ORIGINAL ARTICLE

COMPARISON OF ORAL MINOXIDIL WITH ORAL DUTASTERIDE IN THE TREATMENT OF MALE ANDROGENETIC ALOPECIA- A RANDOMIZED CONTROL TRIAL

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ABSTRACT
INTRODUCTION: Androgenetic alopecia is a genetically predetermined disorder due to excessive response to androgens which affects up to 50% of males. MPHL is the most common hair loss disorder in men. The MPHL is a non-scarring progressive thinning of hair which causes psychological distress affecting quality of life of the patient. Although MAA is often regarded as a relatively minor dermatological condition, hair loss impacts self-image and is a great cause of anxiety and depression in some men. Though various modalities are available for the treatment of androgenetic alopecia, assessment of efficacy of treatment must be considered.
AIMS AND OBJECTIVES:
1. To compare the efficacy of low dose oral minoxidil with that of low dose oral dutasteride.
2. To document the adverse effects associated with that of oral minoxidil and oral dutasteride.
MATERIALS AND METHODS: After obtaining informed consent,64 male patients of age 18-30 years diagnosed to have androgenetic alopecia attending the Department of Dermatology, R L Jalappa Hospital and Research centre from October 2022- March 2024 will be taken for the hospital based Comparative Interventional Study. Among 64 male patients with androgenetic alopecia, 32 patients are treated with oral minoxidil 5mg once daily and 32 patients are treated with oral dutasteride 0.5 mg thrice a week for a period of 12 months.
RESULTS: Efficacy of treatment modality-assessed using means score of GPA -Scale suggests significant improvement in both the groups initially but drastic improvement and patient satisfaction was observed in Group B with subsequent sittings compared to Group A. Patients in Group B had lesser side effects than Group A.
CONCLUSION: This study showed that oral Dutasteride 0.5 mg thrice weekly is a better treatment modality than oral Minoxidil 5mg daily for the treatment of Male Androgenetic alopecia with respect to efficacy, safety and adverse effects.
KEYWORDS: Androgenetic alopecia, Oral Minoxidil, Oral Dutasteride.
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INTRODUCTION

The most prevalent type of alopecia in the world, androgenetic alopecia (AGA), referred to as male pattern hair loss (MPHL) or female pattern hair loss (FPHL), is influenced by genetics and sensitivity to androgens.[1] AGA manifests in a distinctive distribution that is specific to both genders. This disorder is characterized by a progressive loss of scalp terminal hair that usually happens after puberty and has a unique pattern in both males and females.[2] While females tend to maintain their frontal hairline while having diffuse apical hair thinning, which gives the anterior area of the hair a larger appearance, males often exhibit hair loss most prominently at the vertex and frontotemporal regions.[4] Even with its widespread occurrence, AGA can be difficult to treat. The quality of life may be impacted by AGA's effects on appearance and psychosocial experiences (QOL). According to numerous studies, men who lose their hair too soon frequently display emotional discomfort and express major concern to their peers and family.[8,9,10] The chronic nature of the illness is caused by a combination of environmental and hereditary factors.[6,7] Topical minoxidil and oral finasteride are the only two medications for the illness that have received FDA approval in the US.[5] Nonetheless, a number of studies have demonstrated the efficacy of non-FDA-approved therapies in the management of AGA.

Low-dose oral minoxidil and low-dose oral dutasteride have drawn increased attention recently for the treatment of AGA, despite not being FDA authorized.[3] Hence, this study was proposed to assess and compare the efficacy and safety of low dose oral Minoxidil and low dose oral Dutasteride in the treatment of Male Androgenetic Alopecia.

MATERIALS AND METHODS:

This Randomized Control Trial (RCT) hospital based study was conducted in the outpatient department of Dermatology, Venereology and Leprosy in R L Jalappa Hospital and Research Centre, Tamaka, Kolar from October 2022- August 2024 after obtaining Ethical clearance. An informed consent was procured from AGA patients about the participation in the study. Male patients aged 18-30 years with AGA grade 1-5 of Norwood Hamilton scale and patients who had not taken medical treatment for AGA in any form for the past 3 months were included in the study. Patients with alopecia secondary to known endocrinological disorders and systemically ill were excluded from the study. Total sample size of 64 cases were screened from October 2022- August

2024.These patients were divided into two groups – Group A and Group B with 32 patients in each group and randomization was done using COMPUTER GENERATED BLOCK RANDOMIZATION from www.randomization.com

GROUP A: ORAL MINOXIDIL

Patients in Group A were treated with low dose oral Minoxidil 5mg once daily for a period of 12 months.

GROUP B: ORAL DUTASTERIDE

Patients in Group B were treated with low dose oral Dutasteride 0.5mg thrice a week for a period of 12 months.

Assessment of efficacy and safety profile in both groups were done by Global Photographic Assessment (GPA) Scale.

GLOBAL PHOTOGRAPHIC ASSESSMENT(GPA) SCALE:

Patients in this study had undergone serial global photography of vertex and frontal areas at baseline and at subsequent follow up. Lighting and positioning were kept identical for all serial photographs. The serial photographs were assessed independently by a Blinded Third Observer. The Blinded Third Observer gave the grading of the efficacy of the treatment modality based on the Global Photographic Assessment (GPA) Scale. GPA Scale was calculated for all the patients at baseline and at subsequent follow-up. A score of 0,1,2 and 3 was given if the response was <25%, 25-50%, 51-75% and >75% respectively by the Blinded Third Observer. Adverse effects were also documented to assess the safety of both the treatment modalities.

STATISTICAL ANALYSIS:

Study data was entered into Microsoft Excel Data sheet. It was then analysed using SPSS 22 software. Σ(average) was calculated for GPA assessment at end of each follow up. Categorical data was represented in the form of frequencies and proportion. Chi-square Test or Fischer's Exact test was used as Test of significance for qualitative data. Continuous data was represented as Mean and Standard deviation. Independent t-test was used as test of significance to identify the mean difference between two quantitative variables.

RESULTS:

In this study, majority of the patients in Group A and Group B belonged to the age group of 24-30 years (59.38%) followed by 18-23 years of age (40.62%) In this study, there was a familial history of AGA in 60.94% of the individuals. Also 59.3% were skilled professionals followed by students (23.44%), semi-skilled professionals (10.94%) and unskilled workers (6.25%). The most common Norwood Hamilton classification was Type IV (39.06%) followed by Type III (28.13%), Type V (23.44%), Type II (7.81%), Type I (1.56%) The mean GPA Scale at baseline, 12 weeks, 24 weeks, 36 weeks and 48 weeks in Group A was 0, 0.81, 1.72, 2.41 and 2.49 respectively. The mean GPA scale at baseline, 12 weeks, 24 weeks, 36 weeks, 48 weeks in Group B was 0,1.00,1.97,2.57 and 2.94 respectively. P value was <0.001 for GPA after 12 weeks, 24 weeks, 36 weeks and 48 weeks. However, GPA Scale at the end of 36 weeks was not <0.001(p value=0.436). Hence, the data of efficacy of both treatment modalities assessed at the end of 48 weeks using GPA Scale were statistically significant.

The results of GPA Scale were as follows:

Table 1: Efficacy assessed using GPA-Scale

GROUP	MEAN SCORE				
	BASELINE	12 WEEKS	24 WEEKS	36 WEEKS	48 WEEKS
GROUP A	0.00	0.81	1.72	2.41	2.69
GROUP B	0.00	1.00	1.97	2.56	2.94
P Value	NA	<0.001	<0.001	0.436	<0.001

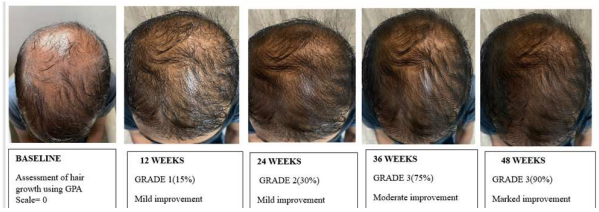
The documentation of adverse effects was as follows:

Table 2: Adverse Effects observed in both the groups.

	Erectile Dysfunction	Pedal Edema	Orthostatic Hypotension	Decreased libido	Hypertrichosis
Group A	0 (0.0%)	4 (12.5%)	6 (18.8%)	0 (0.0%)	14 (43.8%)
Group B	6 (18.8%)	0 (0.0%)	0 (0.0%)	9 (28.1%)	0 (0.0%)

GROUP A

GROUP B



DISCUSSION:

AGA is a multifactorial disorder caused by interactions between several genes and environmental factors. The pathogenesis of patterned baldness differs between men and women. AGA remains a source of psychological distress to the balding men.[11] In this study, majority of AGA patients (59.38%) belonged to 24-30 years of age followed by 18-23 years of age (40.62%). The history of family members with baldness is present in 60% of study population. In this study, the most common Norwood Hamilton classification was Type IV(39.06%) followed by Type III (28.13%) and Type V (23.44%). These findings are in association with the observations of Ratchathorn Panchaprateep et al[12] , Cameron et al[13] , Suparaj Lueangarun et al.[12] There are various treatment modalities for male AGA, but there are only limited effective modalities among which low dose oral Minoxidil and

low dose oral Dutasteride is gaining popularity in recent times since these drugs demonstrated a promising safety and efficacy profile in the treatment of male AGA.

Minoxidil has an essential role in the anagen phase, which could stimulate hair growth. The drug may accelerate the anagen phase by increasing DNA synthesis in anagen bulb. Hence oral minoxidil may be an effective substitute,[16] especially for male AGA and FPHL patients who have not seen positive results from topical minoxidil.[17] Dutasteride is a type I and II 5-ARI that is FDA approved for treatment of benign prostatic hyperplasia and is used off label to treat AGA. Dutasteride is more effective than finasteride since it inhibits both 5-α-reductase types I and II, which results in a 90% decrease in serum DHT levels as opposed to a 70% decrease with finasteride.[14] In our study, the efficacy of both treatment modalities was assessed using GPA scale. At the end of 48 weeks, GPA scale showed a score of 3(>75% improvement) to all cases treated with oral Dutasteride 0.5mg thrice weekly and 68.75% cases treated with oral minoxidil 5 mg. This finding is consistent with the observations of Aditya K Gupta et al and Rachita S Dhurat.[15] In this study, the patients who were treated with Oral Minoxidil 5 mg had adverse effects such as Hypertrichosis(43.8%) followed by orthostatic hypotension (18.8%) and pedal edema (12.5%). This result is in line with the observations of Mesbah Talukder, Amer Shemar in their research.[18] Those patients in Group B who were treated with oral Dutasteride had minimal adverse effects compared to Group A. The side effects were decreased libido (28.1%) and erectile dysfunction (18.8%) which were reversible. This finding is consistent with the research of Yunbu Ding et al.[19]

CONCLUSION:

From the results, it is evident that both the drugs oral Minoxidil and Oral Dutasteride showed significant improvement in the initial few weeks of therapy but patient satisfaction and greater treatment efficacy is seen with low dose oral Dutasteride in the subsequent follow up. Also, the side effects are minimal in patients treated with oral Dutasteride than the patients treated with oral Minoxidil.

Hence, we conclude that oral Dutasteride is a better treatment modality compared to oral Minoxidil for AGA with respect to efficacy, safety and adverse events.

DECLARATION OF PATIENT CONSENT:

The authors certify that the consent forms have been taken appropriately for the patients for their participation in the study and publication of their images and their clinical profile in their journal. Their identity will be concealed.

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CONFLICTS OF INTEREST: No conflicts of interest.

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