Dermatology Clinics & Research
DCR, 1(4): 77-80
wwww.scitcentral.com

ISSN: 2380-5609

Original Research: Open Access

Randomized Comparative Research Study of Topical and Oral Finasteride with Minoxidil for Male Pattern Androgenetic Alopecia in Indian Patients

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Received January 6, 2016; Accepted February 14, 2016; Published February 22, 2016

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.
Objective: To know the efficacy of topical Finasteride it is compared with oral Finasteride along with minoxidil.
Materials and Methods: We randomized about 107 subjects, aged 18-40 years, who came for outpatient consultation for male pattern androgenetic alopecia into two groups. One group (group A) treated with Finasteride 1 mg tablet and topical 5% minoxidil solution, another group (group B) treated with 0.1% topical Finasteride with 5% minoxidil solution for 06 months of study period.
Results: Analysis of the extent of bald area, hair count and number of terminal hair showed no significant difference in both the groups.
Conclusion: Analysis showed no significant difference in the therapeutic response, both topical and oral Finasteride found to be equally effective. So, topical Finasteride found to be a safe alternative drug, with high compliance that avoids 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 1mg is used all over the world for the treatment of androgenetic alopecia [1]. It is approved in the USA and many other countries. On oral Finasteride administration about 2% [2] of the patients had side effects, the common one was erectile dysfunction, loss of libido and decreased ejaculate volume. However, a study conducted by this article author & another study conducted by Tosti et al. [3] 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. Finasteride's efficacy is proven by various clinical trials in adult men with predominant vertex, anterior and midscalp region [4-6].

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 [7]. 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.

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Citation: Narasimhalu CRV. (2016) Randomized Comparative Research Study of Topical and Oral Finasteride with Minoxidil in Male Pattern Androgenetic Alopecia in IndianPattiients. Dermatol Clin Res, 1(4): 77-80.

MATERIALS & METHODS

We randomized about 107 subjects, aged 18-40 years, who came for outpatient consultation for male pattern androgenetic alopecia into two groups. They were diagnosed clinically as male pattern hair loss [8]. One group (group A) treated with Finasteride 1 mg tablet with topical 5% minoxidil solution and another group (group B) treated with 0.1% topical Finasteride with 5% minoxidil solution after informed consent from both of them.

Inclusion criteria were as follows: Age 18-40 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 various other cause for hair loss other than androgenetic alopecia.

Group A were provided with 5% minoxidil solution to apply twice daily and Tab.Finasteride 1mg to be taken orally once a day. The other group, group B is provided with 5% minoxidil and 0.1% Finasteride solution combination solution to apply on the scalp twice daily.

To evaluvate 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^2 area was studied. On the directions of the study conducted by Hajheydari et al. [9] extent of the bald area (in cms), total hair count (per cm^2) & number of terminal hair (per cm^2) is provided by with the following points as given in **Table 1**. 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.

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^2)	No. of terminal hair (per cm^2)
1	8.1-9.5	100-124	65-89
2	6.6-8	125-149	90-114
3	5.1-6.5	150-174	115-139
4	3.5-5	175-200	140-165

Table 2. Score points for response to treatment

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

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Decleration of 1964, as revised in 2013. Informed consent was obtained from all patients for being included in the study.

RESULT

About 107 patients of androgenetic alopecia were randomly enrolled for the study with their consent. 55 patients were assigned in the group A and 52 patients were assigned to group B.

In group A, 1 patient stopped finasteride due to decreased libido, 1 patient left treatment due to cost factor and 3 patients due to poor compliance. 50 patients completed the study for 6 months.

In group B, 1 patient stopped medication due to cost factor and one patient lost to follow up. In this group 50 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.

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.

One patient in group A complained of sexual problem after taking Finasteride oral medication, but no complaint of any sexual problem in group B patients.

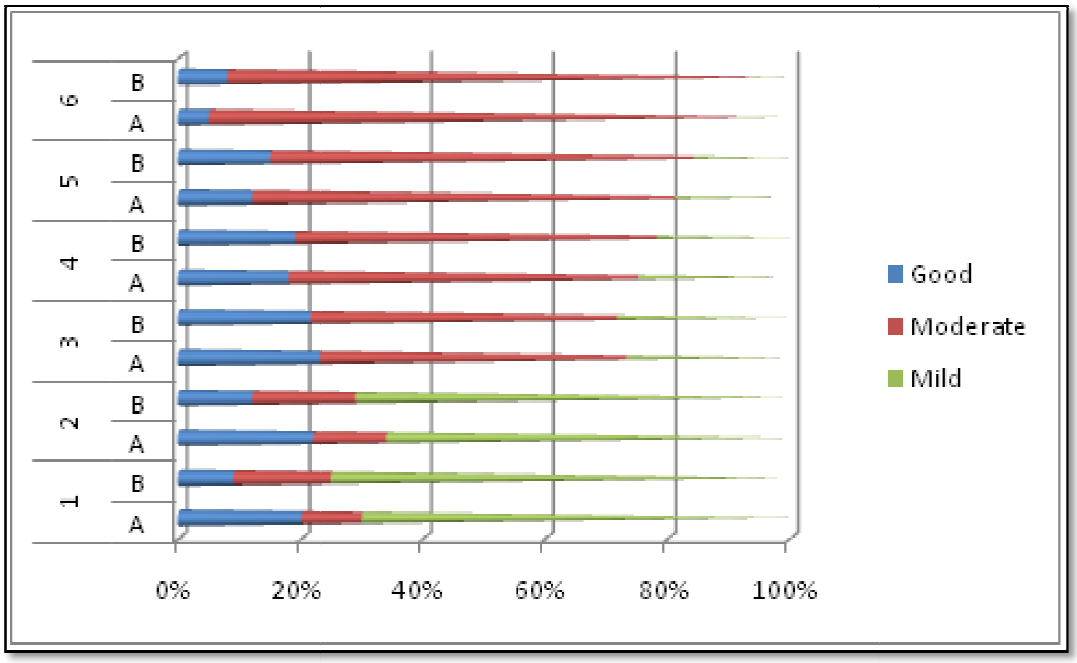
The results of the study (**Table 4**) revealed that there is equally good response to both group (group A) treated with oral Finasteride 1 mg with topical 5% minoxidil and another group (group B) treated with topical Finasteride with minoxidil (**Graph 1**).

Table 3. Hair Count.

		Average hair count per cm^2	
Oral Finasteride	Before	70.13+49.73	P=0.018
	After	112+54.64	
Topical Finasteride	Before	69.38+46.07	
	After	122.63+58.96	

Table 4. Response to medication in percentile

Response in months	Groups	Good	Moderate	Mild
1	A	20	10	70
	B	9	16	75
2	A	22	12	66
	B	12	17	71
3	A	24	52	28
	B	22	51	29
4	A	18	57	25
	B	19	59	22
5	A	12	69	19
	B	15	69	16
6	A	5	86	9
	B	8	85	7



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

DISCUSSION

The main mechanism in androgenetic alopecia is miniaturization of hair follicle. The mature terminal hair turns to vellus hair [10] due to the effect of androgen especially dihydrotestosterone. 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 [11].

Finasteride, a azasteroid is a type 2 isoenzyme, 5 alpha reductase inhibitor [12,13], which inhibits dihydrotestosterone conversion from testosterone. 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 oral Finasteride 1 mg with topical 5% minoxidil and another group (group B) treated with topical Finasteride with 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 01 patient 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 by 01 patients of group A who were taking Finasteride, because of this he was dropped out of the study course. This was proved by many studies in the past like Leyden et al. [4] and Kaufman et al. [14] has shown 2% of patients had sexual side effects. However, RCT conducted by this article author [15] and another study conducted by Tosti et al. [3] proved, sexual and erectile function of those subjects who were treated with Finasteride orally was not reduced compared with their age related controls. Patients of group B didn't complain of the same. So, topical finasteride found to be a much safe and equally effective drug, with high compliance that avoids the unnecessary fear of sexual side effects in the mind of the patients.

CONCLUSION

Not only oral even the topical Finasteride found to be a much safe and equally effective drug, with high compliance that avoids the unnecessary fear of sexual side effects in patients.

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