Section: Dermatology

Systematic Review

EFFICACY AND SAFETY OF LOW-DOSE ORAL MINOXIDIL FOR FEMALE PATTERN HAIR LOSS: A SYSTEMATIC REVIEW

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ABSTRACT

Background: Topical minoxidil is first-line therapy for female pattern hair loss (FPHL), but irritation, cosmetic inconvenience, and poor adherence limit long-term use. Low-dose oral minoxidil (LDOM) is increasingly used off label. The objective is to evaluate the efficacy and safety of LDOM in adult women with FPHL.

Materials and Methods: PubMed/MEDLINE, Embase, Scopus, Web of Science, Cochrane CENTRAL, ClinicalTrials.gov, and WHO ICTRP were searched for English-language studies published from January 2015 through December 2025. Randomized and nonrandomized studies evaluating oral minoxidil at doses <=5 mg/day were eligible. Two reviewers independently screened studies, extracted data, and assessed risk of bias. Because of clinical and methodological heterogeneity, findings were synthesized narratively.

Results: Nine studies were included: five contributed FPHL-specific efficacy evidence, and four mixed-population studies contributed indirect safety evidence only. Doses used in FPHL studies ranged from 0.25 to 2 mg/day, with follow-up generally lasting 24 weeks to 12 months. FPHL-specific studies reported improvements in hair density, hair-shaft diameter, hair shedding, and clinical appearance; comparative evidence did not establish superiority over topical minoxidil. Hypertrichosis was the most frequent adverse effect. Edema, dizziness, tachycardia, and postural symptoms were uncommon and usually mild. Evidence certainty was limited by small samples, heterogeneous regimens and outcomes, short follow-up, and reliance on observational data.

Conclusion: Low-certainty evidence suggests that LDOM may improve hair outcomes and is generally tolerated in selected women with FPHL, particularly when topical minoxidil is ineffective, poorly tolerated, or impractical. Larger, longer, standardized randomized trials are required before routine first-line use can be recommended.

Keywords: Female Pattern Hair Loss, Low-Dose Oral Minoxidil, Oral Minoxidil, Efficacy, Safety, Hypertrichosis, Systematic Review.

INTRODUCTION

Female pattern hair loss (FPHL) is the most common cause of progressive nonscarring alopecia in women. It is characterized by follicular miniaturization and reduced central scalp density and can substantially affect self-esteem and quality of life.[1-6]

Topical minoxidil remains the standard first-line pharmacologic treatment, but adherence may be limited by scalp irritation, residue, changes in hair texture, and the need for continuous application.[7-12] Oral minoxidil was developed as an antihypertensive; hypertrichosis observed at therapeutic doses prompted its use for hair disorders. At doses generally between 0.25 and 5

mg/day, LDOM is increasingly prescribed off label for alopecia.[10-17]

Available studies suggest improvements in hair density, hair-shaft diameter, shedding, and global appearance, while hypertrichosis is the most common adverse event. However, the evidence is difficult to interpret because of heterogeneous doses, mixed populations, varied outcome measures, short follow-up, and concomitant therapies.[13-20]

This systematic review synthesizes evidence published from 2015 to 2025 on the efficacy and safety of LDOM in adult women with FPHL and identifies priorities for future research.

MATERIALS AND METHODS

Design and reporting: The review was conducted in accordance with PRISMA 2020,[21] and methodological guidance from the Cochrane Handbook.[22] A protocol was developed before screening but was not prospectively registered in PROSPERO. Two reviewers independently completed screening, data extraction, and quality assessment; disagreements were resolved by consensus or a third reviewer.

Eligibility criteria

Eligible studies included women aged >=18 years with clinically, dermoscopically, or histopathologically diagnosed FPHL; evaluated oral minoxidil at <=5 mg/day, alone or with another therapy; and reported at least one efficacy or safety outcome. Randomized trials, nonrandomized comparative studies, prospective or retrospective cohorts, observational studies, and case series with at least five participants were included. Reviews, editorials, conference abstracts, case reports, laboratory studies, topical-only studies, male-only studies, non-English publications, and studies without extractable data were excluded.

Population scope and use of indirect safety evidence. Studies of mixed-sex or mixed-alopecia populations were eligible only when they contributed relevant safety data for low-dose oral minoxidil; they were not used to estimate FPHL-specific efficacy unless outcomes for adult women with FPHL were reported separately. This limited inclusion was prespecified because uncommon systemic adverse events and treatment discontinuations are poorly characterized in the small FPHL-only trials. Such data were therefore treated as indirect, supportive safety evidence, reported separately from FPHL efficacy findings, and given less interpretive weight because sex, alopecia subtype, dose, and comorbidity could modify adverse-event rates.

Table 1: PICOS eligibility criteria.

Domain	Eligibility criteria
Population	Women aged 18 years or older with clinically, dermoscopically, or histopathologically diagnosed FPHL for efficacy analyses; mixed-sex or mixed-alopecia cohorts only for indirect, supportive LDOM safety evidence.
Intervention	Low-dose oral minoxidil at 5 mg/day or less, alone or with another medical treatment.
Comparator	Placebo, topical minoxidil, another pharmacologic treatment, combination therapy, or baseline in single-arm studies.
Outcomes	Hair density, shaft diameter, shedding, clinical severity, photographic or patient-reported improvement; adverse events and discontinuation.
Study design	Randomized or non-randomized comparative studies, prospective or retrospective cohorts, observational studies, and case series with at least five participants.

Information sources and search strategy

PubMed/MEDLINE, Embase, Scopus, Web of Science Core Collection, and Cochrane CENTRAL were searched, together with ClinicalTrials.gov and WHO ICTRP. Reference lists of eligible articles and relevant reviews were screened. Search terms combined controlled vocabulary and free text for female pattern hair loss or female androgenetic alopecia, oral or low-dose minoxidil, and efficacy or safety outcomes. Searches covered human, English-language studies published from January 1, 2015, through December 31, 2025; database filters were used where available, and the eligibility criteria were applied during screening where equivalent filters were unavailable. Complete source-specific strategies are provided in Supplementary Material 1.

Study selection and data extraction

Records were managed in EndNote X9 and deduplicated. Two reviewers independently screened titles and abstracts, assessed full texts, and documented exclusion reasons. Extracted variables included study design, sample size, population, dose, comparator, treatment duration, efficacy outcomes, adverse events, and discontinuation.

Risk of bias assessment

Randomized trials were assessed with Cochrane RoB 2, observational studies with the Newcastle-Ottawa Scale, and case series with the Joanna Briggs Institute checklist. Because the included reports differed substantially in design and reporting, risk-of-bias findings were used to guide interpretation and were summarized narratively rather than converted into a pooled quality score.

Outcomes and synthesis

Efficacy outcomes included hair density, hair-shaft diameter, hair shedding, clinical severity, global photographic assessment, and patient-reported improvement. Safety outcomes included hypertrichosis, edema, dizziness, headache, hypotension, tachycardia, palpitations, discontinuation, and serious adverse events. A meta-analysis was planned only for sufficiently comparable studies; because doses, populations, comparators, follow-up, and outcome definitions

differed substantially, results were synthesized narratively.

Ethics

Ethics approval and individual consent were not required because only published, aggregate data were analyzed.

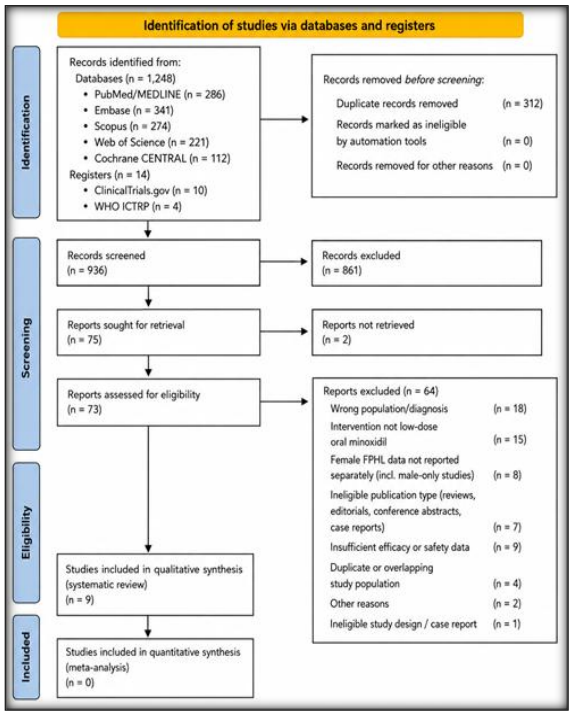


Figure 1: PRISMA 2020 flow diagram of study selection, including reasons for full-text exclusion

RESULTS

Study selection

The search identified 1,248 records. After removal of 312 duplicates, 936 records were screened and 75 reports were sought for retrieval. Two could not be obtained; 73 full texts were assessed and 64 were excluded: wrong population or diagnosis (n = 18), intervention not low-dose oral minoxidil (n = 15), female FPHL data not reported separately, including male-only studies (n = 8), ineligible publication type, including case reports (n = 8), insufficient efficacy or safety data (n = 9), duplicate or overlapping population (n = 4), and other reasons (n = 2). Nine studies were included in the qualitative synthesis: five contributed FPHL-specific efficacy evidence and four contributed indirect, supportive safety evidence only. No meta-analysis was performed because of substantial clinical and methodological heterogeneity.

Study characteristics

The included publications comprised randomized comparative trials, prospective observational studies, retrospective cohorts, case series, and multicenter safety studies published between 2018 and 2024. FPHL studies generally used 0.25-2 mg/day for 24 weeks to 12 months. Some studies assessed monotherapy, whereas others compared oral with topical minoxidil or combined LDOM with antiandrogens. Four studies included mixed-sex, mixed-alopecia, or clinically selected populations and were used only to characterize adverse events as indirect evidence for women with FPHL. The mixed-sex Asilian et al. trial did not report efficacy outcomes separately for women with FPHL and therefore did not contribute to the FPHL-specific efficacy assessment.

Table 2: Characteristics and principal findings of included studies. FPHL, female pattern hair loss; LDOM, low-dose oral minoxidil

Study	Design / population	n	LDOM regimen	Follow-up	Main findings
Sinclair, 2018.[13]	Prospective observational study; women with FPHL	100	0.25 mg/day + spironolactone 25 mg/day	12 months	Reduced shedding and Sinclair score; generally mild adverse effects including postural symptoms and hypertrichosis
Rodrigues-Barata et al., 2020.[12]	Retrospective; women with FPHL	148	0.25-2 mg/day	>=6 months	Clinical improvement in most patients; hypertrichosis was the most frequent adverse effect
Ramos et al., 2020.[14]	Randomized comparative trial; women with FPHL	52	1 mg/day vs topical 5%	24 weeks	Oral and topical treatment produced broadly comparable improvement; hypertrichosis and pedal edema were reported
Vahabi-Amlashi et al., 2021.[23]	Triple-blind randomized trial; women with FPHL	72	0.25 mg/day vs topical 2%	9 months	Hair density and shaft diameter improved in both groups; between-group differences were not significant
Vano-Galvan et al., 2021.[16]	Multicenter retrospective safety cohort; mixed alopecias	1404	0.25-5 mg/day	Variable	Hypertrichosis was most common; systemic adverse events were uncommon and discontinuation was infrequent
Beach et al., 2021.[24]	Retrospective case series; mixed alopecias	74	1.25 mg nightly initially; some escalated to 2.5 mg/day	Mean 10 months	Among 51 patients with confirmed treatment, scalp hair growth and reduced shedding were reported; facial hypertrichosis and lightheadedness were the main tolerability issues

Nascimento e Silva et al., 2022.[25]	Randomized dose-comparison trial; women with FPHL	30	0.25 vs 1 mg/day	24 weeks	Greater response with 1 mg/day than 0.25 mg/day; hypertrichosis was more frequent at the higher dose
Jimenez-Cauhe et al., 2024.[18]	Multicenter retrospective study; hypertension/arrhythmia	264	<=5 mg/day	Variable	Systemic adverse effects were uncommon; 1.5% discontinued because of adverse effects
Asilian et al., 2024.[19]	Randomized comparative trial; mixed-sex androgenetic alopecia; no female FPHL subgroup reported	65	1 mg/day vs topical 5%	6 months	Sex-combined efficacy was excluded from the FPHL assessment; adverse-event findings were retained as indirect safety evidence

Risk of bias assessment

Randomized trials provided the strongest efficacy evidence but were limited by modest sample sizes, short follow-up, incomplete blinding in some studies, and variable outcome measurement. Observational studies were limited by retrospective designs, lack of controls, nonuniform dosing, concomitant therapy, and incomplete adjustment for confounding. These limitations reduced confidence in the magnitude and durability of the reported treatment effects.

Table 3: Study-level risk-of-bias assessment results

Study	Design / tool	Selection / random.	Confound. / dev.	Outcome / reporting	Overall	Principal basis
Sinclair, 2018.[13]	Prospective cohort / NOS	Some concerns	High	Some concerns	Moderate	Single-arm design; combination therapy; no control for confounding.
Rodrigues-Barata et al., 2020.[12]	Retrospective cohort / NOS	Some concerns	High	Some concerns	Moderate	Retrospective selection; nonuniform doses; no untreated comparator.
Ramos et al., 2020.[14]	Randomized trial / RoB 2	Low	Some concerns	Some concerns	Some concerns	Open-label comparison, modest sample, and short follow-up.
Vahabi-Amlashi et al., 2021.[23]	Randomized trial / RoB 2	Low	Low	Some concerns	Some concerns	Limited sample; uncertainty in completeness and consistency of outcome reporting.
Vano-Galvan et al., 2021.[16]	Retrospective cohort / NOS	Some concerns	High	Some concerns	Moderate	Mixed diagnoses and sex; variable dose/follow-up; safety-focused retrospective data.
Beach et al., 2021.[24]	Case series / JBI	High	High	Some concerns	High	Mixed alopecias; no comparator; incomplete follow-up; variable exposure duration.
Nascimento e Silva et al., 2022.[25]	Randomized trial / RoB 2	Low	Some concerns	Some concerns	Some concerns	Small dose-comparison trial with short follow-up.
Jimenez-Cauhe et al., 2024.[18]	Retrospective cohort / NOS	Some concerns	High	Some concerns	Moderate	Selected cardiovascular population; retrospective exposure-level analysis; variable dosing.
Asilian et al., 2024.[19]	Randomized trial / RoB 2	Some concerns	Some concerns	Some concerns	Some concerns	Mixed-sex AGA population; female FPHL outcomes not reported separately; indirect safety evidence only; modest sample and short follow-up.

Note: RoB 2, Cochrane Risk of Bias 2 tool; NOS, Newcastle-Ottawa Scale; JBI, Joanna Briggs Institute checklist. Domain labels are harmonized for display; design-specific tools were applied within their intended domains. Mixed-population studies, including Asilian et al., contributed indirect safety evidence only.

Efficacy

Across the five FPHL-specific studies, most reports described improved hair density or scalp coverage after at least 24 weeks. FPHL-specific comparative trials found broadly similar improvements with oral and topical minoxidil, without a consistent statistically significant between-group advantage. Hair-shaft diameter also improved from baseline with oral therapy. Limited dose-comparison evidence suggested greater efficacy with 1 mg/day than 0.25 mg/day, but with more hypertrichosis. The mixed-sex Asilian et al. trial did not report female FPHL efficacy outcomes separately and was excluded from this efficacy assessment; its adverse-event findings were retained as indirect safety evidence.

Reductions in shedding were generally observed within 3-6 months, whereas visible density improvement was more apparent after 6-12 months. Global photographic and patient-reported outcomes were generally favorable, although assessment was often unblinded or nonstandardized. Evidence that oral therapy improves adherence over topical treatment remains suggestive rather than conclusive.

Safety

Hypertrichosis was the most frequent adverse event and appeared dose related. In the multicenter cohort of 1,404 patients, it occurred in 15.1% and rarely caused withdrawal. Systemic adverse events were uncommon: lightheadedness 1.7%, fluid retention 1.3%, tachycardia 0.9%, headache 0.4%, periorbital edema 0.3%, and insomnia 0.2%.

In the multicenter study of 264 patients with hypertension or arrhythmia, systemic adverse effects were reported in 6.8% of analyzed treatment exposures and discontinuation occurred in 1.5%. Clinically important hypotension and serious cardiovascular events were not identified, but rare-event safety remains uncertain because most studies were retrospective and follow-up was limited.

Table 4: Summary of principal efficacy and safety findings

Outcome	Main finding	Interpretation
Hair density / scalp coverage	Most studies reported improvement after at least 24 weeks; oral and topical minoxidil produced broadly comparable results in comparative trials.	Suggests possible clinical benefit, but the magnitude is uncertain and superiority over topical therapy was not established.
Hair-shaft diameter	Improved from baseline in randomized comparative studies; no consistent between-group advantage over topical treatment.	Suggests treatment-associated improvement, but comparative certainty is limited.
Hair shedding / severity	Shedding generally improved within 3-6 months; visible density changes were clearer by 6-12 months.	Response may require sustained treatment.
Hypertrichosis	Most common adverse event; 15.1% in the 1,404-patient multicenter cohort and more frequent at higher doses.	Principal tolerability concern; usually mild and infrequently caused withdrawal.
Systemic adverse effects	Lightheadedness, fluid retention, tachycardia, headache, and edema were uncommon; discontinuation was low.	Generally favorable short-term safety, but rare and long-term cardiovascular risks remain uncertain.

DISCUSSION

The available evidence suggests that LDOM may improve hair density, shaft diameter, shedding, and clinical appearance in women with FPHL, although confidence in the magnitude and durability of benefit is limited. FPHL-specific comparative trials suggest broadly similar efficacy to topical minoxidil rather than clear superiority. Its main clinical advantage may therefore be convenience and acceptability for patients who cannot tolerate or consistently use topical formulations.

A possible dose-response relationship is suggested by better outcomes with 1 mg/day than 0.25 mg/day, but higher doses may also increase hypertrichosis. The optimal dose remains uncertain because direct comparisons are limited. Treatment should be individualized according to response, tolerability, baseline blood pressure, cardiovascular history, and concomitant medication.

Hypertrichosis is the principal tolerability concern and should be discussed before treatment. Edema, dizziness, tachycardia, and postural symptoms were less frequent and usually mild. Nevertheless, the absence of a serious safety signal should not be interpreted as proof of long-term cardiovascular safety, particularly in medically complex patients.

The evidence base has important limitations: small samples, heterogeneous doses and outcome definitions, short follow-up, retrospective designs, mixed alopecia populations, and concomitant antiandrogen therapy. These factors prevented quantitative pooling and reduce confidence in the estimated treatment effect. Future multicenter, double-blind randomized trials should compare standardized oral doses with topical minoxidil and placebo, use blinded objective outcomes and validated patient-reported measures, and follow participants for at least 12-24 months.

Clinically, LDOM may be considered as an off-label option for selected women with FPHL who have an inadequate response, intolerance, or difficulty adhering to topical minoxidil. Given the reported postural, fluid-retention, and heart-rate effects, treatment decisions should be individualized, with attention to blood pressure, pulse, edema, cardiovascular and renal history, pregnancy status, and concurrent antihypertensive therapy. Patients should be advised to report dizziness, palpitations, ankle swelling, or rapid weight gain.

Strengths and Limitations

Strengths include a broad database search, duplicate independent review, structured risk-of-bias assessment, and inclusion of both efficacy studies and large safety cohorts. Limitations include the absence of prospective protocol registration, restriction to English-language studies, heterogeneous designs and outcomes, indirect mixed-population safety evidence, lack of separately reported female FPHL efficacy outcomes in the Asilian et al. trial, and insufficiently comparable studies for meta-analysis. Formal outcome-specific certainty ratings could not be supported consistently from the available reporting.

CONCLUSION

Available low-certainty evidence suggests that LDOM may improve hair outcomes and is generally tolerated in selected women with FPHL. Its comparative efficacy versus topical minoxidil remains uncertain. Hypertrichosis is the most common adverse effect, while uncommon systemic events and long-term cardiovascular safety remain incompletely characterized. Treatment should therefore remain individualized and monitored, and adequately powered long-term randomized trials are needed before routine first-line use can be supported.

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