

The effect of topical finasteride 0.5% on the outcome of diode laser therapy in the treatment of excess facial hairs in the women with hirsutism

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Abstract

Objective: To determine the effects of topical finasteride 0.5% on the results of diode laser therapy in the treatment of hirsutism.

Methods: This double-blind, placebo-controlled, clinical trial study was conducted at a private clinic in Babol, Iran, between June 2012 and July 2013, and comprised women with idiopathic hirsutism. A diode laser (810nm) treatment was applied monthly for 6 months with an extra session at the 12th month. The device was adjusted individually according to the skin types using Fitzpatrick classification. Patients were divided into 2 groups: those who were given topical finasteride 0.5% and those who were given placebo solution on a daily basis for 5 days before each session.

Results: Of the 104 participants, there were 52(50%) each in placebo and intervention groups. The mean age was 30.71±9.25 years in the former group and 31.55±7.72 in the latter (p=0.61). The mean hair number before treatment in the intervention group was 49.09±12.41 and in the placebo group was 48.78±15.31 (p=0.9). At the end of the 6-month period, the mean number in treatment and placebo groups were 3.26±1.01 and 5.23±1.73 (p<0.001), respectively. After a one-year follow-up, the mean hair count of 3.73±1.20 and 7.36±2.40 was attained in intervention and placebo groups (p<0.001) respectively.

Conclusion: Applying finasteride 0.5% solution to the unwanted facial hairs and performing diode laser at the same area resulted in reduction of unwanted hairs.

Keywords: Finasteride; Hirsutism; Randomised clinical trial; Diode laser. (JPMA 66: 1107; 2016)

Introduction

Excessive growth of hair on women's body in a male pattern is called hirsutism. Hirsutism is diagnosed by excess hair growth in areas sensitive to androgen. It usually indicates an underlying endocrine disease. Almost 5% to 10% of women experience this problem during their lives.¹ Since it has a negative impact on the person's self-esteem and lifestyle, the victim struggles with this issue all the times.² There are different types of hirsutism, with the idiopathic hirsutism being the most common. Patients with normal ovulatory function and androgen levels are diagnosed as idiopathic hirsutism.³

Various underlying aetiologies can lead to this medical problem among women. One of the most important causes is polycystic ovarian disease (PCOD). It is a well-known fact that endocrine system controls hair growth in human body, therefore, most of its aetiological factors are somehow related to endocrine system problems.⁴ Hirsutism is strongly linked with excess amount of androgens.⁵

Different treatment methods have been utilised for the

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management of hirsutism. In traditional methods, excessive hairs are removed temporarily. But, based on the modern philosophy of medicine, it is important to find the underlying aetiology, then a proper treatment plan would be designed to help the patient.⁶ This may include laser therapy and different medications. In some cases it is important to control the underlying cause first, so the hirsutism will be treated subsequently.

Anti-androgens are a family of drugs which can inhibit or control the effects of these hormones. As mentioned, hirsutism is strongly linked with high levels of androgens, so these drugs may come handy in the healing process. Finasteride is one of them. This drug is usually used to treat benign prostate hyperplasia and male pattern baldness. It inhibits type 2 5-alpha reductase enzyme so that testosterone conversion to dihydrotestosterone (DHT) will be blocked.⁷

The 5-alpha reductase enzymes are important in steroid metabolism. They have 3 main metabolic functions. One of them is the synthesis of steroids. Three isoenzymes of 5-alpha reductase have been found, which vary in different tissues with age.⁸ Finasteride, a 4-azasteroid and analogue of testosterone, functions by acting as an inhibitor of the type 2 5-alfa-reductase. It is a potent competitor

inhibitor.⁹

Numerous studies were conducted in order to evaluate the efficacy of different treatment methods; but few tried to evaluate a combined treatment method. The current study was planned to evaluate a combined method for the management of hirsutism. This study was done in order to answer the question: Can we get better results from laser therapy if the patient is receiving topical anti-androgens during treatment period?

Patients and Methods

This double-blind, placebo-controlled, clinical trial study was conducted at a private clinic in Babol, Iran, between June 2012 and July 2013. After the legal and ethical approval of the local health authorities, patients with idiopathic hirsutism assessed as Ferriman and Gallweys score $> 7^{10}$ were recruited. In their first visit to the clinic, all the patients were checked by a dermatologist and a gynaecologist for diagnosing idiopathic hirsutism. All the participants were evaluated for stratification of skin type based on Fitzpatrick skin typing.¹¹ Patients with any history of hormonal therapy and anti-androgen usage were excluded. Patients with history of pregnancy and lactating were also excluded. Patients' new scars in the treatment area were not part of our study. We excluded the patients who had undergone hair removal programmes before. Informed consent was obtained from the participants. All procedures performed in this trial were in accordance with the Helsinki declaration of 1975.

Each patient was given a random number through computerised randomisation. Patients were then equally divided into placebo group and treatment/intervention group based on their previous randomisation. Both groups underwent the same diode laser therapy (810nm, 90 watts, continuous wave; Medart435™, Denmark). Placebo and finasteride did not have any significant difference in odour, colour and other physical characteristics.

Patients were interviewed about their recent menstruation periods and any history of ovulation problems. Blood samples were obtained and sent to a diagnostic laboratory to check their androgen levels. After that patients were sent for ultrasound evaluation

of the pelvis.

In the treatment group topical finasteride 0.5% was applied to unwanted hairs once a day from 5 days before each laser sessions while the control group received a topical placebo whose ineffectiveness had been approved in a pilot study. Finasteride was solved in propylene glycol and was applied as a 0.5% solution. Five milligram pills were used as the source of finasteride. Placebo did not have a significant difference with finasteride solution in taste, colour and odour. Ice pack was used before and after laser therapy for cooling the area. The patients underwent laser therapy for 7 times, once in a month during the first 6 months and once at the 12th month.

Unwanted hairs were counted 4 times during the study. At the baseline, after the third session, after the sixth session, and once after the last laser session at the bottom line (month 12). The hairs were counted by an expert nurse with a magnifier. Counting area was a 5 cm² square zone on the chin. It was done by hand and a photo was taken. Only black hairs were counted.

SPSS 14 was used for statistical analysis. Independent T-test was used for comparing the means and standard deviations (SD) between groups. A repeated-measure analysis was performed for comparing the excessive facial hair in each group during the study follow-up. $P < 0.05$ was considered significant.

Results

Of the 120 patients enrolled, 105(87.5%) were included. Of them 1(0.95%) was excluded during the trial. Of the remainder, there were 52(50%) each in placebo and treatment groups.

The mean age was 30.71+9.25 years in the former group and 31.55+7.72 in the latter ($p=0.61$). In the intervention group, 2(3.8%) women had type-1 skin, 18(34.6%) type 2, 29(55.8%) type 3 and 3(5.8%) type 4 compared to 2(3.8%), 17(32.7%), 31(59.6%) and 2(3.8%) in the placebo group ($p=0.96$) (Table-1).

At the beginning of the study, hair count was 49.09±12.4 in the intervention group and 48.78±15.31 in the placebo group ($p=0.911$). Three months later, the count fell to 16.65±4.76 and 27.96±9.61, respectively ($p < 0.001$). In the

Table-1: Both groups were similar in age and skin type. Skin types based on Fitzpatrick classification.¹¹

Groups	Mean age	P value	Skin type 1	Skin type 2	Skin type 3	Skin type 4	P value	Total
Intervention	31.55 ± 7.72	P=0.614	2	18	29	3	P=0.961	52
Placebo	30.71 ± 9.25		2	17	31	2		52

Table-2: Excessive facial hair was counted four times during the study.

Groups	First month	Third month	P value*	Sixth month	P value*	Twelfth month	P value*
Intervention	49.09 ± 12.4	16.65 ± 4.76	<0.001	3.26 ± 1.01	<0.001	3.73 ± 1.20	0.95
Placebo	48.78 ± 15.31	27.96 ± 9.61	<0.001	5.23 ± 1.73	<0.001	7.36 ± 2.40	0.075
P value**	0.91	<0.001		<0.001		<0.001	

*By Repeated measures

**By independent T test.

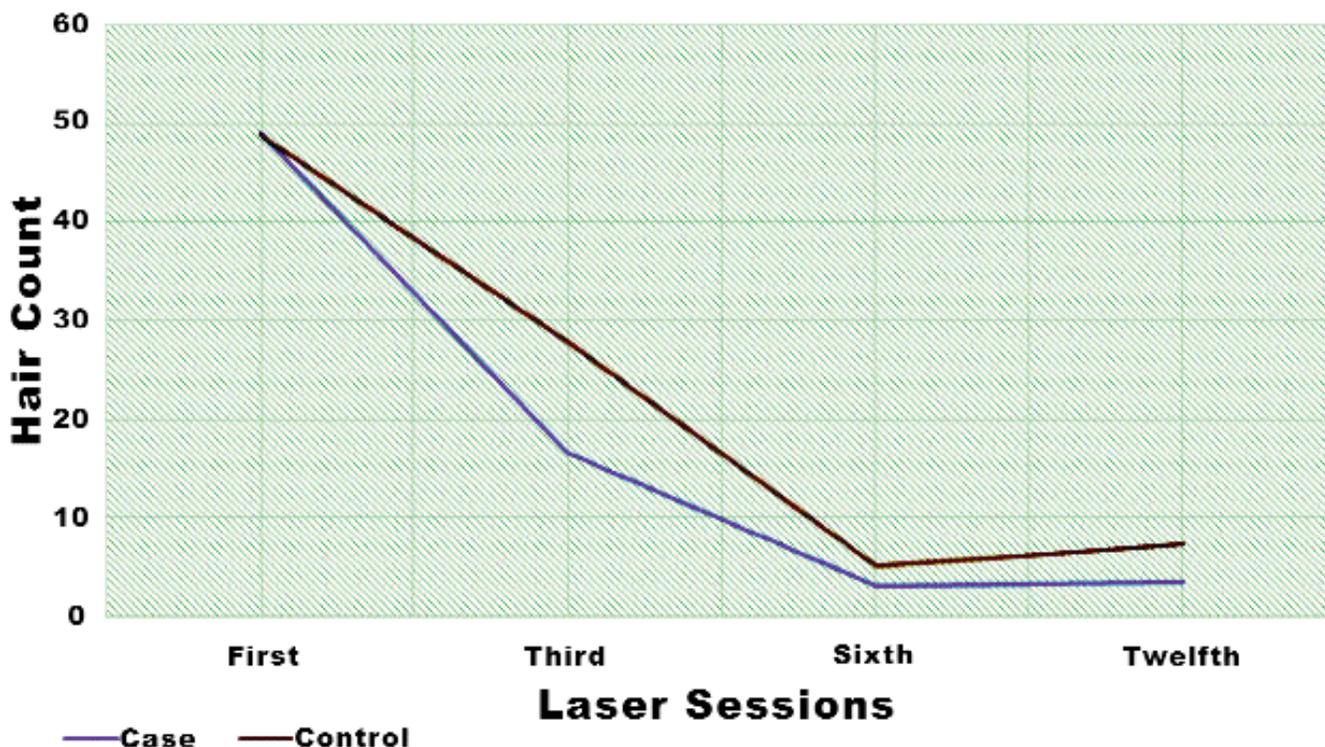


Figure: Unwanted hair numbers during the study.

next counting, it further dropped to 3.26±1.01 and 5.23±1.73 (p<0.001). Between sixth and seventh laser sessions, we had a six-month interval; the hair count slightly rose to 3.73±1.20 in the intervention group and 7.36±2.40 in the placebo group (p<0.001) (Table-2; Figure).

No major side effects were observed among the patients. Some patients reported redness on the area, and hydrocortisone was prescribed for them for three days, 2 times a day. Two (4%) patients in each group had a minor paradoxical hair growth on the treatment region.

Discussions

Based on our results, topical finasteride 0.5% was shown to improve the outcome of laser therapy. Finasteride is an

anti-androgen agent. Anti-androgens have been under observation for the treatment of hirsutism. Several studies have been done on their efficacy. In a clinical trial by Wong et al., in which one group received finasteride and the other spironolactone, mild improvements were recorded after 6 months of treatment. So they concluded that despite the benefits of anti-androgens for hirsute women are limited, they are still good candidates for a drug-dependent treatment plan.¹² It is believed that in hirsute women, higher levels of 5-alpha-reductase can be found in skin, so it gave us the clue to use topical finasteride in order to lower this enzyme's activity in skin and as a consequence reduce unwanted hair in the affected area, especially on the face and chin.^{13,14} Lucas recruited 8 hirsute women in a clinical trial. Every 8

women received both finasteride cream and placebo, finasteride cream (0.25%) on one side of the face and placebo on the other side. Hair thickness and counts were significantly decreased wherever finasteride was applied while nothing significant happened in the placebo receiving sites. Lucas concluded that topical finasteride is a reliable treatment for hirsutism because it decreases hair count and thickness.¹⁵ In another study, hirsute women were given placebo on one side of the face and finasteride cream on the other. Finasteride cream 0.5% was used in that study. Hair numbers were counted and hair thickness was also evaluated by a device. After six months of treatment, they did not notice any beneficial sign of finasteride in comparison to placebo.¹⁶ In another study, no beneficial effects for topical finasteride were observed. Finasteride 0.25 %, 0.5% and placebo were given to the patients groups in that trial;¹⁷ however, statistically their study did not have a high power.

Based on our results, topical finasteride 0.5%, especially when combined with laser therapy, is beneficial in the healing process of hirsute women. We believe that topical finasteride when used alongside laser therapy may delay re-growth of the hair between laser sessions; so as a consequence the final outcome is better. In our results, we observed a slight increase in hair count in control group which may indicate that finasteride have blocked hair re-growth so hair number did not increase in the case group significantly.

A good point in our study was that we used placebo and finasteride on different patients. As for limitations, our samples were not checked by a pathologist and our sample size was small. The follow-up period could be longer, too. An unanswered question is whether we can reduce the number of laser therapy sessions or no?

Conclusion

Topical finasteride 0.5% was found to enhance the outcome of laser therapy in idiopathic hirsutism. It may also reduce the duration of laser therapy. Thus, we suggest that clinicians should not rely on a single therapeutic method. As we observed that combining laser therapy with topical finasteride have quite better results than laser therapy alone. More studies should be conducted on topical administration of androgens in treating hirsutism. Further researches are still needed in order to decide whether they are efficient enough or not.

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Conflict of Interest: Nil

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