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Low-dose oral minoxidil as treatment for non-scarring alopecia: a systematic review

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Abstract

Background Topical minoxidil has been used for almost 40 years to treat alopecia. There is growing evidence supporting off-label use of low-dose oral minoxidil.

Objective To conduct a systematic review evaluating the use of oral minoxidil for all types of alopecia.

Methods A primary literature search was conducted using PubMed in May 2019, utilizing the search term "oral minoxidil AND (hair loss OR alopecia OR baldness)". Reviews, non-English studies, and articles concerning only topical minoxidil were excluded.

Results Ten articles were included for review comprising a total 19,218 patients (215 women and 19,003 men). Oral minoxidil dose ranged from 0.25 to 5 mg daily to twice daily. The strongest evidence existed for androgenetic alopecia and alopecia areata (AA), with 61–100% and 18–82.4% of patients demonstrating objective clinical improvement. Successful treatment of female pattern hair loss, chronic telogen effluvium, monilethrix, and permanent chemotherapy-induced alopecia was also reported. The most common adverse effects with oral minoxidil included hypertrichosis and postural hypotension.

Conclusion Oral minoxidil is a safe and successful treatment of androgenic alopecia and AA. In addition to its therapeutic benefits, practical advantages over topical minoxidil stem from improved patient compliance.

Introduction

Minoxidil was first developed for treatment of hypertension with approximately 20% of patients experiencing hypertrichosis as an unexpected adverse event. It was approved in 1988 after topical formulations were tested for hair loss.[1] Topical minoxidil has now become a staple for hair loss treatment, demonstrating success in non-scarring alopecias.[2,3] While topical minoxidil displays a dose-dependent hair regrowth response, its exact mechanism of action is still not completely understood.[4] Vasodilatory effects are propagated by upregulation of vascular endothelial growth factor (VEGF), increasing cutaneous blood flow with resultant increase in oxygen and growth factor delivery to the hair follicle.[5,6] In addition, minoxidil leads to hair follicle potassium channel activation, prolonging the hair cycle anagen and shortening the telogen phase. Minoxidil may also have immunomodulatory effects by moderating concanavalin A (Con A), an intermediary in the T lymphocyte activation process, causing suppression of T-cells and possible effectiveness in autoimmune alopecias.[7] It is uncertain whether minoxidil can completely reverse follicle miniaturization, with only some studies comparing scalp biopsies pre- and post-treatment demonstrating clinical reversal.[8] Androgenetic alopecia (AGA) patients are commonly encouraged to utilize 5-alpha reductase inhibitors in combination with minoxidil in order to prevent persistent balding because of progressive miniaturization.

Topical minoxidil use has several practical challenges of repeated application, vehicle consistency, cosmetic drawbacks, financial implications, and limited percutaneous absorption. In an effort to improve outcomes and increase patient therapeutic compliance, low-dose oral minoxidil has been used off-label with hopes to achieve higher systemic drug levels and greater clinical efficacy.[9] This systematic review investigates scientific evidence on the use of oral minoxidil in the treatment of different types of alopecia.

Materials and methods

In accordance with PRISMA guidelines, a PubMed database search was performed in May 2019 with the search terms: "oral minoxidil AND (hair loss OR alopecia OR baldness)". Title name and abstract contents were used to screen articles. Inclusion criteria were manuscripts describing the use of oral minoxidil for the treatment of alopecia in human subjects. One

hundred eight studies were excluded for meeting any of the following criteria: studies published solely in a language other than English, animal studies, review articles, and studies that did not specifically reference the oral form of minoxidil (Fig. 1). Articles were assessed based on "Levels of Evidence" developed by the Oxford Centre for Evidence-Based Medicine.

Results

The search yielded 117 unduplicated results, with 10 articles included for final review. A total of 19,218 patients with alopecia (215 women, 19,003 men) were included across four prospective studies, three retrospective studies, and three case reports (Table 1).

Oral minoxidil therapy has been studied in a variety of alopecic types including male and female AGA in four studies (n = 19,079), alopecia areata (AA) in two studies (n = 99), chronic telogen effluvium (CTE) in one study (n = 36), monilethrix in one study (n = 2), chemotherapy-induced alopecia (CIA) in one study (n = 1), and loose anagen hair syndrome (LAHS) in one study (n = 1).

Androgenetic alopecia

The use of oral minoxidil was most widely reported for treatment of AGA, with a total 19,079 patients. The largest prospective cohort study was conducted in Asia and spanned several years, involving 18,918 male AGA patients (mean age 32 years) all treated with the same combination therapy of 1 mg oral finasteride daily, 5% topical minoxidil twice daily, 2.5 mg oral minoxidil twice daily, and 4 ml of a diluted injectable solution (minoxidil, arginine, aspartic acid, caffeine, copper tripeptide, lysine, niacin, panthenol, propanediol, propylene glycol, retinyl palmitate, pyridoxine, sodium hyaluronate, and ubiquinone) once monthly for 6 months. After 6 and 12 months post-treatment, 96 and 80% of patients were satisfied, respectively, with digital photographs demonstrating significant qualitative clinical improvement in all patients. Minor complications were observed in 4.2% of patients, with 651 (3.4%) experiencing pain at the injection site and 56 (0.3%) slight bleeding because of the injection procedure, as well as 42 (0.22%) demonstrating swelling or dizziness because of oral minoxidil, or itching or erythema from topical minoxidil. Sexual dysfunction was reported in 14 (0.07%).[10]

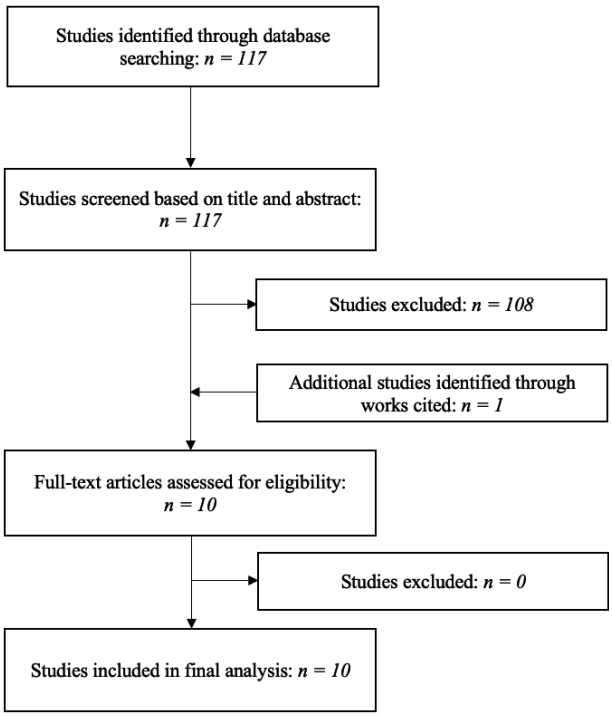

Figure 1 Flow chart depicting PRISMA search for studies using oral minoxidil for the treatment of alopecia

The most recent study on men with AGA was a retrospective study of 41 patients (mean age 33.3 years) and demonstrated clinical improvement using either 2.5 or 5 mg oral minoxidil daily for at least 6 months. Marked improvement (an increase in one or more points on the Norwood-Hamilton scale) occurred in 11 (26.8%) patients. General clinical improvement was noted in 37 patients (90.2%), and the remaining four (9.8%) patients had stabilization of their disease with no worsening.[11] Another retrospective study of 20 subjects (18 women, 2 men; mean age 41 years) were diagnosed with AGA, traction alopecia, or both. Subjects were prescribed 1.25 mg oral minoxidil daily with six (33%) of the 18 patients reporting decreased hair shedding and five (28%) with increased scalp hair. Hypertrichosis was noted in seven (39%) patients but did not discourage subjects from continuing treatment.[12]

In one study of 100 female patients (mean age 48.4 years) with an average AGA diagnosis duration of 6.5 years, 0.25 mg oral minoxidil and 25 mg spironolactone were prescribed daily. Patients with hypotension (number unspecified) were also given 50 mg oral sodium chloride in an effort to attenuate the synergistic effects of minoxidil and spironolactone. Three to 6 weeks after starting treatment, increased hair shedding was seen in 26 patients, with most self-resolving 4 weeks later; only two cases displayed persistent shedding for more than 12 weeks. Hair loss severity score (HLSS) and hair shedding score (HSS) were assessed at 3, 6, 9, and 12 months after the start of treatment with a mean reduction in HSS of 1.1, 2.3, 2.7, and 2.6, respectively. A mean decrease in HLSS of 0.1, 0.85, 1.1, and 1.3 was observed at the same follow-up intervals. Six patients experienced adverse effects related to minoxidil, including four with facial hypertrichosis and two with postural hypotension.[13]

Alopecia areata

From the published literature, 133 patients with AA treated with oral minoxidil have been studied. One prospective study described 65 patients (38 women, 27 men; mean age 31 years) with an average diagnosis duration of 5.9 years. At baseline, 44

Table 1 Summary of studies in human subjects using oral minoxidil for the treatment of non-scarring alopecia

Author (year)	Study Type (level of evidence)	Patients (*N* = 19218)	Alopecia Diagnosis	Treatment	Results	Major Adverse Effects
Jimenez-Cauhe et al (2019)	Retrospective (III)	41 M (mean age 33.3; range 20–55)	AGA	2.5 (*n* = 10) or 5 mg (*n* = 31) oral minoxidil for ≥6 months	37 pt (90.2%) displayed significant improvement	Hypertrichosis: 10/41 (24.3%) Lower leg edema: 2/41 (4.8%)
Cranwell and Sinclair (2018)	Case Report (IV)	1 F (age 11) Initial failed trial of topical minoxidil	LAHS	0.5 mg oral minoxidil per day, with half dose reduction every 2 weeks for 12 months	All pt (100%) with improved shedding and hair density within 3 months	None
Beach (2018)	Retrospective (III)	20 (18 F, 2 M; mean age 41.0 years)	AGA, traction alopecia	1.25 mg oral minoxidil daily	6 pt (33%) with decreased hair shedding 5 pt (28%) with increased scalp hair	Noncompliance in M pt (*n* = 2, 10%) Hypertrichosis in F pt (*n* = 7, 39%)
Tanaka et al (2018)	Prospective (II)	18,918 M (mean age 32; range 18–81)	AGA	1 mg oral finasteride + 2.5 mg oral minoxidil + 5% topical minoxidil twice a day 4 ml injectable solution given once per month for 6 months	96% pt satisfied at 6 months 80% pt satisfied at 12 months (satisfaction ranked on 4-point scale, with 2–4 points = satisfied)	Minor complications: 802/18,918 (4.2%) Pain at injection site: 651/18,918 (3.4%) Bleeding: 56/18,918 (0.3%), Swelling: 42/18,918 (0.22%) Dizziness: 28/18,918 (0.15%) Itching: 7/18,918 (0.04%) Erythema 4/18,918 (0.02%) Sexual dysfunction: 14/18,918 (0.07%) All adverse effects spontaneously resolved
Perera and Sinclair (2017)	Retrospective (III)	36 F (mean age 46.9; range 20–83)	CTE	0.25–2.5 mg oral minoxidil per day for 6 months	Reduction in mean HSS of 1.7 ($P < 0.001$) for first 6 months Reduction in mean HSS of 2.58 ($P < 0.001$) for first 12 months Mean change in HSS was higher in pt with previous 5% topical minoxidil (11 patients, 30.5%)	Postural hypotension: 2/36 (5.5%). Mean change in blood pressure was −0.5 mmHg systolic and +2.1 mmHg diastolic Ankle edema: 1/36 (2.7%) Facial hypertrichosis: 14/36 (39%). Treated with waxing and laser therapy
Sinclair (2017)	Prospective (II)	100 F (mean age 48.44 years; range: 18–80 years)	AGA	0.25 mg oral minoxidil + 25 mg oral spironolactone daily	Mean decrease in HLSS 0.1 at 3 months, 0.85 at 6 months, 1.1 at 9 months, and 1.3 at 12 months Mean decrease in HSS 1.1 at 3 months, 2.3 at 6 months, 2.7 at 9 months, and 2.6 at 12 months	Postural hypotension (*n* = 2, 2%) Facial hypertrichosis (*n* = 4, 4%)
Sinclair (2016)	Case Series (IV)	2 F (ages 40, 35)	Monilethrix	0.25 mg oral minoxidil per day	Pt 1: Significant hair regrowth, reduced breakage, increased	None

Table 1 Continued

Author (year)	Study Type (level of evidence)	Patients (N = 19218)	Alopecia Diagnosis	Treatment	Results	Major Adverse Effects
					volume and length at 6 months Pt 2: Decreased shedding after 3 months. Dose increased to 0.5 mg at 6 months, after which showed significant improvement in density	
Yang and Thai (2016)	Case Report (IV)	1 F (age 39) Initial failed trial of topical minoxidil after postchemotherapy impaired regrowth 6+ months after stopping treatment	PCIA	1 mg oral minoxidil per day for 1 year	All pt (100%) with subjective increase in hair growth at 6 weeks and 1 year, mostly in frontal and parietal areas	None
Fiedler (1988)	Prospective (II)	34 (19 F, 15 M; mean age 31.1; range 17–52) Initial failed trial of topical minoxidil	AA	5 mg oral minoxidil twice per day for 6 months	28 pt (82.4%) showed terminal hair regrowth 6 pt (17.6%) showed no response	No systemic immunosuppression
Fiedler-Weiss et al (1987)	Prospective (II)	65 (38 F, 27 M; mean age 31.0; range 13–55)	AA	5 mg oral minoxidil twice per day	52 pt (80%) with evidence of positive response 12 pt (18%) with cosmetically meaningful response	Facial hypertrichosis: 11/65 (17%)

F, female; M, male; pt, patient; FPHL, female pattern hair loss; AA, alopecia areata; CTE, chronic telogen effluvium; PCIA, permanent chemotherapy induced alopecia; LAHS, loose anagen hair syndrome; AGA, androgenetic alopecia; HLSS, hair loss severity scale; HSS, hair shedding score.

(68%) experienced 75–100% scalp hair loss, while 19 (29%) experienced 25–74%, and two (3%) experienced 0–24%. Patients were treated with 5 mg oral minoxidil twice daily. In an effort to mitigate cardiovascular effects, patients were counseled to limit sodium intake to 2 g daily. In subjects with greater than 75% hair loss, clinical response was seen in 21 (100%), while in subjects with less than or equal to 74% loss, improvement was seen in 31 (70%). Though hair regrowth occurred in 52 (80%) subjects, only 18% had a cosmetically meaningful response. The mean time to therapeutic response was 9.3 weeks and did not correlate with disease duration. Ultimately, 50.7% of patients discontinued treatment because of lack of efficacy or for undisclosed reasons. Adverse events of a 10 mg daily dose included fluid retention in the setting of diet nonadherence, lethargy, depression, palpitations after ingestion of caffeine, alcohol, or decongestants, and facial hypertrichosis in 17% of subjects.[9]

In an open-label study, 34 patients (19 women, 15 men; mean age 31.1 years) with severe AA and no response during the study period to 5% topical minoxidil were treated with 5 mg oral minoxidil twice daily. Clinically, 28 patients (82.4%) demonstrated terminal hair regrowth 6 months after oral therapy initiation, while six patients (17.6%) had no response. Microscopically, T-cell assays 12 months after topical minoxidil initiation and 6 months after oral minoxidil initiation demonstrated similar T-cell suppression with both forms of treatment. Differences, however, were apparent between responders and nonresponders, with responders showing evidence of lymphocyte suppression. The authors concluded that treatment response is likely associated with normalization of T-cell function, rather than suppression of T-cell function.[14]

Chronic telogen effluvium

One retrospective study utilized 0.25–5 mg of oral minoxidil daily for 6 months for the treatment of CTE in 36 women (mean age 46.9 years) with a diagnosis duration of 6.55 years. After treatment, mean HSS significantly improved in 31 subjects (86.1%) from a baseline of 5.64 to 3.90 at 6 months, and to 3.05 at 12 months ($P < 0.001$). HSS scores remained the same in four subjects, and one experienced an increase at 6 months

followed by a decrease at 12 months. Duration of disease and previous history of topical minoxidil demonstrated weak correlations with HSS scores ($R^2 < 0.22$ and 0.11 at 6 and 12 months, respectively). Median change in blood pressure was insignificant with a change of −0.5 mmHg systolic and +2.1 mmHg diastolic, with complications including facial hypertrichosis ($n = 14$), transient, self-resolving postural dizziness ($n = 2$), and ankle edema ($n = 1$).[15]

Monilethrix

A case series described two patients with monilethrix treated with 0.25 mg oral minoxidil daily. The first, a 40-year-old woman, demonstrated significant hair regrowth with increased volume and length at 6 months. The second patient, a 35-year-old woman, experienced only a decrease in shedding without change in hair density after 3 months. Her dose was then increased to 0.5 mg daily, and 6 months later she responded with significant improvement in hair density. No adverse effects were reported.[16]

Chemotherapy-induced alopecia

A case report on the use of 1 mg oral minoxidil daily for 1 year described a 35-year-old woman with a 6-month duration of CIA who had no clinical response to topical minoxidil. A subjective increase in hair growth was noted at 6 weeks and clinically significant regrowth after 1 year (primarily in frontal and parietal areas). Increased numbers of follicles were present, with a decrease in telogen follicles and a reversal of follicle miniaturization 2 years after treatment initiation.[8]

Loose anagen hair syndrome

Another case report described the use of oral minoxidil in an 11-year-old girl with LAHS previously treated with 5% topical minoxidil for 18 months. Topical minoxidil minimally increased hair volume and decreased shedding, and resulted in uneven hair regrowth. Three months after initiation of 0.5 mg oral minoxidil daily, hair shedding patterns evened, hair density increased, and hair color darkened. Oral minoxidil was tapered with a half dose reduction every 2 weeks and fully discontinued after 12 months with syndrome remission. No adverse effects were reported.[17]

Discussion

As a result of the profound physical and psychological consequences of untreated alopecia, better hair loss therapies are needed.[18] Many systemic treatments, such as oral finasteride or spironolactone, are inappropriate choices for some patient populations, such as women of child-bearing potential. Low-dose oral minoxidil is a therapy making its way to the forefront of alopecia treatment, propelled by its minimal side effect profile and ability to be prescribed to almost all patients.

Low-dose oral minoxidil was used safely and effectively in various non-scarring alopecia diagnoses, with dosing regimens ranging from 0.25 to 5 mg daily to twice daily. In general, women required lower doses for maximal effectiveness (0.25–5 mg) compared to men (1.25–5.0 mg). In the AGA studies completed in men, 61–100% of patients treated with oral minoxidil demonstrated objective clinical improvement, with decreased hair shedding and increased hair density and length. Combination therapies employing oral finasteride and oral minoxidil may achieve superior results over minoxidil alone.[10] In AA, oral minoxidil has been used to treat cases refractory to topical 5% minoxidil, with 18–82.4% of patients responding to 5 mg twice daily as evidenced by increased terminal hair regrowth.[9] Use of oral minoxidil to treat CIA, LAHS, and monilethrix is limited to few case reports with reported success in hair growth and improvement of diagnosis.

Serious adverse effects have seldom been published in the literature. One case report described a 50-year-old man with chronic renal failure who developed Stevens-Johnson syndrome after minoxidil initiation, which resolved after cessation of the offending drug.[19] In a similar case report, a 69-year-old woman developed toxic epidermal necrolysis and subsequently died from complications of the condition.[20] In both cases, the use of oral minoxidil was indicated primarily for treatment of hypertension, not hair loss. Consequently, these patients had significant comorbidities less likely to be seen in the general dermatology patient population.

Contraindications to oral minoxidil are limited, though precautions should be taken in several situations. Current contraindications include drug hypersensitivity and history of pheochromocytoma. Given its utility as an antihypertensive, the development of sinus tachycardia, pericarditis, or pericardial effusion must always be considered. Since minoxidil is renally cleared, patients with renal failure or dialysis may require smaller doses, but those with severe hepatic impairment should be monitored closely as well.[21]

The clinical decision to choose oral over topical therapy is multifactorial. A recent editorial outlined the "5 C's of oral minoxidil": convenience, cosmesis, cost-savings, cotherapy, and compliance.[12] Situations to consider are in patients with severe hair loss with a surface area too large for topical coverage alone, multiple topical regimens used, or difficult synchronization with bathing and activity schedules.[12] Therapeutic compliance may be more readily achieved with a daily systemic medication compared to topical therapy.[12] We propose a 6th C regarding the use of oral minoxidil: complicated. Oral minoxidil has proved valuable in treating complicated, refractory cases of alopecia, providing clinically significant hair regrowth in patients who have failed first-line therapy.[8,17]

Although low-dose oral minoxidil appears to be safe with minimal adverse events, systemic effects such as generalized hypertrichosis can be unwanted. When prescribed in combination with other medications that could affect blood pressure, such as spironolactone, it is important to ensure that the patient's baseline blood pressure is within normal limits and

counsel patients regarding the risk of postural hypotension. However, monitoring routine lab values during treatment is not generally recommended. In essence, there is a welcomed role for oral minoxidil in the treatment of alopecia, one that takes full advantage of its medical and practical benefits.

Limitations of this systematic review include low sample size and nonstandardized, subjective reporting of clinical efficacy. Only one large cohort study has been conducted assessing the success of oral minoxidil therapy, with other studies ranging from cases to small prospective or retrospective reports. Although the published results are overwhelmingly positive, further studies using standardized methods of measuring clinical hair regrowth, such as quantitative trichoscopy, will need to be completed to reliably determine oral minoxidil's therapeutic effect in various alopecias. A better understanding of long-term adverse events and duration of therapy are needed to provide generalizable conclusions used to help counsel patients.

Conclusion

There is a growing interest in the use of low-dose oral minoxidil for the treatment of alopecia. Evidence supports that it is an effective treatment in patients with non-scarring alopecia including AGA, CTE, AA, CIA, LAHS, and monilethrix, with cosmetically meaningful results observed in a significant portion of patients. Systemic effects are minimal, with patients most commonly reporting either facial or generalized hypertrichosis. Blood pressure effects were minimal at the 0.25–5 mg daily to twice daily regimens used to treat alopecia. In addition to its therapeutic benefits, practical advantages of oral minoxidil include improved convenience, comfort, cost, and compliance. Though additional studies in the form of large-scale, randomized clinical trials are needed, this systematic review supports the role of low-dose oral minoxidil in treating non-scarring alopecia.

Review questions (answers provided after references)

1 Minoxidil was first developed for the treatment of what condition?
- a Rosacea
- b Hypertension
- c Erectile dysfunction
- d Alopecia

2 True/False: The exact mechanism of minoxidil is still not completely understood.

3 Oral minoxidil was used safely and effectively in non-scarring alopecias with what dosing regimen?
- a 0.25–5 mg twice daily
- b 5–10 mg twice daily
- c 0.25–5 mg thrice daily
- d 5–10 mg thrice daily

4 True/False: Women required higher doses for maximal effectiveness compared to men.

5 Patients with AGA are commonly encouraged to utilize which agent in combination with minoxidil?
- a Platelet-rich plasma
- b Light therapy
- c Camouflaging agents
- d 5-alpha reductase inhibitors

6 True/False: Low-dose oral minoxidil for the treatment of hair loss is considered an off-label use.

7 Which of the following conditions is a contraindication to minoxidil?
- a Pheochromocytoma
- b Complex migraine
- c Rheumatoid arthritis
- d Graves' disease

8 True/False: Oral minoxidil has value in treating complicated, refractory cases of alopecia in patients who have failed first-line therapy.

9 Which diagnostic studies require routine monitoring with low-dose oral minoxidil use?
- a Basic metabolic panel
- b Complete metabolic panel
- c Complete blood count
- d No routine lab values are needed

10 True/False: Challenges of oral minoxidil include repeated application, vehicle consistency, cosmetic drawbacks, financial implications, and limited absorption.

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Review questions answers

1 b
2 True
3 a
4 False
5 d
6 True
7 a
8 True
9 d
10 False

