Comparative Evaluation of the Efficacy and Safety of Oral Finasteride versus Oral Dutasteride in Male Androgenetic Alopecia: An 18-Month Prospective Interventional Study from a Tertiary Care Centre in Uttar Pradesh

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Abstract

Background: Androgenetic alopecia (AGA) is a chronic, androgen-dependent disorder driven by dihydrotestosterone (DHT)-mediated follicular miniaturization. Oral finasteride is the established first-line therapy, while dutasteride, which blocks both type I and type II 5-alpha-reductase isoenzymes, is increasingly used off-label. Head-to-head, long-duration data from Indian patients remain scarce.

Objective: To compare the efficacy and safety of oral finasteride (1 mg/day) and oral dutasteride (0.5 mg/day) in men with AGA at a tertiary care centre in Uttar Pradesh.

Methods: In this prospective interventional comparative study, 120 men aged 18–40 years with Hamilton–Norwood grade II–V AGA were allocated to finasteride (n=60) or dutasteride (n=60) and followed for 18 months. Efficacy was assessed by phototrichogram, global photography and patient self-assessment at 6-month intervals; safety was assessed through clinical monitoring and 3-monthly laboratory investigations.

Results: Baseline demographic and disease-severity parameters were comparable between groups ($p>0.05$ for all). Terminal hair density increased from 160.9 to 175.6 hairs/cm² with finasteride (+9.1%) and from 161.4 to 188.9 hairs/cm² with dutasteride (+17.0%; $p<0.001$ at 18 months). Vellus hair count declined by 10.8% with finasteride versus 20.3% with dutasteride ($p=0.02$). Marked-to-moderate improvement on global photography was seen in 56.7% versus 73.3% of patients respectively ($p<0.01$), and overall marked improvement occurred in 56.7% versus 76.7% ($p<0.001$). Sexual adverse effects were numerically higher with dutasteride (23.3% vs. 16.7% any adverse effect) but the difference was not statistically significant, and no patient discontinued therapy.

Conclusion: Both agents were effective and well tolerated, but dutasteride produced significantly greater and faster improvement in hair density with a comparable safety profile, supporting its preferential use in moderate-to-severe disease or in patients responding inadequately to finasteride.

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Keywords: Androgenetic alopecia, male pattern hair loss, finasteride, dutasteride, 5-alpha-reductase inhibitors, phototrichogram

Introduction

Androgenetic alopecia (AGA), or male pattern hair loss (MPHL), is the most prevalent chronic and progressive hair-loss disorder in men, characterised by a genetically predetermined, androgen-dependent pattern of scalp hair thinning that typically begins with bitemporal recession and vertex involvement. By 50 years of age, nearly half of men show some degree of MPHL, rising to almost 80% by 70 years, and the condition is increasingly observed at an earlier age in Indian men, likely reflecting genetic

susceptibility, urban stress and lifestyle change. [1]

At the molecular level, testosterone is converted to dihydrotestosterone (DHT) by the enzyme 5-alpha-reductase (5AR). DHT binds with high affinity to androgen receptors in dermal papilla cells, progressively shortening the anagen phase and prolonging telogen, so that thick terminal hairs are gradually replaced by fine vellus hairs. Two 5AR isoenzymes contribute to this process: type II, concentrated in the hair follicle and prostate, and type I, more broadly distributed in sebaceous glands and skin. Oral 5-alpha-reductase inhibitors (5ARIs) are the only pharmacological class that directly targets this mechanism. [2]

Finasteride selectively inhibits type II 5AR and reduces serum and scalp DHT by roughly 60–70%, whereas dutasteride blocks both isoenzymes and suppresses serum DHT by more than 90%, producing a theoretically more comprehensive reduction of follicular DHT. This pharmacological distinction has generated growing off-label use of dutasteride in dermatology practice, particularly in Asia, despite finasteride remaining the only drug formally approved for MPHL in most jurisdictions, including India. [2, 3]

Long-term systemic safety of 5ARIs continues to be debated, with reports of sexual dysfunction, mood change and, more recently, proposed associations with metabolic and hepatic effects from chronic tissue-level androgen suppression. [3] Given the paucity of long-duration, head-to-head Indian data comparing finasteride and dutasteride, and considering differences in genetic background, treatment-seeking behaviour and psychosocial burden of hair loss in the Indian population, [4, 5] the present study was designed to compare the efficacy and safety of these two agents over an 18-month follow-up period in a tertiary care setting in Uttar Pradesh.

Materials and Methods

Study Design and Setting

This was a prospective, interventional, comparative study conducted in the Department of Dermatology, Venereology and Leprology, Saraswathi Institute of Medical Sciences, Hapur, Uttar Pradesh, between March 2024 and February 2026, following approval from the Institutional Ethics Committee (Reg. No. EC/NEW/INST/2022/UP/0125) and after obtaining written informed consent from all participants.

Participants

Male patients aged 18–40 years with clinically diagnosed AGA of Hamilton–Norwood grade II–V, attending the dermatology outpatient department, were enrolled. Patients using minoxidil or other anti-androgenic or hair-growth-altering drugs within the preceding 6 months, those with systemic illness, tobacco use, a personal or family history of breast/prostate cancer, or non-compliant patients were excluded. Sample size (60 per group) was calculated from the means and standard deviations reported by Gupta *et al.* [6] for a two-mean comparison at 95% confidence and 80% power.

Intervention and Assessment

Patients were allocated to Group A (oral finasteride 1 mg/day) or Group B (oral dutasteride 0.5 mg/day) for 12 months of continuous therapy with follow-up extended to 18 months. Efficacy was assessed every six months using (i) phototrichogram (DermLite DL5 dermatoscope; terminal hair >60 µm, intermediate 30–60 µm, vellus <30 µm), (ii) a standardised 7-point global photography scale, and (iii) a structured patient self-assessment questionnaire. Safety was assessed through monthly clinical review for adverse effects (decreased libido, erectile dysfunction, ejaculation disorder) and 3-monthly complete blood count, liver and kidney function tests, and urine examination.

Statistical Analysis

Data were analysed using SPSS version 29. Continuous variables were expressed as mean ± SD and compared using Student's t-test or repeated-measures ANOVA with Bonferroni post-hoc correction; categorical variables were expressed as frequency (%) and compared using the chi-square test. Time-to-improvement was analysed by Kaplan–Meier survival analysis with log-rank test. A p-value <0.05 was considered statistically significant.

Results

A total of 120 men completed 18 months of follow-up (60 per group). Baseline characteristics, summarised in Table 1, were statistically comparable between groups, confirming adequate randomisation.

Table 1: Baseline demographic and disease-severity comparability between groups

Baseline Parameter	Finasteride (n=60)	Dutasteride (n=60)	p-value
Predominant age group	26–30 yrs (22)	26–35 yrs (20/19)	0.18
Predominant Hamilton–Norwood grade	Grade III	Grade IV	0.19
Positive hair-pull test	4 (6.7%)	5 (8.3%)	0.72

Both drugs produced progressive improvement in all efficacy parameters, but the magnitude and speed of response were consistently greater with dutasteride, with intergroup differences emerging from the 12-month assessment onward (Table 2, Figure 1). Terminal hair density rose from a comparable baseline to 175.6 hairs/cm² with finasteride versus 188.9 hairs/cm² with dutasteride at 18 months, a difference that was not significant at 6 months but became significant at 12 months and highly significant at 18 months.

Table 2: Comparative efficacy outcomes at 18 months

Efficacy Parameter	Finasteride	Dutasteride	p-value
Terminal hair count, baseline→18 mo (hairs/cm²)	160.9→175.6 (+9.1%)	161.4→188.9 (+17.0%)	<0.001
Vellus hair count, baseline→18 mo	54.8→48.9 (−10.8%)	56.1→44.7 (−20.3%)	0.02
Global photography: moderate–marked improvement at 18 mo	34 (56.7%)	44 (73.3%)	<0.01
Patient self-assessment: improved at 18 mo	41 (68.3%)	47 (78.3%)	<0.05
Overall marked improvement (composite outcome)	34 (56.7%)	46 (76.7%)	<0.001

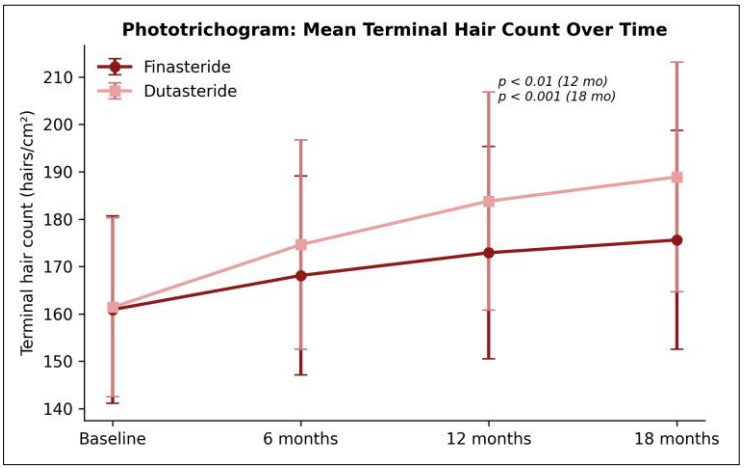

Fig 1: Mean terminal hair count (hairs/cm² ± SD) on phototrichogram at baseline, 6, 12 and 18 months. The intergroup difference was non-significant at 6 months but significant at 12 months (p<0.01) and highly significant at 18 months (p<0.001).

Global photographic assessment showed a similar pattern, with a consistently higher proportion of moderate-to-marked improvement in the dutasteride group at every follow-up visit (Figure 2). At 18 months, 73.3% of dutasteride-treated patients showed moderate-to-marked improvement compared with 56.7% of finasteride-treated patients (p<0.01).

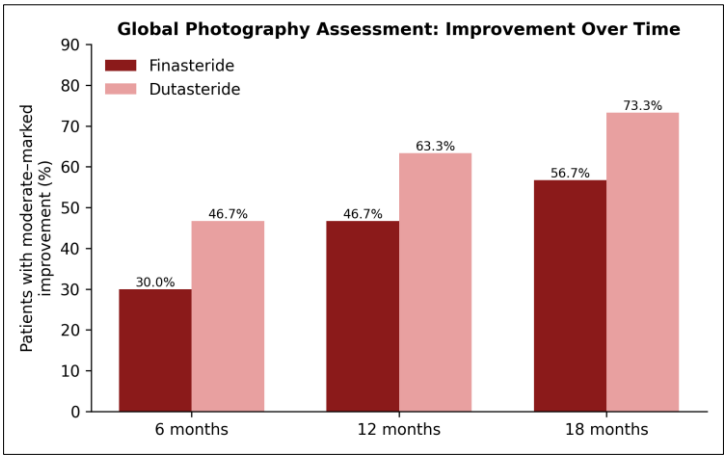

Fig 2: Proportion of patients showing moderate-to-marked improvement on global photography at 6, 12 and 18 months. Improvement rates were consistently higher with dutasteride at every time point, with the gap widening after 12 months.

Reduction in vellus hair count, an index of reversal of follicular miniaturisation, was greater with dutasteride than finasteride (Figure 3). Finasteride reduced vellus hair count from 54.8 to 48.9 hairs/cm² (−10.8%; within-group p=0.03), while dutasteride reduced it from 56.1 to 44.7 hairs/cm² (−20.3%; within-group p<0.001), a between-group difference that was also significant at 18 months (p=0.02).

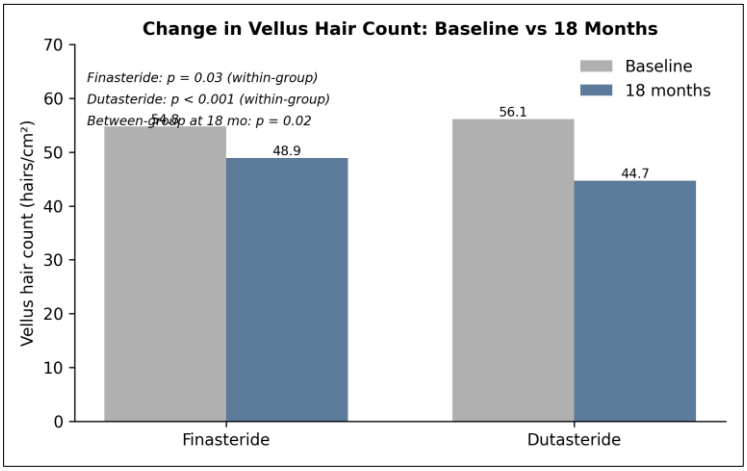

Fig 3: Change in mean vellus hair count from baseline to 18 months in the two treatment groups. Dutasteride produced a significantly greater decline, indicating a greater reversal of follicular miniaturisation.

On Kaplan–Meier analysis, visible clinical improvement occurred earlier with dutasteride: 36.7% of dutasteride-treated patients showed improvement by 3 months versus 20.0% on finasteride, and 73.3% versus 53.3% by 6 months (log-rank p=0.01). Overall composite efficacy (combining phototrichogram, photographic and subjective criteria) showed marked improvement in 76.7% of dutasteride patients versus 56.7% of finasteride patients, and poor response in only 6.6% versus 16.6%, respectively (p<0.001). Sexual adverse effects were numerically more frequent with dutasteride but did not reach statistical significance for any individual effect or for the composite "any adverse effect" category (Table 3). No patient in either group required dose modification or discontinuation, and all laboratory parameters remained within normal limits throughout follow-up in both groups.

Table 3: Adverse effect profile at 18 months

Adverse Effect	Finasteride n (%)	Dutasteride n (%)	p-value
Decreased libido	6 (10.0)	9 (15.0)	NS
Erectile dysfunction	5 (8.3)	8 (13.3)	NS
Ejaculation disorder	3 (5.0)	6 (10.0)	NS
Any adverse effect	10 (16.7)	14 (23.3)	NS

Discussion

This 18-month prospective comparison demonstrates that while both finasteride and dutasteride are effective in male AGA, dutasteride produces a substantially greater and more rapid improvement in hair density, consistent with its dual inhibition of type I and type II 5-alpha-reductase and more comprehensive suppression of scalp DHT. [2] Most participants in both arms were clustered in the 26–35 year age group, mirroring the early-onset pattern reported in Asian populations by Lee *et al.* [4] and in Indian practice by Mysore *et al.* [5], and closely matching the demographic profile (mean age 32.5 years) reported by Jayaprasad *et al.* [19] in a comparable Indian cohort.

Although the dutasteride arm contained a marginally higher proportion of advanced (grade IV–V) disease at baseline, outcomes still favoured dutasteride, suggesting that the observed superiority reflects genuine pharmacological effect rather than a more favourable baseline. This mirrors the observation of Choi *et al.* [15], whose dutasteride-treated patients were older with more severe baseline alopecia yet still showed superior improvement on the BASP classification.

The 27.5 hairs/cm² gain in terminal hair count with dutasteride in the present study closely approximates the pooled mean difference of 28.57 hairs/cm² reported in the meta-analysis by Zhou *et al.* [12], and is considerably larger than the 6-month gains reported by Jayaprasad *et al.* [19] (22.04 vs. 5.88 hairs/cm²), consistent with our finding that the intergroup gap widens progressively after 12 months rather than plateauing, as also described for finasteride alone by Leyden *et al.* [21]. The greater decline in vellus hair count with dutasteride corroborates the systematic review by Almudaimeegh *et al.* [6] and the hair-shaft DHT measurements of Hobo *et al.* [18], which together provide direct pharmacological support for a superior reversal of miniaturisation with dual isoenzyme blockade.

The earlier onset of visible improvement with dutasteride observed here is consistent with the twin study by Stough[23] and the randomised comparison by Harcha *et al.* [9], and may have practical importance: faster perceptible response is likely to improve long-term adherence in a chronic therapy where discontinuation is common. Patient self-assessment paralleled objective findings, in agreement with the meta-analysis by Zhou *et al.* [12] and the review by Estill *et al.* [16], reinforcing that the benefit of dutasteride is both statistically and clinically meaningful.

With respect to safety, the frequencies of sexual adverse effects in our cohort (5–15% across individual effects) fall within the 3.4–15.8% range summarised by Hirshburg *et al.*(10), and the absence of a significant intergroup difference is consistent with the meta-analyses of Lee *et al.* [13] and Zhou *et al.* [13], both of which found comparable tolerability between the two drugs. No patient required discontinuation and laboratory parameters remained stable throughout, in line with the long-term safety observations of Choi *et al.* [15] and Estill *et al.* [16], although the theoretical concerns regarding systemic tissue-level androgen suppression raised by Traish *et al.* [3] warrant continued long-term vigilance beyond the 18-month horizon of this study.

Taken together, these findings support the pathophysiological principle that greater and more sustained suppression of scalp DHT translates into greater reversal of follicular miniaturisation. Finasteride remains an effective, well-established first-line option, particularly in milder disease, whereas dutasteride offers a faster and stronger therapeutic response that may be preferable in moderate-to-severe disease or in patients with an inadequate response to finasteride, provided patients are counselled about the marginally higher, though statistically non-significant, frequency of sexual adverse effects.

Limitations

This single-centre study, while adequately powered and of relatively long duration for this field, was limited to men aged 18–40 years, did not include a placebo arm for ethical reasons, and followed patients for 18 months; longer-term data would help clarify the durability of the observed differences and the evolution of adverse effects with continued use.

Conclusion

In this 18-month prospective comparative study, both oral finasteride and oral dutasteride were effective and safe treatments for male androgenetic alopecia. Dutasteride demonstrated consistently superior efficacy across objective (phototrichogram), photographic and patient-reported outcome measures, with an earlier onset of visible improvement, without a statistically significant increase in adverse effects. These findings support dutasteride as a preferable option in patients with moderate-to-severe disease or an inadequate response to finasteride, while finasteride remains an appropriate first-line therapy in milder disease or where safety concerns predominate.

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