

## Original Research Article

# Comparative study of efficacy of topical minoxidil versus topical minoxidil with finasteride in androgenetic alopecia

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### ABSTRACT

**Background:** Minoxidil and finasteride are most common drugs used in androgenetic alopecia. The objective of the study was to know the efficacy of topical minoxidil solution with and without finasteride.

**Methods:** In total about 30 subjects, aged 18-45 years, who came for outpatient consultation for male pattern androgenetic alopecia were randomized into two groups. Group A was treated with 0.1% topical finasteride and 5% minoxidil solution and Group B was treated with 5% minoxidil solution after taking informed consent from subjects of both groups.

**Results:** Analysis of the extent of bald area, hair count and number of terminal hair showed better results in group A compared to group B.

**Conclusions:** Better results were obtained with combination of topical minoxidil with finasteride than with plain topical minoxidil.

**Keywords:** Androgenetic alopecia, Testosterone, Dihydro testosterone, Male pattern baldness, Topical minoxidil, Topical finasteride

### INTRODUCTION

Androgenetic alopecia (AGA) is most common form of hair loss seen in genetically predisposed individuals. It is characterized by a gradual decline of scalp hair follicles and their eventual miniaturization.<sup>1,2</sup> Male pattern hair loss is mainly due to a combination of genetic predisposition and androgenic effects, hence the term androgenetic alopecia.

AGA is also known as male and female pattern hair loss and it's a area of concern in many members of every society so a prompt diagnosis of different types of alopecia's and early treatment would help the patients whose quality of life is affected.

AGA is a result of miniaturisation of hair follicle and alteration of the hair-cycle dynamics which leads to vellus transformation of the terminal hair follicle. Three phases of the normal hair cycle include an active growth phase (anagen) that last from 2-6 years, followed by a brief stage of regression (catagen) that last 1-2 weeks and the resting phase (telogen) lasting from 5-6 weeks.<sup>4</sup> With each passage through the hair cycle, the duration of the anagen phase decreases whereas the telogen phase elongates. Because the hair length is determined by the anagen phase duration, the maximum length of new anagen hair shorter than that of its predecessor. Also, the period between telogen hair shedding and anagen regrowth becomes longer, leading to reduction in density of hair on the scalp.

Androgen metabolism occurring at the hair follicle level is the factor involved in the pathogenesis of AGA. Elevated activity of 5- $\alpha$  reductase enzyme, that metabolizes testicular testosterone circulating in the blood into DHT in the genetically predisposed hair follicles of the temporal and vertex regions is most significant factor involved in AGA.

The prevalence of AGA appears to vary between different races and ethnicities. Vertex and total AGA prevalence increased with age from 31% (40-55 years of age) to 53% (65-69 years of age).<sup>5</sup> Drug therapies specifically approved by FDA for treating androgenetic alopecia are minoxidil and finasteride which can be used alone or combined.<sup>11</sup> Minoxidil is a FDA approved topical agent for both male and female pattern alopecia, acts as a potassium channel opener and there by increases follicular vascularity, also acts by prolonging anagen phase and shortening telogen phase, increases VEGF on dermal papillae and causes angiogenesis, vasodilatation and also by converting partially miniaturized hair follicles to terminal hair.<sup>12</sup> Finasteride is a competitive inhibitor of type 2, 5- $\alpha$  reductase and inhibits the conversion of testosterone to dihydrotestosterone (DHT), thereby inhibiting miniaturization of hair follicles. It also promotes the anagen phase of hair growth.<sup>12</sup> Studies show that topical finasteride in AGA tends to have similar and good sensitivity as of oral finasteride. The combination therapy has proven to have better effect than monotherapy with topical minoxidil. This clinical study aims to compare the efficacy and safety of two modalities of treatment.

### Objectives

Objectives of current study were to assess the efficacy and feasibility of combination of topical minoxidil and finasteride in patients with AGA and comparison of topical application of 5% minoxidil versus combination of minoxidil and finasteride in AGA.

## METHODS

### Study design, population and sample size

Current study was an interventional prospective, randomized clinical trial. All patients taking treatment for androgenic alopecia from the outpatient department of dermatology, venerology and leprosy at KIMS hospital, Bangalore from May 2019 till November 2019 were included in the study. The patients were in good general health with no evidence of any major systemic disease. Sample size for current study was calculated using the formula

$$\frac{4PQ}{d^2}$$

Where P=percentage of side effects observed from similar study obtained from other articles and Q=1-P.

### Statistical analysis

Statistical package for social sciences (SPSS) for windows version 22.0 released 2013, was used to perform statistical analyses. Descriptive analysis of all the explanatory and outcome parameters was done using frequency and proportions for categorical variables, whereas using mean and SD for continuous variables. Inferential statistics was done using Chi Square test to compare the categorical variables between 2 groups. Mann Whitney test was used to compare the mean hair density, percentage change in hair density and VAS scores between 2 groups at different time intervals. Friedman's test followed by Wilcoxon Signed rank post hoc test was used to compare mean hair density between different time intervals in each group. Wilcoxon signed rank test was used to compare the mean percentage change in hair density between 3 and 6 months in each group. The level of significance was set at  $p < 0.05$ . Computerised random allocation sequence was used to randomly allocate the study patients to group 1 and group 2.

### Inclusion criteria

Inclusion criteria for current study were; male patients suffering from androgenic alopecia, grade II, III or IV (Norwood Hamilton classification, age  $> 18$  years and  $< 45$  years, willingness to use the same shampoo, and to maintain the same hairstyle, hair length and hair color during the entire study and patients who gave their consent.

### Exclusion criteria

Exclusion criteria for current study were; patients below 18 years and more than 45 years, concomitant dermatological disorders on the scalp other than androgenic alopecia, serious cardiovascular diseases (uncontrolled hypertension, angina pectoris, myocardial infarction etc.), renal diseases or hepatic diseases, shaved scalp or undergoing occlusive dressing or other topical scalp treatment, history of treatment with a systemic or locally acting medication which may interfere with the study objectives, such as minoxidil treatment in the past 6 months prior to dosing, finasteride treatment in the past 6 months prior to dosing, or treatment with other investigational hair growth products in the past 6 months.

### Procedure

A total of 30 patients were equally divided into two treatment arms by computerised random allocation. The mean age of the patients was  $29.90 \pm 5.50$  years with minimum 18 and maximum 44 years of age. Patients in both the groups were treated for 6 months. Group A was treated with 0.1% topical finasteride and 5% minoxidil solution and group B was treated with 5% minoxidil solution. 1 ml of solution was applied on scalp twice daily.

After taking informed consent of patients, results were measured by taking digital photographs of frontal and parietal region every 3 months and for determination of target area hair counts, the hair in a 1x1 cm square at the right frontal quadrant was clipped to a length of about 1 mm.

Reproducibility of this area was assured by placing two threads one extending from the glabella to the occiput and one between the two helix. The point of intersection is noted, and a line is drawn tangential from it, at a measured distance a square is marked. Photographs of the target area were taken with a dermoscopy with ipad attached to it at baseline, third month and sixth month.

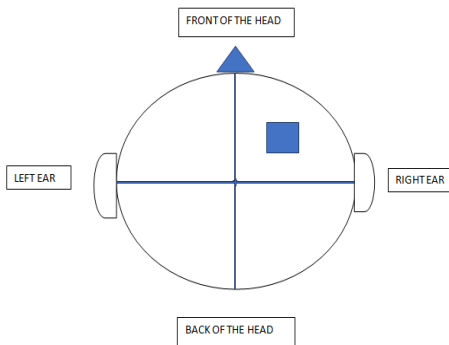


Figure 1: Target area demarcation.

**RESULTS**

Norwood Hamilton grading was used to see the effect of treatment in both the arms at baseline, third month and sixth month. At the end of sixth month, majority of patients improved to grade 2 or grade 3. Better results were obtained with patients treated with combination of 5% topical minoxidil with 1% finasteride than patients treated with only 5% topical minoxidil.

Very few patients felt no improvement even after 6 months of treatment. There was a statistically significant improvement in investigator assessment in the group treated with only 5% minoxidil with finasteride when

compared to the plain 5% minoxidil using Chi square test (Table 1).

**Table 1: Primary efficacy analysis of the two groups at different time intervals using Chi square test.**

Time (months)	Category	Group 1		Group 2		P value
		N	%	N	%	
3	Slightly improved	6	40.0	10	66.7	0.14
	Unchanged	9	60.0	5	33.3	
6	Moderately improved	2	13.3	4	26.7	0.18
	Slightly improved	9	60.0	11	73.3	
	Unchanged	1	6.7	0	0.0	
	Worsened	3	20.0	0	0.0	

**Table 2: Distribution of the patients according to the secondary efficacy analysis.**

Time (months)	Category	Group 1		Group 2		P value
		N	%	N	%	
3	Unchanged	13	86.7	9	60.0	0.10
	Slightly changed	2	13.3	6	40.0	
6	Slightly Decreased	2	13.3	0	0.0	0.10
	Unchanged	4	26.7	1	6.7	
	Slightly changed	9	60.0	12	80.0	
	Moderately changed	0	0.0	2	13.3	

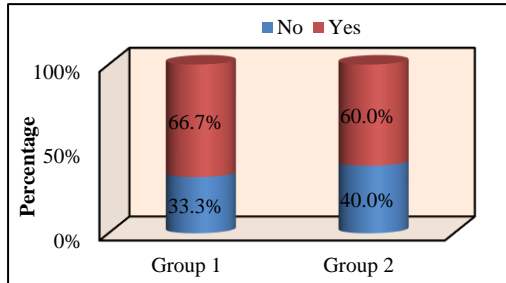
In secondary efficacy analysis, it was observed that the variation at 6 months as compared to 3 months was significant in both the treatment arms. Majority of the patients improved only slightly in both the groups. Worsening of the cases was seen in the treatment arm treated with only 5% minoxidil (Table 2).

**Table 3: Comparison of the dermoscopic analysis for improvements in the two groups.**

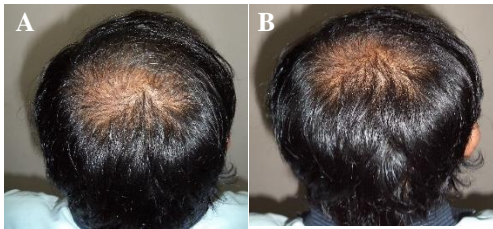
Groups	Time (months)	N	Mean	SD	P value <sup>a</sup>	Sig. Diff	P value <sup>b</sup>
1	Baseline (BL)	15	65.73	13.78	0.005*	BL vs. 3M	0.04*
	3 (3M)	15	68.20	12.50		BL vs. 6M	0.007*
	6 (6M)	15	72.40	15.26		3M vs. 6M	0.008*
2	Baseline (BL)	15	61.27	13.30	<0.001*	BL vs. 3M	0.001*
	3 (3M)	15	65.67	13.06		BL vs. 6M	0.001*
	6 (6M)	15	72.73	14.07		3M vs. 6M	0.001*

\*Statistically significant, <sup>a</sup>derived from Friedman’s test, <sup>b</sup>derived from Wilcoxon signed rank post hoc test

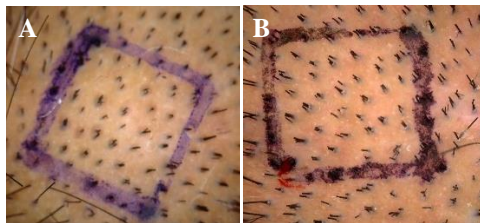
Dermoscopic analysis showed maximum improvement in group treated with minoxidil and finasteride followed by group treated with plain minoxidil (Table 3). The difference in the improvement at 3 months and 6 months among the two treatment arms was statistically significant on the basis of ANOVA test (Figures 3-6).



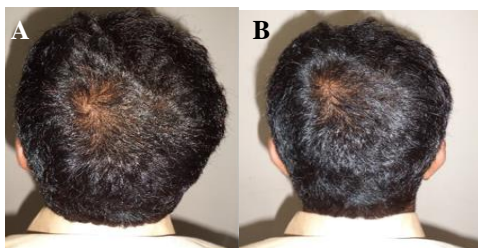
**Figure 2: Distribution of the patients according to the family history of AGA.**



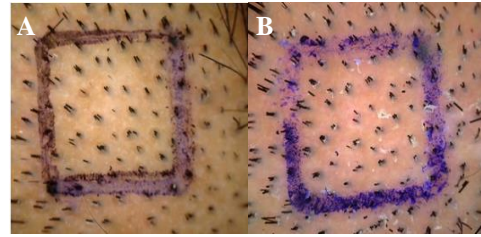
**Figure 3: A) Initial phase before starting a treatment, B) Improvement in the hair density noticed after treatment with combination of topical minoxidil and finasteride for 6 months.**



**Figure 4: A) Dermoscopic image of AGA patient before starting a treatment, B) Increase in the hair count noticed after treatment with combination of topical minoxidil with finasteride after 6 months.**



**Figure 5: A) Initial phase before starting a treatment, B) Improvement in the air density noted after 6 months of treatment with 5% topical minoxidil.**



**Figure 6: A) Dermoscopic image of AGA patient before starting a treatment, B) Improvement in the air density noted after 6 months of treatment with 5% topical minoxidil.**

## DISCUSSION

Male androgenetic alopecia is seen commonly in middle aged men due to genetic, hormonal and environmental factors. It has been shown to disrupt body image, reduced self esteem and increased stress as reflected in the increased demand for treatment.

The main culprit causing miniaturisation of hair follicles in androgenetic alopecia is dihydrotestosterone. Testosterone is converted to 5 alpha dihydrotestosterone by the enzyme 5 alpha-reductase. DHT attaches to androgen receptors of genetically marked hair follicles that causes miniaturization. Finasteride is an inhibitor of type II 5alpha reductase, thus reduces DHT levels.

In current study, majority of patients had onset in age group 26-35 (66%), and the average age of onset was 28.9 years. Total 19 (73.35%) patients had a positive family history when compared to 11 (30%) with a negative family history and maximum improvement by dermoscopic analysis was observed in patients with a negative family history.

The results of the study revealed that there is better response with the group treated with topical Finasteride with minoxidil than the other group treated with plain topical 5% minoxidil. Both groups started getting response to the therapy from the end of second month onwards. Few patients experienced minimal side effects like erythema, scaling, burning and initial headache which were treated with antihistamines and mild topical steroids. No patients experienced undesirable side effects. Though current study is limited by a small cohort of patients and limited duration of study, from the above discussion it is evident that minoxidil with finasteride is a superior treatment modality when compared to minoxidil alone.

## CONCLUSION

Minoxidil and finasteride are best therapeutic options for hair growth and stimulation in patients of AGA. They are promising treatment options in patients who cannot afford hair transplantation and is easy to use. Considerable increase in hair density was seen with

minoxidil when combined with finasteride than minoxidil alone. Results were observed by fourth month of treatment. Minoxidil has better efficacy when combined with finasteride. Better results were obtained with combination of topical minoxidil with finasteride than with plain topical minoxidil. Hence, minoxidil with finasteride is a simple cost-effective and feasible treatment option in patients with AGA with high overall patient satisfaction.

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*Ethical approval: The study was approved by the institutional ethics committee*

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