Journal of Pakistan Association of Dermatologists. 2026;**36(1)**:74-81.

Original Article

Comparative study of the effectiveness of low-dose oral minoxidil vs. topical minoxidil (5%) in male androgenetic alopecia

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Abstract

Background Androgenetic alopecia is estimated to affect almost half of the male population by the age of 50 years. The conventional therapies of topical minoxidil and oral finasteride are associated with poor compliance and adverse effects related to treatment, whereas low-dose oral minoxidil is a promising alternative.

Objective The study aimed to evaluate three aspects, which included efficacy, safety, and patient satisfaction, between two treatments for men with androgenetic alopecia who received topical minoxidil and low-dose oral minoxidil.

Methods A total of 100 male patients with androgenetic alopecia were randomly allocated into two equal groups to receive either topical or oral minoxidil in an open-label comparative study at a tertiary dermatology center. Baseline evaluation included medical history, clinical examination, electrocardiogram, and laboratory tests, while treatment outcomes were analyzed using independent t-test, ANOVA, descriptive statistics, and Kaplan-Meier survival analysis.

Results Hair density increased by 45% in the oral minoxidil cohort, contrasted with a 38% increase in the topical cohort, accompanied by greater patient satisfaction in the oral group (72% against 65%). Mild adverse events were hypertension (10%) associated with oral medication and scalp irritation (15%) linked to topical therapy, but treatment adherence was superior in the oral group (90% compared to 80%).

Conclusion Low-dose oral minoxidil demonstrated greater efficacy and satisfaction relative to topical treatment, with similar moderate adverse effects. These findings validate its effectiveness and tolerability over six months in androgenetic alopecia.

Keywords Androgenetic alopecia; Hair Growth Satisfaction Scale; Kaplan-Meier analysis; Low-dose oral minoxidil; Minoxidil therapy; Norwood-Hamilton scale.

Article Received on 24.01.2026

Revised on 02.03.2026 25.03.2026

Accepted on 25.03.2026

Published on 30.03.2026

Citation: Yadav A, Gupta AK, Rajkumar. Comparative study of the effectiveness of low-dose oral minoxidil vs. topical minoxidil (5%) in male androgenetic alopecia. *J Pak Assoc Dermatol*. 2026;**36(1)**:74-81.
Doi: https://doi.org/10.66344/jpad.v36i1.3327

Introduction

Androgenetic alopecia in men is identified as the most common type of alopecia in males, which usually occurs between the ages of 20 and 30 years and primarily affects the frontal and vertex regions of the scalp.[1,2] The pathogenesis of androgenetic alopecia is mainly attributed to the influence of dihydrotestosterone, and it is estimated to affect 50% of men by the age of 50 years.[3,4] Due to its widespread occurrence and progressive characteristics, androgenetic alopecia is not merely a cosmetic issue but also a considerable psychosocial burden, frequently impacting self-esteem and quality

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of life.

Minoxidil topical application and finasteride oral administration are still among the most crucial and commonly used therapies for androgenetic alopecia.[5] Minoxidil topical application is a peripheral vasodilator that promotes blood circulation to the scalp, and the 5% solution has proven efficacy in encouraging hair growth and slowing down hair loss in clinical trials.[6] Clinical trials conducted by Liu *et al*. (2024) and Balasundaram *et al*. (2023) have found that minoxidil topical application can increase hair density and patient satisfaction. However, its efficacy can be impeded by the need for precise and consistent application.[7,8] Despite proven effectiveness, long-term compliance with topical minoxidil is inadequate due to the difficulty of bi-daily application and isolated side effects.

This therapy could be linked to local side effects like scalp tenderness and aberrant hair growth, which have been observed in a few cases (<10%) in clinical trials and are generally mild and insignificant.[9] Oral finasteride is a 5-alpha-reductase inhibitor, which decreases dihydrotestosterone levels responsible for miniaturization of follicles in androgenetic alopecia.[10] Although successful in halting the progression of hair loss, finasteride therapy can be linked to treatment-related adverse effects like sexual dysfunction and mood changes, resulting in discontinuation of therapy in a few cases.[11,12] The extensive implementation of this method is additionally constrained by the possibility of systemic negative consequences and patients' reluctance to engage in extended hormonal treatment.

Low-dose oral minoxidil has been identified as a promising treatment alternative that could potentially enhance patient compliance, decrease irritation of the scalp caused by topical minoxidil application, and offer benefits in patients who do not respond well to conventional treatments such as topical minoxidil and oral finasteride, thus proving its superiority in terms of tolerability and efficacy in selected patients.[13] Recent observational studies and small clinical trials indicate positive results regarding hair density enhancement and tolerability with low-dose oral minoxidil; however, these studies are constrained by limited sample sizes, brief follow-up periods, and the absence of standardized comparative outcome measures.[14]

Prior clinical investigations have evaluated the safety and efficacy of topical and low-dose oral minoxidil in the treatment of male androgenetic alopecia.[15] Nevertheless, direct comparison research concerning their impacts on hair growth, undesirable effects, and patient satisfaction is still scarce. Consequently, this study was conducted to thoroughly compare these two therapy modalities regarding clinically significant results, aiming to provide clearer evidence for optimizing treatment selection, enhancing patient adherence, and informing the clinical management of androgenetic alopecia.

Most of the existing research assesses topical or oral minoxidil separately, and comprehensive head-to-head comparison studies evaluating efficacy, safety, and patient satisfaction between these two methods are limited. The deficiency in the literature restricts evidence-based decision-making in choosing the most effective therapy approach for male androgenetic alopecia.

This study was undertaken to thoroughly compare topical 5% minoxidil and low-dose oral minoxidil concerning clinically significant outcomes, including hair growth metrics, adverse effects, and patient-reported satisfaction. This study seeks to provide better, evidence-based information for optimizing medication selection, improving adherence, and enhancing the overall clinical care of androgenetic alopecia through a direct comparison of these two therapeutic methods.

Methods

This open-label, randomized comparative clinical trial was performed in the Department of Dermatology, Venereology, and Leprology at a

tertiary care teaching hospital for over six months. The Institutional Ethics Committee granted ethical permission before participant recruitment (25/CRC/2019 dated 26.08.2021), and written informed consent was collected from all individuals before their inclusion in the study.

The study comprised 100 male patients aged 18 to 50 years, all clinically diagnosed with Grade II-V androgenetic alopecia using the Norwood-Hamilton classification. Patients who had undergone any hair growth treatment in the prior six months were excluded. Further exclusion criteria encompassed a history of hypertension, cardiovascular disease, documented hypersensitivity to minoxidil, prior use of systemic or topical hair growth treatments within the last six months, unrealistic treatment expectations, and inability or unwillingness to adhere to scheduled follow-up appointments. The sample size was determined using a conventional procedure for comparative clinical trials, predicated on previously documented variations in treatment response, with an assumed 95% confidence level and 80% statistical power. Participants were recruited via successive sampling and randomly assigned to two equal groups (n=50 each) using a computer-generated randomization process to ensure impartial allocation.

At baseline, demographic information and clinical history, including the onset and duration of hair loss, family history of androgenetic alopecia, and previous treatment, were documented. The severity was assessed utilizing the Norwood-Hamilton scale by a certified dermatologist. Treatment expectations were evaluated using a standardized questionnaire indicating minimal, moderate, or significant improvement. The safety evaluation encompassed pulse rate, blood pressure, 12-lead ECG, complete blood count, liver function assays (bilirubin, AST, ALT, ALP), and coagulation profile (PT/INR). Group A participants administered oral minoxidil at a dosage of 2.5 mg once daily, whilst Group B used 5% topical minoxidil (1 mL) bi-daily for a duration of six months. All participants received guidance on administration, advantages, and side effects, while adherence was assessed through monthly follow-ups and self-reporting.

Clinical evaluations were performed at baseline and monthly for duration of six months. The efficacy was assessed using alterations in Norwood-Hamilton grading and standardized scalp images. Patient satisfaction was evaluated monthly utilizing the Hair Growth Satisfaction Scale (0-3). Adverse effects and clinical observations were meticulously documented.

Data was analyzed utilizing SPSS version 26. Continuous variables were presented as mean±SD and compared utilizing independent and paired t-tests; categorical variables were evaluated as frequencies and percentages. ANOVA explored differences among follow-ups, while Kaplan-Meier analysis examined the time to improvement. A p-value less than 0.05 is considered significant.

Result

The two treatment groups were comparable with respect to baseline demographic characteristics. Approximately 24-26% of participants in both groups were aged 18-35 years. The severity distribution of alopecia was also comparable between groups, with Grades 3-4 being the most prevalent (24%), while Grades 1, 2, and 5-6 ranged between 10% and 16%, indicating similar baseline disease severity **(Table 1)**.

Table 1 Distribution of demographic variables among respondents.

Parameter/ Category	*Group 1: Low-dose Oral Minoxidil N (%)*	*Group 2 Topical Minoxidil N (%)*
Age Category (Years)		
18-22	12 (24%)	12 (24%)
23-27	13 (26%)	13 (26%)
28-32	13 (26%)	13 (26%)
33-35	12 (24%)	12 (24%)
Alopecia Grade		
Grade 1	5 (10%)	5 (10%)
Grade 2	8 (16%)	8 (16%)
Grade 3	12 (24%)	12 (24%)
Grade 4	12 (24%)	12 (24%)
Grade 5	8 (16%)	8 (16%)
Grade 6	5 (10%)	5 (10%)

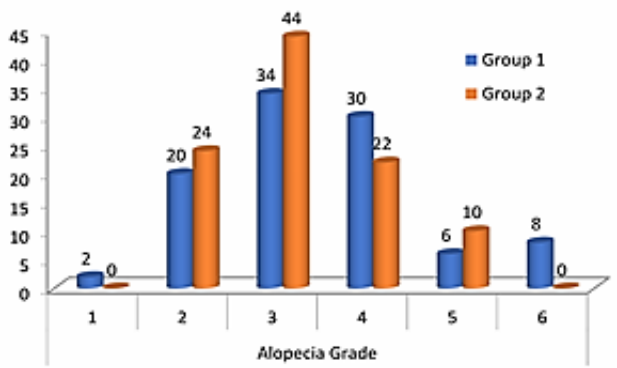

Figure 1 Distribution of alopecia grades among study groups.

Table 2 Illustration of clinical efficacy and safety outcomes at 6 months between low-dose oral minoxidil and topical minoxidil 5%.

Parameters/ Category	*Group 1 (n=50) N (%)*	*Group 2 (n=50) N (%)*	*p-value*
Treatment response at 6 months			
No Change	0 (0%)	3 (6%)	
Stabilized	9 (18%)	16 (32%)	
Mild Improvement	22 (44%)	19 (38%)	<0.01*
Marked Improvement	18 (36%)	8 (16%)	
Withdrawn/Dropout	1 (2%)	11 (22%)	
Overall Improvement Grade			
Grade 0	1 (2%)	10 (20%)	
Grade 1	9 (18%)	17 (34%)	<0.01*
Grade 2	22 (44%)	19 (38%)	
Grade 3	18 (36%)	4 (8%)	
Adverse Effects			
Hypertrichosis	10 (20%)	9 (18%)	
Desquamation	0 (0%)	1 (2%)	
Irritation	0 (0%)	1 (2%)	0.19
Itching	0 (0%)	1 (2%)	
Light-headedness	3 (6%)	0 (0%)	
Palpitations	1 (2%)	0 (0%)	
Transient shedding	0 (0%)	3 (6%)	

At baseline, the distribution of alopecia grades was evenly distributed throughout the groups.

In low-dose oral minoxidil cohort, 24% of patients had Grade 3 alopecia, whereas 24% presented with Grade 4 alopecia. In the topical minoxidil cohort, 24% of patients were categorized as Grade 3 and 24% as Grade 4. Grade 6 alopecia was noted in 10% of patients in both groups **(Figure 1)**.

The data in **Table 2** indicate that low-dose oral minoxidil yielded markedly improved clinical results compared to topical minoxidil after six months. A greater percentage of patients in the oral group attained significant improvement (36% vs. 16%). Overall improvement (Grades 2 and 3 combined: 80% vs. 46%), while a higher proportion of patients in the topical group exhibited no change or ceased treatment (22% dropout vs. 2% in the oral group) (p<.01). The improvements grading further validated the higher effectiveness of oral medication, as fewer patients were classified in the lower improvement categories (Grade 0-1) compared to the topical group. Adverse effects were predominantly minor and similar across groups (p=.19), with hypertrichosis identified as the most prevalent adverse effect in both cohorts. The findings suggest that low-dose oral minoxidil demonstrates enhanced clinical efficacy and improved treatment retention, with no substantial rise in side events.

The findings in **Table 3** indicated that individuals administered low-dose oral minoxidil experienced markedly enhanced subjective improvement and satisfaction relative to those utilizing topical minoxidil 5%. A much greater percentage of individuals in the oral group strongly concurred that their bald area had diminished (36% vs. 8%, p=.019) and indicated substantial hair growth (32% vs. 12%, p=.012). The oral group exhibited significantly greater satisfaction with scalp appearance in both the frontal and vertex regions, with p values between 0.008 and 0.043. Despite the lack of statistical significance in perceived effectiveness for mitigating hair loss (p=.09), the total patient satisfaction score was significantly elevated in the oral minoxidil cohort (6.71±1.14) relative to the topical group (4.86±1.32, p<.01). These data demonstrate greater patient-reported efficacy and satisfaction with low-dose oral minoxidil compared to topical treatment.

Discussion

Male androgenetic alopecia is a prevalent, progressive disorder caused by androgen-induced follicular shrinkage.[16] While topical 5% minoxidil is commonly employed as a primary treatment, its effectiveness may be constrained by patient adherence and localized adverse reactions.[17] Low-dose oral minoxidil has surfaced as a viable option,

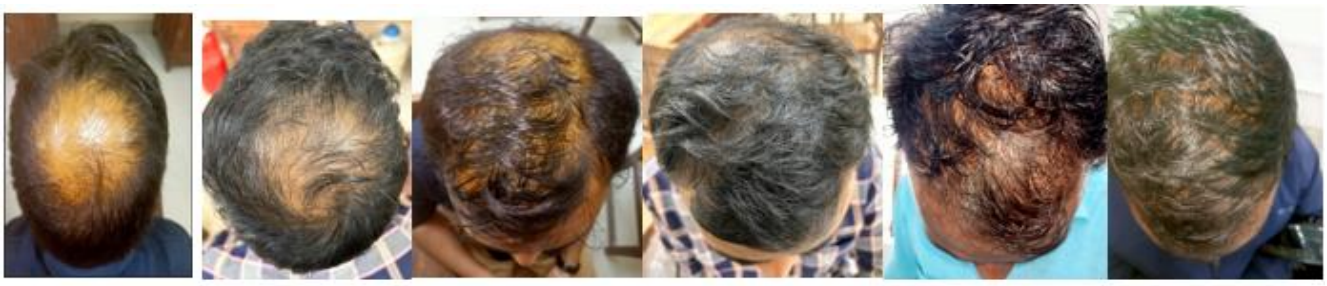

Figure 2 Photographs of Group 1 patients receiving low-dose oral minoxidil before therapy and after therapy.

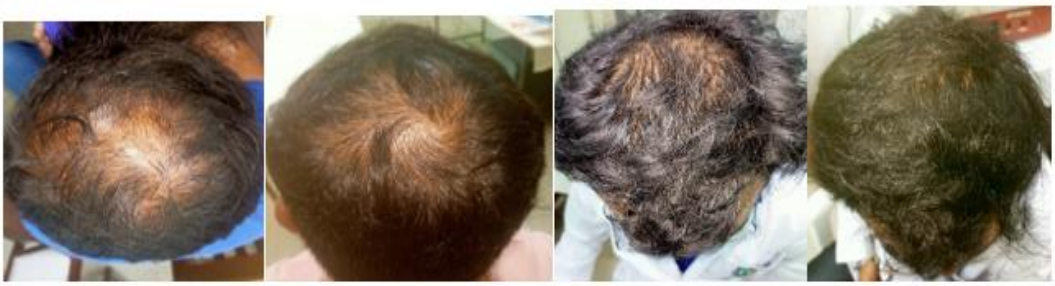

Figure 3 Photographs of Group 2 patients receiving topical minoxidil 5% before therapy and after therapy.

with promising efficacy and acceptable safety when monitored.[18] Consequently, it is imperative to compare the efficacy of low-dose oral minoxidil with topical 5% minoxidil to inform appropriate treatment strategies for male androgenetic alopecia.

In the present study, grade 3 alopecia was noted in 34% of participants administered oral minoxidil and in 44% of those receiving topical 5% minoxidil. Tan *et al*. (2021) similarly identified grade 3 AGA as the predominant severity category in their sample, comprising about 40% of cases, which aligns with our findings and indicates that moderate disease is the most prevalent clinical manifestation in treatment-seeking individuals.[19] Moreover, Mu *et al*. (2021) and several prior studies reported grade 4 alopecia in roughly 22% of patients undergoing topical treatment and 30% of those getting systemic medication, with a portion of these patients ultimately necessitating surgical intervention.[20] The findings reveal that a significant number of patients exhibit advanced diseases, which may exhibit reduced responsiveness to pharmacological treatment alone and are more likely to require procedural intervention, highlighting the urgent requirement for early diagnosis and prompt therapeutic action.

The average age was 28.12 years in the oral minoxidil group and 27.94 years in the topical group, aligning with the findings of Nargis *et al*. (2017), who indicated that androgenetic alopecia primarily impacts men aged 21-30 years.[21] These data indicate that AGA frequently manifests in early adulthood, underscoring the necessity for prompt diagnosis and suitable therapeutic measures, since early management may mitigate disease development and reduce additional hair loss in younger people.

After four weeks of treatment, 56% of patients in the oral minoxidil cohort did not possess additional hair loss, whereas 32% experienced ongoing shedding. Conversely, 64% of patients on topical 5% minoxidil demonstrated no significant change, 32% attained stability, and 4% suffered ongoing hair loss. These findings indicate a relatively earlier clinical response in the oral minoxidil cohort. Panchaprateep *et al*. (2024) also showed that low-dose oral minoxidil yielded quicker and more significant enhancements in hair growth metrics compared to topical therapy, with quantifiable gains in hair density noted within the first months of treatment.[22] Moreover, research by Asilian *et al*. (2024) in a

Table 3 patient-reported treatment efficacy and satisfaction scores between low-dose oral minoxidil (Group 1) and topical minoxidil 5% (Group 2)

Domain/ Response Category	*Group 1 n (%)*	*Group 2 n (%)*	*P value*
Perceived reduction in bald area			0.019
Strongly agree	18 (36%)	4 (8%)	
Agree	22 (44%)	14 (28%)	
Neutral	9 (18%)	18 (36%)	
Disagree	0 (0%)	3 (6%)	
Strongly disagree	0 (0%)	0 (0%)	
Perceived hair growth			0.012
Greatly increased	16 (32%)	6 (12%)	
Moderately increased	24 (48%)	12 (24%)	
Slightly increased	9 (18%)	18 (36%)	
No change	0 (0%)	5 (10%)	
Perceived effectiveness in slowing hair loss			0.09
Very Effective	24 (48%)	18 (36%)	
Somewhat effective	21 (42%)	12 (24%)	
Not very effective	9 (18%)	9 (18%)	
Satisfaction - Front of scalp			0.043
Very satisfied	10 (20%)	0 (0%)	
Satisfied	12 (24%)	10 (20%)	
Neutral	20 (40%)	13 (26%)	
Dissatisfied	7 (14%)	6 (12%)	
Satisfaction - Vertex/Top of scalp			0.008
Very Satisfied	16 (32%)	4 (8%)	
Satisfied	20 (40%)	9 (18%)	
Neutral	13 (26%)	14 (28%)	
Dissatisfied	0 (0%)	12 (24%)	
Overall satisfaction with appearance			0.013
Very Satisfied	18 (36%)	6 (12%)	
Satisfied	20 (40%)	12 (24%)	
Neutral	11 (22%)	15 (30%)	
Dissatisfied	0 (0%)	6 (12%)	
Overall patient satis-faction score (Mean±SD)	6.71±1.14	4.86±1.32	<0.01

randomized clinical trial revealed similar efficacy between low-dose oral and topical 5% minoxidil; however, the oral formulation was linked to a more rapid subjective experience of hair growth enhancement.[23] When analyzed in conjunction with our findings, these trials bolster the evidence that oral minoxidil may have a more expedited therapeutic effect compared to topical formulations, but long-term comparative safety and adherence profiles are crucial factors for clinical decision-making.

At three months, 70% of patients on oral minoxidil indicated modest improvement, and 4% displayed marked improvement, while just 18% of patients in the topical group reported similar improvement. At six months, oral treatment led to significant improvement in 36% of patients and an overall clinical improvement rate of 98%, whereas Villani *et al*. (2021) documented a maximum improvement rate of 26.8% in their cohort treated with topical minoxidil.[24] These findings indicate the greater effectiveness of oral minoxidil in our study relative to previously published results for topical treatment. Despite topical users exhibiting fewer improvements, the dropout rate was 22%, signifying relatively diminished adherence. Conversely, Gao *et al*. (2023) indicated that low-dose oral minoxidil was both safe and efficacious for androgenetic alopecia, with considerable enhancements in hair density and a favorable tolerability profile.[25] This data corresponds with the substantial overall improvement shown in our oral therapy cohort.

Both therapy techniques were largely well accepted. Consistent with the findings of Godse *et al*. (2023), one patient in the oral minoxidil cohort of our trial ceased treatment because of palpitations, and 20% experienced hypertrichosis.[26] In their trial, hypertrichosis was the most reported side effect; nevertheless, it was primarily moderate and did not usually need cessation. In our cohort of topical users, side effects included scalp irritation, pruritus, and desquamation, with 4% experiencing increased shedding. The safety findings in this study align with previous publications, demonstrating that both oral and topical minoxidil are typically well tolerated, with foreseeable and tolerable side effects.

Moreover, low-dose oral minoxidil had a more rapid onset and superior overall clinical improvement relative to topical 5% minoxidil in male androgenetic alopecia, with both therapies being generally well tolerated. Oral therapy was linked to systemic symptoms, including hypertrichosis and intermittent palpitations, while topical therapy was constrained by localized discomfort and reduced adherence. The limited sample size, brief follow-up period, and single-center design restrict

generalizability, underscoring the necessity for larger, long-term randomized studies to validate comparative efficacy and safety.

Conclusion

In conclusion, both low-dose oral minoxidil and topical 5% minoxidil are efficacious treatment modalities for male androgenetic alopecia. Oral minoxidil may provide superior clinical efficacy and improved adherence in certain patients due to its enhanced systemic bioavailability. In contrast, topical minoxidil is a well-established first-line therapy characterized by a favorable safety profile and minimal systemic exposure. Treatment selection must be tailored according to disease severity, patient adherence, tolerability, and the potential for adverse effects. Future investigations must prioritize extensive randomized controlled trials with prolonged follow-up to elucidate optimal dose, long-term safety, especially cardiovascular outcomes and to examine combination and individualized therapy approaches for enhanced clinical management.

Declaration of patient consent Authors certify that they have obtained all appropriate patient consent.

Financial support and sponsorship None.

Conflict of interest No conflict of interest.

Author's contribution

AKY: Substantial contribution to study design, acquisition of date, manuscript writing.

AKG,RK: Substantial contribution to study design, manuscript writing, critical review of the manuscript.

Every author has given final approval of the manuscript version to be published and agreed to be accountable for all aspects of the work.

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