short.

Conclusion

The treatment of Androgenetic Alopecia with oral 1 mg finasteride was shown to be more successful than that with topical 5% minoxidil.

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