

## Original Research Article

# A cross-sectional randomized comparative study of topical minoxidil solution with and without finasteride in male pattern androgenetic alopecia in South Indian patients

C. R. V. Narasimhalu\*

Department of Skin & STD, Saveetha Medical College, Saveetha University, Kancheepuram, Tamil Nadu, India

**Received:** 04 December 2017

**Revised:** 03 January 2018

**Accepted:** 05 January 2018

**\*Correspondence:**

Dr. C. R. V. Narasimhalu,

E-mail: [drnarasimhalu@saiskinclinic.in](mailto:drnarasimhalu@saiskinclinic.in)

**Copyright:** © the author(s), publisher and licensee Medip Academy. This is an open-access article distributed under the terms of the Creative Commons Attribution Non-Commercial License, which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

### ABSTRACT

**Background:** Finasteride is one of the common drugs used in androgenetic alopecia. Literature speaks about sexual side effects in about 2% of the patients. To overcome this, we used topical finasteride. The objective of the study was to know the efficacy of topical minoxidil solution with and without finasteride.

**Methods:** We randomized about 300 subjects, aged 18-45 years, who came for outpatient consultation for male pattern androgenetic alopecia into two groups. One group (group A) treated with 0.1% topical finasteride with 5% minoxidil solution and another group (group B) treated with 5% minoxidil solution after informed consent from both of them.

**Results:** Analysis of the extent of bald area, hair count and number of terminal hair showed no significant difference in both the groups.

**Conclusions:** No significant difference in the therapeutic response of topical minoxidil solution whether its plain or added with topical finasteride. So, adding topical finasteride in the minoxidil solution found to be of no value. It only adds up the cost and also creates the unnecessary fear of sexual side effects in the mind of the patients.

**Keywords:** Androgenetic alopecia, Testosterone, Dihydro testosterone, Male pattern baldness, Loss of libido, Topical finasteride

### INTRODUCTION

Loss of hair is a worrisome problem for many men. The main cause of the same is androgenetic alopecia. The supposed to be the drug of choice in male pattern androgenetic alopecia treatment is finasteride. Finasteride 1 mg is used all over the world for the treatment of androgenetic alopecia.<sup>1</sup> It is approved in the USA and many other countries. On oral Finasteride administration about 2% of the patients had side effects, the common one was erectile dysfunction, loss of libido and decreased ejaculate volume.<sup>2</sup> However, a study conducted by this article author & another study conducted by Tosti et al

showed that the sexual and erectile function of those subjects who were treated with Finasteride orally was not reduced compared with their age related controls.<sup>3</sup> Finasteride's efficacy is proven by various clinical trials in adult men with predominant vertex, anterior and midscalp region.<sup>4-6</sup>

The main mechanism in androgenetic alopecia is miniaturization of hair due to the effect of androgen especially dihydrotestosterone. Finasteride is a type 2, 5 alpha reductase inhibitor; it inhibits dihydrotestosterone conversion from testosterone. Dihydro testosterone is active form of testosterone; produced from testosterone

by type 2, 5 alpha reductase.<sup>7</sup> Although, testosterone, is responsible for sexual function after puberty, and it is not by the dihydrotestosterone. In spite of the explanation and clinical trials, people were afraid to use oral Finasteride. To overcome this, topical finasteride was attempted in patients of androgenetic alopecia. This study was conducted to know the true efficacy of topical minoxidil solution with finasteride compared to plain minoxidil solution.

**METHODS**

We randomized about 300 subjects, aged 18-45 years, who came for outpatient consultation at Sai Skin and Cosmetology centre, Saveetha Medical College from August 2016 to July 2017 for male pattern androgenetic alopecia into two groups. They were diagnosed clinically as male pattern hair loss.<sup>8</sup> One group (group A) treated with 0.1% topical finasteride with 5% minoxidil solution and another group (group B) treated with 5% minoxidil solution after informed consent from both of them.

Inclusion criteria were as follows: age 18-45 years, maximum diameter of the bald area less than 10 cms, with good physical health, patient stopped previous treatments for androgenetic alopecia for a period of six months. Exclusion criteria were patients on treatment for hair loss and those patients who have various other cause for hair loss other than androgenetic alopecia.

Group A were provided with 0.1% topical finasteride with 5% minoxidil solution. The other group, group B is provided with plain 5% minoxidil solution to apply on the scalp twice daily.

To evaluate the medicines effect, patient were consulted before the study, after fortnight then every month end for follow up. Every time during consultation, the extent of the bald area, total hair count and terminal hair count in per cm<sup>2</sup> area was studied. On the directions of the study conducted by Hajheydari et al extent of the bald area (in cms), total hair count (per cm<sup>2</sup>) and number of terminal hair (per cm<sup>2</sup>) is provided by with the following points as given in Table 1.<sup>9</sup> The responses of the treatment were scored as given in Table 2. By calculating the number of people falling in good, moderate and mild, those results were depicted in Table 4 in an month wise manner.

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki declaration of 1964, as revised in 2013. Informed consent was obtained from all patients for being included in the study. Statistical tool was analyzed with the IBM software Package (SPSS Statistics, NY, USA).

**RESULTS**

About 300 patients of androgenetic alopecia were randomly enrolled for the study with their consent. 150

patients were assigned in the group A and 150 patients were assigned to group B.

In group A, 2 patient left treatment due to cost factor and 3 patients due to poor compliance. 145 patients completed the study for 6 months.

**Table 1: Consultation with measurement of hair count, terminal hair and extent of bald area.**

Points	Extent of bald area (in cms)	Total hair count (per cm <sup>2</sup> )	No. of terminal hair (per cm <sup>2</sup> )
1	8.5-9.9	110-134	75-99
2	7-8.4	135-159	100-124
3	5.5-7	160-184	125-149
4	4-5.5	185-210	150-175

**Table 2: Score points for response to treatment.**

Response to treatment	Score
Mild	3-6
Moderate	7-9
Good	10-12

In group B, 1 patient stopped medication due to cost factor and one patient lost to follow up. In this group 149 patients were followed up till the end of the study period.

There is a good reduction in the size of the bald area by one cm from the end of the third month onwards in both the groups.

Subjective and objective improvement of hair growth was felt by most of the patients from the second month end onwards.

**Table 3: Hair count.**

Average hair count per cm <sup>2</sup>			
<b>0.1% topical finasteride with 5% minoxidil solution</b>	Before	70.13±49.73	p=0.018
	After	112±54.64	
<b>5% plain topical minoxidil solution</b>	Before	69.38±46.07	
	After	122.63±58.96	

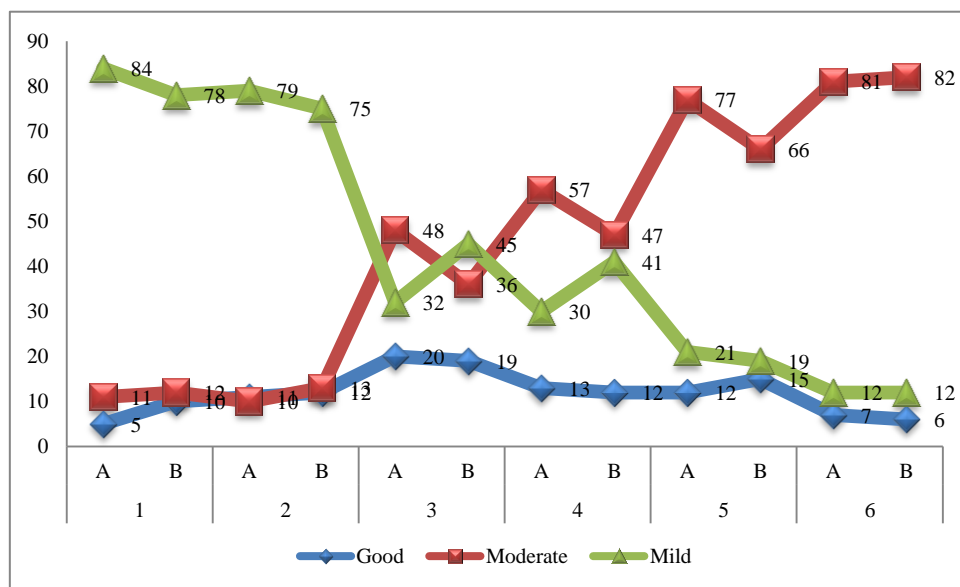
The average hair count before and after therapy was well depicted in Table 3 with p=0.018.

Very few patients felt not much improvement even after 6 months of treatment.

Three patients in group A and two patients in group B felt mild burning sensation and erythema on application of topical medications that was treated with antihistamines and mild topical steroids.

**Table 4: Response to medication in percentile.**

Response in months	Groups	Good	Moderate	Mild
1	A	05	11	84
	B	10	12	78
2	A	11	10	79
	B	12	13	75
3	A	20	48	32
	B	19	36	45
4	A	13	57	30
	B	12	47	41
5	A	12	77	21
	B	15	66	19
6	A	7	81	12
	B	6	82	12



**Figure 1: Graph representing the monthly response to the medication in group A & B.**

One patient in group A complained of sexual problem after applying Finasteride with minoxidil solution, but no complaint of any sexual problem in group B patients.

The results of the study (Table 4) revealed that there is equally good response to both group (group A) treated with topical 0.1% topical finasteride with 5% minoxidil solution and another group (group B) treated with plain topical 5% minoxidil solution (Figure 1).

**DISCUSSION**

The main mechanism in androgenetic alopecia is miniaturization of hair follicle. The mature terminal hair turns to vellus hair due to the effect of androgen especially dihydrotestosterone.<sup>10</sup> Testosterone is converted to 5 alpha dihydrotestosterone. The enzyme causing this is 5-alpha reductase. 5 alpha dihydrotestosterone is five times more potent than

testosterone. This dihydrotestosterone attaches itself to the androgen receptors of the genetically marked hair follicle that causes the miniaturization. Not only miniaturizations occur even the rate of hair growth reduces.<sup>11</sup>

Finasteride, a azasteroid is a type 2 isoenzyme, 5 alpha reductase inhibitor, which inhibits dihydrotestosterone conversion from testosterone.<sup>12,13</sup> This type 2 isoenzyme is present in the hair follicles and its activity is important in controlling the end organ hyperactivity causing androgenetic alopecia.

The results of the study (Table 4) revealed that there is equally good response to both group (group A) treated with topical Finasteride with minoxidil and another group (group B) treated with plain topical 5% minoxidil. Both groups started getting response to the therapy from the end of second month onwards.

Very few patients, 03 patients in group A and 02 patients in group B, felt mild burning sensation and erythema on application of topical medications, that was treated with antihistamines and mild topical steroids showing the topical preparations were relatively safe. But the undesired side effect, loss of libido was reported in group A who were taking finasteride in only one individual. The studies on sexual side effects in the past like Leyden et al and Kaufman et al has shown 2% of patients had sexual side effects.<sup>4,14</sup> However, RCT conducted by this article author<sup>15</sup> and another study conducted by Tosti et al proved, sexual and erectile function of those subjects who were treated with finasteride orally was not reduced compared with their age related controls.<sup>3</sup> Patients of group B didn't complain of the same. So, topical finasteride found to be equally effective drug, but this study proves there is no additional benefit of adding topical finasteride in the minoxidil solution.

## CONCLUSION

No significant difference in the therapeutic response of topical minoxidil solution whether its plain or added with topical finasteride. So, adding topical finasteride in the minoxidil solution found to be of no value. It only adds up the cost and also creates the unnecessary fear of sexual side effects in the mind of the patients.

*Funding: No funding sources*

*Conflict of interest: None declared*

*Ethical approval: The study was approved by the institutional ethics committee*

## REFERENCES

1. Roberts JL, Fielder V, Imperato-McGinley J, et al. Clinical dose ranging studies with Finasteride, a type 2 5 alpha reductase. J Am Acad Dermatol. 1999;40:930-7.
2. Arndt KA, Hsu JTS. Manual of dermatologic therapeutics. 7th ed. Lippincott Williams & Wilkins; 2006: 339-340.
3. Tosti A, Piraccini BM, Soli M. Evaluation of sexual function in subjects taking finasteride for the treatment of androgenic alopecia. J Eur Acad Dermatol Venereol. 2001;15:418-21.
4. Leyden J, Dunlap F, Miller B, et al. Finasteride in the treatment of men with frontal male pattern hair loss. J Am Acad Dermatol. 1999;40:930-7.
5. Brenner S, Matz H. Improvement in androgenic alopecia in 53-76 years old men using oral Finasteride. Int J Dermatol. 1999;38:928-30.
6. Price VH, Menefee E, Sanchez M, Ruane P, Kaufman KD. Changes in hair weight and hair count in men with androgenetic alopecia after treatment with Finasteride, 1 mg, and daily. J Am Acad Dermatol 2002;46:517-23.
7. Valia RG, Valia AR. IADVL textbook of dermatology. Volume 1. 3rd ed. 894.
8. Hamilton JB. Male hormone stimulation is prerequisite and an incitement in common baldness. Am J Anat. 1942;71:451-60.
9. Hajheydari Z, Akbari J, Saeedi M, Shookoohi L. Comparing the therapeutic effects of Finasteride gel and tablet in treatment of the androgenetic alopecia. Indian J Dermatol Venerol Leprol. 2009;75:47-51.
10. Kligman AM. The comparative histopathology of male pattern baldness and senescent baldness. In: De Villez RL, editor. Clinics in dermatology. Philadelphia: Lippincot; 1998: 108-113.
11. Hoffmann R, Van Neste D. Recent findings with computerized methods for scalp hair growth measurements. J Invest Dermatol Symp Proc. 2005;10:285-8.
12. Cafardi JA. Springer international ed. The manual of Dermatology. 2015: 21.
13. Wolff K, Goldsmith LA, Katz SI, Gilchrest BA, Paller AS, Lefell DJ. Fitzpatrick's Dermatology in general medicine. 7 th ed. 2008: 768.
14. Kaufman KD, Olsean EA, Whiting D, et al. Finasteride in the treatment of man with androgenetic alopecia. J Am Acad Dermatol. 1998;39:578-9.
15. Narasimhalu CRV. Randomized questionnaire based case-control research study on evaluation of the sexual function in Indian patients taking oral Finasteride for androgenetic alopecia. Dermatol Therapy. 2015;4:231-4.

**Cite this article as:** Narasimhalu CRV. A cross-sectional randomized comparative study of topical minoxidil solution with and without finasteride in male pattern androgenetic alopecia in South Indian patients. Int J Res Dermatol 2018;4:46-9.