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ORIGINAL ARTICLE

Efficacy and safety of oral minoxidil 5 mg in male patients with androgenetic alopecia.

Saira Muaaz[1], Sumera Hanif[2], Talat Masood Akbar[3], Tariq Rasheed[4], Haroon Nabi[5]

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ABSTRACT… Objective: To determine efficacy and safety of oral minoxidil 5mg in male patients with androgenetic alopecia. **Study Design:** Non Randomized Clinical Trial. **Setting:** Department of Dermatology, Lahore Medical and Dental College/ Ghurki Trust and Teaching Hospital Lahore. **Period:** 14th April 2022 to 31st July 2023. **Methods:** It was a non-randomized clinical trial in which 30 male patients were enrolled according to inclusion criteria. Oral minoxidil 5mg once daily was given to patients for 24 weeks. This study was conducted at Department of Dermatology Lahore Medical and Dental College/ Ghurki Trust and Teaching Hospital Lahore with ethical letter no LM&DC/ 5363-64. Efficacy was measured by hair thickness, global photographic assessment and self-assessment questionnaire. Safety was measured by history, physical examination and laboratory investigations. **Results:** Two patients left treatment due to side effects (exacerbation of asthma and hypertrichosis) and 1 patient was lost to follow up. Therefore, total results were for 27 patients. Mean change in hair thickness was significantly increased from baseline 0.026±0.008 mm to 0.037±0.008 mm with p value 0.002 at 24 weeks. Global photographic assessment of patient's scalp shows marked improvement. Patient self- assessment questionnaire showed satisfaction of patients with significant p value < .001. Side effects noted were hypertrichosis in 77% and mild headache in 7% patients. All laboratory parameters remained within normal range. **Conclusion:** Oral minoxidil is a safe and effective drug. It has significantly increased hair thickness and improved appearance in our patients.

Key words: Androgenetic Alopecia, Minoxidil.

INTRODUCTION

Alopecia caused by androgens in genetically susceptible persons is known as androgenetic alopecia (AGA).[1] It is a form of non-scarring hair loss, affecting 50% of males over 50 years of age and occur after menopause in women.[2] Profound hair loss affects standard of health of a person.[2] Autosomal dominant gene mutations cause baldness in men.[3] This is a polygenic disorder inherited from any of the two parents or endocrinal factors causing increase in level of dihydrotestosterone.[1]

Androgenetic alopecia puts psychological impact on affected individuals.[4] It affects all races.[4] The interaction between dermal papillae and hair follicles affected by androgens plays a critical role in miniaturization of hair follicles.[4] Alteration in hair cycle dynamics due to stepwise reduction of hair follicles causes androgenetic alopecia.[4] Balding scalp has increased concentration of DHT, 5 α-reductase and androgen receptors.[5] The increase concentration of androgens and androgen receptors causes increase expression of genes which regulate follicular cycling.[4]

Many treatment options are available for androgenetic alopecia including topical and oral medications. Topical medications include minoxidil and finasteride; other treatment modalities e.g. microneedling, platelet rich plasma, low level laser light (LLLT) are being performed, but their use is limited due to their side effects and cost.[2] Oral medications include Finasteride and Spironolactone. For many years, the FDA-approved medications used to treat alopecia were topical minoxidil and oral finasteride but many patients develop irritant or

1. MBBS, Post Graduate Resident Dermatology, LMDC / Ghurki Trust Teaching Hospital, Lahore.
2. MBBS, FCPS, Senior Registrar Dermatology, LMDC / Ghurki Trust Teaching Hospital, Lahore.
3. MBBS, FCPS, Associate Professor Dermatology, LMDC / Ghurki Trust Teaching Hospital, Lahore.
4. MBBS, FCPS, Professor Dermatology, Jinnah Hospital, Lahore.
5. MBBS, FCPS, Professor Dermatology, LMDC /Ghurki Trust Teaching Hospital, Lahore,

Correspondence Address:
Dr. Saira Muaaz
Department of Dermatology
LMDC / Ghurki Trust Teaching Hospital, Lahore.
ferryland2@gmail.com

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allergic contact dermatitis with topical minoxidil.[3] If topical minoxidil is stopped, baldness occurs again withing 6 months, hence it demands continuous usage.[6] Finasteride may cause loss of libido, erectile dysfunction, and inhibition of spermatogenesis.[7] Therefore, we are in search of new therapies for androgenetic alopecia.[8]

Oral minoxidil use for male pattern androgenetic alopecia is getting enhanced attention.[9] It is derived from piperidinopyrimidine.[10] Minoxidil is a vasodilator drug originally approved for treatment of hypertension in 1979 with doses from 10-40 mg daily (maximum dose 100mg /day).[11] Majority of side effects occur with high doses; administered for treatment of systemic hypertension; including, fluid retention, increase hair growth, pleural effusion and abnormal electrocardiographic findings due to which patients do not prefer to take this medication.[9] Minoxidil in androgenetic alopecia is given at low doses (1.25-5 mg/ day) with minimal side effects.[8]

It is an easily accessible drug, which is economical and safe in healthy persons at low dose.[5] Tablet minoxidil can also be used along with other topically applied drugs.[10] In low doses oral Minoxidil has also been used as an off-label medication for many other diseases including traction alopecia, monilethrix, frontal fibrosing alopecia, alopecia areata (AA), permanent chemotherapy- induced alopecia and loose anagen hair syndrome.[12]

Oral minoxidil promote hair growth through several ways, including (a) prolongation of anagen phase, (b) hyperpolarization of cell membrane through opening of potassium channels, thus inhibiting calcium entry and promoting hair growth, (c) delay in hydrolysis of cAMP through inhibition of phosphodiesterase thus causing vasodilatory action.[13]

Minoxidil has 5 advantages including (1) easy to swallow as compared to applying topically (2) enhance cosmesis (3) cost saving (4) easy co-therapy with other topical applications (5) good compliance to treatment.[14]

A study was conducted by Panchaprateep et al to evaluate the efficacy and safety of oral minoxidil for the treatment of male pattern hair loss. Side effects noted were pedal edema (10%) and hypertrichosis (93%) of patients. No significant side effects were noted ($p = 0.007$).[9]

Jimenez-Cauhe et al conducted a study based on effectiveness and safety of low-dose oral minoxidil in males with androgenetic alopecia and the physical improvement was noted in 37 (90.2%) patients, with 11 (26.8%) of these patients present with marked improvement.[15]

Currently no study has been done on the use of oral minoxidil in male androgenetic alopecia patients in Pakistan therefore the rationale of our study is to check efficacy and safety of oral minoxidil in male patients with androgenetic alopecia in our population.[9]

METHODS

After approval from institutional ethical committee this single arm clinical trial was conducted at Department of Dermatology Lahore Medical and Dental College /Ghurki Trust and Teaching Hospital Lahore with ethical letter no LM&DC/ 5363-64.It was a Non randomized clinical trial. The study duration was six months. Tablet Minoxidil 5mg was given in once daily dosage. Inclusion criteria were male patients aged 19-50 years with AGA classified as type III vertex, IV, V, VI, VII utilizing modified Norwood–Hamilton classification, diagnosed by history, physical examination and strong family history of androgenetic alopecia, Not using alternate hair loss treatments such as other topical, oral medications or LLLT .Exclusion criteria were patients with abnormal blood pressure (BP) of systolic BP < 90 or > 180 mmHg and diastolic BP <60 or > 120 mmHg, abnormal pulse rate (PR)<60 or > 100 /min, medical conditions with abnormal liver function test, history of abnormal thyroid conditions, history of preexisting or current medical or psychiatric disorders, coronary artery disease, cerebrovascular disease, uncontrolled diabetes mellitus and pheochromocytoma. A sample size of 30 patients were measured by using 90% confidence level, 9% margin of

error and considering the proportion of patients showed clinical improvement as 37(90.2%).

After taking informed written consent males with mild to moderate AGA (III vertex, IV, V, VI, VII modified Norwood–Hamilton classification) were enrolled. Every morning 5 mg minoxidil was given for 24 weeks. First dose of oral Minoxidil was given to patients at night to reduce the risk of orthostatic hypotension. Efficacy and safety were assessed at 24 weeks after treatment.

Efficacy of treatment was assessed by hair thickness measurements, global photographic assessment and with self- assessment questionnaire.

For accurate measurements of hair thickness, we defined 1 specific location on the scalp, 24 cm from glabella on vertex in midpoint of coronal plane. From there we cut five hairs in close proximity to the scalp. The Thickness of those 5 hairs shafts were measured using Coral draw 12 software and then averaged.

Global photographic assessment was done by using mobile camera standardized global photographs were taken. Hair growth improvement was assessed by using a standardized 7-point rating scale (−3 to +3) in which (+3 = greatly increased, +2 = moderately increased, +1 = slightly increased, 0 = no change, −1 = slightly decreased, −2 = moderately decreased, −3 = greatly decreased) as compared to baseline.

Using a validated, self-assessment questionnaire consisting of four questions on treatment efficacy and three questions about satisfaction with their appearance, the patients assess their scalp hair.

Safety assessment was done by taking history, physical examinations, laboratory investigations, chest x-ray and electrocardiography.

All clinical symptoms including postural hypotension, orthopnea, chest pain, and sexual dysfunction along with vital signs, weight blood pressure (both standing and sitting), hypertrichosis and pitting edema were evulated.

By using SPSS version 21.0 data was analyzed. For numerical variables like age and duration of hair loss mean and standard deviation were calculated. Frequency and percentage were measured for nominal variables like global photographic assessment at twenty four weeks as compared to baseline and side effects. One sample t test was applied to measure statistical significance with P values of < 0.05 was taken as statistically significant. To compare all adverse events (AEs) and severe AEs (SAEs) a Fisher exact test was applied.

RESULTS

The study included 30 males aged 19-59 years. Two patients left treatment due to side effects and 1 patient was lost to follow up, so these are the results of 27 patients.

Variables	N (%)	Mean±SD (Range)
Age (years)		29.7±5.77 (19-43)
Marital status		
Married	16 (59.3)	
Unmarried	11(40.7)	
Smoking Status		
Yes	23 (85.2)	
No	4 (14.8)	
Prior Treatment		
Yes	22 (81.5)	
No	5 (18.5)	
Underlying Disease		
Yes	23 (85.2)	
No	4 (14.8)	
Family History		
Yes	19 (70.4)	
No	8(29.6)	

Table-I. Summary statistics of variables (N=27)

Among 27 Patients Norwood Hamilton Score of 19 (70.4%) patients was III vertex, 6 (22.2%) patients with IV, 1(3.70%) with V and 1(3.70%) patient with score of VI.

Norwood Hamilton Score

Baseline Norwood Hamilton Classification	Total Patients
III Vertex	19(70.4%)
IV	6(22.2%)
V	1(3.70%)
VI	1(3.70%)

Parameters	Mean ±SD	P-Value
Hair Thickness		
Baseline	0.026±0.008	.002
24 weeks	0.037±0.008	

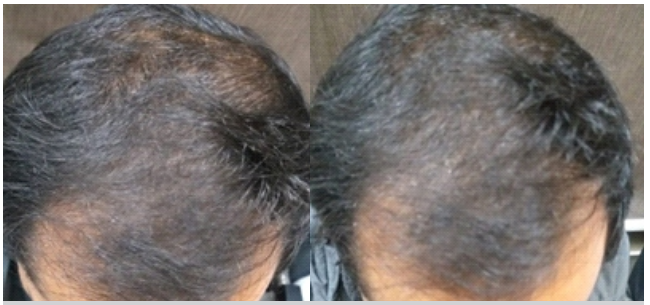
Table-II. Hair thickness baseline to 24 weeks (in mm)

Norwood Hamilton score observed in majority of patients was III vertex. Mean change in hair thickness was significantly increased from baseline (0.026±0.008 mm to 0.037±0.008 mm) with p value 0.002 at 24 weeks.

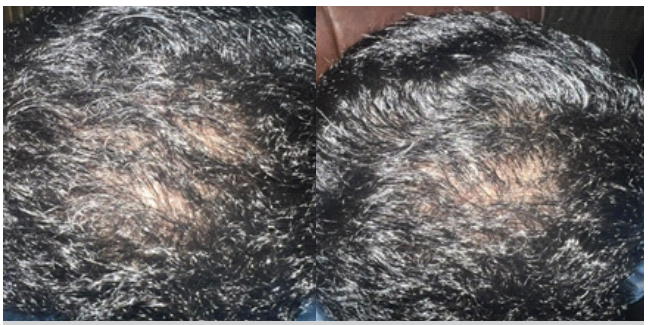
Global photographic assessment of patient's scalp showed marked improvement with (score > + 1 or 1-40% improvement) in 8(29.6%) patients, an improvement scale score of > + 2 (moderate increase, + 41–70% improvement) in 15(55.5%) patients and 3 (large increase, > +70–100% improvement) improvement in 3(11.1%) patients and 1(3.7%) patient did not show any improvement at all. Representative photographs are shown in Figure-1 and 2.

Patient Self -Assessment Questionnaire showed that Most of the patients were satisfied with the results with significant P value <.001.

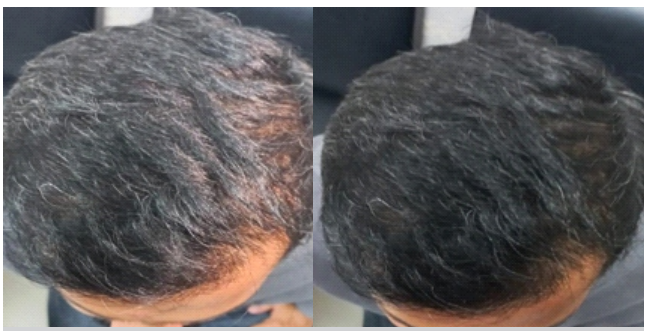
7-point Rating Scale	N (%)
-3	0
-2	0
-1	0
0	1(3.7%)
+1	8(29.6%)
+2	15(55.5%)
+3	3(11.1%)



Clinical images: Before and after treatment



Clinical images: Before and after treatment



Clinical images: Before and after treatment

Patient Satisfaction	T Score	Mean Difference	P-Value
Q1: Size of bald spot getting smaller	21.63	2.00	<.001
Q2: Appearance of my hair	24.19	2.63	<.001
Q3: Growth of hair	45.61	2.96	<.001
Q4: Slowing hair loss	18.56	2.14	<.001
Q5a: Satisfaction with frontal hair line	15.54	2.14	<.001
Q5b: Satisfaction with hair on top	18.03	2.41	<.001
Q5c: Satisfaction with hair overall	15.39	2.30	<.001

There were no significant side effects were observed during the study. Few side effects were noted, most common being generalized hypertrichosis (77%) and mild headache in (7%) patients. One patient left treatment due to exacerbation of asthma after starting treatment and 1 patient left treatment due to generalized hypertrichosis. One patient was lost to follow up. No cardiovascular effects or pitting edema were observed in any patient. Vital signs and blood pressure remained normal. All laboratory parameters remained within normal range. Chest x-ray and electrocardiography were also normal in all patients.

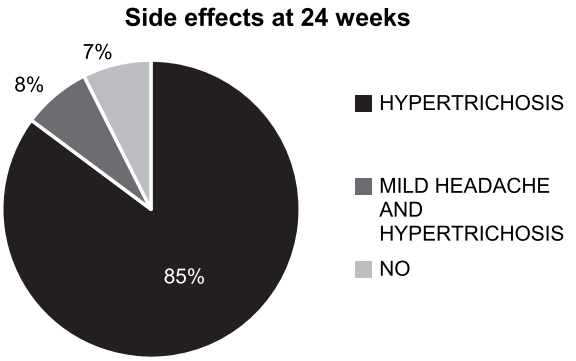


Figure-1

DISCUSSION

Minoxidil is an effective treatment option for androgenetic alopecia as it decreases hair fall and increases hair thickness.[16,17] It promotes early entry of resting hair follicles into anagen phase thus shortens telogen phase.[18,19] Minoxidil conversion to minoxidil sulfate (active form) by follicular transferase and sulfate metabolite is necessary for its pharmacological action.[20] Patients with higher sulfotransferase activity might respond more favourably than those with lower activity.[20] Minoxidil promotes the β-Catenin signaling pathway and vascular endothelial growth factors (VEGF) release.[20]

According to our study's findings, patients with androgenetic alopecia benefited from oral minoxidil in terms of both hair growth and thickness. Non comparative study design, small sample size, single centered study were obvious limitations of our study.

Panchaprateep et al enrolled 30 patients in their study whose whose hair density considerably increased from baseline (from 58.5 ± 11.8 to 67.4 ± 14.5 l mm) at 24 weeks (P \0.001).[9] Asilian A et al in their study noticed change in hair thickness from baseline 17.85 ± 2.92 to 20.30 ± 3.22 at point of 24cm from glabella (p< 0.001).[21]

Our study results indicate that oral minoxidil has significantly increased hair growth from baseline in androgenetic alopecia based on all of our evaluations. Hair thickness increased from baseline (0.026±0.008) to (0.037±0.008) with (p/0.002) after 24 weeks of treatment.

Panchaprateep et al in their study observed that on global photographic assessment, with a 100% improvement (score > +1 or + 1–40% improvement) on the vertex area at 24 weeks. An improvement scale score of > + 2 (moderate increase, + 41–70% improvement) and score of > + 3 (large increase, > +70–100% improvement) were reported in 93.3% of patients in the vertex and 73.3% of patients in the frontal area.[9] In their study Asilian A et al .noted a significant improvement in hair density in the topical minoxidil group based on expert panel photographic assessment of the vertex 24 cm from the glabella.[21]

In comparison to above studies global photographic assessment of our patient's scalp shows marked improvement with (score > + 1 or 1-40% improvement) in 8(29.6%) patients, An improvement scale score of > + 2 (moderate increase, + 41–70% improvement) in 15(55.5%) patients and 3 (large increase, > +70–100% improvement) improvement in 3(11.1%) patients and 1(3.7%) patient did not show any improvement at all.

Significantly most of the patients showed improvement in scalp hairs as well as satisfaction with the appearance as showed by self -assessment questionnaire with significant p value of <.001.

Jimenes et al in their study observed that 10 (24.3%) patients had developed hypertrichosis, 2 (4.8%) patients had developed lower limb

edema and 1(2.4%) patient had developed hair shedding. Adverse effects noted were mild and tolerable. Due to pedal edema Only 1 patient left the treatment. Vañó-Galván S et al included 1404 patients in their study and noted hypertrichosis in (15.1%), due to which 14 patients left treatment (0.5%). Systemic side effects were noted in 29(1.2%) patients including insomnia (0.2%), periorbital edema (0.3%), headache (0.4%), tachycardia (0.9%), fluid retention (1.3%) and lightheadedness (1.7%) due to which they discontinued treatment. No severe side effects were noted.[22]

In comparison to above studies no serious adverse effects were noted. Few side effects were noted, most common being generalized hypertrichosis (77%) and mild headache in (7%) patients. One patient (33%) left treatment due to exacerbation of Asthma after starting treatment and 1 patient left treatment due to hypertrichosis. One patient was lost to follow up.

Regarding hemodynamic effects orthostatic hypotension was not observed in any patient. There was no significant change in vital signs. One patient who was hypertensive became normotensive with the use of oral minoxidil.

CONCLUSION

Low dose oral minoxidil 5mg is a safe and effective drug for male patients with androgenetic alopecia. It significantly increases hair growth and hair thickness. It is easily available and inexpensive drug. Oral minoxidil is a good treatment option for those who cannot tolerate topical minoxidil or did not respond to other treatments.

CONFLICT OF INTEREST0

Dr Saira Muaaz, Dr Sumera Hanif, Dr Talat Masood Akbar, Prof. Tariq Rasheed, Prof. Haroon Nabi have received research support of medication as investigators, and Dr Saira Muaaz as speaker from Schazoo pharmaceuticals company.

SOURCE OF FUNDING

Schazoo pharmaceutical laboratories

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AUTHORSHIP AND CONTRIBUTION DECLARATION	
1	**Saira Muaaz:** Conceptualization, writing manuscript, overall project management.
2	**Sumera Hanif:** Conducted experiments, contributed to data analysis.
3	**Talat Masood Akbar:** Assisted in writing section, critical revision.
4	**Tariq Rasheed:** Literature collection, contribute to discussion section.
5	**Haroon Nabi:** Supervisor, assisted with formatting, final proof reading.