

An Open, Randomized, Comparative Study of Oral Finasteride and 5% Topical Minoxidil in Male Androgenetic Alopecia

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Key Words

Androgenetic alopecia · Finasteride · Minoxidil

Abstract

Background and Aim: Androgenetic alopecia (AGA) is undoubtedly the most common form of hair loss in males. It is a condition which may cause cosmetic and psychosocial problems in androgen-dependent cases. In this open, randomized and comparative study we evaluated the efficacy of oral finasteride and 5% topical minoxidil treatment for 12 months in 65 male patients with mild to severe AGA. **Methods:** We randomly assigned 40 (61.53%) patients to receive 1 mg/day oral finasteride for 12 months, and 25 (38.47%) patients applied 5% topical minoxidil solution twice daily for 12 months. **Results:** There were no significant differences between the 2 groups considering age, age of onset of hair loss, family history and type of hair loss ($p > 0.05$). In the clinical evaluation at the endpoint of treatment, the clinical cure rates (i.e. increased intensity of hair) were 80% (32/40) for the oral finasteride group and 52% (13/25) for the 5% topical minoxidil group. Encountered side effects were all mild, and there was no need to stop the treatment. In the group given oral finasteride, side effects were noted in 7 patients: 6 patients suffered from loss of libido, and 1 patient had an increase in other body

hairs; irritation of the scalp was seen in 1 patient in the group administered 5% minoxidil. These adverse events disappeared as soon as the treatment was stopped. The laboratory data on both drug groups did not show any statistically or clinically significant intragroup changes from baseline values to the endpoint ($p > 0.05$), except the level of serum total testosterone which was increased, and free testosterone and serum prostate-specific antigen in the finasteride group which were statistically decreased from baseline values to the endpoint ($p < 0.05$). **Conclusion:** In this comparative study of systemic finasteride and topical minoxidil, it was concluded that both drugs were effective and safe in the treatment of mild to severe AGA, although oral finasteride treatment was more effective ($p < 0.05$). Adverse events were not considered important either, and these side effects disappeared as soon as the treatment was stopped.

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Introduction

Androgenetic alopecia (AGA) is very common, accounting for approximately 95% of patients with hair loss. Although the condition is so frequently seen, it is sometimes considered a physiologic sign of aging, causes considerable discomfort to patients and has been proven to

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impair their quality of life [1]. In the pathogenesis, it requires an adequate presence of androgens and a genetic predisposition. In the balding scalp, a miniaturization of genetically programmed hair follicles is driven by an increased uptake, metabolism and conversion of testosterone to dihydrotestosterone (DHT) by 5 α -reductase [2, 3]. In men with AGA, hair loss occurs in the frontotemporal and vertex regions of the scalp. A formal staging system is the Norwood-Hamilton scale [4].

After a diagnosis of AGA has been established, appropriate therapy can be implemented. The goal of therapy is a reversal of the miniaturization process and/or stabilization of hair loss. Hair growth promoters for AGA can be classified as either hormone response modifiers or biological response modifiers [5].

One of the hormone modifiers is finasteride, which is a synthetic 4-azasteroid that specifically inhibits type II 5 α -reductase presenting primarily in the scalp hair follicles, prostate, epididymis, vas deferens, seminal vesicles and fetal genital skin. It blocks the peripheral and systemic conversion of testosterone to DHT [5, 6]. After approval of finasteride in the USA for the treatment of men with male AGA by the Food and Drug Administration there are some reports that support the efficacy of finasteride in male AGA [7–13].

Minoxidil is the best-known biological response modifier. Its mechanism of action on hair growth is not fully understood. Although it does not exert hormonal or immunosuppressant actions, minoxidil has a mitogenic effect on epidermal keratinocyte cultures and increases follicular DNA replication in a monkey model [5]. There are some reports showing the efficacy of minoxidil in male AGA [14–16].

Therefore, we performed a clinical trial in men with AGA to compare the efficacy and safety of 5% topical minoxidil with finasteride.

Patients and Methods

This was a 52-week, randomized, open, comparative trial which included 65 patients with AGA conducted at the Department of Dermatology of Gülhane Military Medical Academy. Men eligible for inclusion in the trial were 18–50 years old with naturally dark hair and AGA characterized as vertex and frontal pattern type II, III, IV or V according to the modified Norwood-Hamilton scale. The patients were in good general health with no evidence of systemic illnesses (e.g. cardiac, psychiatric or scalp disease). Those known to be hypersensitive to minoxidil or finasteride were excluded, as were patients who concomitantly used hair restorers or systemic drugs (steroids, cytotoxic agents, vasodilators, antihypertensive agents, anticonvulsant drugs, β -adrenergic receptor blockers, diuretics or

any of the following specific agents: spironolactone, cimetidine, diazoxide, cyclosporine or ketokonazole. The protocol and informed consent form were approved by institutional review boards, and verbal informed consent was obtained from each patient before enrollment in the trial.

Pretreatment laboratory studies included a complete blood cell count with differential, urinalysis with microscopic examination, liver function tests and determination of levels of lactic dehydrogenase, calcium, phosphorus, creatinine, uric acid, blood urea nitrogen, prostate-specific antigen (PSA), serum electrolytes, thyroxine, thyroid-stimulating hormone, testosterone, free testosterone, luteinizing hormone and follicle-stimulating hormone. Patients were requested to maintain the same hair style, hair color and hair length throughout the study. Forty randomly assigned patients (61.5%) received 1 mg/day oral finasteride (Propecia®, Merck-Sharp-Dohme Corp.), and 25 (38.5%) patients applied 5% topical minoxidil solution (Rogaine® for men extra strength, Pharmacia and Upjohn Co.) twice daily for 12 months. Standardized global photographs of the frontal/parietal region were taken with the patient's head in a stereotactic device to ensure consistency of patient positioning and photographic distance. After the 1-year treatment period, the laboratory studies were carried out once more and the data about the adverse events were taken.

After the baseline visit, patients returned to the clinic for efficacy and safety evaluations every 3 months to the end of the trial.

At the end of the treatment period, the clinical evaluation was done by the photographs and clinical view on a 7-point scale as follows: 1 = dense growth (71–100% increases from baseline); 2 = moderate growth (41–70% increases from baseline); 3 = minimal growth (1–40% increases from baseline); 4 = no change; 5 = minimal loss (71–100% decreases from baseline); 6 = moderate loss (41–70% decreases from baseline), and 7 = marked loss (1–40% decreases from baseline).

The assignment to one of the seven points of the scale was done by global impression by two of our authors (G.A. and E.A.). When there was a disagreement, a third author (Z.K.) was consulted.

The statistical analysis was carried out using an SPSS programmer. Results were expressed as means \pm standard deviation and were considered to be significant at $p < 0.05$. Therapeutic efficacy was evaluated by the χ^2 test. The Kruskal-Wallis one-way ANOVA and Mann-Whitney U test were used to compare the efficacy of therapy according to hair loss classified with the modified Norwood-Hamilton scale. The Student t test was used to compare the demographic data differences between treatment groups at baseline.

Results

Sixty-five men with AGA were enrolled in the study. The patients' ages ranged from 18 to 50 years, with an average of 27.5 ± 6.31 years. Patient demographic and hair loss features at baseline are shown in table 1. The treatment groups were not significantly different at baseline with respect to the age of the patients, the age at which hair loss began, the type of hair loss and family history.

At the end of the treatment, hair growth was seen in 32 patients (80%) – 6 patients (15%) had dense growth, 12 patients (30%) moderate growth and 14 patients (35%)

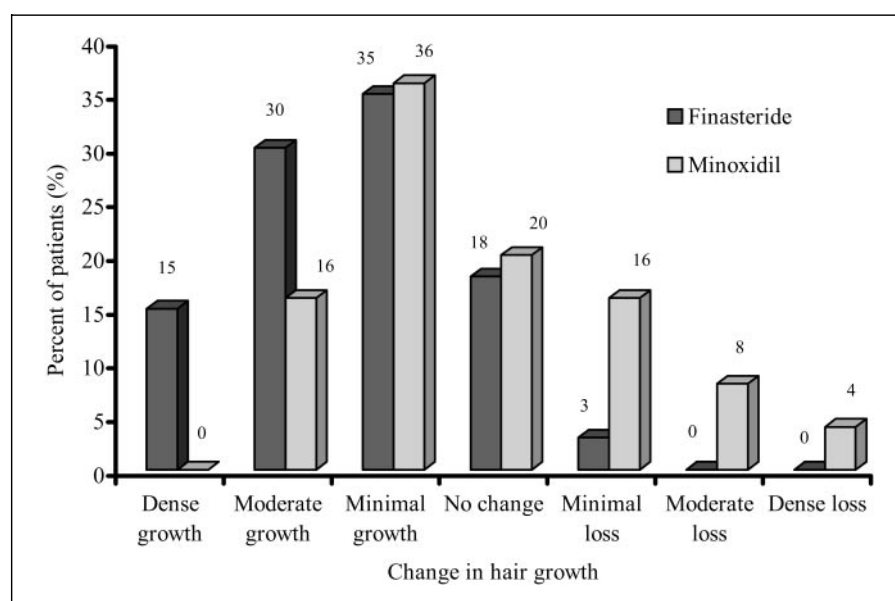


Fig. 1. Clinical assessment at the end of treatment (percentage of men with change in hair growth).

Table 1. Characteristics of all patients in the study

	Minoxidil group	Finasteride group
Number of patients	25 (38.5)	40 (61.5)
Age (mean \pm SD), years	27 \pm 6.1	28 \pm 6.5
Age at which hair loss began (mean \pm SD), years	24 \pm 5.3	23 \pm 4.6
Number of patients with family history	14 (56)	15 (38)
Number of patients with each hair loss pattern (according to the modified Norwood-Hamilton scale)		
II	7 (28)	10 (25)
III	8 (32)	15 (38)
IV	6 (24)	7 (17)
V	4 (16)	8 (20)

SD = Standard deviation. Figures in parentheses indicate percentages.

minimal growth; no change was seen in 7 patients (18%), and hair loss was seen in 1 patient (3%) in the finasteride group (fig. 1). Figure 2 shows baseline and month 12 global photographs of 3 representative finasteride-treated patients rated as having dense hair growth compared with baseline.

The comparison of types of hair loss with respect to the efficacy of finasteride according to the modified Norwood-Hamilton scale at the end of treatment is shown in table 2. Although the results of types III and IV are better than those of the other types, they are not statistically significant ($p > 0.05$).

In the minoxidil group, at the end of the treatment, hair growth was seen in 13 patients (52%) – 4 patients (16%) had moderate growth and 9 patients (36%) minimal growth; no change was seen in 5 patients (20%), and hair loss was seen in 7 patients (28%) (fig. 1). Figure 3 shows baseline and month 12 global photographs of 2 representative minoxidil-treated patients rated as having moderately increased hair growth compared with baseline.

The comparison of types of hair loss with respect to the efficacy of topical minoxidil according to the modified Norwood-Hamilton scale at the end of treatment is shown in table 3.

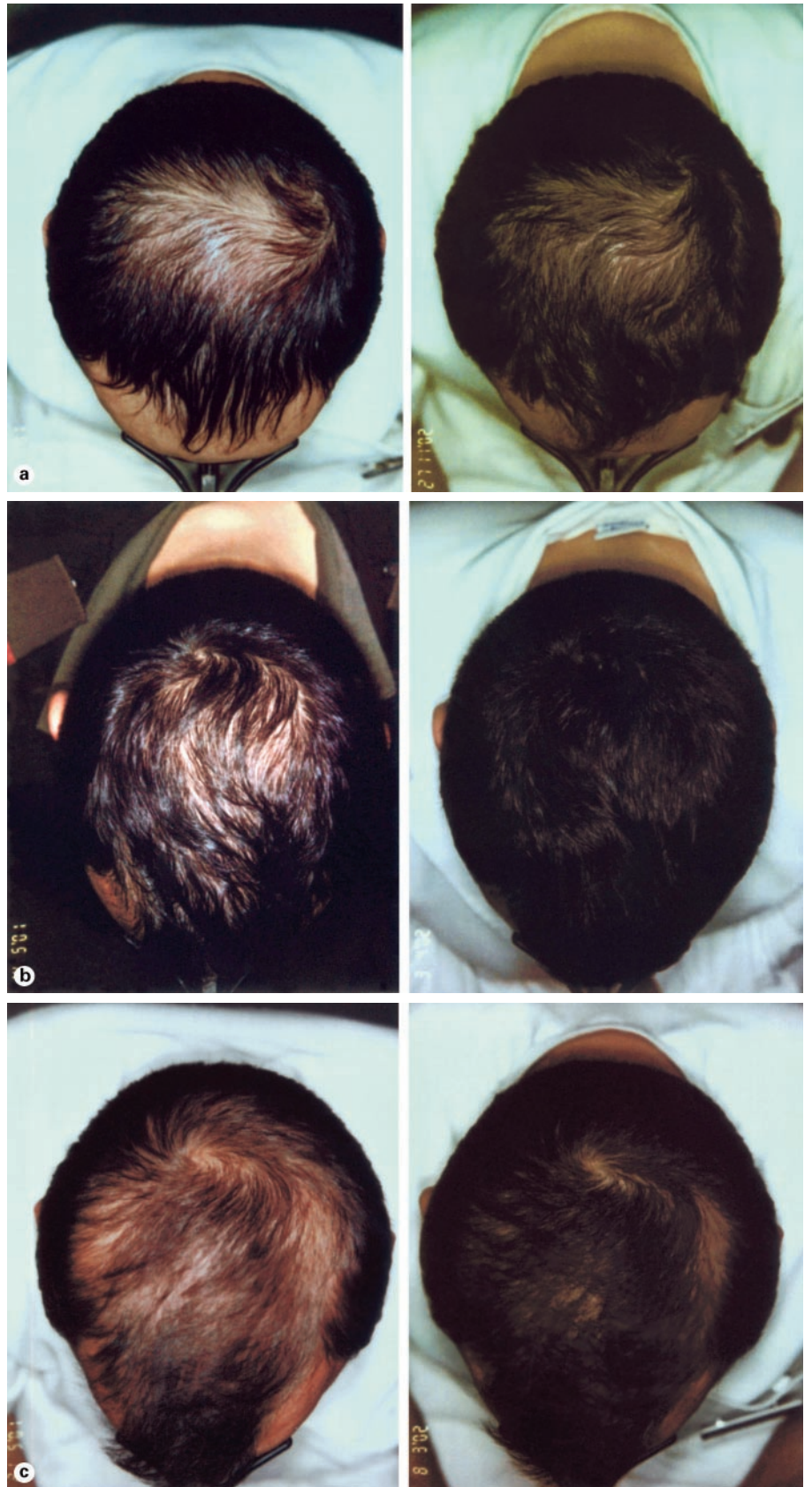


Fig. 2a–c. Baseline and month 12 global photographs of men treated with finasteride rated as having dense hair growth from baseline by expert panel review.

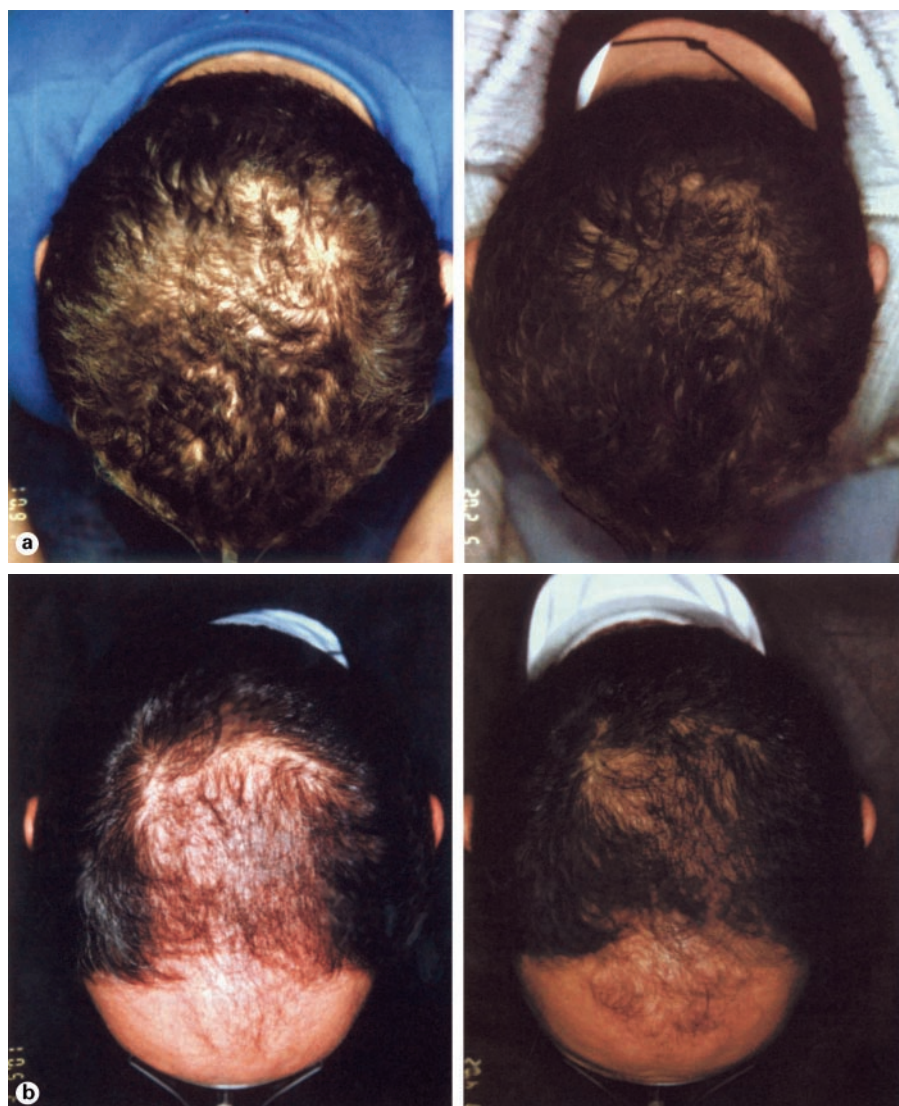


Fig. 3a, b. Baseline and month 12 global photographs of men treated with minoxidil rated as having moderately increased hair growth from baseline by expert panel review.

Table 2. The efficacy of finasteride evaluated by photographs on a 7-point scale on hair loss according to the modified Norwood-Hamilton scale at the end of treatment

Type of hair loss (according to Norwood-Hamilton classification)	Patients	7-point scale (mean \pm SD)	χ^2	p
Type II	10	3.0 \pm 1.15	2.11	0.55
Type III	15	2.4 \pm 1.27		
Type IV	7	2.4 \pm 1.27		
Type V	8	2.75 \pm 0.7		
Total	40	2.6 \pm 1.0		

p value from the Kruskal-Wallis test.

Table 3. The efficacy of topical minoxidil evaluated by photographs on a 7-point scale on hair loss according to the modified Norwood-Hamilton classification at the end of treatment

Type of hair loss (according to Norwood-Hamilton scale)	Patients	7-point scale (mean \pm SD)	χ^2	p
Type II	7	3.7 \pm 1.4	1.23	0.745
Type III	7	3.7 \pm 1.6		
Type IV	7	3.4 \pm 0.9		
Type V	4	4.5 \pm 1.7		
Total	25	3.76 \pm 1.4		

p value from the Kruskal-Wallis test.

Table 4. Mean serum levels of total testosterone, free testosterone and PSA

	Minoxidil			Finasteride		
	at baseline	at month 12	p	at baseline	at month 12	p
Serum total testosterone (normal = 241–827 ng/dl)	518	515	>0.05	427	480	<0.05
Serum free testosterone (normal = 8.7–54.7 ng/ml)	23	24	>0.05	18	14	<0.05
Serum PSA (normal = <4 ng/ml)	1	1	>0.05	0.7	0.4	<0.05

Treatment with finasteride and minoxidil was generally well tolerated, and no patient discontinued the study because of any adverse effects of treatment. These were noted in 7 patients [6 patients suffered from loss of libido (15%), and 1 patient had an increase in other body hairs (2.5%)] in the oral finasteride group, and irritation of the scalp was seen in 1 patient (4%) in the 5% minoxidil group. These adverse events disappeared as soon as the treatment was stopped.

The laboratory data on both drug groups did not show any statistically or clinically significant intragroup changes from baseline values to the endpoint ($p > 0.05$), except that the level of serum total testosterone was increased and free testosterone and PSA in the finasteride group were statistically decreased from baseline values to the endpoint ($p < 0.05$). Finasteride slightly increased serum total testosterone from a median of 427 ng/dl at baseline (normal range = 241–827) to 480 ng/dl at month 12, whereas serum free testosterone and serum PSA fell slightly from a median of 18 pg/ml and 0.7 ng/ml at baseline (normal range = 8.7–54.7 and <4) to 14 pg/ml and 0.4 ng/ml, respectively, at month 12. In the minoxidil group, the mean serum levels of total testosterone, free testosterone and PSA were not changed (table 4).

Discussion

This is an open, randomized study comparing topical minoxidil and finasteride in the treatment of AGA in men. Many studies have been published on the efficacy of these drugs, alone or in comparison with placebo.

The first drug approved for the treatment of male pattern alopecia, over a decade ago, by the US Food and Drug Administration was topical minoxidil, which was developed after the discovery that the active ingredient caused hypertrichosis when taken orally for the treatment

of hypertension. Its mechanism of action is still unclear, but it has no apparent effect on androgen metabolism. After topical application, minoxidil increases the duration of the anagen phase, leading to production of hairs that are progressively thicker and longer [1].

A number of large multicenter, double-blind trials have been conducted to compare topical 2 or 3% minoxidil versus placebo. The use of minoxidil has been shown to induce a conversion of vellus to terminal hairs in approximately 30% of patients. Approximately 10% of men on minoxidil demonstrated some cosmetically noticeable regrowth, and 30% experienced stabilization. The therapeutic effect peaks at 1 year and thereafter diminishes with time [14]. Price et al. [15] recorded the quantitative estimation of hair growth using hair weight and number for 120 weeks in 4 groups of 9 men with AGA. They stated that, although not compared statistically, the placebo and untreated groups behaved in similar fashion and that, in contrast, the 5 and 2% minoxidil treatment groups showed a statistically significant increase in mean percentage change in interval weight from baseline compared with placebo [15]. In women, minoxidil is also efficacious, with 50% experiencing stabilization and minimal regrowth and 13% showing moderate regrowth [5].

Historical experience suggests that applying higher concentrations of topical minoxidil may enhance its therapeutic efficacy without an increased safety risk. Olsen et al. [16] reported that in men with AGA, 5% topical minoxidil was clearly superior to 2% topical minoxidil and placebo in increasing hair growth, and the magnitude of its effect was marked (45% more hair regrowth than with 2% topical minoxidil at week 48) in their 48-week, randomized, double-blind, placebo-controlled multicenter study [14].

The combination of topical minoxidil with topical tretinoin has been proposed but is limited by irritation of the

scalp, and the benefits have not been substantiated in large studies [17, 18].

In recent years, finasteride has been developed. It directly affects androgen metabolism by reducing the amount of DHT converted from testosterone. It was expected to regrow miniaturized hairs in male AGA. A small pilot study in males aged 18–35 years with mild to moderate AGA, comparing oral finasteride 5 mg daily to placebo, showed a definite finasteride benefit. In two multicenter 1-year trials, 1,553 men (18–41 years of age) with AGA received oral finasteride 1 mg/day or placebo, and 1,215 men continued in blinded extension studies for a second year. The results of these studies were that finasteride treatment improved scalp hair by all evaluation techniques at 1 and 2 years and clinically significant increases in hair count were observed with finasteride treatment [7]. A similar study examining the use of finasteride in 326 men with predominantly frontal alopecia also found a significant improvement compared to placebo subjects [8]. Dose-finding studies were conducted to compare the efficacy of 5 mg versus 1, 0.2 and 0.01 mg finasteride to treat AGA in men, indicating that 1 mg finasteride daily can be regarded as a safe and efficient approach for treatment [9].

In a 24-month double-blind, placebo-controlled multicenter study of 28 men with AGA, aged 53–76 years, Brenner and Matz [10] stated that in middle-aged and elderly men with benign prostatic hypertrophy and AGA, treatment with finasteride 5 mg results in an increase in hair growth.

A 24-month double-blind, randomized, placebo-controlled, parallel-group, multicenter study of 424 men was conducted to determine the efficacy and tolerability of finasteride 1 mg on hair growth/loss in men aged 41–60 years with mild to moderate, predominantly vertex male pattern hair loss. Whiting et al. [19] reported that analysis of global photographic assessment data showed significant improvement in hair growth for men in the finasteride group compared with those taking placebo beginning at month 6 ($p < 0.001$) and maintained through month 24 ($p < 0.001$).

Recently, the Finasteride Male Pattern Hair Loss Study Group reported that in men with AGA, long treatment with finasteride 1 mg/day over 5 years was well tolerated, led to durable improvements in scalp hair growth and slowed the further progression of hair loss that occurred without treatment [20].

Shapiro and Kaufmann [21] summarized the published peer-reviewed literature on the use of finasteride in the treatment of men with AGA and stated that it was an

effective treatment for men's AGA at an optimal dose of 1 mg/day.

Combination therapy has been shown in a study of Diani et al. [22], who compared the effects of 20 weeks of oral administration of 0.5 mg finasteride, topical 2% minoxidil and combined finasteride-minoxidil treatments on hair production by the scalp of balding adult male stump-tail macaques. For the hair growth study, 21 monkeys were placed into one of the 4 groups: topical vehicle ($n = 6$), topical 2% minoxidil ($n = 5$), oral 0.5 mg finasteride in combination with topical vehicle ($n = 5$) and oral 0.5 mg finasteride in combination with topical 2% minoxidil ($n = 5$). They concluded that the combination with finasteride and minoxidil produced a highly significant increase in hair weight over the 20-week study compared to vehicle as well as a highly significant elevation (additive effect) compared to minoxidil alone and to the combination of finasteride and vehicle [22]. This combination therapy can be prescribed to very motivated patients.

In this study with the recommended dose schedule and treatment period, and the randomly assigned patients receiving topical minoxidil and oral finasteride, the clinical cure rates are 52 and 80%, respectively, similar to those of the above studies, but the clinical rates of the finasteride group were high. This may be due to the patient group being younger.

In an open, randomized, parallel-group study, Khandpour et al. [23] evaluated and compared the efficacy of oral finasteride (1 mg/day), topical 2% minoxidil solution and topical 2% ketoconazole shampoo alone and in combination in 100 male patients (in the age group 18–35 years, mean 24.86 years) with AGA of Hamilton grades II–IV. The patients were placed into 4 groups: oral finasteride ($n = 30$), oral finasteride in combination with topical minoxidil ($n = 36$), topical minoxidil ($n = 24$) and finasteride in combination with topical ketoconazole ($n = 10$). They evaluated the patients on three bases: patients' self-assessment, physician's assessment and global photographic assessment. They stated that subjects receiving finasteride alone or in combination with minoxidil or ketoconazole showed a statistically significant improvement over minoxidil alone and concluded that the therapeutic efficacy is enhanced by combining the two drugs acting on AGA [23]. In their study, hair growth occurred in 86.67% (26/30) of the finasteride recipients. Our results are that 80% of the finasteride group (32/40) had hair growth. And also the results were similar with those of this study considering the minoxidil group, i.e. 42 and 52%, respectively.

Saraswat and Kumar [24] compared the efficacy of topical 2% minoxidil and oral finasteride in 99 men with moderate AGA. At 12 months, the increase in total hair count was higher in men taking finasteride (minoxidil vs. finasteride, 9.6 ± 0.9 vs. 17.7 ± 2 hairs; $p = 0.003$). During the same period, thick hair counts increased by 19.4 ± 1.5 hairs in the former group and by 24.4 ± 2.5 hairs in the latter group ($p = 0.21$). They concluded that both agents were equally effective in stopping the progression of AGA, but minoxidil produced a faster initial improvement whereas finasteride produced marginally better results with the increasing duration of treatment [24]. They evaluated the patients by thick hair counts and global photographs. In their study, at 12 months, visible improvement in appearance was seen in 32 patients (62%) in the finasteride group compared with 26 patients (56%) in the minoxidil group.

During our study period of 1 year, 8 adverse events were reported by 8 of the 65 patients with no reason for discontinuation of treatment. These results were similar to the other studies mentioned above. The side effects of minoxidil are mainly dermatologic. An irritant contact dermatitis of the scalp occurs in 7.5% of patients, and facial hypertrichosis occurs in 5% of women [25–28]. Finasteride is generally well tolerated with few side effects. The main concern for physicians and patients using finasteride is the possible occurrence of sexual side effects, which have been reported in approximately 2% of subjects enrolled in the clinical trials for the evaluation of drug efficacy. Sexual dysfunction occurs in less than 2% of subjects, with 1.8% experiencing decreased libido (1.3% placebo), 1.3% erectile dysfunction (0.7% placebo) and 0.8% decreased ejaculate volume (0.4% placebo). All side effects are reversible not only upon discontinuation but in 58% of those continuing therapy [5, 7, 8]. Tosti et al. [29] evaluated the sexual function in 236 subjects taking finasteride (1 mg) compared with 236 age-matched controls using the International Index of Erectile Function, and the results showed no statistical differences regarding the total index or the 5 single domains (erectile function, orgasmic function, sexual desire, intercourse satisfaction, overall sexual satisfaction) explored by the International Index of Erectile Function.

Finasteride is contraindicated in women of childbearing potential because of a risk of external genitalia abnormalities in a male fetus. A double-blind, randomized, placebo-controlled study of finasteride 1 mg/day for 12 months in 137 postmenopausal women (41–60 years of age) with AGA has shown no benefit although finasteride was generally well tolerated; it did not increase hair growth or slow the progression of hair thinning [30, 31].

Drake et al. [32] designed a study to assess the biochemical dose-response effects of finasteride in the circulation as well as the target organ, the scalp skin. They revealed that even at low doses, finasteride decreased scalp skin DHT levels by approximately 60% within 42 days of beginning treatment, and they did not observe a significant dose-response effect on the basis of serum testosterone percent change from baseline, and median serum testosterone levels were variably increased among treatment groups [32]. In our study, the mean serum total testosterone levels were also increased, but free testosterone levels were decreased. The reduction observed in serum PSA is well understood, and for men in whom serum PSA is used as part of a screening evaluation for prostate cancer, guidelines have been published for interpretation in patients receiving finasteride treatment [7].

The treatment of AGA is difficult. Clinicians need to be well informed about current treatment options, their success rates and limitations, and the uncertainty of individual outcomes defined. All authors agree that the management of the patient with male AGA is time-consuming, requiring medical assessment, detailed explanation, full discussion of all related problems, including stress and possible psychopathology, and continuing supervision of any medical treatment.

In this comparative study of topical minoxidil and systemic finasteride, it was concluded that both drugs were effective and safe in the treatment of mild to severe AGA, although oral finasteride treatment was more effective ($p < 0.05$). Adverse events were not considered important either, and these side effects disappeared as soon as the treatment was stopped. A combination therapy with finasteride and minoxidil may be more effective as mentioned by Khandpour et al. [23]. Also, further studies comparing finasteride and minoxidil and encompassing quantitative parameters, such as changes in hair counts, density and hair shaft diameters, for the objective assessment of their efficacy are essential. Finally, the different points of the impact of the two types of treatment suggest the possibility that treatment combining topical minoxidil and oral finasteride could produce more effective results in all clinical symptoms. Preclinical data suggest that oral finasteride and topical minoxidil have additive effects on hair growth, but this requires clarification in humans.

References

- Vecchio F, Guarrera M, Rebora A: Perception of baldness and hair density. *Dermatology* 2002;204:33–36.
- Hoffmann R: Male androgenetic alopecia. *Clin Exp Dermatol* 2002;27:373–382.
- Sawaya ME: Androgenetic alopecia: Overview. *J Cutan Med Surg* 1999;3(suppl 3):S14–S20.
- Bouhanna P: Multifactorial classification of male and female androgenetic alopecia. *Dermatol Surg* 2000;26:555–561.
- Wiseman MC, Shapiro J: Therapeutic approach to androgenetic alopecia. *J Cutan Med Surg* 1999;3(suppl 3):S21–S29.
- McClellan KJ, Markham A: Finasteride: A review of its use in male pattern hair loss. *Drugs* 1999;57:111–126.
- Kaufman KD, Olsen EA, Whiting D, Savin R, et al: Finasteride in the treatment of men with androgenetic alopecia. *J Am Acad Dermatol* 1998;39:578–589.
- Leyden J, Dunlap F, Miller B, Winters P, Lebowitz M, et al: Finasteride in the treatment of men with frontal male pattern hair loss. *J Am Acad Dermatol* 1999;40:930–937.
- Roberts JL, Fiedler V, Imperato-McGinley J, Whiting D, Olsen E, et al: Clinical dose ranging studies with finasteride, a type 2 5 α -reductase inhibitor, in men with male pattern hair loss. *J Am Acad Dermatol* 1999;41:555–563.
- Brenner S, Matz H: Improvement in androgenetic alopecia in 53–76-year-old men using oral finasteride. *Int J Dermatol* 1999;38:928–930.
- Whiting DA: Advances in the treatment of male androgenetic alopecia: A brief review of finasteride studies. *Eur J Dermatol* 2001;11:332–334.
- Wolff H, Kunte C: Current management of androgenetic alopecia in men. *Eur J Dermatol* 1999;9:606–609.
- Hoffmann R, Happle R: Current understanding of androgenetic alopecia. II. Clinical aspects and treatment. *Eur J Dermatol* 2000;10:410–417.
- Messenger AG: Medical management of male pattern hair loss. *Int J Dermatol* 2000;39:585–586.
- Price VH, Menefee E, Strauss PC: Changes in hair weight and hair count in men with androgenetic alopecia, after application of 5 and 2% topical minoxidil, placebo, or no treatment. *J Am Acad Dermatol* 1999;41:717–721.
- Olsen EA, Dunlap FE, Funicella T, Koperski JA, et al: A randomized clinical trial of 5% topical minoxidil versus 2% topical minoxidil and placebo in the treatment of androgenetic alopecia in men. *J Am Acad Dermatol* 2002;47:377–385.
- Walsh DS, Dunn CL, James WD: Improvement in androgenetic alopecia (stage V) using topical minoxidil in a retinoid vehicle and oral finasteride. *Arch Dermatol* 1995;131:1373–1375.
- Sinclair RD, Dawber RPR: Androgenetic alopecia in men and women. *Clin Dermatol* 2001;19:167–178.
- Whiting DA, Olsen EA, Savin R, Halper L, et al: Efficacy and tolerability of finasteride 1 mg in men aged 41 to 60 years with male pattern hair loss. *Eur J Dermatol* 2003;13:150–160.
- Kaufman KD: The Finasteride Male Pattern Hair Loss Study group: Long-term (5-year) multinational experience with finasteride 1 mg in the treatment of men with androgenetic alopecia. *Eur J Dermatol* 2002;12:38–49.
- Shapiro J, Kaufman KD: Use of finasteride in the treatment of men with androgenetic alopecia (male pattern hair loss). *JID Symp Proc* 2003;8:20–23.
- Diani AR, Muholland MJ, Shull KL, Kubice MF, et al: Hair growth effects of oral administration of finasteride, a steroid 5 α -reductase inhibitor, alone and in combination with topical minoxidil in the balding stump-tail macaque. *J Clin Endocrinol Metab* 1992;74:345–350.
- Khandpour S, Suman M, Reddy BS: Comparative efficacy of various treatment regimens for androgenetic alopecia in men. *J Dermatol* 2002;29:489–498.
- Saraswat A, Kumar B: Minoxidil vs finasteride in the treatment of men with androgenetic alopecia. *Arch Dermatol* 2003;139:1219–1221.
- Scheman AJ, West DP, Hordinsky MK, Osburn AH, West LE: Alternative formulation for patients with contact reactions to topical 2 and 5% minoxidil vehicle ingredients. *Contact Dermatitis* 2000;42:241.
- Friedman ES, Friedman PM, Cohen DE, Washenik K: Allergic contact dermatitis to topical minoxidil solution: Etiology and treatment. *J Am Acad Dermatol* 2002;46:309–312.
- Trattner A, David M: Pigmented contact dermatitis from topical minoxidil 5%. *Contact Dermatitis* 2002;46:246.
- Dawber RPR, Rundegren J: Hypertrichosis in females applying minoxidil topical solution and in normal controls. *J Eur Acad Dermatol Venereol* 2003;17:271–275.
- Tosti A, Piraccini BM, Soli M: Evaluation of sexual function in subjects taking finasteride for the treatment of androgenetic alopecia. *J Eur Acad Dermatol Venereol* 2001;15:418–421.
- Price VH, Roberts JL, Hordinsky M, Olsen EA, et al: Lack of efficacy of finasteride in postmenopausal women with androgenetic alopecia. *J Am Acad Dermatol* 2000;43:768–776.
- Thai KE, Sinclair RD: Finasteride for female androgenetic alopecia. *Br J Dermatol* 2002;147:812–813.
- Drake L, Hordinsky M, Fiedler V, Swinehart J, Unger WP, et al: The effects of finasteride on scalp skin and serum androgen levels in men with androgenetic alopecia. *J Am Acad Dermatol* 1999;41:550–554.