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Comparative Study of Efficacy and Safety Profile of Topical Minoxidil 5% Versus Oral Minoxidil 2.5 Mg In Patients with Androgenetic Alopecia in Tertiary Care Teaching Hospital

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ABSTRACT

Background: Patterned hair loss, also known as androgenic alopecia, is a prevalent hair condition impacting many adults, particularly males. Characterised as progressive thinning of hair with loss, playing a significant role in one's cosmetic appearance inducing psychological distress, if left untreated.
Objective: The main aim of this study is to evaluate the efficacy and safety profile of 5% topical minoxidil solution compared to 2.5 mg oral minoxidil for treating androgenetic alopecia.
Material and Methods: It was a randomized study including 80 patients with pattern hair loss who were allocated into two equal groups. First group received 5% topical minoxidil solution whereas the second group received **2.5 mg oral minoxidil once daily** for duration of **6 months. Outcomes were evaluated at two months interval. Global photographic evaluation** and **patient self-assessment scores** were used to assess efficacy in both groups. At each follow up visit, all patients were monitored for adverse effects.
Results: Following the conclusion of the treatment, a significant improvement in hair density was observed in both groups. The results of patient self-assessment were similar across both groups, with no substantial differences noted and only minor adverse effects reported.
Conclusion: Both topical 5% minoxidil and oral 2.5 mg minoxidil have proven to be effective and safe in enhancing hair growth and density, producing comparable results between the two treatment groups.

Keywords: *Androgenetic alopecia, Oral minoxidil, Topical minoxidil, Global photographic assessment, Patient self-assessment.*

INTRODUCTION

Scalp hair is a crucial aspect of our aesthetic features, closely linked to health and youthfulness. It also provides photoprotection for the scalp.[1`] Several factors influence hair growth and maintenance, including diet, overall health, age, sex, and hormonal levels. Any fluctuations in these factors can affect hair growth and density.[1] Numerous hair disorders can result in hair loss, which may be either temporary or permanent.[2] Prompt diagnosis and intervention can help halt progression or restore hair. Hair disorders can manifest differently in men and women, with pattern baldness or androgenetic alopecia being the most common causes of reduced density and hair loss in men, particularly those over 30 years of age, and it can affect about 15% postmenopausal women .[2,3,4] Psychological impacts of pattern hair loss (PHL) can be significant, as it may cause individuals to appear older, thereby diminishing their self-esteem.[3,4] PHL is attributed to increased levels of dihydrotestosterone (DHT), which leads to the miniaturization of hair and ultimately the reduction of hair follicles.[2] Hair loss in PHL is characterized by progressive follicular miniaturization, with a shorter anagen phase,

and prolonged telogen duration.[5] Early intervention can help delay and restore hair growth. Although various surgical and medical therapies exist to help recover lost hair, no treatment can permanently restore hair.[2,3,4]All of these options require long-term maintenance therapy. Topical minoxidil has been extensively utilized for the treatment of male pattern hair loss (MPHL).[2] In this study, we aim to compare the efficacy and safety of topical minoxidil against oral minoxidil in androgenetic alopecia.

AIMS AND OBJECTIVES

The aim of this research was to assess the efficacy and safety of topical minoxidil (5%) compared to oral minoxidil (2.5mg) in individuals suffering from androgenetic alopecia. The evaluation was conducted through global photographic assessment and patient self-assessment.

MATERIAL AND METHODS

The investigation was a one-year, prospective, single-centre, randomized interindividual study that obtained approval from the local ethics committee and was carried out in accordance with the principles delineated in the Declaration of Helsinki (approval reg.No.684/IEC/R-23-03-2023) and CTRI/2024/03/063477. Written informed consent was secured from all patients involved in the study. The investigation encompassed eighty patients in good general health devoid of any indication of systemic illnesses, specifically those over 18 years of age of both genders suffering from androgenetic alopecia (Males- Stages 1 to 4 of the modified Norwood-Hamilton classification and females- Stages 1 and 2 of the Ludwig scale). The assessment of pattern hair loss was conducted using the modified Norwood Hamilton scale for men and the Ludwig scale for women.[6,7,8]

The criteria for exclusion encompassed pregnant and lactating women. Patients under 18 years, those with systemic conditions (such as PCOD, heart disease, epilepsy, cancer, etc.), patients with a history of prior surgery for hair restoration, individuals with active scalp infections or seborrheic dermatitis. Furthermore, patients with types of alopecia other than androgenetic alopecia or a documented allergy to either medication employed in the study were also excluded.[9] A thorough medical history and clinical examination were performed on all participants to guarantee that all exclusion criteria were adequately addressed.

A total of 80 patients took part in the study, which involved a random assignment into two groups of forty individuals each, as determined by a computer-generated randomization chart. The first group was treated with 5% topical minoxidil, while the second group received 2.5mg of oral minoxidil. Patients in group A were instructed to apply 1ml of 5% topical minoxidil using a dropper and to gently massage their scalp once daily for a duration of 6 months. Patients in group B were directed to take 2.5mg of oral minoxidil once daily for 6 months. Follow-up assessments were conducted at 0, 2, 4, and 6 months. Both groups were advised against changing their hairstyle and were instructed to avoid hair colouring or any other hair treatments during the study period. Patients in group B were also advised to monitor their blood pressure at monthly intervals. Follow-up evaluations were carried out at 0, 2, 4, and 6 months, and serial photographs were taken at baseline and subsequently at the end of the second, fourth, and sixth months.

The outcomes were evaluated through a global photographic assessment, wherein photographs were captured using a digital camera at baseline and during each subsequent visit. Standardized scalp photography involved creating a central hair part with a cotton-tipped applicator, utilizing the nose as an anatomical reference for the part. Patients were instructed to sit in a well-lit room, maintaining the same posture at each visit for the photography sessions. To assess improvements in hair growth, a standardized 7-point rating scale was employed (-3 = marked worsening, -2 = moderate worsening, -1 = mild worsening, 0 = no change, 1 = mild improvement, 2 = moderate improvement, 3 = marked improvement).[10,11] For the evaluation of response, patients' self-assessment was utilized (<25% = satisfactory, 25-50% = good, 50-75% = very good response, >75% = excellent response).[12] Clinical photographs were taken at each visit to document the progress. Furthermore, all patients were monitored for any potential adverse effects.

STATISTICAL ANALYSIS

The data collected was organized in an Excel spreadsheet, with the assistance of a statistician. The means and standard deviations of the measurements for each group were utilized for statistical analysis (SPSS 22.00 for Windows; SPSS Inc, Chicago, USA). The difference between the two groups was assessed using the student's t-test and the chi-square test, with the significance level established at $p < 0.05$.

RESULTS

The demographic characteristics of the patients involved in the study are outlined in Table 1. At the baseline, both groups showed no significant differences in terms of age, sex distribution, disease duration, baseline pattern hair loss grading according to the modified Norwood Hamilton scale and Ludwig scale, locality, and family history (P-value > 0.05). This indicates that the groups were comparable before the therapy commenced.

The outcomes for the two groups were evaluated using global photographic assessment and a visual analogue scale. Clinical photographs taken before and after treatment for one patient from each group are depicted in Figures 1 and 2 (topical 5% minoxidil) and Figures 3 and 4 (oral 2.5 mg minoxidil).

An analysis of the case distribution based on global photographic assessment showed a statistically significant difference within the two groups at baseline and after 6 months of therapy (P value < 0.0001), as detailed in Tables 2 and 3. However, no statistical difference was found in the global photographic assessment at the end of the therapy between the two groups (P value < 0.43), as indicated in Table 4.

The patient self-assessment revealed no statistical difference between the two groups (P value > 0.05), as illustrated in Figure 5. Regarding adverse effects, 11 patients in group A and 8 patients in group B experienced adverse effects, but both treatments were well tolerated by the patients, with no major adverse effects reported in either group, as represented in Table 5. The types of adverse effects reported by the patients are shown in Figure 11.

In terms of scoring of adverse drug reactions (ADRs) among the study groups using the WHO-UMC (Table 6), Naranjo scale scoring (Table 7), Modified Hartwig and Siegel severity assessment scale (Table 8), and preventability of ADRs by Schmock and Thorton Preventability scale (Table 9), both groups showed statistically insignificant results in terms of ADR (P value > 0.05).

TABLE 1: Demography of the patients included in the study

Demographic data	Group A (Topical Minoxidil)	Group B (Oral Minoxidil)	P value
Age in years (Mean ±SD)	25.97±7.59 years	28.64±7.28 years	0.5
Sex ratio (Male: Female)	28:12	26:14	0.2
Duration of disease in months (Mean ±SD)	20.97±14.59	22.44±17.62	0.5
Locality (Urban: Rural)	36:4	27:13	0.5
Positive family history of AGA	31	35	0.5
Baseline Stage of AGA in men Stage I, II, III, IV	9:13:6:0	7:11:5:1	0.25
Baseline Stage of AGA in women Stage I, II	8:4	10:6	0.18

TABLE 2: Global photographic assessment scores in Group A

Topical minoxidil Group A	At baseline Mean ± SD	At 2 months Mean ± SD	At 4 months Mean ± SD	At 6 months Mean ± SD
Global photographic assessment	-1.68±0.70	0.29±0.46	1.00±0.63	1.68±1.08
P- value		<0.0001	<0.0001	<0.0001

Group A (Topical 5% minoxidil)

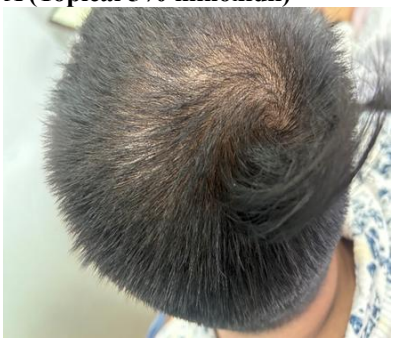

Figure 1(a)

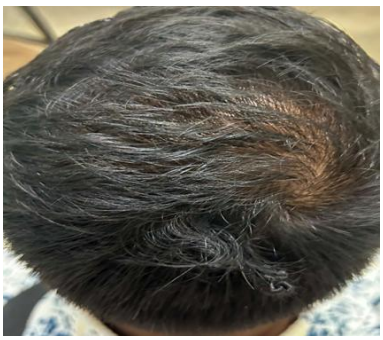

Figure 1(b)

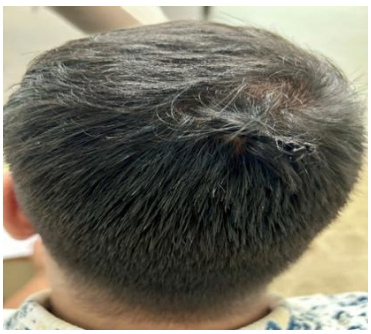

Figure 1(c)

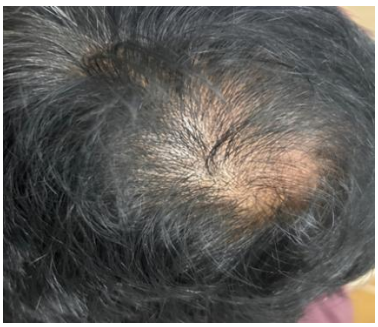

Figure 2(a)

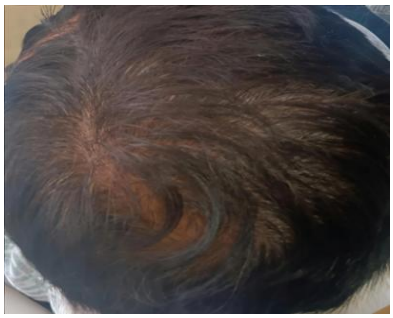

Figure 2(b)

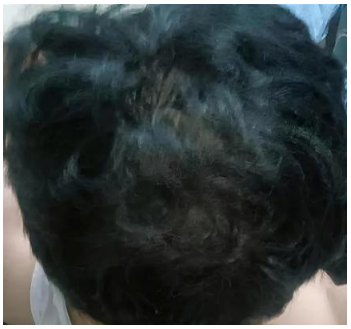

Figure 2(c)

Group B (Oral 2.5 mg minoxidil)

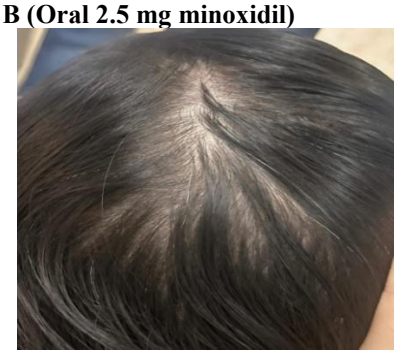

Figure 3(a)

Figure 3(b)

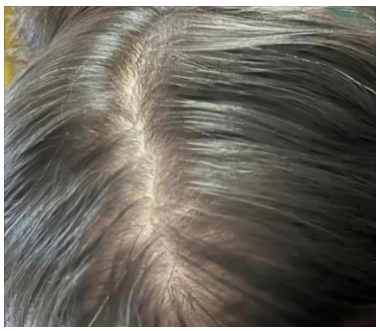

Figure 3(c)

Figure 4(a)

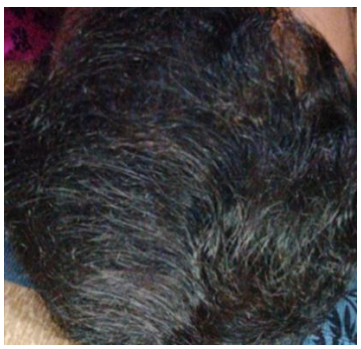

Figure 4(b)

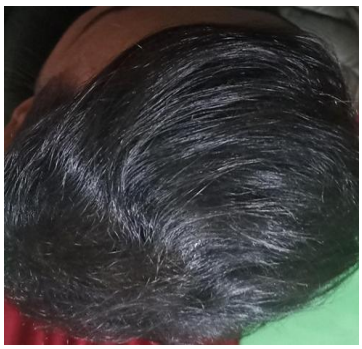

Figure 4(c)

TABLE 3: Global photographic assessment scores in Group B

Oral minoxidil Group B	**At baseline Mean ± SD**	**At 2 months Mean ± SD**	**At 4 months Mean ± SD**	**At 6 months Mean ± SD**
Global photographic assessment	-1.72±0.74	0.32±0.56	1.04±0.54	1.44±1.16
P- value		<0.0001	<0.0001	<0.0001

TABLE 4: Intergroup comparison of Global photographic assessment in the two Treatments groups

Time of assessment	**Topical Minoxidil Group A (Mean ± SD)**	**Oral Minoxidil Group B (Mean ± SD)**	**t- test**	**p-value**
0 month	-1.68±0.70	-1.72±0.74	0.20	0.84
2 months	0.29±0.46	0.32±0.56	- 0.22	0.83
4 months	1.00±0.63	1.04±0.54	-0.25	0.80
6 months	1.68±1.08	1.44±1.16	0.79	0.43

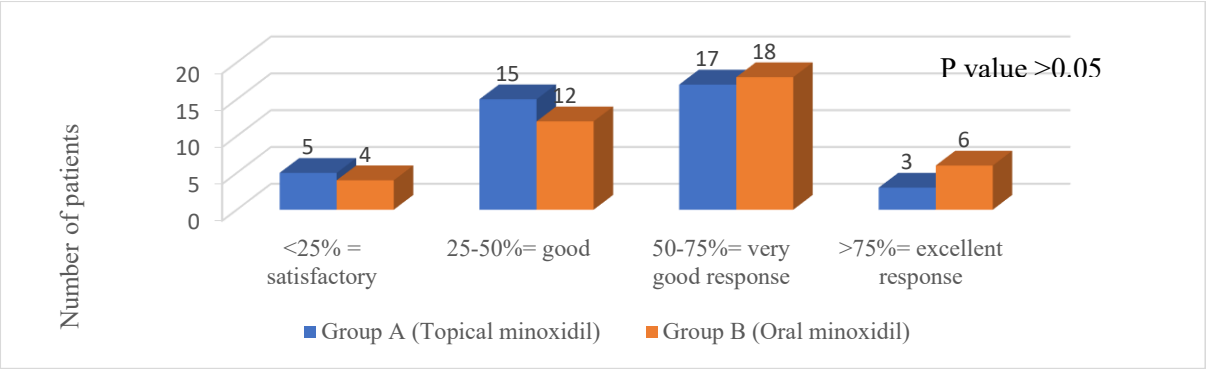

Figure 5: Patients Self assesment.

TABLE 5: Adverse drug reactions among the study groups

ADR	Topical Minoxidil	Oral Minoxidil	Total	P value
Present	11 (27.5%)	8(20%)	19(33.93%)	0.785
Absent	29 (72.5%)	32 (80%)	61(66.07%)	

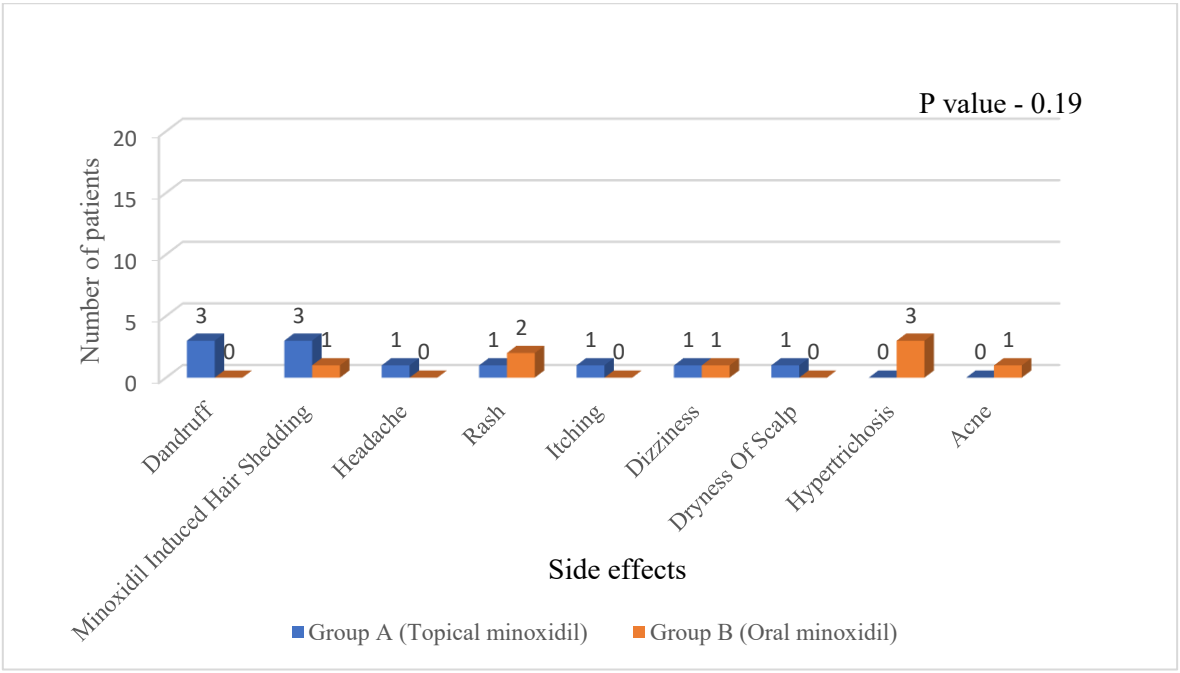

Figure 6: Types of ADRs among the study groups

TABLE 6: WHO-UMC casualty assessment scale among the study groups

Score	Topical Minoxidil	Oral Minoxidil	Total	P value
Certain	2	0	2	>0.05
Probable	8	7	15	
Possible	1	1	2	
Unlikely	0	0	0	

TABLE 7: Naranjo scale scoring among study groups

Score	Topical Minoxidil	Oral Minoxidil	Total	P value
Definite	0	0	0	>0.05
Probable	1	0	1	
Possible	10	8	18	
Doubtful	0	0	0	

TABLE 8: Severity of ADRs by Modified Hartwig and Siegel severity assessment scale

Scale	Level	Topical Minoxidil	Oral Minoxidil	Total	P value
Mild	1	8	7	15	>0.05
	2	3	1	4	
Moderate	3	0	0		
	4(a)	0	0		
	4(b)	0	0		
Severe	5	0	0		
	6	0	0		
	7	0	0		

TABLE 9: Preventability of ADRs by Schmock and Thorton Preventability scale

Scale	Topical Minoxidil	Oral Minoxidil	Total	P value
Definitely Preventable	0	0	0	>0.05
Probably Preventable	0	0	0	
Not Preventable	11	8	18	

DISCUSSION

Pattern hair loss is a condition that impacts the scalp, typically beginning in males in their late twenties and in females during perimenopause. In males, the bitemporal followed by vertex region are the most commonly affected areas, while in females, the crown and bitemporal regions are primarily involved.[4,13] The pathogenesis of pattern hair loss is multifactorial, influenced by a variety of factors such as genetic predisposition, age, hormonal imbalances, stress, and inflammation.[3] A physical examination of the scalp, along with trichoscopy, aids in categorizing the condition into different stages of hair loss.[14] This condition can result in considerable cosmetic concerns, negatively impacting the emotional and psychological well-being of patients, which can subsequently reduce their daily quality of life (DQOL).[3,4]

The treatment of pattern hair loss presents challenges due to its recurrent nature and the necessity for ongoing therapy. Effective treatment strategies aim to enhance blood flow, neuromodulation, and the inhibition of the DHT hormone. A variety of pharmacological and non-pharmacological treatment options are available, including topical minoxidil, oral finasteride, intralesional platelet-rich plasma, intralesional growth factors, botulinum toxin injections, oral minoxidil, hair transplants, nutritional supplements, laser therapy, antiandrogens, mesotherapy, and camouflage techniques. Among these, topical minoxidil and oral finasteride are FDA approved.[2,3,4]

Topical minoxidil has been widely utilized for treating androgenetic alopecia. It is thought to encourage angiogenesis, vasodilation, and exhibit anti-inflammatory and antiandrogenic properties. The active metabolite, minoxidil sulfate, facilitates the opening of ATP-sensitive potassium channels, which decreases calcium influx and prevents the inhibition of hair growth. Topical minoxidil is offered in both liquid and foam formulations. The liquid version contains alcohol and propylene glycol, which are crucial for dissolving the medication and enhancing its absorption through the skin. Typically, 2% and 5% minoxidil solutions are employed. Ongoing usage is necessary to sustain treatment outcomes, as stopping the medication usually results in the reversal of its therapeutic benefits.[2,3,9]

Oral minoxidil was initially utilized for the management of resistant cases of hypertension. However, it was observed that patients receiving oral minoxidil for hypertension developed hypertrichosis. This finding led to the repurposing of oral minoxidil for treating pattern hair loss. It is offered in tablet strengths of 2.5 mg and 10 mg. Although the oral formulation is not approved by the FDA for hair loss treatment, clinical trials have demonstrated its efficacy at low doses (ranging from 0.25 to 2.5 mg daily) in stimulating hair regrowth. It is available in both oral and sublingual forms. While minoxidil is typically well tolerated, it may lead to various side effects, especially when used topically, such as exacerbation of seborrheic dermatitis and contact dermatitis. Oral minoxidil may also result in cardiovascular and hematologic side effects, including hypotension. Nevertheless, these side effects are minimal when low-dose minoxidil is employed for the treatment of androgenetic alopecia (AGA). Regular monitoring is essential.[2,3,9]

Although topical minoxidil has been thoroughly researched, there is a notable deficiency in studies concerning oral minoxidil. This research gap motivated us to undertake a study to assess the effectiveness and impact of oral minoxidil among the treated individuals. In our investigation, the majority of participants were aged between 20 and 40 years. The mean age of individuals in group A (topical minoxidil group) was 25.97±7.59 years, whereas in group B (oral minoxidil group), it was 28.64±7.28 years (p value=0.5). The research included 28 males and 12 females in group A, while group B consisted of 18 females and 26 males. The duration of the disease was 20.97±14.59 months for group A and 22.44±17.62

months for group B (p value=0.5). In group A, 36 patients lived in urban areas and 4 in rural areas. Conversely, in group B, 27 patients resided in urban settings and 13 in rural locations (p value=0.5). At the Baseline stage of AGA in men, group A had 9 patients in stage -I, 13 in stage -II, and 6 in stage -III. In group B, there were 7 patients in stage -I, 11 in stage -II, 5 in stage -III, and 1 in stage -IV (p value=0.25). Women at the Baseline Stage of AGA in Group A, there were 8 patients in stage -I and 4 in stage -II. In group B, there were 10 patients in stage -I and 6 in stage -II (p value=0.18). The baseline demography between the two groups was statistically insignificant.

In Group 1, the average global photographic assessment scores for Group A was recorded at 0.29±0.46, 1.00±0.63, and 1.68±1.08 at the end of the 2nd, 4th, and 6th months, respectively, compared to a baseline value of -1.68±0.70, with a p-value of <0.0001 (see table no 2). Numerous previous studies have reported significant enhancements in global photographic assessment following the application of topical minoxidil for the treatment of AGA.[15,16]

In Group 2, the average global photographic assessment scores for Group B was noted at 0.32±0.56, 1.04±0.54, and 1.44±1.16 at the conclusion of the 2nd, 4th, and 6th months, respectively, from a baseline value of -1.72±0.74, with a p-value of <0.0001 (see table no 3). Numerous previous studies have indicated considerable improvements in global photographic assessment following the administration of oral minoxidil for AGA treatment.[17,18,19]

The intergroup comparison of global photographic assessment between the two treatment groups reveals no statistically significant difference, with a p-value of 0.43, as illustrated in table no 4, which was similar to previous studies.[20,21]

In our study, by the conclusion of a 6-month period, patient self-assessment regarding hair growth improvement revealed that 15 patients in group A reported a good response, while 17 patients indicated a very good response. In contrast, group B had 12 patients reporting a good response and 18 patients reporting a very good response. The differences between the groups were statistically insignificant (p value=0.50).[20,21]

Concerning adverse effects observed in our research, eleven patients in group A and eight patients in group B experienced adverse effects. In group A, three patients reported dandruff, three patients experienced minoxidil-induced hair shedding, and one patient each reported headache, rash, itching, dizziness, and scalp dryness. In group B, one patient reported minoxidil-induced hair shedding, two patients reported rash, three patients experienced hypertrichosis, and one patient each reported dizziness and acne. The adverse effects noted in both groups were transient and resolved upon discontinuation of the treatment, similar to previous studies.[20,21,22]

The assessment of causality for adverse drug reactions was conducted utilizing the WHO-UMC causality assessment scale, which categorizes drug reactions into certain, probable, possible, and unlikely. In group A, there were two certain ADRs (specifically, two instances of dandruff in the topical minoxidil group), eight probable cases, and one possible case. Conversely, group B reported seven probable ADRs and one possible ADR.

According to the Naranjo scale, group A exhibited one probable ADR and ten possible ADRs, while group B had eight possible ADRs.

The severity of the ADRs was also evaluated using the Modified Hartwig and Siegel severity assessment scale. All adverse drug reactions were classified as mild, corresponding to severity level 1, with eight patients from group A and seven patients from group B, followed by level 2, which included three patients from group A and one patient from group B. Based on the Schmock and Thorton Preventability Scale, all adverse drug reactions were deemed not preventable. Statistically, both groups showed no significant differences in terms of ADRs.

CONCLUSION

This research validates the efficacy of both topical and oral minoxidil in treating androgenetic alopecia. Both forms of minoxidil exhibited mild to moderate enhancements in hair growth among patients with AGA. At the conclusion of 6 months, topical and oral minoxidil proved to be nearly equally effective based on a global photographic evaluation of AGA using a standardized 7-point rating scale. Furthermore, both treatments demonstrated equivalent efficacy at the 6-month mark when assessed through patient self-assessment. In this investigation, both topical and oral minoxidil presented minor adverse drug reactions, with no statistically significant difference observed between the two groups. The majority of adverse drug reactions were mild and preventable.

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