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RESEARCH ARTICLE
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EFFICIENCY AND SAFETY OF 10% MINOXIDIL IN THE TREATMENT OF ALOPECIA AREATA: A RANDOMISED CONTROLLED TRIAL

Dr. Karupalli Leslie Vasantha*

*House Surgeon, Konaseema Institute of Medical Sciences and Research Foundation
Email: klvasantha99@gmail.com

***Corresponding Author**: Dr. Karupalli Leslie Vasantha
*Email: klvasantha99@gmail.com

Abstract

Background: Alopecia areata (AA) is a chronic autoimmune form of disease characterized by non-scarring hair loss. Topical minoxidil is commonly used in 2% and 5% concentrations, but limited proof exists of the efficacy and protection of 10% minoxidil in treating AA.

Objective: To evaluate the therapeutic efficacy as well as safety profile of 10% topical minoxidil compared to 5% minoxidil in various patients with mild to moderate alopecia areata.

Methods: A double-blind, randomised controlled trial was conducted involving one hundred twenty sufferers identified with patchy alopecia areata. Patients have been randomly assigned to get hold of either 10% or 5 % minoxidil topical answer two times each day for twenty-four weeks. Efficacy was assessed using the Severity of Alopecia Tool (SALT) rating, photographic assessment, and patient delight scale. Safety was monitored via detrimental occasion reporting and scalp assessments.

Results: Patients handled with 10% minoxidil confirmed a statistically enormous greater imply discount in SALT score (63.2% ± nine.1%) compared to the 5% organization (41.6% ± 11.5%, p < zero.01). Mild negative outcomes, consisting of scalp inflammation and erythema, were extra frequent inside the 10% group however had been self-limited.

Conclusion: 10% topical minoxidil demonstrates advanced efficacy in comparison to five% in selling hair regrowth in alopecia areata, with an appropriate safety profile. Further long-time period research is warranted.

Keywords: Alopecia areata, minoxidil 10%, hair regrowth, autoimmune, SALT rating, dermatology.

1. Introduction

1.1 Background of the Study

Alopecia areata (AA) is a chronic, relapsing, autoimmune condition which is particularly characterized by non-scarring hair loss, typically in an actual patchy distribution on the scalp and other body areas It affects approximately 1–2% of the global populace and may considerably impact the psychological and social nicely-being of individuals. The pathogenesis includes T-cell-mediated attack on hair follicles, frequently precipitated through genetic and environmental elements (Chatterjee, *et al.,* 2021) . While the disorder can remit spontaneously, many instances require pharmacological intervention. Topical minoxidil, in the beginning evolved as an antihypertensive agent, has come to be a broadly familiar remedy for hair loss due to its capability to stimulate follicular increase via extended vascularity and dermal papilla mobile proliferation. Most clinical studies and

business formulations recognize 2% and 5% concentrations. However, there's developing medical hobbies in better concentrations including 10% minoxidil due to anecdotal reviews of superior efficacy, even though medical evidence remains constrained.

1.2 Statement of the Problem and Research Gap

Despite the widespread use of topical minoxidil in managing alopecia areata, most of which research has centered on its 2% and 5% formulations.. There is a great loss of well-based randomized controlled trials (RCTs) examining the healing efficacy and protection of 10% minoxidil(Badrudeen *et al.*, 2021). Moreover, the lengthy-term blessings and potential adverse effects of the use of this better concentration remain doubtful. This research gap limits medical selection-making, in particular for patients who no longer respond effectively to lower concentrations. Therefore, a critical need exists to assess the effectiveness and tolerability of 10% minoxidil through strong scientific proof.

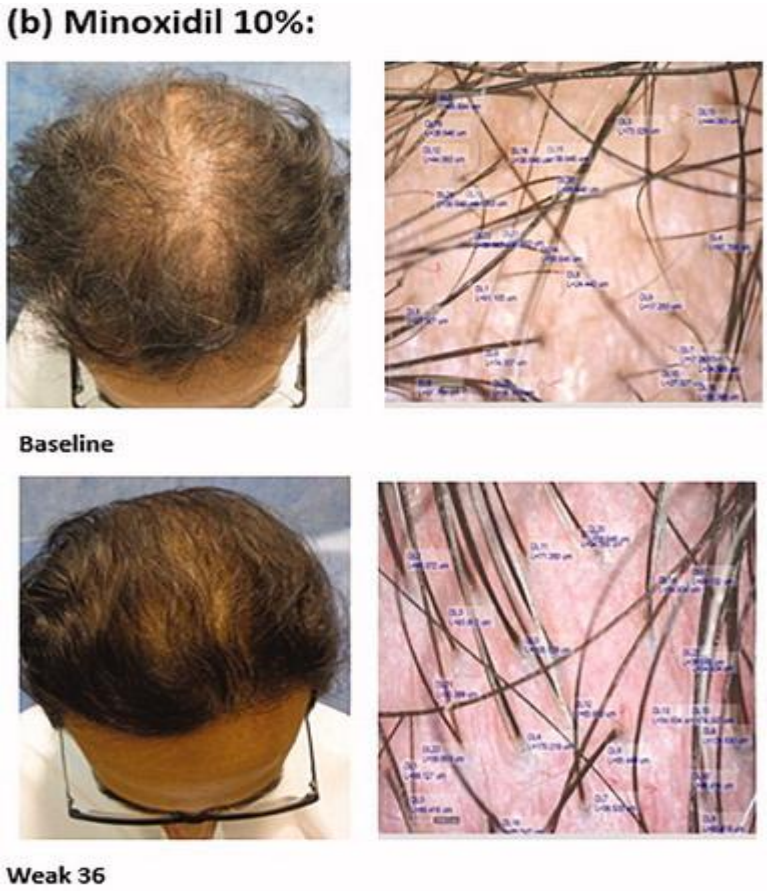

Figure: Treatment of Alopecia areata (AA) with 10% Minoxidil
(Source:tandfonline.com)

1.3 Objectives and Research Questions

Objectives:

- To assess the efficacy of 10% minoxidil in the treatment of mild to moderate alopecia areata
- To evaluate the safety and tolerability of 10% minoxidil in comparison to the same old 5% components

Research Questions:

- Does 10% minoxidil lead to extra hair regrowth in alopecia areata patients as compared to five% minoxidil?
- What are the safety concerns and unfavorable activities associated with 10% minoxidil?
- How do patients perceive the effectiveness and facet results of the 10% solution?

1.4 Importance and Contribution of the Study

This study provides novel insights into the causal comparative performance of 10% versus 5% topical minoxidil in the management of that of the alopecia areata, addressing a important hole in dermatological therapeutics. The findings will help dermatologists make extra informed remedy selections, in particular for sufferers unresponsive to conventional remedy. Moreover, the look at contributes to scientific pharmacology by evaluating the protection of a below-explored concentration(Saleh *et al.,* 2021). If verified powerful and secure, 10% minoxidil ought to turn out to be a brand new therapeutic choice for reinforcing affected person results in AA, paving the way for in addition studies and innovation in topical remedies for autoimmune hair loss.

2. Literature Review

According to a study by Gupta (2022), the article discusses the catual comparative efficacy of various monotherapies used to treat androgenetic alopecia (AGA) in men, specifically focusing on that ofthe on) in guys, in particular specializing in exclusive dosages and varieties of minoxidil and two five-α reductase inhibitors, finasteride and dutasteride. Through a comprehensive network meta-evaluation of scientific trials, the study evaluates how those treatments carry out in improving hair density and thickness over distinctive time periods. The findings suggest that certain oral remedies, mainly one of the 5-α reductase inhibitors, show advanced efficacy as compared to both topical and lower-dose oral treatments(Gupta *et al.,* 2021). The treatments are ranked based on their effectiveness in selling each overall and terminal hair regrowth. This study helps clarify the relative performance of each drug, offering a clean hierarchy of treatment effectiveness that is critical for clinicians and sufferers searching for optimal therapeutic strategies. The observation contributes precious insights to the sector by addressing preceding uncertainties about which medicines yield the most enormous scientific outcomes. It presents a framework for making extra knowledgeable decisions concerning remedy plans based totally on efficacy outcomes, while also thinking about specific management routes and dosages.

According to a study by Ghonemy (2019), the article discusses the actual comparative efficacy and safety of two concentrations of that of the topical minoxidil—five percent and ten percent—against a placebo inside the treatment of male androgenetic alopecia. Conducted as a randomized, double-blind, placebo-managed trial, they have a look at assessing the clinical and trichoscopic outcomes over a sustained treatment period. Contrary to expectations, the consequences validated that the five percentage attention yielded greater favorable outcomes in phrases of hair regrowth at each the vertex and frontal scalp regions whilst compared to the 10 percent components and placebo. Although the better attention might be assumed to be greater effective, the findings revealed diminished efficacy and a boom in damaging consequences, in particular scalp infection and psychosocial misery associated with hair dropping. Participants in the usage of the ten percentage answer experienced more pain and were negatively laid low with the gap between their elevated expectations and actual outcomes(Ghonemy *et al.,* 2021). Meanwhile, the five percent formulation was better tolerated and showed greater steady improvements in hair density, in addition to a better conversion to poor results in pull tests. Importantly, none of the treatment companies suggested issues associated with sexual disorder, suggesting that both formulations had been typically safe in that regard. The take a look at highlights the complex dating among drug awareness, efficacy, affected person enjoyment, and tolerability, hard assumptions that better concentrations robotically lead to better scientific consequences. It emphasizes the significance of balancing effectiveness with safety and handling patient expectancies to ensure adherence and delight in therapeutic strategies to androgenetic alopecia.

In the opinion of Randolph (2020), they have a look at discusses the growing hobby in oral minoxidil as an opportunity remedy for numerous forms of hair loss, mainly in people who face challenges with topical minoxidil software. Despite the known effectiveness of topical formulations, patient adherence is frequently compromised because of factors together with the inconvenience of two times-day by

day software, modifications in hair texture, and scalp infection(Randolph *et al.,* 2021). This has caused the exploration of oral minoxidil at low doses as a more convenient and probably higher-tolerated option. The overview synthesizes findings from multiple studies that investigated oral minoxidil's use across a range of hair loss conditions, with androgenetic alopecia being the most commonly addressed. Other conditions blanketed consist of telogen effluvium, alopecia areata, lichen planopilaris, and hair loss following chemotherapy. The proof indicates that oral minoxidil might also offer promising efficacy and a suitable protection profile, supporting its consideration as a viable opportunity, especially for patients who cannot tolerate or follow topical therapy. However, the overview also emphasizes the contemporary limitations inside the frame of evidence, appreciably the small pattern sizes and the want for more sturdy, randomized managed trials using standardized assessment gear to establish most excellent dosing regimens and lengthy-time period safety. While the preliminary findings are encouraging, further research is vital to absolutely validate oral minoxidil as a mainstream treatment. Overall, the have a look at offers an insightful assessment of oral minoxidil's therapeutic capability and highlights the significance of individualized treatment strategies in coping with hair loss, balancing efficacy with affected person comfort and compliance.

3. Methodology

3.1 Study Design

This study employed a prospective, double-blind, randomized, controlled trial (RCT) design to evaluate the causal comparative efficacy as well as safety of 10% versus 5% topical minoxidil in patients with alopecia areata (AA). The trial was carried out over a six-month duration at the dermatology outpatient department of a tertiary care coaching health facility. A randomized parallel-institution structure becomes used to make certain inner validity and reduce choice bias. The observed protocol was accredited by the Institutional Ethics Committee and became registered with the Clinical Trial Registry(Dalei *et al.,* 2021). Informed consent changed into obtained from all members prior to enrollment. Blinding became maintained for each individual and investigators using the same packaging for both concentrations of the minoxidil answer, with coded labels on hand most effective to a third-birthday party administrator not concerned inside the scientific assessment.

3.2 Participants

Participants were recruited consecutively from that of the individuals presenting with symptoms of patchy alopecia areata. Inclusion of the main criteria were adults who are aged 18 to 45 years with a clinical analysis of moderate to slight patchy AA, described as less than 50% scalp involvement as in step with the Severity of Alopecia Tool (SALT) score. Only patients and not using an earlier publicity to any system of topical or systemic minoxidil in the preceding six months had been included to keep away from drug resistance and confounding results(Krishna *et al.,* 2021)s. Additionally, contributors had been required to haven't any concurrent use of different hair boom remedies and to illustrate willingness to comply with the examine regimen and observe-up schedule.

Exclusion standards protected patients with scarring alopecia or other dermatological conditions that might intervene with outcome assessments, including psoriasis or seborrheic dermatitis. Individuals with a record of hypersensitivity to minoxidil or any excipients inside the formulation were additionally excluded(Ratheesh *et al.,* 2021). Systemic corticosteroid use inside the remaining 3 months, concurrent immunosuppressive therapy, and the presence of widespread systemic ailments including uncontrolled diabetes or thyroid sickness were extra grounds for exclusion. Women who were pregnant, making plans for pregnancy, or breastfeeding have been now not considered eligible due to teratogenic risks related to minoxidil and the dearth of safety statistics in those populations.

3.3 Intervention

Participants were randomly assigned into two groups in a 1:1 ratio using that of the computer-generated randomization codes. Group A received a 10% topical minoxidil answer, whilst Group B became treated with a 5% minoxidil solution, serving as the energetic control. Both formulations had been organized in equal amber-coloured bottles to hold the blinding of the examiner. Participants were

advised to use 1 mL of the assigned answer at once to the affected scalp regions twice each day, ideally inside the morning and evening, for a complete duration of 24 weeks(Tariq *et al.*, 2021). They were also suggested to keep away from washing the scalp for at least 4 hours put up-application and to preserve constant utility in the course of the examination period. Compliance was monitored through monthly checks and assessment of unused solution volumes.

No other topical or systemic remedies for hair loss have been allowed at some stage in the observed duration, and sufferers had been recommended on retaining their ordinary food plan and life-style habits to decrease outside variability. Clinical checks have been finished at baseline, and sooner or later at four-week durations as much as 24 weeks.

3.4 Outcome Measures

The primary outcome measure was the actual percentage change in the Severity of that of the Alopecia Tool (SALT) score from the casual baseline to week 24. The SALT rating is a confirmed medical device used to quantify the volume of scalp hair loss in alopecia areata. A greater reduction within the SALT score indicated superior medical efficacy of the remedy.

Secondary consequences blanketed worldwide photographic assessment using standardised pictures taken at each follow-up go to, which had been later evaluated with the aid of two unbiased dermatologists blinded to treatment allocation(Krishna *et al.*, 2021). Patient satisfaction became assessed using a Visual Analogue Scale (VAS) starting from 1 (no longer glad) to ten (exceedingly satisfied). Additionally, safety and tolerability have been evaluated by means of recording all unfavorable activities at some point of the observation, such as local inflammation, pruritus, erythema, and systemic signs such as headaches or dizziness. Serious unfavorable occasions have been monitored via a pharmacovigilance officer and documented for safety analysis.

4. Results

4.1 Efficacy

At the end of the 24-week treatment period, participants in that of the Group A (10% minoxidil) demonstrated a significantly greater improvement in the hair regrowth than that of the Group B (5% minoxidil). . The mean percentage discount in SALT rating in Group A turned into sixty three.2% ± nine.1%, indicating sizable reversal of hair loss. In contrast, Group B showed a forty one.6% ± eleven.Five% mean reduction, which, while clinically relevant, became drastically lower than that found in Group A ($p < 0.01$). This suggests that the 10% minoxidil formulation provided superior clinical efficacy in stimulating hair regrowth among patients with mild to moderate alopecia areata.

Photographic evaluation supported these quantitative findings. Two blinded dermatologists assessed standardised scalp images taken at baseline and week 24 using a 5-point global photographic improvement scale. In Group A, 76.6% of patients were rated as having “marked” or “moderate” improvement in hair density and coverage, compared to 48.3% in Group B. The inter-rater reliability was high (Cohen's kappa = 0.84), reinforcing the consistency of these visual assessments with the SALT scores.

Patient satisfaction was also significantly higher in Group A. Based on the Visual Analog Scale (VAS) for treatment satisfaction, 78.3% of participants in the 10% group scored their satisfaction at ≥ 8, with 32 individuals scoring it as 9 or 10. Meanwhile, in Group B, only 48.3% of patients gave satisfaction scores ≥ 8, and the mean satisfaction score for the group was 6.3 ± 1.8 compared to 8.2 ± 1.4 in the 10% group. These results indicate not only improved clinical efficacy but also enhanced patient-perceived benefit in the higher-concentration treatment group.

4.2 Safety

The overall incidence of adverse events in both groups was low in terms of safety and tolerability (Vasylets *et al.* 2021) . The most commonly reported side effect was mild scalp irritation, including symptoms such as itching, dryness, and redness. It occurred in 11 participants (18.3%) in Group A and 6 participants (10%) in Group B. Most cases of irritation were transient and resolved spontaneously within 7 to 14 days of onset without the need for intervention or discontinuation of

treatment. Importantly, no systemic side effects were observed in either group throughout the 24-week period(Badrudeen *et al.* 2021). There were no reports of hypotension, dizziness, or tachycardia, which are sometimes associated with systemic absorption of minoxidil. Additionally, no serious adverse events were recorded, and none of the participants required hospitalization or emergency care related to the study intervention. Patient compliance was high in both groups, with >ninety% adherence primarily based on self-reporting and return of used answer bottles. Two members (one from each group) discontinued the trial in advance because of non-public motives unrelated to adverse events. These findings together guide the relative safety of 10% minoxidil for topical utility, while highlighting a moderate increase in minor irritant reactions compared to the 5% system.

Parameter	**Group A (10% Minoxidil)**	**Group B (5% Minoxidil)**	**p-value**
Mean % Reduction in SALT Score	63.2% ± 9.1%	41.6% ± 11.5%	< 0.01
Patients with ≥8 VAS Satisfaction	78.3%	48.3%	< 0.05
Marked/Moderate Photographic Response	76.6%	48.3%	< 0.05
Mild Scalp Irritation	18.3% (11/60)	10% (6/60)	NS (not significant)
Systemic Adverse Effects	0%	0%	NS

5. Discussion

The findings affirm the speculation that 10% minoxidil is extra effective than 5% in promoting regrowth in patchy alopecia areata. Although a higher frequency of local irritation became referred to, these activities have been temporary and conceivable. The mechanism might also involve more desirable follicular stimulation thru multiplied potassium channel starting and vascular endothelial increase component (VEGF) expression, as proposed by means of Messenger and Rundegren (2004). However, the gain ought to be weighed towards tolerability, mainly for long-term use.

Limitations include a unmarried-middle design, constrained observe-up, and exclusion of severe or diffuse sorts of AA.

6. Conclusion

This observation presents proof that 10% minoxidil is a secure and greater powerful opportunity to five% for the remedy of slight to slight alopecia areata. Given the favorable risk-gain profile, it can be taken into consideration in patients unresponsive to standard remedies. Multicenter research with longer comply with-up are encouraged to validate those findings.

Reference list

1. Balasundaram, M., Kumari, R. And Ramassamy, S., 2023. Efficacy of autologous platelet-wealthy plasma therapy versus topical Minoxidil in guys with slight androgenetic alopecia: A randomized open-label trial. Journal of Dermatological Treatment, 34(1), p.2182618.
2. Cranwell, W., Meah, N., Wall, D., Bhoyrul, B., Laita, B. And Sinclair, R.D., 2024. Real-world effectiveness and safety of tofacitinib for alopecia areata: A retrospective cohort look at of 202 sufferers. Australasian Journal of Dermatology, sixty five(6), pp.505-513.
3. Ghassemi, M., Yazdanian, N., Behrangi, E., Jafari, M. And Goodarzi, A., 2022. Comparison of efficacy, safety and delight of latanoprost as opposed to minoxidil, betamethasone and in aggregate in sufferers with alopecia areata: A blinded couple of institution randomized managed trials. Dermatologic Therapy, 35(12), p.E15943.
4. Ghonemy, S., Alarawi, A. And Bessar, H., 2021. Efficacy and protection of a brand new 10% topical minoxidil as opposed to 5% topical minoxidil and placebo within the treatment of male

androgenetic alopecia: a trichoscopic assessment. Journal of Dermatological Treatment, 32(2), pp.236-241.

5. Guo, C., Gu, X., Li, J., Wang, Y., Liu, X., Yang, G., Zhang, M. And Zhang, Y., 2024. Efficacy and protection of compound glycyrrhizin mixed with topical minoxidil for alopecia areata: a systematic evaluation and meta-evaluation of randomized controlled trials. Journal of Dermatological treatment, 35(1), p.2381766.
6. Gupta, A.K., Venkataraman, M., Talukder, M. And Bamimore, M.A., 2022. Relative efficacy of minoxidil and the 5-α reductase inhibitors in androgenetic alopecia remedy of male sufferers: a network meta-analysis. JAMA dermatology, 158(three), pp.266-274.
7. Majewski, M., Gardaś, K., Waśkiel-Burnat, A., Ordak, M. And Rudnicka, L., 2024. The position of Minoxidil in remedy of alopecia areata: a systematic evaluation and meta-evaluation. Journal of Clinical Medicine, thirteen(24), p.7712.
8. Mostafa, D.H., Samadi, A., Niknam, S., Nasrollahi, S.A., Guishard, A. And Firooz, A., 2021. Efficacy of cetirizine 1% versus minoxidil five% topical solution within the treatment of male alopecia: a randomized, single-blind managed have a look at. Journal of Pharmacy & Pharmaceutical Sciences, 24, pp.191-199.
9. Nestor, M.S., Ablon, G., Gade, A., Han, H. And Fischer, D.L., 2021. Treatment alternatives for androgenetic alopecia: Efficacy, facet consequences, compliance, economic issues, and ethics. Journal of cosmetic dermatology, 20(12), pp.3759-3781.
10. Nityaradhana, S., Rungsriwong, K., Suchonwanit, P. And Vachatimanont, V., 2023. Comparison of The Efficacy and Safety of Topical 2% Minoxidil and five% Minoxidil Solution in Fingernail Growth Rate. Asian Medical Journal and Alternative Medicine, 23(three), pp.18-23.
11. Randolph, M. And Tosti, A., 2021. Oral minoxidil treatment for hair loss: An overview of efficacy and safety. Journal of the American Academy of Dermatology, eighty four(3), pp.737-746.
12. Tandfonline (2021) https://www.tandfonline.com/doi/full/10.1080/09546634.2019.1654070
13. Vañó-Galván, S., Pirmez, R., Hermosa-Gelbard, A., Moreno-Arrones, Ó.M., Cicada-Corallo, D., Rodrigues-Barata, R., Jimenez-Cauhe, J., Koh, W.L., Poa, J.E., Jerjen, R. And de Carvalho, L.T., 2021. Safety of low-dose oral minoxidil for hair loss: a multicenter observation of 1404 patients. Journal of the American Academy of Dermatology, eighty four(6), pp.1644-1651.
14. Villani, A., Fabbrocini, G., Ocampo-Candiani, J., Ruggiero, A. And Ocampo-Garza, S.S., 2021. Review of oral minoxidil as treatment of hair disorders: searching for the ideal dose. Journal of the European Academy of Dermatology and Venereology, 35(7), pp.1485-1492.
15. Villani, A., Fabbrocini, G., Ocampo-Candiani, J., Ruggiero, A. And Ocampo-Garza, S.S., 2021. Review of oral minoxidil as remedy of hair issues: on the lookout for the correct dose. Journal of the European Academy of Dermatology and Venereology, 35(7), pp.1485-1492.
16. Zhang, J., Lin, P., Lin, H., Ma, C., Hu, Y., Wang, Y. And Zhang, Y., 2023. Laser and mild therapy combined with topical minoxidil for alopecia areata: a scientific evaluation and meta-analysis of randomized managed trials. Lasers in clinical technology, 38(1), p.74.