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Comparison of the effect of 2% Finasteride topical solution versus 5% Minoxidil topical solution in the treatment of androgenic alopecia in men: A quasi-experimental study

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A B S T R A C T

Introduction: About 50% of men experience different types of hair loss by the age of 50. To treat this problem, based on the Food and Drug Administration (FDA), the aim of this study was to compare the effect of 2% topical finasteride solution versus 5% topical minoxidil solution in the treatment of androgenic alopecia in men.

Materials & Methods: The study was quasi-experimental and was conducted on 194 men with the initial complaint of hair loss in the dermatology clinic of Imam Reza Hospital in Ardabil during September 2020 and June 2021, who were randomly divided into two equal groups by the random block method. Data were collected by a checklist and then analyzed by using descriptive statistical methods in SPSS V.21. The significance level was considered less than 0.05.

Results: In the minoxidil and finasteride group, the pull test was negative in 17.7% and 24.5% of patients during the first month, respectively. In 2-3% of patients in the minoxidil group, tension headache and scalp irritation were reported, but no such side effects were found in the finasteride group. In general, reduction of hair loss and hair regrowth during six months of continuous use of the drug was observed in 65.6% of patients in the minoxidil group and 85.4% of patients in the finasteride group.

Conclusion: Topical solutions of finasteride and minoxidil were effective and safe in the treatment of mild to severe androgenetic alopecia in men.

Keywords: Alopecia, Finasteride, Minoxidil, Men

➢ **Cite this paper**
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Introduction

Almost 50% of men experience various types of hair loss by the age of 50 (1-2). Since androgenetic alopecia (AGA) is common in men but does not have life-limiting or physically injurious effects, the negative psychosocial impact of AGA is frequently presented as a crucial driving force for the development of effective treatments to stop hair loss or encourage regrowth. To treat this problem, the FDA and the European Medical Association have considered only oral finasteride (a competitive inhibitor of type 2 5-alpha reductase) and topical minoxidil (a K channel opener and vasodilator) to be sufficient for male pattern hair loss. By dilating the peripheral blood vessels, minoxidil stimulates the hair follicles, and they go from a resting state to an active growth state. Dihydroxy testosterone (DHT) level returns to normal within 14 days of stopping the treatment (3).

After the systemic use of finasteride for the treatment of androgenic alopecia, a change in hair growth occurs within 12 months (4). It seems that the side effects of oral finasteride in the treatment of men suffering from alopecia are high and mostly included in the subcategory of mental and sexual disorders (5). In its systemic use, various side effects such as gynecomastia, breast sensitivity, malignant neoplasms of the male breast, decrease in ejaculation volume, decrease in testicle size, testicular pain, decrease in penile curvature, decrease in penis size, sexual dysfunction, male infertility, malignant prostate cancer, and prostatitis have been reported (6). In humans, finasteride, a type II-selective 5-alpha-reductase inhibitor, as a causative agent of decreasing DHT level, is effective in the treatment of male androgenic alopecia (7). Over the past five years, new evidence suggests that topical FNS may be a promising treatment with far fewer complications than systemic therapy. Topical finasteride for the treatment of androgenic alopecia is a nascent field of research, limited to a few randomized controlled trials, prospective studies, and retrospective medical records. Overall, data from studies conducted on the efficacy and safety of topical FNS in androgenetic alopecia (AGA) show promising results compared to its systemic type. Although preliminary results on the use of topical FNS are limited, reviewed studies suggest that topical FNS may be safe for use in patients who wish to avoid systemic side effects. This case becomes particularly important in women with androgenic alopecia because the use of systemic finasteride is considered to be an X category and is prohibited due to hormonal suppression during pregnancy (4).

No serious side effects have been reported in the topical use of finasteride. However, minor side effects such as skin irritation called erythema and contact dermatitis, as well as increased liver enzymes, bedwetting, testicular pain, headache, presyncope, and oropharyngeal pain have been reported (8-9). The prescription of topical medicine for skin disease is a much-studied and debated topic. Pharmacokinetic and dynamic properties, solubility, concentration, potency, drug interactions, absorption, and degradation depend on the exact formulation and how the drug is administered. Currently, topical formulations of FNS as gels and solutions have been tested at various concentrations, and all of them have improved hair growth (10). In general, considering that the effectiveness of minoxidil in the treatment of AGA has been confirmed for many years, and systemic finasteride also has FDA approval. However, the presence of many side effects in the systemic use of FNS and its prohibition during pregnancy prompted us to change the formulation of this drug to a topical one and examine its therapeutic effect and possible side effects during this research.

The aim of this study was to compare the effect of 2% topical finasteride solution versus 5% topical minoxidil solution in the treatment of androgenic alopecia in men.

Materials and methods

Study design and participants

This study was a quasi-experimental one with a simultaneous comparison group (parallel) to compare the effect of 2% topical finasteride solution and 5% topical minoxidil solution in the treatment of androgenetic alopecia in men referred to the clinic of Imam Reza Hospital in Ardabil between September 2020 and June 2021.

Patients with a confirmed initial diagnosis of androgenetic alopecia (AGA) by a specialist physician and who had not used any medications for hair loss for at least one month prior to study enrollment were included in the study. Exclusion criteria comprised a gap exceeding one week in medication adherence (i.e., discontinuation of prescribed treatment for more than one week), use of additional hair loss treatments—whether traditional or commercial—for more than one week during the study period, and failure to attend scheduled monthly follow-up visits.

Sample size and Randomization

The necessary sample size in the 95% confidence interval in the Cochran formula $\frac{z^2_{1-\frac{\alpha}{2}} pq}{d^2}$ with parameters d=0.05 and p=0.85 was 194 patients, which were divided based on random block design by generating the random order into two groups. Both patients and the evaluating physician were blinded to treatment allocation. Solutions were identically packaged in unlabeled 30 mL bottles (A/B).

Assessment of Pull test

A pull test measures the severity of hair loss. During a pull test, a dermatologist grasps small sections of hair, about 40 strands, from different parts of the scalp and gently tugs. If six or more strands fall out, it’s known as active hair loss (positive), and if less than six strands are obtained, the pull test results are considered negative. A hair-pull test is when a medical professional literally pulls on your hair to check for excessive or active hair shedding. It’s often used to help diagnose conditions like androgenetic alopecia (the medical term for male pattern hair loss), telogen effluvium (a form of temporary hair shedding), and other causes of hair loss like alopecia areata and scarring alopecia. This test has sensitivity and specificity of 87% and 90%, respectively (11).

Intervention

The first group with 98 patients was treated with Finasteride topical solution (bottle A), and the second group with 96 patients was treated with Minoxidil topical solution (bottle B). Before starting the treatment, all patients completed the personal consent form to enter the study. We conducted follow-up and monthly examinations after the treatment. Before starting the treatment and during the monthly follow-up, the patients and the specialist doctor did not know about the contents of the bottle of solutions. They were included in the study with the initial diagnosis of androgenic alopecia by a specialist doctor and not taking any medicine for hair loss within a month before entering the study. Patients who had not used any hair loss medication for more than a week before the study and did not return for monthly examinations were excluded from the study. The patients included in the study had visited every month for examination and follow-up of the effects of the drugs. The checklist contains two parts: 1) Patient's appearance also assessed by doctor's evaluation, 2) Pull test results.

A pull test examination was assigned for each patient, which was gradually completed during each monthly visit, and the condition of the patients was recorded accurately and continuously. Patients were followed up for six months while taking the drug and one month after stopping the drug and underwent monthly examinations. How to do the pull test is by putting the doctor's fingers between the hairs of the patient (active areas in terms of shedding) and grabbing (pulling). It is checked in three different areas of the head, including the front,

top, and crown, and the pull test results were considered as positive if five or more hairs were removed. To provide a 2% topical finasteride solution, pure finasteride powder was mixed with 96% alcohol in a specific ratio according to the chemical formulas of the drug, and no signs of material precipitation were observed during the composition and after the work was completed. The composition was obtained without using heat and by stirring while adding pure finasteride powder. After making the medicine in the laboratory, the solutions were poured into 30 cc bottles by the laboratory manager, who had no knowledge of the specialist doctor and the patients. Due to the difficulty of making minoxidil solution, prepared solutions available in the market were used, and in the laboratory, they were poured into bottles similar to finasteride and with the same volume (30 cc) by the laboratory manager. All the stages of making medicine and preparing the bottles were done within a week by the respected manager of the chemistry laboratory, and then the medicines were transferred to the skin clinic and were shared among the patients. Patients drip the solution every 12 hours (morning and night) in the areas of hair loss or sparseness in the amount of one cc (15-20 drops). There was no need to rub or massage the scalp after use. It was explained to the patients that it is better to avoid washing the head until the drug is absorbed. More details are located in Figure 1.

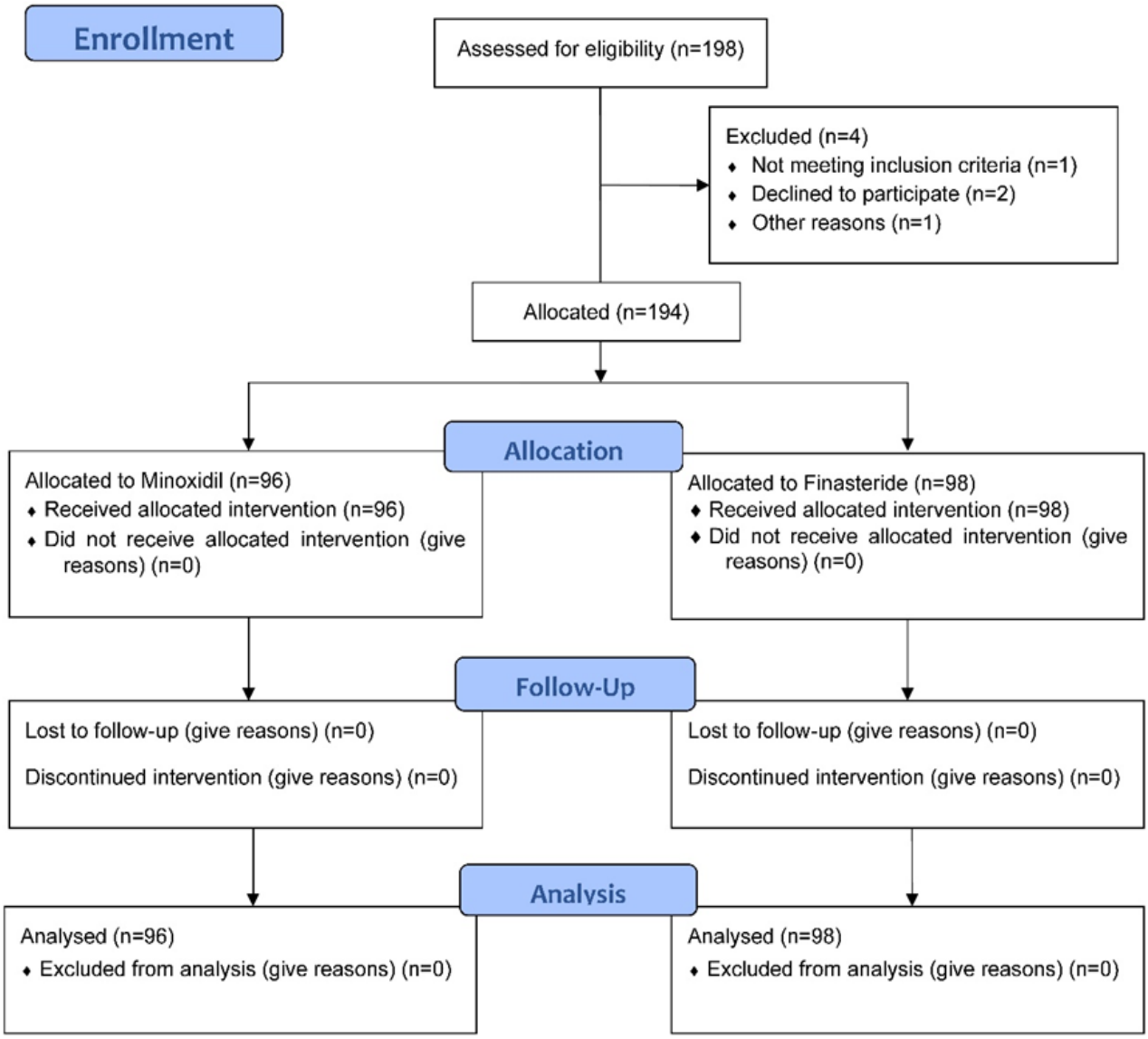

Figure 1. Consort diagram of the participants in the study

Ethical consideration

This study was approved by the ethics committee of Ardabil University of Medical Sciences with code IR.ARUMS.REC.1399.148. Also, acquiring informed permission, ensuring anonymity, and following the Declaration of Helsinki were considered.

Statistical and Data Analysis

The demographic data was analyzed using descriptive statistics, with the variables being presented as mean, standard deviation, frequency, and percentage. The statistical test used in the analysis was the chi-square test. The analyses were conducted using SPSS V.21, with a significance threshold of less than 0.05.

Results

Most participants in the study were men aged 26-33 (42%). 62% of them had miscellaneous and freelance jobs, and most of them had high school diplomas and bachelor's degrees (55%). 83% of male participants were residents of urban areas. Most of the patients in two groups were in the age group 26-33 years old, with 41% and 44%, respectively (Table 1).

Table 1. Demographic information of studied patients.

Variables	Categories	Treatment name				P-value (Chi-square)
		Finistraide		Minoxidil		
		n	%	n	%	
Age (years)	18-25	19	19	16	17	0.890
	26-33	40	41	42	44	
	34-41	25	26	23	24	
	42-50	14	14	15	15	
Job	Non employee	62	63	59	61	0.650
	Employee	36	37	37	39	
Education	Diploma	12	12	14	15	0.780
	Bachelor	55	56	51	53	
	Master and PhD	31	32	31	32	
Place of residence	Urban	82	84	79	82	0.690
	Rural	16	16	17	18	
Marital status	Married	72	73	68	٧١	0.740
	Single	26	27	28	٢٩	

The results of the chi-square test showed that there was no significant difference between the two groups in terms of negative pull test results in the first month, but from the second month to the seventh month, these differences were significant (Table 2). The study assessed the effectiveness and side effects of finasteride and minoxidil for hair loss treatment over six months. The negative pull test rate (indicating reduced hair shedding) increased in both groups, reaching 87% in the finasteride group and 61% in the minoxidil group by the sixth month. Hair regrowth was observed in 79.9% of finasteride users and 72.9% of minoxidil users, mainly from the vertex to the front of the scalp. After stopping treatment, 50% of minoxidil users experienced increased hair shedding, compared to only 5% in the finasteride group. Side effects included worsened dandruff (63.5%), scalp irritation, mild hair color

dulling, and body hair growth, but 90% of these resolved after discontinuation. No effects on libido were observed. Overall, 88.7% of finasteride users reported effectiveness, and 79.5% noticed increased hair growth. Unlike minoxidil, finasteride did not promote hair growth on the sides of the head. No serious physical or mental side effects were reported. Finasteride had the highest adherence in the second month (98%), while minoxidil had 96% adherence in the first month. Minor irregularities in usage occurred in later months for both groups. The pull test showed improved results over time, with negative pull test cases rising from 24% to 82% in the finasteride group and from 17% to 32% in the minoxidil group by the seventh month (Figure 2).

Table 2. Relationship between negative pull tests and the type of drug using.

Follow up	Treatment name		P-Value (Chi-square)
	Finstraide	Minoxdil	
First month	24(24.5%)	17(17.7%)	0.250
Second month	52 (53.1%)	37(38.5%)	0.042
Third month	70 (71.4%)	48 (50%)	0.002
Fourth month	79 (80.6%)	53 (55.2%)	0.001
Fifth month	84 (85.7%)	58 (60.4%)	0.007
Sixth month	87 (90.6%)	61(63.5%)	0.003
Seventh month	82 (85.4%)	32(65.6%)	0.001

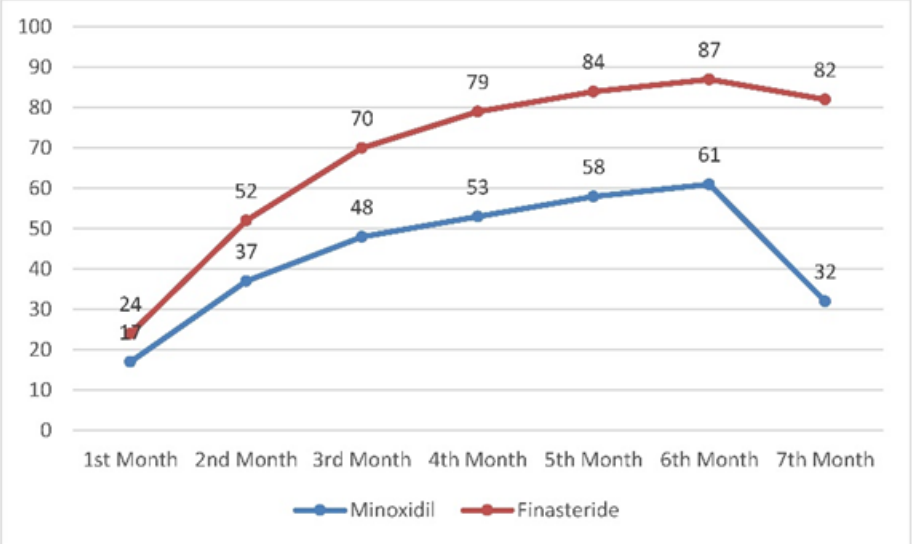

Figure 2. Number of negative cases of Pull Test.

Discussion

The study compares the effectiveness, side effects, and adherence of finasteride and minoxidil in treating hair loss over six months in men. In the minoxidil and finasteride group, the pull test was negative in 38.5% and 53% of patients during the first month, respectively. In 2-3% of patients in the minoxidil group, tension headache and scalp irritation were reported, but no such side effects were found in the finasteride group. In general, reduction of hair loss and hair regrowth during six months of continuous use of the drug was observed in 62.2% of patients in the minoxidil group and 88.7% of patients in the finasteride group.

European evidence-based guidelines recommend topical minoxidil (MNX) and oral finasteride (F) for the treatment of AGA in men (12–13). On the other hand, the systemic side effects or adverse reactions that oral finasteride may induce, such as depression and sexual dysfunction, may be reduced by using the topical formulation. Tests ranging from 0.005% to 1% have demonstrated the effectiveness of topical finasteride (13–15). However, a recent phase III, randomized, 28-week, controlled clinical study involving 458 adult males suggests that 0.25% topical finasteride might be the optimal dose in terms of safety and effectiveness (16). MNX and F function through two different methods. MNX probably acts as a vasodilator to increase scalp microcirculation, although its precise mode of action is still understood.

By blocking type II 5α-reductase, F decreases the change of testosterone into DHT. Combining MNX and F may improve therapy efficacy more than taking them alone because they have different mechanisms of action. Additional research is required to determine the most effective formulation, but some studies in the literature have demonstrated the higher effectiveness of a combined solution of 0.1% or 0.25% finasteride mixed with 3% or 5% MNX in the galenic formulation (16–18). This study aimed to evaluate the efficacy of two registered separate solutions of 2% finasteride and 5% minoxidil lotion without propylene glycol (PG), which was selected to lessen the likelihood of negative effects associated with PG.

Both medications under investigation demonstrated a considerable benefit in suppressing male hair loss, according to data gathered from patient responses and a specialist doctor's examinations. This is consistent with the findings of earlier comparable research (17–18). Compared to 73% of patients in Lee's study (4), 88.7% of patients taking Finasteride solution in this trial did not experience hair loss by the end of the sixth month, and 79.5% of patients thought that their hair had grown in the regions where it was falling out. Finasteride and minoxidil have been shown to be effective in controlling and preventing hair loss and even hair regrowth in nearly all previous studies on the topic. Chandrashekar's study (19) found that 84.44% of patients using topical Finasteride had positive results, and the current study found that the results were 63.5% for minoxidil solution and 88.7% for finasteride solution. Prior research on topical finasteride solution and its comparison and combination with minoxidil solution was designed to include a small number of men; for instance, Chandrashekar's study only included 45 participants. In contrast, the current study's sample size was significantly larger than that of earlier studies and looked at a population of over 200 people, reaching 194 after patients who met exclusion criteria were excluded. In the Heydari study, which was carried out in 2009, 1% Finasteride gel also demonstrated positive results after six months of use. However, the various concentrations that have been used to prepare Finasteride topical solution indicate that most likely the range of 0.1% to 0.25% has therapeutic effectiveness. In contrast, after six months, the finasteride 2% solution in this trial showed a higher success rate (88.7%). Additionally, the length of drug use is crucial; it appears that the effects last for at least six months when used consistently. This notion was also seen in Nandini's research, which found that, in accordance with other studies, the medicine must be used for at least 8 to 12 months in order to have the desired impact. After a continuous treatment period, it is likely best to maintain therapy at a reduced dose and in conjunction with minoxidil or other medications to maximize its effectiveness. In our investigation, the concentration of 5% with a prescription of one cc was shown to be the therapeutic dose required to prevent hair loss in the case of topical minoxidil solution, which appears to require a therapeutic dose of 3-5% and must be applied at least twice daily to be successful. Similar to our findings, Piraccini et al.'s RCT trial showed that topical finasteride is well tolerated and dramatically increases hair count when compared to

a placebo. It has a comparable impact to oral finasteride (14).

The limitation of this study was the non-use of drugs in combination in this study as a separate group to measure their efficacy alone and in comparison with single drugs. Also, the lack of focus on specific age ranges and the failure to include stress and genetics to understand their impact in this study were other limitations of the present study. The strengths of the present study include its innovativeness, accessibility, cost-effectiveness, and applicability.

Conclusion

The results of this study showed that both finasteride and minoxidil topical solution were effective and safe in the treatment of mild to severe androgenetic alopecia in men. Future studies should be done on this topic with a larger sample size in other places.

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Conflict of interest

The authors declare no conflict of interest.

Authors' contributions

Conceptualization: MR, AS, Methodology: MR, LR, Validation: MR, Formal Analysis: AS, AM, Investigation: MR, AS, Data Curation:MR, AS, Writing– Original Draft Preparation: AS, LR, Supervision: MR, Project Administration: AS.

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