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Efficacy and safety of topical 5% minoxidil in treatment of androgenetic alopecia

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Abstract
Background: Androgenetic alopecia (AGA) is a common form of non-scarring alopecia, affecting both men and women. The process that causes hair follicle shrinking is complex and involves several factors, including a genetic predisposition and susceptibility to androgens. Minoxidil used topically is a medication that has received approval from the food and drug administration (FDA). There are a lot of adverse effects and its effectiveness is low. The objective of this study was to assess the safety and effectiveness of using 5% minoxidil topically to treat AGA.
Methods: This single arm interventional study was carried out on 10 patients, both sexes, with AGA who did not receive any treatment within at least 6 months before the start of the study, subjected to topical 5% minoxidil application twice daily for three months. Efficacy was assessed clinically at baseline, after 3 months and after three months follow up.
Results: After treatment, the mean value of degree of improvement was 60±14.91, 4(40.0%) patients showed moderate response, 4(40%) patients showed marked response, and 2(20%) patients showed excellent response. After 3 months follow up, the mean value of degree of improvement was 68±19.32. Three patients (30%) showed moderate response, 3(30%) patients showed marked response, and 4(40%) patients showed excellent response. There was a significant negative correlation between degree of improvement and duration of disease after treatment, the less the duration of disease the better the improvement. The degree of improvement was also significantly negatively correlated with patients' ages; a smaller age difference was associated with a statistically insignificant but positive change.
Conclusions: Topical application of 5% minoxidil proved to be effective and safe in the treatment of AGA, demonstrating significant improvement in terminal hair count and hair shaft thickness after 3 months of treatment.

Keywords: Efficacy, safety, topical minoxidil, androgenetic alopecia

Introduction
Androgenetic alopecia (AGA) is the most common cause of non-scarring alopecia worldwide. At least 80% of males and 50% of women will be affected by the time they reach 70 years of age, and it can start at any point after puberty. As people get older, the disease becomes more common; the white race is the most affected, followed by the Asian and African American populations [1]. Despite its benign medical condition, AGA can undermine a patient's sense of self-worth and mental health [2].
The pathogenesis of AGA is multifactorial, involving genetic, hormonal factors, and the presence of systemic diseases. Additionally, hair follicles in persons with genetic susceptibility are more sensitive to androgens than normal ones. Five-alpha-reductase enzyme converts free testosterone into 5- alpha dihydrotestosterone (5-α DHT), which then binds to the androgen receptor (AR) in the dermal papilla (DP) of the hair follicle, leading to miniaturization and eventual atrophy of the hair follicles [3]. It is diagnostic when a trichoscopic examination shows a loss of hair density and variety in hair diameter of above 20% in both sexes [4].
There is a continuous need for new treatment modalities for AGA. Currently, there are only three US Food and Drug Administration approved treatments: topical minoxidil, oral finasteride, and low-level laser therapy (LLLT) [5].
One effective medication for hypertension is minoxidil, a powerful peripheral vasodilator. Potassium channels in vascular smooth muscles and hair follicles are affected, so the anagen

phase is prolonged and the telogen phase is shortened. This results in increased hair length and thickness. It has several side effects such as headaches, hypertrichosis, irritation, and contact dermatitis [6, 7]. It is noticed that hair regrowth achieved with topical minoxidil is lost several months after stopping treatment, so continued use is necessary to sustain its benefits [8].

The purpose of the study was to evaluate the efficacy and safety of topical minoxidil 5% in treatment of AGA.

Materials and Methods

This single arm interventional study was carried out on 10 patients, both sexes, with AGA who did not receive any treatment within at least 6 months before the start of the study, subjected to topical minoxidil application. The study was done from March 2024 to June 2025 after approval from the Ethical Committee Tanta University Hospitals, Tanta, Egypt (approval code: 36264MS541/3/24). An informed written consent was obtained from the patients.

Participants were not included if they had any of the following conditions: keloidal tendency, psoriasis, lichen planus, positive Koebner phenomenon, cardiac, hepatic, renal, or any major medical illness; pregnant or lactating women were also not allowed; and patients with a history of bleeding disorders or anticoagulant medications such as aspirin, warfarin, or heparin were also not allowed.

All patients were subjected to complete history taking, general examination, dermatologic examination.

At the initial presentation, digital photographs and trichoscopic pictures were taken from every patient. Male patients were evaluated according to Norwood-Hamilton classification, and female patients were evaluated according to Ludwig classification. A punch biopsy was taken from the scalp for histopathological analysis and immunohistochemical staining. Evaluation and comparison of the photographs by three independent committees before and after the procedure. Evaluation of the trichoscopic pictures, histopatholgical results and immunohistochemical results.

Patients were subjected to topical application of minoxidil 5% (Minoxilook manufactured by El Esraa Pharmaceutical Optima) twice daily over a period of 3 months.

Efficacy assessment

Clinical assessment, Grading of AGA: Male patients according to Norwood-Hamilton Scale and female patients according to Ludwig's Scale at baseline, the end of treatment (after 3 months) and after 3 months follow up.

Digital photographs: All patients were digitally photo-documented using 12 megapixels' camera. Pictures of the frontoparietal area, back view and lateral view were obtained for every patient. All photographs were taken with the same camera and with the same lightening and location.

Global Aesthetic Improvement Scale

Patients' progress was assessed by three dermatologists who were blinded to their treatments using the Global Aesthetic Improvement Scale (GAIS) Score at two weeks and three months post-treatment, respectively. There were four levels of improvement indicated by the responses: mild (0-25%), moderate (26-50%), noticeable (51-75%), and excellent (76-100%).

Safety assessment

The patients were instructed to notify the investigators of any adverse events, including redness, discomfort, ecchymosis, infection, or allergic reactions. All side effects, whether observed by the investigators or by the patients, were reported.

Statistical analysis

The statistical analysis was carried out using SPSS v26, a program created and maintained by IBM Inc. of Chicago, Iowa, USA. Histograms and the Shapiro-Wilks test were used to check if the data was normal. To compare the two groups' quantitative parametric variables—means and standard deviations (SD)—we utilized an unpaired Student's T-test. To evaluate quantitative non-parametric data, which was shown as interquartile range (IQR) and median, the Mann-Whitney U test was employed. When applicable, we used Fisher's exact test or Chi-square test to examine qualitative variables, which were given as percentages and frequencies. Using the Pearson moment correlation equation, we checked for correlations between different variables. Statistical significance was determined by a two-tailed P value less than 0.05.

Results

Demographic data and side effects were enumerated in table 1

Table 1: Demographic data and side effects in the studied patients

		N = 10
Age (years)		27.9±9.27
Sex	Male	4(40.0%)
	Female	6(60.0%)
Family history		6(60.0%)
Previous treatment		3(30.0%)
Skin disease		4(40.0%)
Age at onset of the disease (years)		22.7±6.45
Duration of disease (years)		6±3.97
Side effects	Dandtuff	4(40.0%)
	Hypertrichosis in face	1(10.0%)
	Scalp irritation	1(10.0%)

Data are presented as Mean ± SD or frequency (%).

Global Assessments International Scale were enumerated in table 2

Table 2: Global Assessments International Scale in the studied patients

	N = 10
After treatment	43.5±17
Poor	1(10.0%)
Moderate	6(60.0%)
Marked	3(30.0%)
Excellent	0(0.0%)
Follow up	20.5±14.99
Poor	7(70.0%)
Moderate	3(30.0%)
Marked	0(0.0%)
Excellent	0(0.0%)

Data are presented as Mean ± SD or frequency (%).

The degree of improvement was negatively correlated with the length of the sickness following therapy; a shorter time of illness was associated with better results. Additionally, a statistically insignificant correlation was found between patients' ages and their degree of recovery, the less the age the better the improvement but insignificant (Table 3).

Table 3: Correlation between degree of improvement with age, onset of disease, AGA stage

	Degree of improvement (%)			
	After treatment		3 months follow up	
	r_s	P. value	r_s	P. value
Age (years)	-0.48	0.16	-0.006	0.986
Onset of disease (years)	-0.34	0.337	0.113	0.755
Duration of disease (years)	-0.709	0.022*	-0.245	0.495

r_s: Spearman coefficient. * Significant P value <0.05.

In all groups that were evaluated, there was no relationship between the demographic data and the degree of improvement (Table 4).

Table 4: Relation between degree of improvement with demographic data in in studied groups

		N = 10	Degree of improvement	
			After treatment	3 months follow up
Sex	Male	4	40 (20- 65)	25 (5 - 50)
	Female	6	40 (30 - 70)	15 (10 - 30)
U(p)			11 (0.914)	10.5 (0.762)
Family history	Negative	4	30 (20 - 40)	10 (10 - 50)
	Positive	6	55 (30 - 70)	20 (5 - 40)
U(p)			6 (0.257)	10.5 (0.762)
Previous medications	Negative	7	40 (30 - 70)	20 (5 - 50)
	Positive	3	30 (20 - 60)	10 (10 - 20)
U(p)			6 (0.383)	7.5 (0.517)
Other skin diseases	Negative	6	45 (20 - 70)	25 (10 - 50)
	Positive	4	35 (30 - 60)	10 (5- 20)
U(p)			9.5 (0.610)	4.5 (0.114)
Special Habits	Negative	9	40 (20 - 70)	10 (5 - 50)
	Positive	1#	65	40
U(p)			-	-

Data are presented as median (IQR). U: Mann Whitney test

Case 1: A 22-year-old male patient with AGA. Figure

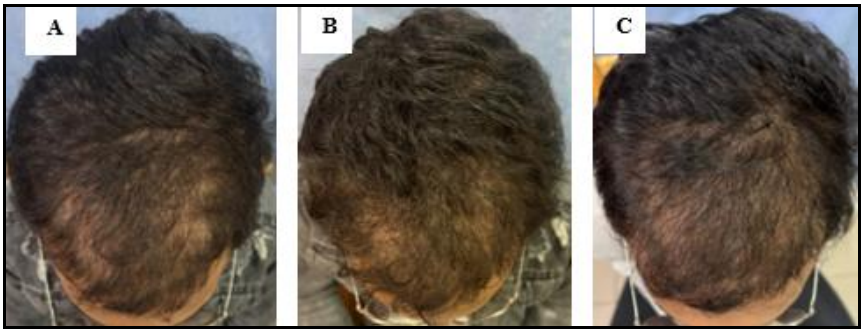

Fig 1: Clinical photos (A) at baseline (B) after treatment showing moderate improvement and (C) at follow up showing regression of improvement

Discussion

AGA is the most common form of alopecia worldwide. This condition develops when the body reacts too strongly to male hormones. AGA manifests in a way that is exclusive to humans and other animals. However common it may be, AGA isn't always easy to treat. [7].

Regarding the degree of improvement according to GAIS Score, it was 43.5±17. After 3 months follow up regarding the degree of improvement regressed and with Mean ± SD 20.5±14.99. Similarly, Ersan *et al.* [9] showed better results compared to this study which may be explained by less number of sessions (single session), larger sample size, all included patients were males and older age group with average of 34.65 years old. Additionally, Park *et al.* [10] administered microneedling once weekly to 39 AGA patients (12 female and 27 male) for a duration of three months. In this case, evaluation occurred three months following the beginning of treatment. In terms of density and thickness, there was a striking improvement. Mean hair density increased by 24.9 hairs/cm^2. Contrary to the current study, which found no association between patient age or duration of hair loss and treatment response, other factors that could explain this finding include a different technique (microneedling), a larger sample size, a different assessment time, and an older age group with a mean age of 42.5 years.

Regarding minoxdil, it has been evaluated many times before. A study done by Olsen *et al.* [11]

on 352 men who suffered from male pattern hair loss (MPHL) in all. One hundred seventy-two people took a placebo, and eighty-ten people used topical minoxidil. The minoxidil group had a considerably larger mean change in hair density at 4 months compared to the placebo group (20.9 vs 4.7 respectively). Perhaps because of the greater sample size and length of minoxidil treatment in that trial,

the current study did not achieve the same good outcomes. Also a study done by Elshebiny *et al*. [12] on 15 male AGA patients. They received topical minoxidil 5% twice daily for 6 months. There was increase in hair density by 31.83 hairs/cm^2. These results are higher than the current study. This may be due to longer duration of treatment (6 months) and larger number of patients included.

Another study was done by Balasundaram *et al*. [13] on 64 male individuals diagnosed with AGA. those who were randomly assigned to either monthly platelet-rich plasma (PRP) injections for three months or six months of 5% minoxidil. We tracked the change in hair density in the target region three months after treatment began. On average, the minoxidil group saw a 7.12% rise in hair density compared to the PRP group's 8.18%. Statistical analysis failed to reveal a discernible difference between the categories. Another study was done by Singh *et al*. [14] 80 patients were placed into four groups for the study. One group received simply topical minoxidil. The second group received PRP together with minoxidil. The third group received normal saline. Finally, group four received PRP alone. Patients were monitored three months after therapy began, and interventions were performed monthly for that duration. The hair density increased by 9 hairs/cm^2 in the minoxidil group, by 48.5 hairs/cm2 in the PRP plus minoxidil group, and by 31.83 hairs/cm^2 in the PRP group.

The research had some limitations, one of which was a limited sample size. Research only took place at one location. For a brief time, there was little follow-up with patients.

Conclusions

Topical application of 5% minoxidil proved to be effective and safe in the treatment of AGA, demonstrating significant improvement in terminal hair count and hair shaft thickness after 3 months of treatment. However, these gains were not sustained during follow-up, suggesting the need for continuous treatment to maintain therapeutic benefit. Younger age, shorter disease duration, and earlier stages of alopecia were associated with better response, although not always statistically significant. No major adverse events were reported, confirming the favorable safety profile of topical minoxidil in this cohort.

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Nil

Conflict of Interest

Not available

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Not available

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