International Journal of Innovative Technologies in Social Science

e-ISSN: 2544-9435

Scholarly Publisher
RS Global Sp. z O.O.
ISNI: 0000 0004 8495 2390

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ARTICLE TITLE	EFFICACY AND SAFETY OF LOW-DOSE ORAL MINOXIDIL IN THE TREATMENT OF ANDROGENETIC ALOPECIA – A LITERATURE REVIEW
ARTICLE INFO	Filip Kieloch, Agnieszka Fitas, Karol Kanon, Mathias Spitaleri, Wiktor Gąska, Oskar Sienkiel, Julia Głowacka, Wojciech Gąska, Dawid Sewruk, Karolina Dębek-Kalinowska. (2025) Efficacy and Safety of Low-Dose Oral Minoxidil in The Treatment of Androgenetic Alopecia – A Literature Review. *International Journal of Innovative Technologies in Social Science*. 3(47). doi: 10.31435/ijitss.3(47).2025.3656
DOI	https://doi.org/10.31435/ijitss.3(47).2025.3656
RECEIVED	27 July 2025
ACCEPTED	30 August 2025
PUBLISHED	08 September 2025
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EFFICACY AND SAFETY OF LOW-DOSE ORAL MINOXIDIL IN THE TREATMENT OF ANDROGENETIC ALOPECIA – A LITERATURE REVIEW

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ABSTRACT

Introduction: Androgenetic alopecia (AGA) is a chronic progressive form of hair loss affecting a significant portion of the adult population. Although topical minoxidil has a proven efficacy, it is often associated with low adherence due to adverse effects and the inconvenience of use. Increasing attention is being paid to low-dose oral minoxidil (LDOM), which may represent a therapeutic alternative with a favorable safety profile.
Purpose of The Work: The aim of this study was to assess the efficacy and safety of low-dose oral minoxidil (≤5 mg/day) in the treatment of androgenetic alopecia based on current clinical trial data.
Material and Methods: A narrative literature review was conducted, including studies published in English between 2019 and 2024, concerning the efficacy and safety in patients with AGA. A total of 9 publications meeting the inclusion criteria were analyzed.
Results: The analyzed studies demonstrated that LDOM increases both the number and diameter of hair in patients – in both men and women. The best results were observed at doses of 1-5 mg/day, although even very low doses (0.25 mg/day) yielded measurable effects. Adverse events were generally mild – most commonly hypertrichosis and cardiovascular symptoms (e.g., tachycardia), with incidence increasing with dose. Serious complications were rare and occurred primarily in patients with pre-existing heart disease.
Conclusion: Low-dose oral minoxidil is an effective and well-tolerated treatment option for AGA. Further studies are needed to standarize dosing and assess the long-term safety of the therapy.

KEYWORDS

Oral Minoxidil, Low-Dose Oral Minoxidil, Androgenetic Alopecia, AGA Treatment, Minoxidil Side Effects

CITATION

Filip Kieloch, Agnieszka Fitas, Karol Kanon, Mathias Spitaleri, Wiktor Gąska, Oskar Sienkiel, Julia Głowacka, Wojciech Gąska, Dawid Sewruk, Karolina Dębek-Kalinowska. (2025) Efficacy and Safety of Low-Dose Oral Minoxidil in The Treatment of Androgenetic Alopecia – A Literature Review. *International Journal of Innovative Technologies in Social Science*. 3(47). doi: 10.31435/ijitss.3(47).2025.3656

Introduction.

Androgenetic alopecia is the most common form of hair loss in adults, characterized by the gradual atrophy and miniaturiaztion of hair follicles in specific areas of the scalp. In men, the changes are mainly located in the frontoparietal and vertex regions, whereas in women, thinning typically occurs in the central frontoparietal area. It is estimated to affect approximately half of the male population and 40% of women throughout their lifetime [1, 2]. Although the disease does not pose a threat to physical health, its psychological impact is considerable, leading to decreased self-esteem, increased psychological stress and a heightened risk of depressive disorders [3].

Minoxidil, originally used as an antihypertensive drug, was discovered to stimulate hair growth. Its exact mechanism of action in the treatment of alopecia is not fully elucidated; however, it is known to dilate blood vessels, thereby improving follicular perfusion and prolonging the anagen phase, which supports hair regeneration [4, 5].

Despite the widespread use of topical minoxidil, patients frequently encounter issues such as the need for daily application, unpleasant odor of the formulation, and skin irritation. These factors negatively affect treatment adherence and overall efficacy [6]. Consequently, low-dose oral minoxidil (LDOM) is gaining increasing popularity, offering greater convenience for patients. The doses of LDOM used in AGA treatment are significantly lower than those used for hypertension, which substantially reduces the risk of adverse effects [7]. The most frequently reported side effects of LDOM include mild hypertrichosis, slight lower limb edema, and tachycardia [8, 9]

Despite the growing popularity of low-dose oral minoxidil, further research is required to confirm its safety and efficacy, determine optimal dosing regimens, and establish clear treatment indications.

The objective of this paper is to review the available scientific literature on the efficacy and safety of low-dose oral minoxidil in patients with androgenetic alopecia.

State of Knowledge

The pathomechanism of androgenetic alopecia is associated with the action of dihydrotestosterone (DHT) which binds to androgen in the hair follicle, initiating the process of follicular miniaturization. This results in a shortened anagen (growth) phase and a gradual transition of follicles into the telogen (resting) phase, leading to the development of thin, short hair and its eventual loss [10].

The treatment of androgenetic alopecia is based on various strategies aimed at inhibiting follicular miniaturization. Pharmacological agents – both topical and systemic – as well as procedural methods are used. In addition to minoxidil, which remains the first-line agent in the treatment of AGA and whose mechanism of action is discussed below, the following are commonly used:

Finasteride, a type II 5-α-reductase inhibitor, reduces dihydrotestosterone levels and effectively halts AGA progression in men [11]. An alternative, particularly in more resistant cases, is dutasteride – a drug with a broader mechanism of action [12].

In women, especially those with signs of hyperandrogenism, antiandrogens such as spironolactone or cyproterone acetate are utilized [13].

Adjuvant therapies include platelet-rich plasma (PRP), mesotherapy and microneedling, which stimulate follicular regeneration and hair growth [14]. In advanced cases**,** hair transplantation using the FUE technique proves to be an effective method [15].

Promising but still experimental approaches include cell-based therapies, modulators of the Wnt/β-catenin signaling pathway, and prostaglandin inhibitors [16, 17].

Minoxidil acts primarily as an activator of ATP-sensitive potassium channels (KATP channels), which leads to vasodilation and improved microcirculation in the scalp. This action results in enhanced delivery of nutrients to hair follicles [18, 19]. Consequently, it is possible to extend the anagen phase and delay the transition into the telogen phase, which positively affects hair number and quality [20].

Studies have shown that minoxidil exerts a stymulatory effect on dermal papilla cells, promoting the production of vascular endothelial growth factor (VEGF), a key molecule in angiogenesis and follicular nourishment [21]. The increased vascularization surrounding the follicle enhances its activity and regeneration.

Additionally, minoxidil demonstrates mitogenic activity – stimulating the proliferation of keratinocytes and fibroblasts within the hair follicle, which may contribute to thickening and lengthening of the hair shaft [22, 23]. There is also evidence that the minoxidil modulates prostaglandin activity – increasing PGE2 levels and inhibiting PGD2 – which may be relevant in the pathophysiology of androgenetic alopecia [24].

It is important to note that minoxidil is a prodrug, activated by the enzyme sulfotransferase (SULT1A1) in the epidermis, which converts it into minoxidil sulfate, the pharmacologically active form. Therefore, individual differences in SULT1A1 activity may explain the variable response to treatment among patients [25].

Material and Methods

The objective of this study was to conduct a narrative literature review focusing on the assessment of efficacy and safety of low-dose oral minoxidil in the treatment of androgenetic alopecia.

Review included clinical trials and systematic reviews on the use of oral minoxidil at doses ≤5 mg/day for the treatment of androgenetic alopecia in adults, published in English between 2019 and 2024. Excluded were studies addressing other types of alopecia, topical minoxidil use only, studies lacking data on dosage or efficacy, as well as case reports, commentaries, and publications without full-text access.

The literature review was conducted using major medical databases such as PubMed, Scopus and Google Scholar. The search strategy was based on combinations of the following keywords: oral minoxidil; low-dose minoxidil; androgenetic alopecia; male pattern baldness; female pattern hair loss; efficacy; safety and adverse effects.

Nine articles were analyzed based on compliance with the established inclusion criteria. The selected publications were assessed in full-text with regard to dosage, efficacy and safety of oral minoxidil at doses ≤5 mg/day. Data were collected on study participants, dosing regimens, treatment duration, outcomes and adverse effects. The analysis included studies of various designs, which allowed for a comprehensive discussion of the topic.

Results

The statistical results presented in this review are directly extracted from cited studies and were not independently analyzed or pooled by the authors.

Efficacy

In the study by Panchaprateep and Lueangarun (2020) involving 30 men with androgenetic alopecia, a dose of 5 mg of oral minoxidil per day was administered. After 12 weeks of treatment, an average increase of 26.4 hair/cm² was observed, and after 24 weeks – 35.1 hair/cm². The average hair diameter increased from 58.5 μm to 62.8 μm, which was also statistically significant. Global photographic assessment revealed improvement in all participants – 43% of patients achieved the maximum efficacy rating (+3), corresponding to a 75-100% increase in hair count [26].

In a randomized clinical trial by Penha et al. (2024), the efficacy of oral minoxidil 5mg once daily was compared with 5% topical minoxidil twice daily among 90 men with androgenetic alopecia. A total of 68 patients completed the full 24-week treatment cycle. After 24 weeks, the oral minoxidil group demonstrated an average increase in terminal hair count at the vertex area of 23.4 hair/cm², although this did not reach statistical significance (p=0.09). The total hair count increase in this area was 5.5 hair/cm² (p=0.32). In the frontal area, the increase in terminal hair count was 3.1 hair/cm² (p=0.27), and in total hair count – 2.6 hair/cm² (p=0.32). Photographic analysis indicated that oral minoxidil outperformed topical minoxidil in vertex improvement (24% vs 12%), but not in frontal region [27].

In a retrospective study by Jimenez-Cauhe et al. (2019) involving 16 men with androgenetic alopecia, oral minoxidil was administered at 5 mg/day in 15 patients and 2, 5 mg/day in one patient, as monotherapy. After3 months of treatment, hair growth improvement was noted in 12 patients (75%), including significant improvement in 6 individuals (37.5%), Efficacy was assessed using the Norwood-Hamilton scale and photographic analysis [28].

In a randomized study by Nascimento E Silva et al. (2022) involving 30 women with female pattern hair loss (FPHL), the efficacy of oral minoxidil at doses of 0.25 mg and 1 mg daily over 24 weeks was compared. After this period, a mean increase of 20.1 hair/cm² was noted in the 0.25mg group and 27 hair/cm² in the 1 mg group. This difference indicated slightly higher efficacy with the higher dose, although the study did not demonstrate statistically significant differences between the groups [29].

In the study by Vahabi-Amlashi et al. (2021), the efficacy of oral minoxidil at 0.25mg/day was compared with topical 2% minoxidil applied twice daily in 72 women with FPHL. After 9 months of therapy, the oral group showed an increase in mean hair diameter from 0.044 mm to 0.048 mm and in hair density from 102 to 115 hair/cm². The differences between the oral and topical groups were not statistically significant [30].

A randomized comparative trial evaluated the efficacy of oral minoxidil at 1 mg/day for 24 weeks among 25 women with FPHL. After 24 weeks, the total hair count increased from 164.6 to 184.7 hair/cm², while terminal hair count rose from 106.5 to 112.6 hair/cm² [31].

In a retrospective study by Vastarella et al. (2020) involving women with FPHL, oral minoxidil was administered at 1.25 mg/day for 24 weeks. After the treatment period, results showed an increase in hair density in the frontal area (by 38%) and in the vertex area (by 23%) [32].

- In the study by Pirmez and Salas Callo (2020), the efficacy of a very low dose of oral minoxidil (0.25 mg/day) was evaluated in 25 men with androgenetic alopecia aged 23-52 years, observed over 24 weeks. Results were assessed using quantitative trichoscopy. After treatment, the authors reported a statistically significant increase in total hair count per cm² in both the frontal region(from 104.7 ± 25.6 to 117.1 ± 25.9; p < 0, 01) and the vertex region (from 143.5 ± 28.1 to 154 ± 27.5; p = 0.02). A significant increase in terminal hair count in the frontal area was also observed (from 52.7 ± 20.8 to 59.9 ± 20.5; p = 0.01). In both regions, the number of new hair (combined vellus and terminal) significantly increased: from 52.0 ± 17.9 to 57.2 ± 18.5 (p=0.03) in the frontal area and from 52.0 ± 17.1 to 58.8 ± 16.5 (p < 0.01) in the vertex area [33].

Safety

This review confirmed that oral minoxidil is well tolerated, and the literature describes only mild adverse effects, with frequency depending on dosage. In clinical studies of men receiving 5 mg/day, the most common adverse effects were excessive body hair (hypertrichosis) – 15.6%, headaches (6.3%), and dizziness (3.1%), with no serious cardiovascular complications reported [26]. At lower doses (e.g., 0, 25 – 1 mg/day), adverse effects were less frequent – hypertrichosis occurred in 4.8% of patients, and cardiac symptoms (palpitations, tachycardia) in 1.6% [28, 33]. Among women using 1 mg/day, the most frequently reported side effect was increased facial hair (12.5%), whereas with 0.25 mg/day, the incidence was 4.3% [29, 30]. Rare cases (<1%) of peripheral edema and hypotension were reported, though these rarely required discontinuation of treatment [31, 32]. The most serious potential complication is pericardial effusion, observed in only 0.5% of patients at doses ≤5 mg/day, primarily among those with pre-existing heart disease [34].

Conclusions

Low-dose oral minoxidil (LDOM) is gaining increasing recognition as an effective and well-tolerated treatment modality for androgenetic alopecia, offering an alternative to topical preparations. A review of the available clinical studies indicates that LDOM at doses ≤5 mg/day, in both women and men, can lead to a significant increase in hair count and diameter, as well as improvement in patients' subjective evaluation of treatment outcomes. The highest efficacy was observed at doses of 1-5 mg/day, although even very low doses (e.g., 0.25 mg/day) demonstrated a beneficial effect on hair growth, which may be relevant for patients particularly sensitive to adverse effects.

The safety profile of LDOM, as assessed in the analyzed studies, appears favorable. The most frequently reported adverse events were hypertrichosis, mild cardiovascular symptoms (palpitations, tachycardia), lower limb edema, as well as headaches and dizziness. Most of these effects were transient and did not necessitate discontinuation of treatment. Serious complications, such as pericardial effusion, were extremely rare and occurred primarily in patients with pre-existing cardiovascular conditions. Therefore, careful patient selection and monitoring of potential adverse effects – especially in individuals with cardiac disease – are recommended.

In light of the current data, LDOM can be considered an effective and relatively safe solution for the treatment of AGA, with the potential to significantly improve patients' quality of life through easier administration and satisfactory aesthetic results. Nevertheless, further multicenter, randomized clinical trials with larger patient cohorts and longer follow-up periods are necessary. Such studies will enable the standardization of treatment regimens, determination of optimal doses according to sex and disease severity, and a better understanding of the long-term safety profile of this therapeutic approach.

Disclosure

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Conflict of interest: The authors report no conflict of interest
Financial disclosure: The study did not receive any funding
Institutional Review Board Statement: Not applicable
Informed Consent Statement: Not applicable
Data Availability Statement: Not applicable

All authors have read and agreed with the published version of the manuscript

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