Original Research Article

Comparative Evaluation of Efficacy and Safety of 5% minoxidil and 1 mg finasteride in Male Patients of Androgenetic Alopecia

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Abstract

Objective: Androgenetic Alopecia (AGA) is a common cause of hair loss among male. Two FDA approved drugsminoxidil and finasteride seems to be more promising for its treatment. This study compares both the drugs in term of efficacy & safety. **Methods:** About76 patients enrolled in Group-A &70 patients in Group-B were treated with topical 5% minoxidil 1 ml twice daily& oral 1 mg finasteride once daily respectively. **Evaluation of efficacy**: parameters-Scalp hair counts & Investigator assessment. Evaluation of safety was done by Clinical Evaluation and Adverse Event Reports. After completion of study hair count was 25.07% & 41.72% in Group-A & B respectively with p-value < 0.05. **Investigator assessment**: About 7 patients showed marked improvement in Group-A, while 31 patients in the Group-B. Safety Evaluation: irritation of the scalp observed in 15% patients and Hypertrichosis of facial hair in 3% patients in Group A, loss of libido observed in 3.2% patient in Group B. **Conclusion:** Both drugs were effective and safe in the treatment of AGA. Oral finasteride was found to be more effective ($p<0.05$).

Keywords: Hair follicles, Baldness, Hair count, Male androgenetic alopecia, Topical minoxidil, Oral finasteride

Introduction

Male androgenetic alopecia (MAGA) is characterized by the miniaturization of the hair follicles in the frontal and parietal scalp [1]. Prevalence may vary, seen in around 50% of men beyond age 40 [2, 3]. There are a lot of treatments available in the market but in spite of these people are still suffering with baldness and seeking a reliable option. Currently, two FDA-approved medicines used for AGA are topical minoxidil and oral finasteride [2, 3]. Finasteride is a 5α-reductase inhibitor prevents the conversion of testosterone to dihydrotestosterone,responsible for AGA [4].Minoxidil first developed to be an antihypertensive agent; Hypertrichosis was observed as a side effect which led to its formulation as a topical agent for AGA [5].Minoxidil opens ATP-sensitive potassium channels, leading to a vasodilatory effect. Other actions on the hair follicles have been suggested - increased expression of various growth factors like VEGF in dermal papillae, hepatocyte growth factor observed to enhance the size of the hair follicles and stimulate & prolong the Anagen phase of the hair cycle [6, 7].Only a few data comparing the oral drug finasteride 1 mg daily and minoxidil5% topical solution 1 ml twice daily are available. Two of the included studies examined finasteride 1 mg against twice daily topical application of minoxidil 2% solution [8, 9] and both studies showed superiority for finasteride. At 12 months the mean change from baseline total hair count was 36.1 hairs/cm2 (29.1%) for finasteride 1 mg and 19.6 hairs/cm^2 (14.8%) for minoxidil 2%, twice daily application ($p = 0.003$). This article will be helpful in providing a

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useful information and determining an appropriate treatment strategy for the male patient of androgenetic alopecia.

Material and Methods

This was an observational, prospective, open-label; parallel study approved by the institutional ethical committee and was conducted for duration of 12 months. A total of 146 male patients in good health having AGA with II to V grade on the modified Norwood Hamilton classification [10] were enrolled for the study with their written informed consent complied with all the inclusion and exclusion criteria.

The sample size is calculated with the following formula

$$n = \frac{Nz^2p(1-p)}{d^2(N-1)+z^2P(1-P)}$$

Where,

n = sample size,z= z statistic for a level of confidence, N= Population size

P= expected prevalence or proportion (50%), d= precision (in proportion of one; if 3%, = 0.03),

Inclusion Criteria: All diagnosed AGA males of age between 18-40 years

Exclusion Criteria: Patients with other cause of baldness and patient who had used minoxidil in last 6 months or finasteride in the last 12 months or allergic to either drug or used ketoconazole, tar, selenium shampoos, topical tretinoin, the topical steroid in the last 2 weeks were excluded from the study.

Patients were enrolled in two separate Groups. Group A- Comprised of 76 patients who received minoxidil 5% topical solution 1 ml twice a day and Group B- Comprised of 70 patients received oral finasteride 1 mg tablet once a day.128 of the 146 patients completed the one year study period of which 66 were treated with 5% minoxidil 1 ml topical solution twice daily and 62 were treated with finasteride 1 mg oral drug once daily (18 subjects lost to follow-up and they were not considered for efficacy and safety evaluation). Patients' demographic and hair loss features at baseline were similar among the both Groups.

Efficacy Evaluation

Scalp Hair Counts: Hairs were measured within 1-cm diameter circular areas with the help of a COSCAM (USB-225) cosmetic camera, Manufacturer SOME TECH INC. In order to analyse hair count, a clipped area of vertex was selected. A line was drawn from the left pinna, passing through the vertex to the right pinna. Then, cut a 1-cm diameter circular hole at the end of the rectangular plastic template with the fixed length from a midpoint between eyebrows to the vertex. The individual template was created at the first visit. At each subsequent visit, the same area was identified and hairs were clipped. The hair counts were measured twice and used the mean to evaluate the efficacy.

Investigator Assessment: Standardized colour global photographs of the affected area were taken with the head in a stereotactic positioning device. A blinded evaluator was used to review the paired baseline and post-treatment photographs with the use of the standardized 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).

Safety Evaluation*:* Evaluation of safety was done by clinical evaluation and adverse event reports.

Statistical Analysis

The collected data was entered in the MS Excel sheet for statistical analysis. The significance of change in hair count from baseline were performed using the paired t-test. The significance of hair count change between minoxidil and finasteride were performed using the unpaired t-test. Differences of global photographic assessment were analysed by the unpaired t-test. The variation of data should be expressed in terms of the standard deviation (SD).P-values are supposed to be statistically significant if values are less than 0.05.

Results

Scalp Hair Count: As shown in Table 1, in Group-A (minoxidil) from the baseline to 3-month change in hair count was 4.03%. Baseline to 6 & 9 month it was 19.91% and 25.07% respectively with p-value < 0.05. In Group-B (finasteride) from the baseline to 3-month change in hair count was 9.17 % Baseline to 6 & 9 month it was 24.63% and 41.72% 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. 40.27 hairs/cm^2 (41.72%) compared to Group-A which is 23.86 hair/cm^2 (25.07%), statistically this difference was significant (p-value: <0.05).

Investigator Assessment

Table 2 illustrates the change in Global photographic assessment score after the treatment in both Groups. In Group-A 66.67 % patients had shown improvement in hair growth according while no change was seen in 33.33% (22 patients). In Group-B, 72.52 % patients shown improvement in hair growth and in 20.96 % patients, no change was seen.

Safety Evaluation

There was no significant adverse effect in both finasteride and the minoxidil Group. The Group treated with oral finasteride, side effects were noted in 4 patients: 2 patients suffered from loss of libido, two showed other side effect (hair loss), irritation of the scalp was seen in 10 patients and 2 patients had increase other body hairs in the group administered 5% minoxidil as depicted in Figure 1. These adverse events disappeared as soon as the treatment was stopped.

Table 1: Scalp Hair Count values (per square centimetre) before and after treatment

	Group A - minoxidil (66 Patients)				B - finasteride (62 Patients)			
	Before Treatment	After Treatment			Before Treatment	After Treatment		
	Baseline	3	6	9	Baseline	3	6	9
Mean	95.18	104.03	114.14	116.5	96.52	109.18	120.29	136.79
Standard Deviation (SD)	± 8.2	± 3.24	± 20.56	± 24.79	11.67	± 14.14	± 20.45	± 24.89
% change	-	4.03	19.91	25.07	-	9.17	24.63	41.72
T score	-	6.23	2.15	5.85	-	3.64	4.59	3.57
p - value	-	1E-05	0.035	0.0001	-	0.0006	2E-05	0.0007

Table 2: Global photographic assessment after treatment in Group-A and Group-B

Group	A – minoxidil (66 Patients)		B – finasteride (62 Patients)	
Patients	Total	%	Total	%
-1	0	0	2	3.2
0	22	33.33	15	24.19
+1	8	12.12	4	6.4
+2	29	43.93	10	16.12
+3	7	10.6	31	50

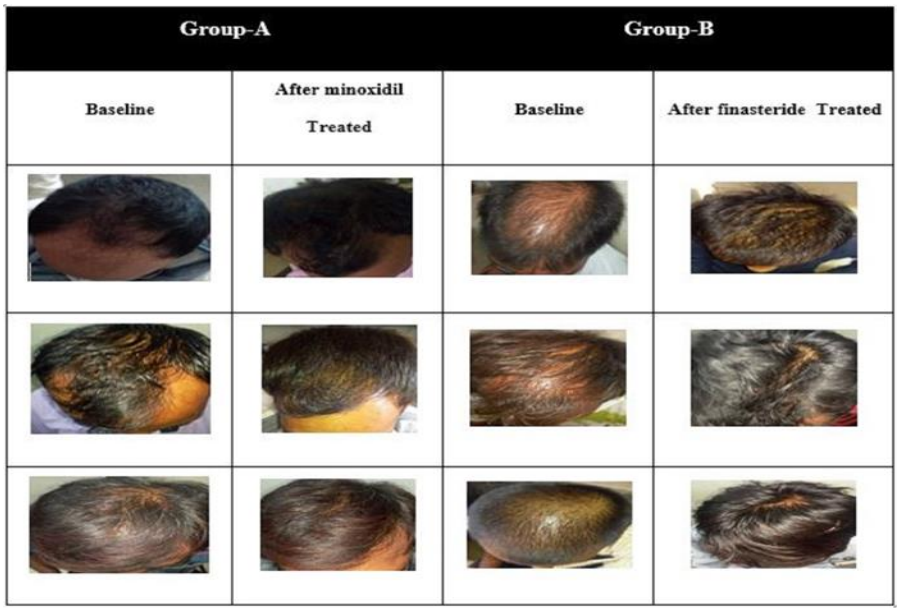

Fig 1: Global photographic assessment after treatment in Group-A and Group-B

Discussion

In this open, randomized and comparative study, we evaluated the efficacy of oral finasteride and 5 % topical minoxidil treatment for 9 months in 128 male patients with mild to severe AGA. In our study, the mean age of patients in Group A was 27.90 years, the mean age of the patients in Group B was 29.13 years and the difference in age between the two groups was statistically not significant (P= 0.9).

Scalp Hair Counts Assessment

The change in mean hair count from baseline to 9 months, was more in Group B (finasteride) 40.27 hairs/cm^2 (41.72%) compared to Group A (5% minoxidil) 23.86 hair/ cm^2 (25.07%), statistically this difference was significant (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 96.52 ±11.67/cm^2, which increased by 41.07 % to mean 136.79 ±24. /cm^2 at 9 months (P=0.0007). 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). Our finding is similar to that Blume-peytavi et al (2019) [12], Bao et al (2020) [13] and Tsuboi et al (2009) [14] observed a significant increase in hair count.

Investigator Assessment

In finasteride Group 31 patients had marked improvement on 7-point visual analogue scale, while only 7 patients showed marked improvement in the minoxidil Group. Figure 2 shows some of the improved and marked hair growth images taken with the help of COSCAM (USB-225) cosmetic camera. Arca et al finds a better outcome for finasteride 1 mg daily against minoxidil 5 % topical solution applied twice daily at the global photographic assessment of the frontal/parietal region at 12 months (80 % vs. 52 % improvement) [9].

Safety Assessment

In finasteride treatment, major side effects observed were a loss of libido, seen in two patients & 2 patients complained of hair loss. In the minoxidil group, irritation of the scalp in 10 patients and hypertrichosis of facial hair in two patients was observed. Our findings are similar to the Arca et al study [9].

Conclusion

In this comparative study both drugs were found to be effective and safe in the treatment of male AGA Out of all evaluation methods special attention was given to hair count as it shows the more accurate data and this is not subjective. On that evaluation parameter, oral 1 mg finasteride was found to be more effective ($p< 0.05$) than topical 5% minoxidil. Adverse events were not considered important either, and these side effects disappeared as soon as the treatment was stopped. The management of the patient with male AGA is time-consuming, requiring medical assessment, detailed explanation with counselling and reassurance, and continued supervision of any medical treatment. Clinicians need to be well informed about current treatment options, their success rate and limitations.

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