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Original Article

Comparison of Efficacy of Topical Finasteride Versus Topical Minoxidil in Treatment of Androgenetic Alopecia

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ABSTRACT

Comparative monotherapy data on topical finasteride versus topical minoxidil in androgenetic alopecia remain limited. **Objective:** To compare the efficacy and safety of topical finasteride 0.25% and topical minoxidil 5% in adults with androgenetic alopecia. **Methods:** This assessor-blinded, parallel-group randomized comparative clinical trial was conducted at the Department of Dermatology, Sheikh Zayed Medical College and Hospital, Rahim Yar Khan, from 21-03-2024 to 20-09-2024. Fifty-eight participants aged 18-45 years were randomized by an opaque-slip lottery method to topical finasteride once nightly or topical minoxidil twice daily for 24 weeks. Normality was assessed with the Shapiro-Wilk test. Categorical variables were compared using Pearson chi-square or Fisher exact tests, between-group continuous outcomes with the Mann-Whitney U test, and within-group baseline versus week-24 changes with paired t-test or Wilcoxon signed-rank test as appropriate. **Results:** Baseline characteristics were comparable between groups. Responder rate was higher with minoxidil than finasteride (13/29, 44.8 vs 2/29, 6.9; p=0.001). Hair density improved significantly within both groups from baseline to week 24. The between-group difference in week-24 hair density was not statistically significant (p=0.184), but percent change in hair density (p=0.020) and Global Photographic Assessment Score (p=0.046) favored minoxidil. Adverse effects were mild and comparable, and no sexual side effects were reported. **Conclusions:** Over 24 weeks, topical minoxidil achieved a higher response rate and better photographic improvement than topical finasteride, although absolute week-24 hair density did not differ significantly between groups. Both treatments were generally well tolerated.

INTRODUCTION

Androgenetic alopecia (AGA) is a chronic progressive, patterned hair-loss condition, which is marked by progressive follicular miniaturization and shortening of the anagen phase. It affects both males and females and may significantly decrease self-esteem and quality of life [1]. Topical treatment remains a focus on treatment. Topical Minoxidil is the most long-established topical therapy, and topical formulations with finasteride have been investigated to maintain local effects and minimize the systemic adverse-effect issues of oral therapy [2, 3]. Topical finasteride evidence has indicated that it can enhance hair results at tolerable levels, although there is no uniform outcome based on formulation, concentration, sex composition, and study design. The data (systematic and cohort) still indicate promise but not consistent superiority of topical finasteride in all environments [4, 5]. Further research on new delivery methods and comparative regimens has proposed that follicular targeting can be optimized with the use of finasteride plus minoxidil or in optimized carriers, which might not necessarily indicate monotherapy effectiveness [5, 6]. The practical patient-reported outcomes and pooled evidence also indicate that combination therapy is beneficial in specific patients, and randomized comparative evidence in female pattern hair

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loss also demonstrates better results when using combined topical therapy as compared to minoxidil alone [7-9].

Despite growing interest in topical finasteride, direct head-to-head monotherapy comparisons with topical minoxidil remain limited, especially in local clinical settings using both trichoscopic and global photographic outcomes. This study aimed to compare the efficacy and safety of topical finasteride versus topical minoxidil in patients with androgenetic alopecia.

METHODS

This assessor-blinded, parallel-group randomized comparative clinical trial (NCT06826001) was carried out in the Department of Dermatology, Sheikh Zayed Medical College and Hospital, Rahim Yar Khan, from 21-03-2024 to 20-09-2024 after approval by the Institutional Review Board and Ethical Clearance Committee (Ref No. 48/IRB/SZMC/SZH; dated 21st March 2024). Written informed consent was obtained from all participants before enrolment. The sample size was calculated for comparison of two independent proportions using the method described by Lemeshow *et al.* [10]. Expected response proportions were taken from Rossi and Caro [11], in whom topical finasteride monotherapy showed an approximate response rate of 8% and topical minoxidil monotherapy about 41%. Using a 95% confidence level and 80% power, the minimum required sample was 26 participants per group. After adding 10% for possible attrition, the final sample size was set at 29 participants per group (total n=58). Patients of either gender aged 18-45 years with clinically diagnosed AGA were eligible. Male-pattern hair loss was graded using the Hamilton classification as modified by Norwood [12, 13], whereas female-pattern hair loss was graded using the Ludwig classification [14]. Treatment-naive patients or those who had stopped any anti-alopecia therapy for at least six months were included. Exclusion criteria were scalp infection or inflammation, psoriasis, seborrheic dermatitis, known hypersensitivity to study drugs, systemic illnesses affecting hair growth (including thyroid dysfunction, anemia, and major hormonal disorders), and pregnancy or lactation. Simple randomization was performed by a lottery method. Fifty-eight identical opaque folded slips were prepared by a staff member who was not involved in outcome assessment; 29 slips were labeled Group A and 29 Group B. After confirmation of eligibility and consent, each participant drew one slip, which determined the assigned group. Because the slips were opaque and indistinguishable before opening, allocation remained concealed until assignment. Group A received topical finasteride 0.25% solution once daily at night to the affected scalp, while Group B received topical minoxidil 5% solution twice daily in the morning and evening for 24 weeks. Participants were instructed to apply the medication to a dry scalp using the supplied applicator and to avoid any other topical or systemic hair-loss treatment during follow-up. In this comparative trial, the minoxidil group served as the active comparator control group. Participant blinding was not feasible because the dosing frequency and formulations differed between groups. However, assessor blinding was maintained by coding standardized photographs and trichoscopic records before review. The same dermatologist, who was unaware of treatment allocation, assessed clinical response at scheduled visits. Follow-up visits were scheduled at baseline, 12 weeks, and 24 weeks. Trichoscopy was performed over a predefined 1-cm^2 target area on the vertex scalp at fixed magnification, using the same digital dermoscopic setup and calibration grid throughout follow-up. The target area was re-identified at each visit using baseline photographs and standardized scalp landmarks relative to the midline and frontal hairline to improve measurement consistency. Hair density was recorded as hairs/cm^2. Global photographic response was assessed on a modified 5-point Global Photographic Assessment Score (GPAS) ranging from -1 (worse) to 3 (marked improvement); a score of 0 indicated no visible change, and scores of 1 or above indicated clinical improvement. This photographic approach was based on validated global scalp-coverage assessment methods that have been used in alopecia research [15]. Adverse effects including scalp irritation, erythema, hypertrichosis, and sexual side effects, were recorded at each visit. Adherence was monitored by patient interview and inspection of residual medication volume at follow-up visits, although no electronic adherence tool was used. The primary outcome was treatment response at week 24. Additionally, although week-12 data were collected per protocol, they were not retained in the final analyzable dataset, which further limited repeated-measures analyses. For responder classification, either criterion alone was considered sufficient: (i) at least 15% increase in hair density from baseline, or (ii) clinically meaningful photographic improvement reflected by a GPAS score of 1 or higher at week 24. During reanalysis of the locked dataset, all participants classified as responders also met the 15% hair-density criterion, which explains why the overall cohort mean change remained lower than the responder threshold.

Data were analyzed using SPSS version 26.0. Normality of continuous variables and paired differences was assessed with the Shapiro-Wilk test. Quantitative variables were summarized as median (interquartile range, IQR) when non-normally distributed and as mean ± standard deviation

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where appropriate for descriptive clarity. Baseline between-group comparisons for continuous variables and between-group outcome comparisons at week 24 were performed using the Mann-Whitney U test because several key variables were non-normally distributed. Within-group changes from baseline to week 24 were analyzed using a paired t-test when paired differences approximated normality and a Wilcoxon signed-rank test otherwise. Categorical variables were compared using the Pearson chi-square test or Fisher's exact test when expected cell frequencies were below 5. Treatment effect for the primary responder outcome was expressed as relative risk (RR) with 95% confidence interval (CI). A p-value ≤ 0.05 was considered statistically significant. Because the final locked analytical dataset retained complete quantitative measurements for baseline and week 24 but not analyzable week-12 numerical values, inferential repeated-measures analyses were limited to the available analyzable time points. Fifty-eight participants were randomized, with 29 allocated to topical finasteride and 29 to topical minoxidil. A CONSORT-style participant flow summary is provided (Figure 1).

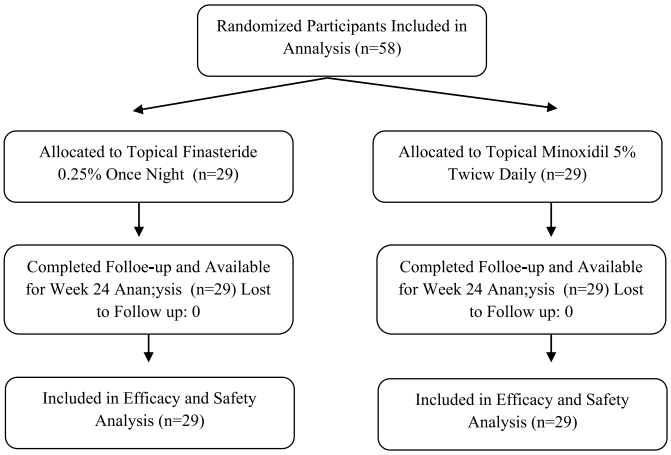


Figure 1: CONSORT Style Participant Flow of the Randomized Comparative Trial

RESULTS

Baseline demographic and disease characteristics were comparable between the two treatment groups. No statistically significant between-group differences were observed for age, sex distribution, duration of alopecia, family history, baseline severity score, or baseline hair density (Table 1).

Table 1: Baseline Characteristics of the Study Groups (n=58)

Variables	Finasteride (n=29)	Minoxidil (n=29)	p-value
Age, Years	27.00 (23.00-34.00)	30.00 (22.00-40.00)	0.255
Male Sex, n (%)	20 (69.0%)	22 (75.9%)	0.557
Duration of Alopecia, Years	5.00 (3.00-7.00)	4.00 (3.00-6.00)	0.169
Positive Family History, n (proportion)	13 (44.8%)	15 (51.75)	0.599
Baseline Clinical Severity Score	3.00 (2.00-5.00)	3.00 (2.00-5.00)	0.879
Baseline Hair Density, hairs/cm^2	159.00 (143.00-168.00)	147.00 (137.00-167.00)	0.375

Values are shown as median (IQR) or n (%). Continuous variables were compared with the Mann-Whitney U test. Categorical variables were compared with Pearson chi-square test

Treatment response at week 24 favored topical minoxidil. Responders were more frequent in the minoxidil group than in the finasteride group, corresponding to a relative risk of 6.50 (95% CI: 1.61-26.28). Adverse effects were infrequent, mild, and broadly comparable between groups; no sexual side effects were reported in either arm (Table 2).

Table 2: Primary Efficacy and Adverse Effects at Week 24 (n=58)

Outcomes	Finasteride (n=29), n (%)	Minoxidil (n=29), n (%)	p-value	Effect Measure
Responders	2 (6.9%)	13 (44.8%)	<0.001*	RR 6.50 (95% CI 1.61-26.28)
Scalp Irritation	6 (20.7%)	2 (6.9%)	0.253	–
Erythema	3 (10.3%)	4 (13.%)	<0.001	–
Hypertrichosis	6 (20.7%)	4 (13.%)	0.487	–
Sexual Side Effects	0 (0.0%)	0 (0.0%)	–	–

Values are shown as n (proportion). Pearson chi-square test was used for responder status and hypertrichosis; Fisher exact test was used for scalp irritation and erythema because expected cell counts were <5. RR = relative risk; CI = confidence interval. * Statistically significant at p ≤ 0.050

Within-group analysis showed significant improvement in hair density from baseline to week 24 in both treatment arms. The change was statistically significant with Wilcoxon signed-rank testing in the finasteride group and with paired t-testing in the minoxidil group (Table 3).

Table 3: Within-Group Comparison Of Hair Density from Baseline to Week 24

Group	Baseline Hair Density, Median (IQR)	Week-24 Hair Density, Median (IQR)	Statistical Test	p-value
Finasteride	159.00 (143.00-168.00)	164.00 (151.00-175.00)	Wilcoxon signed-rank	<0.001*
Minoxidil	147.00 (137.00-167.00)	172.00 (153.00-191.00)	Paired t-test	<0.001*

IQR = interquartile range. Test choice was based on the

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distribution of paired differences. * Statistically significant at p ≤ 0.050.

Despite clear within-group improvement in both arms, the between-group difference in absolute week-24 hair density was not statistically significant. However, the percent change in hair density and GPAS score were significantly better in the minoxidil group. The overall cohort average increase in hair density remained below the responder threshold because summary statistics included both responders and non-responders; on dataset review, all 15 responders met the 15% hair-density criterion (Table 4).

Table 4: Between-Group Comparison of Week-24 Quantitative Outcomes

Variables	Finasteride, Median (IQR)	Minoxidil, Median (IQR)	p-value
Week-24 Hair Density, hairs/cm^2	164.00 (151.00-175.00)	172.00 (153.00-191.00)	0.184
Percent Change in Hair Density	7.13 (-0.37-9.45)	11.67 (1.42-24.40)	0.020*
Global Photographic Assessment Score	0.00 (0.00-0.00)	1.00 (0.00-2.00)	0.046*

All variables in this table were compared using the Mann-Whitney U test. IQR = interquartile range. * Statistically significant at p ≤ 0.050

DISCUSSION

This trend indicates that either of the topical agents might have a short-term use, although minoxidil had a more predictable clinically noticeable outcome in this group. The present research results are directionally in line with the pilot randomized trial by Rossi and Caro, who found response proportions of about 8% in topical finasteride monotherapy and 41% in topical minoxidil monotherapy after six months [11]. The latter trend is quite similar to the current reanalysis-based findings and can be interpreted to mean that the response of minoxidil monotherapy is more guaranteed to give a visible effect in the short term than topical finasteride monotherapy. There is also evidence provided by comparative studies that topical finasteride might be at an advantage in use as part of combination therapy, but not as monotherapy. Al Sayed *et al.* demonstrated significant clinical and trichoscopic improvements with topical finasteride and minoxidil in female pattern hair loss with no significant between-group difference in effect [16], and Asad *et al.* and Bharadwaj *et al.* found the combination of finasteride and minoxidil superior to monotherapy regimens [17, 18]. These results are in line with the fact that the low rate of responders in the current finasteride arm may be due to the constraints of short-term monotherapy and not due to total biologic activity. Greater evidence in favor of multimodal treatment is provided by Tumrani *et al.* and Erfan *et al.* who demonstrated the superiority in regrowth results in patients using platelet-rich-plasma-combination regimens relative to comparator regimens [19, 20]. In comparison, in men, Rostami-Mogaddam *et al.* found a greater improvement of 2% topical finasteride than 5% minoxidil [21], which could be attributed to a higher topical finasteride concentration or differences in design, baseline severity, adherence, and measurement. Rai *et al.* also demonstrated positive long-term outcomes of topical finasteride and minoxidil versus oral-finasteride-based treatment, which once again indicates that topical finasteride can be more efficacious when used as a part of combination therapy [22]. The current results were overall encouraging in regard to safety. The phase III trial conducted by Piraccini *et al.* showed that topical finasteride is capable of enhancing the number of target area hair at considerably lower systemic exposure levels compared to oral finasteride [23], which lends credibility to the biologic plausibility of topical finasteride as a safer local agent of antiandrogenism. In the present study, the adverse effects were mild, and there were no sexual side effects in both groups. Nevertheless, compliance was only followed up by interview and residual medication volume; thus, slight differences in compliance might have been missed.

There are several limitations to the study. It was a single-center trial with a rather limited sample size and a limited follow-up period in a chronic disease where treatment response might still be developing after 24 weeks. Participant blinding was infeasible due to differing dosing frequencies, potentially introducing performance bias in subjective outcomes, though assessor blinding was maintained. Adherence assessment relied solely on subjective methods (interview and residual volume) without objective monitoring, and differing dosing frequencies may have introduced systematic compliance differences between groups. In addition, although follow-up was clinically scheduled at baseline, 12 weeks, and 24 weeks, the final locked analytical dataset retained analyzable quantitative repeated-measure values for baseline and week 24 only, which restricted formal within-group statistical analysis to those time points. Week-12 data were not analyzable in the final dataset, restricting repeated-measures analyses across all three scheduled time points. Future multicenter registered trials with longer follow-up, complete repeated-measures data, standardized instrument reporting, and stronger adherence monitoring are recommended.

CONCLUSIONS

Topical minoxidil achieved a higher week-24 responder rate and better global photographic improvement than topical finasteride in this cohort of patients with androgenetic alopecia. Both treatments were generally

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well tolerated, and both groups improved from baseline, but the between-group difference in absolute week-24 hair density was not statistically significant. These findings support cautious short-term preference for topical minoxidil as monotherapy, while also indicating that larger, longer, and better-documented comparative trials are still needed.

Authors' Contribution

Conceptualization: FH
Methodology: FH
Formal analysis: FH, MU
Writing and Drafting: FH, TH, MKS, MU, NK, NK
Review and Editing: FH, TH, MKS, MU, NK, NR

All authors approved the final manuscript and take responsibility for the integrity of the work

Conflict of Interest

All the authors declare no conflict of interest.

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