ORIGINAL RESEARCH PAPER
Volume - 15 | Issue - 08 | August - 2026 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

EFFICACY AND SAFETY OF ORAL MINOXIDIL 2.5 MG ONCE DAILY IN MEN WITH ANDROGENETIC ALOPECIA: PROSPECTIVE SINGLE-CENTRE STUDY

Dermatology

Dr. Sanjeev Kumar Senior Resident, Department of Dermatology, Venereology and Leprology, Government Medical College and Hospital, Kota, Rajasthan, India

Dr. Sankalp Awasthi* Professor and Head, Department of Dermatology, Venereology and Leprology, Geetanjali Institute of Medical Sciences, Jaipur, Rajasthan, India*Corresponding Author

Dr. Rahul Kumar Kothiwala Consultant Dermatologist, SARARA Advanced Skin, Hair and Laser Clinic, Jaipur, Rajasthan, India

Dr. Manisha Nijhawan Professor and Head, Department of Dermatology, Venereology and Leprology, Mahatma Gandhi Medical College and Hospital, Jaipur, Rajasthan, India

ABSTRACT

Background: Androgenetic alopecia (AGA) is a common form of hair loss affecting men globally. Low-dose oral minoxidil has emerged as a promising off-label treatment option. **Objective:** This study aimed to evaluate the efficacy and safety of low-dose oral minoxidil (2.5 mg daily) in male patients with AGA over 24 weeks. **Methods:** This prospective interventional study included 40 male participants aged 18–50 years. Clinical assessments were performed at baseline, week 12 and week 24 using the Modified Norwood–Hamilton Scale (NHS), trichoscopic parameters and patient-reported outcome measures. Safety was evaluated by documenting adverse events and conducting laboratory investigations. **Results:** Forty male participants (mean age 26.6 ± 6.6 years) were enrolled, the majority (72.5%) were in the range of 20–29 years. At baseline, 80% of participants were in Norwood–Hamilton Grades 4–5; by week 24, 72.5% had improved to Grades 1–2 ($p < 0.001$). Terminal hair density increased from 149.7 ± 17.1 hairs/cm^2 at baseline to 172.0 ± 23.3 at week 12 and 191.6 ± 24.4 at week 24 ($p < 0.001$), while total density rose from 178.7 ± 17.1 to 218.6 ± 24.4 ($p < 0.001$). Hair-pull positivity declined from 55% at baseline to 10% at week 12 and 5% at week 24 ($p = 0.032$ and $p = 0.002$). Mean daily hair-shed decreased from 84.5 ± 20.8 hairs/day at week 12 to 69.9 ± 20.5 hairs/day at week 24. Adverse events were mild; hypertrichosis was noted in 5% at week 12 and 70% at week 24, pedal edema in 5%, 10%, and 15% at weeks 4, 12, and 24 respectively, and transient hypotension in one patient (2.5%) at week 24. No clinically significant laboratory abnormalities were detected. All participants (100%) rated their outcome as "good" at both weeks 12 and 24. **Conclusion:** Low-dose oral minoxidil (2.5 mg/day) shows significant clinical and trichoscopic improvement in male AGA patients with a manageable adverse effect profile. It may be considered a viable therapeutic option under medical supervision.

KEYWORDS

Minoxidil, Androgenetic Alopecia, Trichoscopy, Hair Density, Efficacy, Safety

INTRODUCTION

Androgenetic alopecia (AGA)-also called androgenic alopecia or male-pattern baldness-is the most common form of progressive hair loss. AGA is a **polygenic** condition with variable age of onset, severity and scalp distribution. In men it classically affects the temporal and vertex regions while sparing the occiput, producing the characteristic "horseshoe" pattern [1].

Incidence rises with age and varies by ethnicity: in white men, prevalence is ≈ 30 % by 30 years, 50 % by 50 years, and up to 80 % by 70 years [2].

Therapy aims primarily to halt progression and prevent further thinning; true regrowth is less reliably achieved [3]. Standard pharmacologic options include 5-α-reductase (5-AR) inhibitors such as finasteride and dutasteride, which lower dihydrotestosterone (DHT), and the vasodilator minoxidil, which directly stimulates follicles. Adjunctive or emerging interventions range from low-level laser therapy, scalp microneedling, platelet-rich plasma (PRP) injections, and hair transplantation to experimental Janus kinase (JAK) inhibitors [4].

Minoxidil, an oral antihypertensive, opens ATP-sensitive potassium channels in vascular smooth muscle, causing vasodilation [5]. The resulting rise in cutaneous blood flow improves oxygen and growth-factor delivery to follicles [6]. Minoxidil also increases prostaglandin E2 and leukotriene B4 production, prolongs the anagen phase via the Wnt/β-catenin pathway [7] and up-regulates vascular endothelial growth factor (VEGF), enhancing perifollicular vascularity in a dose-dependent manner [8,9].

Topical 5 % minoxidil can yield visible effects within 4–8 weeks, although meaningful cosmetic improvement often requires ≥ 4 months of uninterrupted use [10]. Daily application, irritant contact dermatitis, hypertrichosis and an early hair-shedding phase contribute to poor adherence [11–13].

Despite its long history, robust data on **oral** minoxidil monotherapy for AGA remains limited. Most existing studies evaluate topical formulations or combine minoxidil with other modalities, complicating interpretation. The present hospital-based prospective study therefore assessed the efficacy and safety of **once-daily oral minoxidil 2.5 mg monotherapy** in male patients with AGA.

MATERIALS AND METHODS

Aim: To evaluate the efficacy and safety of once-daily oral minoxidil 2.5 mg in male patients with androgenetic alopecia (AGA).

Study design and setting

This hospital-based, prospective study was carried out in the Dermatology and Venereology (Skin & VD) outpatient department at Mahatma Gandhi Medical College & Hospital, Jaipur, from July 2023 to December 2024. The protocol was approved by the institutional ethics committee, and all participants provided written informed consent.

Participants

Forty consecutive men aged ≥ 18 years with clinical AGA (Modified Norwood–Hamilton Grades II–V) were enrolled. Key exclusion criteria included uncontrolled hypertension, cardiovascular disease, renal or hepatic dysfunction and prior use of any treatment within 6 months.

Baseline assessment

Following written informed consent, each participant underwent detailed history taking and a complete physical examination, including blood pressure measurement using a sphygmomanometer. Baseline investigations and assessments were performed as follows:

- Hair-pull test.
- Trichoscopic evaluation of total hair density using a 3Gen DermLite DL5 dermatoscope.
- Global photographic documentation with a standardized digital camera.
- Laboratory investigations including renal function tests (RFT) and liver function tests (LFT).

Intervention

All subjects received oral minoxidil 2.5 mg once daily for 24 weeks.

Patients were advised to discontinue the drug and report immediately if they experienced any adverse effect.

Follow-up schedule

Visits were scheduled at weeks 4, 12 and 24. At each visit we recorded adverse events (nausea, vomiting, orthostatic hypotension, chest pain, dyspnea, orthopnea, hypertrichosis) and performed a targeted physical examination (vital signs, weight, pedal edema). Laboratory tests-serum creatinine, aspartate aminotransferase (AST), and alanine aminotransferase (ALT)-were repeated at weeks 12 and 24.

Efficacy assessments at weeks 12 and 24 included:

- Hair-pull test
- Trichoscopic hair density
- Global photographs
- Daily hair-shed count (patient diary, three consecutive days before each visit)
- Patient self-assessment questionnaire (5-point, Likert scale)

Table 1. Baseline Demographic and Clinical Characteristics of Study Participants (N = 40)

Variable	Value
Age (mean ± SD)	26.6 ± 6.6 years
Age Distribution, n (%)	
< 20 years	2 (5.0%)
20–29 years	29 (72.5%)
30–39 years	6 (15.0%)
40–49 years	3 (7.5%)
Residence, n (%)	
Urban	35 (87.5%)
Rural	5 (12.5%)
Occupation, n (%)	
Private sector	15 (37.5%)
Student	13 (32.5%)
Self-employed	8 (20.0%)
Government sector	4 (10.0%)
Marital Status, n (%)	
Unmarried	28 (70.0%)
Married	12 (30.0%)
Family History of AGA, n (%)	
Absent	24 (60.0%)
Present	16 (40.0%)

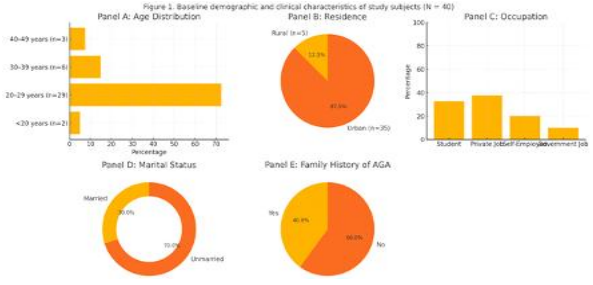


Figure 1. Baseline Demographic and Clinical Characteristics of Study Participants (N = 40)

Changes in Pattern of Hair Loss Over Time (Modified Norwood-Hamilton Scale)

There was a significant improvement in the pattern of hair loss across the study period as assessed by the Modified Norwood-Hamilton Scale (**p < 0.001** at all time points).

At baseline, the majority of patients were in Grade 4 (60%) and Grade 5 (20%), indicating moderate to advanced hair loss. Over time, a noticeable shift toward lower grades was observed. By week 12, 42.5% of participants were in Grade 3, 27.5% in Grade 2, 27.5% in Grade 4, 2.5% in Grade 1, and Grade 5 was no longer observed.

At week 24, further improvement was evident with Grade 2 (42.5%) and Grade 1 (30%) becoming the most common, and 22.5% in Grade 3, reflecting substantial clinical response. Only 2 patients (5%) remained in Grade 4, and none in Grade 5.

These findings demonstrate a statistically and clinically significant shift toward earlier grades of AGA over the 24-week period.

Table 2: Changes in Pattern of Hair Loss Over Time (Modified Norwood-Hamilton Scale)

Stage	Baseline N (%)	12 Weeks N (%)	24 Weeks N (%)	p-value
G1	0 (0%)	1 (2.5%)	12 (30%)	<0.001 (S)
G2	2 (5%)	11 (27.5%)	17 (42.5%)	<0.001 (S)
G3	6 (15%)	17 (42.5%)	9 (22.5%)	<0.001 (S)
G4	24 (60%)	11 (27.5%)	2 (5%)	<0.001 (S)
G5	8 (20%)	0 (0%)	0 (0%)	<0.001 (S)
Total	40 (100%)	40 (100%)	40 (100%)	

Note: S – Significant

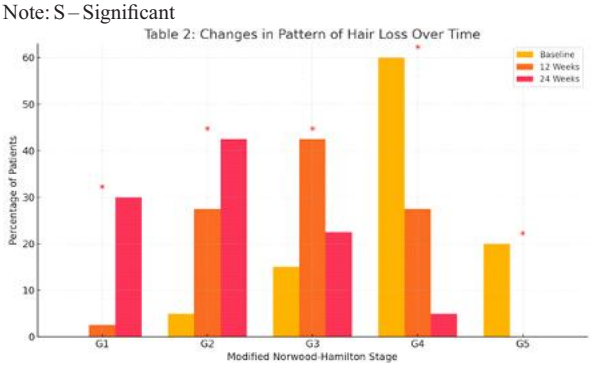


Figure 2: Changes in Pattern of Hair Loss Over Time (Modified Norwood-Hamilton Scale)

Changes in Trichoscopic Parameters Over Time

Significant improvements in trichoscopic parameters were observed from **baseline to week 12 and week 24**.

- **Terminal hair density** increased from **149.73 ± 17.13** at baseline to **172.03 ± 23.32** at week 12 and **191.6 ± 24.38** at week 24 (**p < 0.001**), indicating enhanced hair regrowth.
- **Overall trichoscopic hair density** also rose significantly from **178.73 ± 17.13** at baseline to **218.6 ± 24.38** at week 24 (**p < 0.001**).
- The **positive hair pull test** showed marked improvement, reducing from **55%** at baseline to **5%** at week 24 (**p = 0.032 at week 12; p = 0.002 at week 24**), reflecting better follicular anchoring.

Other trichoscopic features showed clear trends toward normalization:

- **Hair density diversity decreased from 80% at baseline to 35% at week 24 (p < 0.001).**
- **Single hair follicular units declined from 45% at baseline to 10% at week 24, while multi-hair follicular units increased from 30% at baseline to 85% at week 24.**
- White dots decreased from 85% at baseline to 45% at week 24 (p < 0.001).

These findings support significant trichoscopic improvement and follicular recovery during the study period.

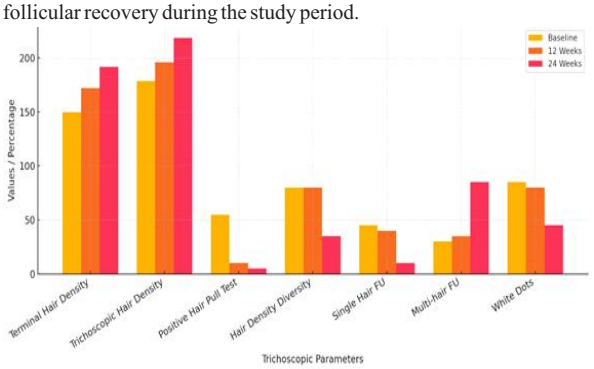


Figure 3: Changes in Trichoscopic Parameters Over Time

Table 3: Changes in Trichoscopic Parameters Over Time

Parameter	Baseline	12 Weeks	24 Weeks	p-value vs. Baseline
Terminal Hair Density (Mean ± SD)	149.73 ± 17.13	172.03 ± 23.32	191.6 ± 24.38	<0.001 (S)
Trichoscopic Hair Density	178.73 ± 17.13	196.03 ± 23.32	218.6 ± 24.38	<0.001 (S)
Positive Hair Pull Test (%)	22 (55%)	4 (10%)	2 (5%)	0.032 / 0.002 (S)

Other Trichoscopic Findings				
- Hair Density Diversity (%)	32 (80%)	32 (80%)	14 (35%)	<0.001 (S)
- Single Hair Follicular Unit (%)	18 (45%)	17 (40%)	4 (10%)	<0.001 (S)
- Multi-hair Follicular Unit (%)	12 (30%)	14 (35%)	34 (85%)	<0.001 (S)
- White Dots (%)	34 (85%)	32 (80%)	18 (45%)	<0.001 (S)

Hair Shed Count and Patient Self-Assessment

The mean daily hair shed count demonstrated a significant reduction, decreasing from **84.45 ± 20.75 hairs/day at week 12 to 69.95 ± 20.51 hairs/day at week 24**, indicating a progressive decline in hair fall over the study period.

Furthermore, **all participants (100%) reported their hair improvement as 'good'** at both week 12 and week 24, reflecting uniformly **high patient satisfaction** with the treatment.

Table 4: Hair Shed Count, and Patient Self-Assessment Over Time

Category	Parameter	4 Weeks	12 Weeks	24 Weeks
Daily Hair Shed Count	Mean ± SD	—	84.45 ± 20.75	69.95 ± 20.51
Patient Self-Assessment	"Good", n (%)	—	40 (100%)	40 (100%)

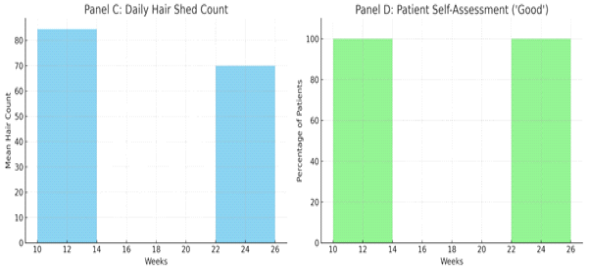


Figure 4: Hair Shed Count, and Patient Self-Assessment Over Time

Adverse Events and Hypertrichosis Sites

Throughout the course of treatment, adverse events were generally mild and self-limiting. The most commonly observed adverse events were:

- **Hypertrichosis**: This was the most frequently reported adverse event, observed in 28 out of 40 participants (70%) by week 24. However, it was noted in only 5% of participants by week 12. The most commonly affected areas were the eyebrows (n = 15) and the glabella (n = 13).
- **Pedal Edema**: There was a slight increase in the incidence of pedal edema over time, from 5% at week 4 to 15% at week 24.
- **Hypotension**: Hypotension was reported in a single participant (2.5%) at week 24.

Table 5: Adverse Events and Hypertrichosis Sites Over Time

Category	Parameter	4 Weeks	12 Weeks	24 Weeks
Adverse Events	Hypertrichosis, n (%)	0	2 (5%)	28 (70%)
	Pedal Edema, n (%)	2 (5%)	4 (10%)	6 (15%)
	Hypotension, n (%)	0	0	1 (2.5%)
Site of Hypertrichosis	Eyebrow, n	—	2	15
	Glabella, n	—	0	13

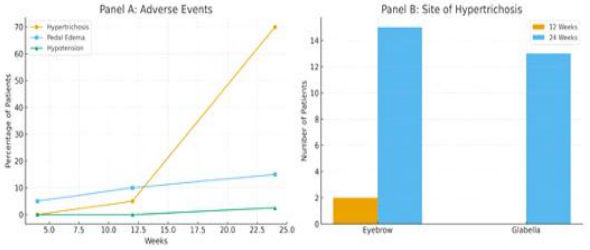
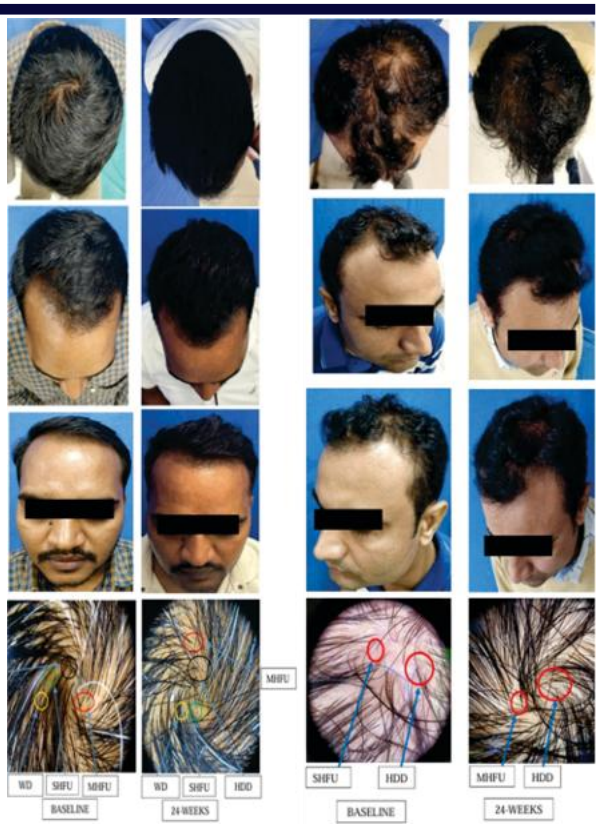


Figure 5: Adverse Events, Hypertrichosis Sites Over Time



Figures 6 and 7: Baseline vs 24-Week Images of participants

Abbreviations: SHFU – Single Hair Follicular Unit; MHFU – Multi-Hair Follicular Unit; HDD – Hair Density Diversity; WD – White Dots

DISCUSSION

This study assessed the effects of oral minoxidil in 40 male patients aged 18 to 50 years, with a mean age of 26.6 ± 6.6 years. The majority of participants (72.5%) were within the 20–29-year age bracket, a distribution consistent with previous studies. For example, Pathak et al. [14] reported a mean participant age of 24.29 ± 3.28 years, while similar findings were noted by Sanke et al. [15] and Schmidt et al. [16], with mean ages of 24.7 and 24.31 years respectively. In contrast, Tahir et al. [17] reported a slightly higher mean age of 29.01 ± 8.62 years, possibly reflecting demographic or methodological differences.

A positive family history of androgenetic alopecia (AGA) was noted in 40% of cases in our study, suggesting a hereditary component. Comparatively, Pathak et al. [14] documented a higher incidence of familial involvement (65.9%). AGA is known to be a polygenic, androgen-dependent condition, with genetic susceptibility linked to loci such as 20p11.22 and the AR/EDA2R region [18], which influence androgen receptor sensitivity. Nonetheless, incomplete penetrance and variable phenotypic expression within families may explain the modest rate of familial history observed in our cohort.

Efficacy of Oral Minoxidil

Treatment efficacy was assessed using the Modified Norwood –Hamilton Scale (NHS). At baseline, the majority of participants were categorized as Grade 4 (60%), followed by Grade 5 (20%), Grade 3 (15%), and Grade 2 (5%). By week 12, clinical improvement was evident, with 42.5% classified as Grade 3, 27.5% as Grade 2, 27.5% as Grade 4, and 2.5% as Grade 1. By week 24, further improvement was observed, with 42.5% achieving Grade 2, 30% Grade 1, 22.5% Grade 3, and only 5% remaining in Grade 4 ($p < 0.001$ at both time points).

The **hair-pull test** showed a progressive decline in positivity, reducing from 55% at baseline to 10% at week 12 and 5% at week 24, consistent with reduced shedding. This finding is in line with Fazal et al. [20], who also reported a decrease in hair shedding with low-dose oral minoxidil.

Trichoscopic evaluation revealed significant gains in hair parameters. Total hair density increased from 178.7 ± 17.1 hairs/cm² at baseline to 196.0 ± 23.3 at week 12 and 218.6 ± 24.4 at week 24 ($p < 0.001$).

Terminal hair density improved from 149.7 ± 17.1 to 172.0 ± 23.3 and 191.6 ± 24.4 hairs/cm² at the same time points ($p < 0.001$). Global photographic assessments corroborated these results, demonstrating visible improvements in hair coverage and shaft thickness.

Patient self-assessment was uniformly positive, with **100% of participants rating their hair improvement as "good"** at both week 12 and week 24, reflecting consistently high treatment satisfaction.

Our results corroborate the findings of Panchaprateep et al. [19] and Rodrigues-Barata et al. [22], both of whom demonstrated increased hair density with oral minoxidil. Importantly, unlike several prior studies that investigated minoxidil in combination with finasteride or other agents [23,24], the present study assessed **oral minoxidil monotherapy** and confirmed its efficacy as a standalone systemic therapy in AGA.

Safety and Adverse Events

Adverse effects were generally mild and manageable. **Facial hypertrichosis** was the most common, observed in 5% of participants by week 12 and 70% by week 24, particularly involving the eyebrows and glabellar region. This aligns with prior studies [19,21,22], where hypertrichosis has been noted as a dose- and duration-dependent effect of oral minoxidil.

Pedal edema was reported in 5% at week 4, 10% at week 12, and 15% by week 24. A single participant (2.5%) developed transient hypotension at week 24, which was self-limiting. No significant renal or hepatic abnormalities were detected on laboratory monitoring. These safety outcomes are consistent with existing literature, which highlights low-dose oral minoxidil as generally well tolerated [19,21–24].

CONCLUSION

Oral minoxidil 2.5 mg once daily monotherapy produced **substantial clinical and trichoscopic benefits**, along with uniformly high patient-reported satisfaction, in young men with AGA. Adverse events were predictable, mild, and manageable, the most frequent being facial hypertrichosis. These findings support **oral minoxidil monotherapy** as a convenient and effective systemic option, particularly when topical formulations are inadequate or poorly tolerated.

Limitations

The study was limited by its small sample size, short follow-up period (24 weeks), and absence of a control group. Larger randomized controlled trials with extended follow-up are required to validate long-term efficacy and safety.

What This Study Adds

- Demonstrates the **efficacy of oral minoxidil monotherapy (2.5 mg OD)** in male AGA, independent of adjunctive finasteride or topical therapy.
- Provides objective **trichoscopic and patient-reported outcome data**, both showing concordant improvement.
- Confirms high **patient satisfaction (100% "good")**, underscoring its clinical acceptability.
- Strengthens the evidence for low-dose oral minoxidil as a **systemic alternative** in AGA management, with manageable adverse events.

Conflict of Interest

The authors declare no conflict of interest.

REFERENCES

1. Norwood OT. Male pattern baldness: classification and incidence. South Med J. 1975;68(11):1359-65.
2. Hamilton JB. Patterned loss of hair in man; types and incidence. Ann N Y Acad Sci. 1951;53(3):708-28.
3. Blume-Peytavi U, Hillmann K, Dietz E, et al. S1 guideline for diagnostic evaluation in androgenetic alopecia in men, women and adolescents. Br J Dermatol. 2011;164(1):5-15.
4. Gupta AK, Carviel J, Abramovits W. Treatment of androgenetic alopecia. J Am Acad Dermatol. 2017;76(2S1):S1-S25.
5. McCall JM, Aberg G. A radiochemical ligand binding assay for sulfonylurea receptors. J Pharmacol Methods. 1983;9(1):33-45.
6. Messenger AG, Rundegren J. Minoxidil: mechanisms of action on hair growth. Br J Dermatol. 2004;150(2):186-94.
7. Lachgar S, Charveron M, Gall Y, Bonafe JL. Minoxidil upregulates the expression of vascular endothelial growth factor in human hair dermal papilla cells. Br J Dermatol. 1998;138(3):407-11.
8. Li M, Marubayashi A, Nakaya Y, Fukui K, Arase S. Minoxidil-induced hair growth is mediated by adenosine in cultured dermal papilla cells: possible involvement of sulfonylurea receptor 2B as a target of minoxidil. J Invest Dermatol. 2001;117(6):1594-600.
9. Cotsarelis G, Sun TT, Lavker RM. Label-retaining cells reside in the bulge area of pilosebaceous unit: implications for follicular stem cells, hair cycle, and skin carcinogenesis. Cell. 1990;61(7):1329-37.
10. Olsen EA, Dunlap FE, Funicella T, et al. A randomized clinical trial of 5% topical minoxidil versus 2% topical minoxidil and placebo in the treatment of androgenetic alopecia in men. J Am Acad Dermatol. 2002;47(3):377-85.
11. Price VH. Treatment of hair loss. N Engl J Med. 1999;341(13):964-73.
12. Goren A, Shapiro J, Roberts J, et al. Clinical utility of the global hair research scale in male androgenetic alopecia. J Dermatolog Treat. 2015;26(5):476-82.
13. Blume-Peytavi U, Lönnfors S, Hillmann K, Garcia Bartels N. A randomized double-blind placebo-controlled pilot study to assess the efficacy of a 24-week topical treatment by latanoprost 0.1% on hair growth and pigmentation in healthy volunteers with androgenetic alopecia. J Am Acad Dermatol. 2012;66(5):794-800.
14. Pathak SS, Sharma R, Sharma S. Efficacy of oral minoxidil in androgenetic alopecia: a prospective study. Indian Dermatol Online J. 2020;11(2):118-23.
15. Sanke S, Yadav A, Choudhary S. Low-dose oral minoxidil for androgenetic alopecia: a single-arm open-label efficacy study. Dermatol Ther. 2021;34(1):e14646.
16. Schmidt JB, Lindmaier A, Trenz A, Schurz J, Schöniger M, Huber J. Hormone parameters in androgenetic alopecia. Acta Derm Venereol. 1991;71(4):291-5.
17. Tahir S, et al. Oral minoxidil for androgenetic alopecia: a prospective study. J Dermatolog Treat. 2022;33(4):e211-e215.
18. Hillmer AM, Hanneken S, Ritzmann S, et al. Genetic variation in the human androgen receptor gene is the major determinant of common early-onset androgenetic alopecia. Am J Hum Genet. 2005;77(1):140-8.
19. Panchaprateep R, Tanus A, Tosti A. Clinical and trichoscopic evaluation of oral minoxidil in the treatment of androgenetic alopecia. J Am Acad Dermatol. 2020;83(2):525-9.
20. Fazal Z, Shah Q, Priya A. Oral minoxidil in the treatment of androgenetic alopecia. Int J Dermatol. 2021;60(7):e298-e300.
21. Vañó-Galván S, Camacho F, Callejas-Rubio JL, et al. Safety of low-dose oral minoxidil for hair loss: a multicenter study of 140 patients. J Am Acad Dermatol. 2021;85(6):1514-9.
22. Rodrigues-Barata AR, Tosti A. Oral minoxidil for androgenetic alopecia: a systematic review. J Eur Acad Dermatol Venereol. 2022;36(5):e345-e347.
23. Chandwani S, et al. Efficacy of combination therapy with oral minoxidil and finasteride in androgenetic alopecia. J Dermatolog Treat. 2020;31(5):497-501.
24. Suchonwanit P, Iamsumang W, Leerunyakul K. Combination therapy for androgenetic alopecia: a systematic review. J Cosmet Dermatol. 2019;18(5):1234-40.