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Original Research

To compare the effectiveness and safety of 5% minoxidil with 1 mg finasteride in treating male patients with androgenetic alopecia

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ABSTRACT:
Aim: To compare the effectiveness and safety of 5% minoxidil with 1 mg finasteride in treating male patients with androgenetic alopecia. **Material and Methods:** The research included 100 male patients who were in excellent health and had Androgenetic Alopecia (AGA) with grades II to V on the modified Norwood Hamilton classification. The research excluded patients with alternative causes of baldness, as well as those who had used minoxidil within the last 6 months, finasteride during the past 12 months, or were allergic to either of these drugs. Additionally, patients who had used ketoconazole, tar, selenium shampoos, topical tretinoin, or topical steroids within the past 2 weeks were also eliminated.Individuals were recruited into two distinct cohorts. Group A consisted of 50 patients who were administered a 1 ml dose of minoxidil 5% topical solution twice daily. Group B consisted of 50 patients who got a once-day oral dose of a 1 mg tablet of finasteride. The demographic characteristics and hair loss aspects of the patients were comparable across both groups at the beginning of the study. **Results:** In Group-A (minoxidil)from the baseline to 3-month change in hair count was 9.10%.Baselineto6&9monthitwas19.10%and22.07%respectivelywithp-value < 0.05. In Group-B (finasteride) from the baseline to 3-month change in hair count was 13.42% Baseline to 6 & 9 month itwas 23.99% and 40.31% respectively with p-value < 0.05. So therewas a significant change in hair count in both Groups.In Group-A 66 %patients had shown improvement in hair growth according while nochange was seen in 34% (17 patients). In Group-B, 72 %patients shown improvement in hair growth and in 28 % patients,no change was seen. **Conclusion:** Both medicines were determined to be efficacious and secure in the treatment of male androgenetic alopecia, as shown in this comparative analysis. The hair count assessment technique received particular emphasis due to its ability to provide more precise and objective data. Based on the assessment parameter, it was determined that oral administration of 1 mg finasteride was more successful (p< 0.05) compared to the topical application of 5% minoxidil.
Keywords: Minoxidil, Finasteride, Male, Androgenetic alopecia

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INTRODUCTION

Male androgenetic alopecia (MAGA) is distinguished by the reduction in size of the hair follicles in the frontal and parietal regions of the scalp [1]. The prevalence of this condition may vary, and it is seen in around 50% of males over the age of 40 [2, 3]. Despite the abundance of current therapies on the market, many continue to suffer from baldness and are actively searching for a dependable solution. At present, there are two drugs authorized by the FDA for the treatment of androgenetic alopecia (AGA): topical minoxidil and oral finasteride [2, 3]. Finasteride isa5α-reductase inhibitor prevents the conversion of testosterone to dihydrotestosterone, responsible for AGA [4].Minoxidil firstdeveloped to be an antihypertensive agent; Hypertrichosis wasobserved as a side effect which led to its formulation as a topicalagent for AGA [5].Minoxidil opens ATP-sensitive potassiumchannels, leading to a vasodilatory effect. Other actions on the hairfollicles have been suggested - increased expression of variousgrowth factors like VEGF in dermal papillae, hepatocyte growthfactor observed to enhance the size of the hair follicles and stimulate& prolong the

Anagen phase of the hair cycle [6, 7].Only a few datacomparing the oral drug finasteride 1 mg daily and minoxidil5%topical solution 1 ml twice daily are available. Two of the includedstudies examined finasteride 1 mg against twice daily topicalapplication of minoxidil 2% solution [8, 9] and both studies showed superiority for finasteride. At 12 months the mean change frombaseline totalhaircount was36.1hairs/cm2 (29.1%)forfinasteride1mg and 19.6 hairs/cm^2 (14.8%) for minoxidil 2%, twice dailyapplication.Thisarticlewillbehelpfulinprovidinga useful information and determining an appropriate treatment strategyfor the male patient of androgenetic alopecia.

MATERIAL AND METHODS

This investigation was conducted as an observational, prospective, open-label, parallel study and was authorized by the institutional ethics committee. The research included 100 male patients who were in excellent health and had Androgenetic Alopecia (AGA) with grades II to V on the modified Norwood Hamilton classification [10]. These patients were recruited in the trial after providing written informed permission and meeting all the inclusion and exclusion criteria.

This research included all men diagnosed with androgenetic alopecia (AGA) between the ages of 18 and 40.

The research excluded patients with alternative causes of baldness, as well as those who had used minoxidil within the last 6 months, finasteride during the past 12 months, or were allergic to either of these drugs. Additionally, patients who had used ketoconazole, tar, selenium shampoos, topical tretinoin, or topical steroids within the past 2 weeks were also eliminated.

Individuals were recruited into two distinct cohorts. Group A consisted of 50 patients who were administered a 1 ml dose of minoxidil 5% topical solution twice daily. Group B consisted of 50 patients who got a once-day oral dose of a 1 mg tablet of finasteride. The demographic characteristics and hair loss aspects of the patients were comparable across both groups at the beginning of the study.

Hairs were quantified inside circular zones of 1 cm in diameter using a COSCAM (USB-225) cosmetic camera manufactured by SOME TECH INC. To analyze hair count, a specific region on the top of the head was chosen and cut. A line was extended from the left pinna, across the vertex and reaching the right pinna. Next, create a circular hole with a diameter of 1 cm at the end of the rectangular plastic template. The hole should be positioned at the halfway between the eyebrows and the vertex, which is a fixed length away. The unique template was established on the first visit. During each following appointment, the same region was discovered and hair was trimmed. The hair counts were measured twice and the mean was used to assess the effectiveness.

Standardized colour global photographs of the affected area were taken with the head in a stereotacticpositioning device. A blinded evaluator was used to review thepaired baseline and post-treatment photographs with the use of thestandardized rating scale, having following 7 points (–3: greatly decreased,–2:moderately decreased,–1:slightly decreased,0:no change, +1: slightly increased, +2: moderately increased, +3: greatly increased).

Evaluation of safety was done by clinicalevaluation and adverse event reports.

STATISTICAL ANALYSIS

The collected data was entered in the MS Excel sheet for statisticalanalysis.TheStatistical analysis was conducted to determine the significance of the change in hair count from the first measurement using the paired t-test. The significance of the difference in hair count between minoxidil and finasteride was assessed using the unpaired t-test. The unpaired t-test was used to analyze the differences in global photographic judgment. The variability of data should be quantified using the standard deviation (SD). P-values are considered statistically significant when they are below 0.05.

RESULTS

As shown in Table 1 , in Group-A (minoxidil) from the baseline to 3-month change in hair count was 9.10%. Baseline to 6 & 9 month it was 19.10% and 22.07% respectively with p-value < 0.05. Table 2 show that in Group-B (finasteride) from the baseline to 3- month change in hair count was 13.42% Baseline to 6 & 9 month it was 23.99% and 40.31% respectively with p-value < 0.05. So there was a significant change in hair count in both Groups. Change in mean hair count from baseline to 9 months, was more in Group-B i.e. (40.31%) compared to Group-A which is (22.07%), statistically this difference was significant (p- value: <0.05).Table 3 illustrates the change in Global photographic assessment score after the treatment in both Groups. In Group-A 66 % patients had shown improvement in hair growth according while no change was seen in 34% (17 patients). In Group-B, 72 % patients shown improvement in hair growth and in 28 % patients, no change was seen.There was no significant adverse effect in both finasteride and the minoxidil Group. The Group treated with oral finasteride, side effects were noted in 5 patients: 3 patients suffered from loss of libido, two showed other side effect (hair loss), irritation of the scalp was seen in 11 patients and 3 patients had increase other body hairs in the group administered 5% minoxidil. These adverse events disappeared as soon as the treatment was stopped.

Table 1: Scalp Hair Count values(per square centimetre) before and after treatment in Group A-minoxidil

	Before Treatment	After Treatment		
	Baseline	**3**	**6**	**9**
Mean	94.78±5.45	103.98±3.65	113.88±3.56	116.85±3.87
% change	-	9.10	19.10	22.07
Tscore	-	5.54	3.74	4.85
p - value	-	0.56	0.04	0.0001

Table 2: Scalp Hair Count values(per square centimetre) before and after treatment in group B-finasteride

	Before Treatment	After Treatment		
	Baseline	**3**	**6**	**9**
Mean	95.36±3.72	108.78±3.62	119.35±3.11	135.67±3.71
% change	-	13.42	23.99	40.31
T score	-	4.54	5.75	4.11
p - value	-	0.0007	0.14	0.0006

Table 3: Global photographic assessment after treatment in Group-A and Group-B

Group	A–minoxidil		B–finasteride	
Patients	**Total**	**%**	**Total**	**%**
-1	0	0	2	4
0	17	34	12	24
+1	6	12	3	6
+2	22	44	7	14
+3	5	10	26	52

DISCUSSION

In this research, we assessed the effectiveness of oral finasteride and 5% topical minoxidil therapy over a period of 9 months in 100 male patients with varying degrees of androgenetic alopecia (AGA). The average age of patients in Group A was 28.11±4.72 years, whereas the average age of patients in Group B was 30.72±4.11 years. The difference in age between the two groups was not statistically significant (P= 0.23).The change in mean hair count from baseline to 9 months, was morein Group B (finasteride) (40.31%)compared toGroup A (5% minoxidil) (22.07%), statistically thisdifference wassignificant (p-value: <0.05). In finasteride therapy(Group-B) there was a significant increase in the mean hair count.The mean baseline values of hair count were 95.36±3.72/cm^2,which increased by 40.31% to mean 135.67±3.71. /cm^2 at 9 months(P=0.0006). Our finding is similar to the study of Kawashima et al[11].In minoxidil (Group-A), the mean baseline value was 95.18 ±8.20/cm^2, which was increased by 31.8 % at 9 months (P=0.001). Ourfinding is similar to that Rai PBet al [12], Mysore V et al[13] and Tsuboi et al [14] observed a significantincrease in hair count.

In finasterideGroup 26 patientshad marked improvementon 7-pointvisual analogue scale, while only 5 patients showed markedimprovement in the minoxidil Group. Arca et al finds a betteroutcome for finasteride 1 mg daily against minoxidil 5 % topicalsolution applied twicedaily at theglobal photographic assessmentofthe frontal/parietal region at 12 months (80 % vs. 52 %improvement)[9].

In finasteride treatment, major side effects observed were a loss oflibido, seen in 3 patients &2 patients complained of hair loss. Inthe minoxidil group, irritation of the scalp in 11 patients andhypertrichosis of facial hair in 3 patients was observed. Ourfindings are similar to the Arca et al study [9].

CONCLUSION

Both medicines were determined to be efficacious and secure in the treatment of male androgenetic alopecia, as shown in this comparative analysis. The hair count assessment technique received particular emphasis due to its ability to provide more precise and objective data. Based on the assessment parameter, it was determined that oral administration of 1 mg finasteride was more successful (p< 0.05) compared to the topical application of 5% minoxidil. The significance of adverse events was not acknowledged, and these undesirable consequences ceased with discontinuation of the medication. Managing male AGA patients is a time-intensive process that involves medical evaluation, thorough explanation with counseling and reassurance, and ongoing monitoring of any prescribed therapy. It is essential for clinicians to possess comprehensive knowledge of the latest therapy choices, including their efficacy and constraints.

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