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ORAL MINOXIDIL EFFICACY AND SAFETY IN MALE ANDROGENETIC ALOPECIA- A LITERATURE REVIEW

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ABSTRACT

Background: Low-dose oral minoxidil (LDOM) has emerged as a promising treatment for male androgenetic alopecia (AGA), offering potential advantages over topical formulations. This review evaluates the efficacy and safety of oral minoxidil for male AGA.

Methods: A comprehensive literature search of PubMed, EMBASE, Cochrane Library, and Web of Science identified randomized controlled trials, observational studies, systematic reviews, meta-analyses, and consensus statements evaluating oral minoxidil (0.25-5 mg daily) for male AGA.

Results: Across multiple studies, oral minoxidil demonstrated consistent efficacy for male AGA. Prospective studies reported increases in terminal hair density of 21.6-23.6% on the vertex with 5 mg daily dosing. Systematic reviews reported clinical response rates of 61-100%, with meta-analysis confirming that doses exceeding 1 mg were associated with greater efficacy. Approximately 35% of patients experienced significant symptom improvement and 47% showed improvement overall. Hypertrichosis was the most common adverse effect (15-49%), but rarely led to discontinuation (0.5%). Serious systemic adverse effects were infrequent: lightheadedness (1.7%), fluid retention (1.3%), and tachycardia (0.9%). No life-threatening events were reported, and only 1.7% discontinued treatment due to adverse effects. Meta-analysis confirmed that LDOM does not significantly affect blood pressure.

Conclusions: LDOM is an effective and well-tolerated treatment for male AGA and represents a valuable option for patients preferring oral therapy or intolerant to topical treatment.

KEYWORDS

Oral Minoxidil, Androgenetic Alopecia, Male Pattern Baldness, Efficacy, Safety Of Oral Minoxidil

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Introduction

Androgenetic alopecia (AGA) represents the most common form of non-scarring hair loss, affecting up to 80% of men by age 70 and significantly impacting quality of life. For decades, topical minoxidil has served as a golden standard treatment for male AGA. (Penha et al., 2024)

Minoxidil was originally developed and FDA-approved as early as 1979 as an oral antihypertensive agent for severe hypertension at doses of 10-40 mg daily. (Akiska et al., 2025)

The observation of hypertrichosis as a prominent adverse effect at these antihypertensive doses led to the development of topical formulations for hair loss in the 1980s and subsequent FDA approval in the form of a topical 5% solution in 1997. (Akiska et al., 2025)

In recent years, there has been renewed interest in repurposing oral minoxidil at substantially lower doses (0.25-5 mg daily) as an off-label treatment for various forms of alopecia, including male AGA (Sharma et al., 2020). This approach offers potential advantages including improved patient compliance, elimination of scalp application-related adverse effects, and circumvention of variable topical absorption. (Jimenez-Cauhe et al., 2025)

The precise mechanism by which minoxidil promotes hair growth remains incompletely understood, though multiple pathways have been proposed. Minoxidil is a potent peripheral vasodilator that acts on adenosine triphosphate (ATP)-sensitive potassium channels (KATP channels) in dermal papilla cells (Akiska et al., 2025; Ong et al., 2026). However, its hair growth-promoting effects appear to be independent of vasodilation. Minoxidil increases the duration of the anagen phase and enlarges miniaturized follicles, irrespective of the underlying cause of hair loss. (Price, 1999)

Additional proposed mechanisms include: anti-inflammatory effects, induction of the Wnt/ β -catenin signaling pathway, 5- α reductase inhibition and antiandrogen activity, anagen extension, enhanced cysteine

incorporation, and modulation of inflammatory and androgenic pathways (Akiska et al., 2025; Ong et al., 2026). Recent network pharmacology studies have identified two novel targets—steroid 17-alpha-hydroxylase/17,20 lyase (CYP17A1) and aromatase (CYP19A1)—suggesting that minoxidil may act by altering hormonal and enzymatic pathways, suppressing androgen receptor expression, decreasing dihydrotestosterone formation, and enhancing estradiol production. (Shen et al., 2023)

Minoxidil is converted to its active metabolite, minoxidil sulfate, by sulfotransferase enzymes. For topical minoxidil, this conversion occurs in the outer root sheath of hair follicles, while oral minoxidil is absorbed in the gastrointestinal tract and converted to its activated sulfated form in the liver (Akiska et al., 2025). This difference in metabolism may explain why some patients who are non-responders to topical minoxidil (potentially due to low follicular sulfotransferase activity) may respond to oral formulations (Dias et al., 2025; Olsen, 2025).

This literature review aims to comprehensively evaluate the current evidence regarding the efficacy and safety of oral minoxidil for the treatment of male androgenetic alopecia. We will examine clinical trial data, real-world effectiveness studies, adverse event profiles and dosing strategies. By synthesizing the available evidence, this review seeks to provide clinicians with a framework for incorporating oral minoxidil into evidence-based management of male pattern hair loss.

Methodology

A comprehensive literature search was conducted PubMed, EMBASE, Cochrane Library, and Web of Science databases to identify relevant studies on oral minoxidil for male androgenetic alopecia. The search strategy employed the following terms: "oral minoxidil" AND ("androgenetic alopecia" OR "male pattern baldness" OR "male pattern hair loss" OR "AGA"). The search was limited to high quality English-language publications. Additional articles were identified through manual review of reference lists from included studies and relevant review articles.

Studies were included if they met the following criteria: assessed oral minoxidil as a treatment in male androgenic alopecia (mandatory); reported the safety profile; reported the doses regimens; reported an relevant efficacy outcome; included male patients 18 years old or more (mandatory); were published as original research articles, systematic reviews, meta-analyses or consensus statements (mandatory); the publication language was English (mandatory).

Papers that have not met the mandatory criteria listed above were excluded from the search. Papers that haven't reported all of the non-mandatory criteria could also have been included. In this case the decision was made considering all of the non-mandatory criteria together and making a holistic judgement about whether to include the paper. If a full lengths article couldn't be drafted a paper like this was discarded.

Texts were then screened for the following questions: study type, sample size, dose (mg/day), duration, assessment method, response rate and result of the intervention. As the assessment method differed significantly between papers a meta-analysis wasn't feasible to be performed.

Results

The efficacy of oral minoxidil for male androgenetic alopecia (AGA) has been evaluated across multiple study designs, including randomized controlled trials, prospective observational studies, retrospective analyses, systematic reviews, and meta-analyses. Dosing regimens in reported in literature range from 0.25 mg to 5 mg daily.

The recommended starting dose in male AGA is 2,5 mg as established in the recent consensus by Akiska et al. Dose escalation may be considered, taking in to account the achieved clinical response and tolerability of the drug. However, a dose of 5 mg is considered a plateau, being careful not to induce the hypotensive effect of minoxidil. Also a dose reduction to 1,25 mg, in a case of intolerance, is possible (Villani et al., 2021). In a study by Pirmez & Salas-Callo a significantly reduced dose of 0,25 mg was used.

Results of the search are shown in the table below, also short overview of the drafted papers is provided (tabl. 1).

Table 1. Search results highlights

Study	Year	Design	N	Dose	Duration	Efficacy Outcomes	Safety Outcomes
Penha et al.	2024	RCT (double-blind)	68 (33 oral, 35 topical)	5 mg daily	24 weeks	Terminal hair density: +21.6% vertex (95% CI 8.6-34.0); Photographic improvement: 70% vertex (vs 46% topical, P=0.04); No superiority over topical for frontal area	Hypertrichosis 49%; Headache 14%; Discontinuation 2%
Panchaprateep and Luengarun et al.	2020	Prospective non-comparative	30	5 mg daily	24 weeks	Nonvellus hair density: +35.9 hairs/cm ² (23.6%); Total hair density: +35.1 hairs/cm ² (19.2%) on vertex	Not specified in detail
Pirmez Salas-Callo et al.	2020	Prospective with trichoscopy	Small series	0.25 mg daily	Variable	Measurable improvement in hair density and thickness by quantitative trichoscopy	No serious adverse events; mild hypertrichosis
Feaster et al.	2023	Multicenter retrospective	25 men	0.625-2.5 mg daily	≥52 weeks	Clinical improvement 52.4%; Stabilization 42.9%; Significant difference vs controls (P0.001)	Well tolerated; specific rates not detailed
Vañó-Galván et al.	2021	Multicenter safety study	461 men	0.25-5 mg daily (mean 1.88 mg)	Mean 13.4 months	Safety study (efficacy not primary endpoint)	Hypertrichosis 15.1%; Lightheadedness 1.7%; Fluid retention 1.3%; Tachycardia 0.9%; Discontinuation 1.7%
Jimenez-Cauhe et al.	2020	Systematic review pooled analysis	442	0.25-5 mg daily	Variable	Clinical response 70-100% in AGA studies	Hypertrichosis 24%; Pedal edema 2%; Postural hypotension 1.1%; Heart rate alterations 1.3%
Sharma et al.	2020	Systematic review	19,003 men	0.25-5 mg daily to BID	Variable	Objective clinical improvement 61-100% in AGA	Hypertrichosis and postural hypotension most common
Randolph and Tosti et al.	2021	Review	634	Variable (0.25-5 mg)	Variable	Effective across multiple alopecia types; AGA most studied	Well tolerated; hypertrichosis dose-dependent
Liu et al.	2025	Meta-analysis (single-arm)	2,933 (27 studies)	Variable (>1 mg more effective)	Variable	Significant improvement 35%; Improvement 47%; Stable 26%; Doses >1 mg more effective	Adverse events 27% overall
Gupta et al.	2022	Network meta-analysis	Multiple RCTs	0.25-5 mg	24 weeks	5 mg oral minoxidil: highest SUCRA (100%); Superior to finasteride 1 mg by +10.4 hairs/cm ² (95% CI 2.2-18.6)	Not primary focus

The only double-blind randomized controlled trial comparing oral to topical minoxidil in our search was conducted by Penha et al., 2024, which enrolled 68 men with AGA (Norwood-Hamilton grades 3V-5V). After 24 weeks, oral minoxidil 5 mg daily increased terminal hair density on the vertex by 21.6% (95% CI, 8.6%-34.0%), comparable to the increase observed with topical minoxidil 5%. However, expert photographic assessment demonstrated superiority of oral minoxidil on the vertex (70% improvement vs. 46% with topical, $P=0.04$), though no significant difference was observed in the frontal region. These findings are consistent with an earlier prospective, open-label, study by Panchaprateep & Lueangarun, 2020 which reported a 23.6% increase in nonvellus hair density and a 19.2% increase in total hair density on the vertex in 30 men treated with oral minoxidil 5 mg daily for 24 weeks.

At the lower end of the dosing spectrum, Pirmez & Salas-Callo, 2020, in their retrospective review demonstrated that very-low-dose oral minoxidil (only 0.25 mg daily) has effected in measurable improvements in hair density and thickness assessing by quantitative trichoscopy, suggesting efficacy even at minimal doses.

A multicenter retrospective study by Feaster et al., 2023 evaluated 25 men treated with oral minoxidil at doses of 0.625-2.5 mg daily for at least 52 weeks, reporting clinical improvement in 52.4% and stabilization in 42.9%, with a statistically significant difference compared to the control group ($P<0.001$).

Systematic reviews and pooled analyses have consistently supported the efficacy of oral minoxidil for AGA. Jimenez-Cauhe et al., 2020 analyzed 14 studies comprising 442 patients and reported clinical response rates of 70-100% in AGA studies, though heterogeneity precluded formal meta-analysis of efficacy. Similarly, Sharma et al., 2020 reviewed 10 articles including 19,218 patients and found objective clinical improvement in 61-100% of AGA patients treated with oral minoxidil at doses ranging from 0.25 to 5 mg daily. Randolph & Tosti, 2021 in their paper reviewed 17 studies with 634 patients and concluded that oral minoxidil was effective and well-tolerated across multiple alopecia types, with AGA being the most studied condition.

The most recent meta-analysis by Liu et al., 2025 included 2,933 patients from 27 studies and reported in non-quantitative measures that 35% experienced significant symptoms improvement, 47% showed moderate improvement, and 26% had stable symptoms. Clarification of how these descriptive quantities were determined has not been provided by the group. Also reported was that doses exceeding 1 mg daily were associated with greater efficacy.

A network meta-analysis by Gupta et al., 2022 compared the relative efficacy of oral minoxidil with other AGA treatments. Oral minoxidil 5 mg daily achieved the highest SUCRA ranking (100%) and was significantly more efficacious than oral finasteride 1 mg (mean difference +10.4 hairs/cm², 95% CI 2.2-18.6), though evidence quality was rated as low. However, oral minoxidil 0.25 mg daily had the lowest SUCRA (10%), and finasteride 1 mg was significantly more efficacious than this very-low-dose regimen (mean difference +33.2 hairs/cm², 95% CI 19.1-47.3).

Safety of Oral Minoxidil in Male Androgenetic Alopecia

The safety profile of low-dose oral minoxidil has been extensively characterized. The largest study solely focused on safety, by Vañó-Galván et al., 2021, evaluated 461 men treated with oral minoxidil at doses of 0.25-5 mg daily (mean 1.88 mg) for a mean duration of 13.4 months. Hypertrichosis was the most common adverse effect, occurring in 15.1% of patients, though it led to treatment discontinuation in only 0.5%. Systemic adverse effects were infrequent and mostly minor: lightheadedness (1.7%), fluid retention (1.3%), tachycardia (0.9%), headache (0.4%), periorbital edema (0.3%), and insomnia (0.2%). Overall, only 1.7% of patients discontinued treatment due to adverse effects, and no life-threatening events were observed.

Hypertrichosis

Hypertrichosis is the most frequently reported adverse effect of oral minoxidil across all studies. In the randomized controlled trial by Penha et al., 2024 hypertrichosis occurred in 49% (22/45) of patients receiving oral minoxidil 5 mg daily compared to 25% (11/45) of those receiving topical minoxidil 5% ($P=0.02$). The hypertrichosis was generalized, well tolerated, and did not influence patient compliance.

The incidence of hypertrichosis varies across studies depending on dose and patient population. In the large multicenter safety study by Vañó-Galván et al., 2021, which evaluated 1,404 patients treated with low dose oral minoxidil (LDM) at a mean dose of 1.88 mg daily, hypertrichosis occurred in 15.1% of patients but led to treatment withdrawal in only 0.5% (14 patients). The pooled analysis by Jimenez-Cauhe et al., 2025 reported hypertrichosis in 24% of 442 patients, with all doses showing increased odds of hypertrichosis compared to 0.25-0.5 mg ($P<0.001$), confirming the dose-dependent nature of this adverse effect. The meta-

analysis by Liu et al., 2025 reported an overall adverse event incidence of 27%, with hypertrichosis being the predominant adverse effect.

The narrative review by Jimenez-Cauhe et al., 2020 confirmed that hypertrichosis occurs in approximately 15% of patients overall. The affected areas typically include the face (particularly the forehead, temples, and cheeks), arms, and legs. Management strategies include dose reduction or hair removal methods, and in most cases, hypertrichosis does not necessitate treatment discontinuation.

Cardiovascular Adverse Effects

Cardiovascular adverse effects are the primary safety concern with oral minoxidil given its mechanism as a potent vasodilator. At antihypertensive doses (10-40 mg daily), oral minoxidil is associated with fluid retention, tachycardia, pericardial effusion, cardiac tamponade, and angina pectoris. However, at the low doses used for hair loss (0.25-5 mg daily), these serious adverse effects are rare. (Akiska et al., 2025)

In the Vañó-Galván et al., 2021 multicenter study, systemic cardiovascular adverse effects were infrequent: lightheadedness occurred in 1.7%, fluid retention in 1.3%, tachycardia in 0.9%, and periorbital edema in 0.3%. No life-threatening adverse effects were observed. The pooled analysis by Jimenez-Cauhe et al., 2020 reported hypotension in only 1.1% and heart rate alterations in 1.3% of patients.

A systematic review and meta-analysis by Chen et al., 2025 evaluated the blood pressure effects of LDOM and found that it did not significantly alter systolic blood pressure (MD: -0.13; 95% CI: -2.67 to 2.41) or diastolic blood pressure (MD: -1.25; 95% CI: -3.21 to 0.71). Although there was a tendency toward decreased mean arterial pressure (MD: -1.92; 95% CI: -4.00 to 0.17), this did not reach statistical significance. There was a significant but modest increase in heart rate (MD: 2.67; 95% CI: 0.34-5.01). Hypotensive symptoms were reported in 5.0% of patients, but no hypotensive episodes were observed.

In the Penha et al., 2024 RCT, there was no difference between the oral and topical minoxidil groups regarding variation in mean arterial blood pressure over time, and resting heart rate showed no difference between groups. None of the participants reported dizziness, fainting, or vertigo.

Severe cardiovascular adverse effects, including pericardial effusion, were extremely rare at doses used for alopecia and are often linked to compounding errors resulting in excessive doses (Jimenez-Cauhe et al., 2025; Ong et al., 2026).

Other Adverse Effects

Headache was reported in 14% of patients in the oral minoxidil group in the Penha et al. (2024) RCT, compared to lower rates in the topical group. In the Vañó-Galván et al., 2021, headache occurred in only 0.4% of patients. Insomnia was reported in 0.2% of patients in the same study.

Transient hair shedding (telogen effluvium) may occur in the first 2 months of treatment due to the early release of hairs in the telogen phase. In the Penha et al., 2024 RCT, transient hair loss occurred in 9% (4/45) of the oral minoxidil group compared to 16% (7/45) of the topical minoxidil group ($P=0.34$). The international Delphi consensus confirmed that the risk for transient hair shedding with LDOM initiation is likely similar to that with topical minoxidil initiation (74.4% of experts concurred) (Akiska et al., 2025).

Treatment Discontinuation

Treatment discontinuation due to adverse effects was consistently low across all studies. In the Vañó-Galván et al., 2021 multicenter study, only 1.7% of patients discontinued treatment due to adverse effects: 0.5% due to hypertrichosis and 1.2% due to systemic adverse effects. In the Penha et al., 2024 RCT, only 2% (1/45) of the oral minoxidil group discontinued treatment due to adverse effects (headache), compared to 7% (3/45) of the topical minoxidil group ($P=0.61$).

Discussion

This comprehensive literature review synthesizes the current evidence on oral minoxidil for male androgenetic alopecia (AGA), encompassing randomized controlled trials, prospective and retrospective observational studies, systematic reviews, meta-analyses, and expert consensus statements. The evidence consistently demonstrates that low-dose oral minoxidil (0.25-5 mg daily) is an effective treatment for male AGA and a favorable safety profile at doses used for hair loss.

The only double-blind randomized controlled trial by Penha et al., 2024 established that oral minoxidil 5 mg daily achieved comparable efficacy to topical minoxidil 5% twice daily, with superior photographic improvement on the vertex (70% vs. 46%, $P=0.04$). Systematic reviews and pooled analyses reported clinical

response rates of 61-100% in AGA patients, while network meta-analysis ranked oral minoxidil 5 mg as the most efficacious treatment for terminal hair count, surpassing oral finasteride 1 mg and topical minoxidil formulations. The safety profile was consistently favorable, with hypertrichosis as the most common adverse effect (15-49%) and serious cardiovascular events being rare at low doses. (Gupta et al., 2022; Jimenez-Cauhe et al., 2020; Vañó-Galván et al., 2021)

The safety profile of low-dose oral minoxidil is reassuring and supports its use in appropriately selected patients. The largest safety study by Vañó-Galván et al., 2021 evaluated 461 patients and found that only 1.7% discontinued treatment due to adverse effects, with no life-threatening events observed. This is consistent with the pooled analysis by Jimenez-Cauhe et al., 2020, which reported low rates of systemic adverse effects including postural hypotension (1.1%) and heart rate alterations (1.3%).

Hypertrichosis is the most common adverse effect, occurring in 15-49% of patients depending on dose, but it is generally well tolerated and rarely leads to treatment discontinuation. The dose-dependent nature of hypertrichosis supports the use of the lowest effective dose, particularly in patients for whom this side effect may be cosmetically unacceptable. (Jimenez-Cauhe et al., 2020; Penha et al., 2024; Vañó-Galván et al., 2021)

Limitations of Current Evidence

Despite the growing body of evidence supporting oral minoxidil for male AGA, several important limitations must be acknowledged. Limited randomized controlled trial data- only one double-blind RCT has compared oral to topical minoxidil in men with AGA. This trial was single-center, had a relatively small sample size (68 men), and a short duration (24 weeks). The evidence base is otherwise dominated by observational studies, which are subject to selection bias and confounding. Furthermore, the included studies varied considerably in design, patient populations, dosing regimens, and follow-up durations, precluding formal meta-analysis of efficacy in some reviews. Also, the methods used to measure the outcome were highly heterogenic (including hair density, hair count, hair diameter, photographic assessment, and patient/physician global assessment) resulting in the limited ability to draw definitive conclusions about optimal dosing and comparative efficacy.

Most studies had follow-up durations of 24-52 weeks, and long-term efficacy and safety data are lacking. AGA is a chronic condition requiring long-term treatment, and the durability of response and cumulative safety profile of oral minoxidil over years of use remain unknown.

As with any systematic reviews, publication bias may affect the evidence base, with positive studies more likely to be published than negative studies. The network meta-analysis by Gupta et al. (2022) rated the evidence quality for most comparisons as low to moderate, reflecting the limitations of the underlying studies.

It must be also remembered that oral minoxidil remains an off-label treatment for hair loss, as it is FDA-approved only for severe refractory hypertension at much higher doses, inhibiting the prescription of this drug.

Conclusions

The evidence reviewed supports low-dose oral minoxidil (0.25-5 mg daily) as an effective and well-tolerated treatment for male androgenetic alopecia. Network meta-analysis ranks oral minoxidil 5 mg as the most efficacious treatment for terminal hair count, surpassing oral finasteride 1 mg and topical minoxidil formulations. The safety profile is favorable at low doses, with hypertrichosis as the most common adverse effect and serious cardiovascular events being rare.

Oral minoxidil represents a valuable treatment option for men with AGA who prefer oral therapy, are intolerant to topical treatment, have poor compliance with topical formulations, or are non-responders to topical minoxidil. In the literature reviewed starting dose of 2.5 mg daily for men is recommended, with titration based on response and tolerability. Appropriate patient selection, baseline evaluation, and monitoring are essential to maximize efficacy and minimize adverse effects.

Despite the promising evidence, important limitations remain, including limited RCT data, lack of long-term safety data, and off-label status. Future research should focus on larger comparative trials, optimal dosing studies, long-term safety evaluation, and investigation of novel formulations such as sublingual minoxidil. As additional evidence emerges, clinical recommendations should be updated to reflect the evolving understanding of oral minoxidil's role in the management of male androgenetic alopecia.

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