

Research

## The Efficacy of Topical Finasteride in the Treatment of Idiopathic Hirsutism

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### Abstract

**Objective:** Hirsutism is the presence of excess terminal hairs in females in a male-like pattern. The most accepted hypothesis for the development of hirsutism is increased 5- $\alpha$  reductase activity in hair follicles of hirsute women. Based on this hypothesis, this study is designed to evaluate the effects of finasteride cream (a 5- $\alpha$  reductase inhibitor) on idiopathic hirsutism.

**Methods:** Forty women with idiopathic hirsutism, received finasteride cream 0.25% twice a day for 6 months on their chins. Mean thickness of three hair samples of each patient was measured before and after a 6-month finasteride cream therapy. Ferriman-Gallwey score of the chin area was also determined.

**Results:** Mean hair thickness decreased from  $49.0 \pm 1.2 \mu\text{m}$  to  $37.4 \pm 0.7 \mu\text{m}$  ( $p < 0.001$ ). Mean Ferriman-Gallwey score was also decreased from  $3.2 \pm 0.41$  to  $2.2 \pm 0.76$  ( $p < 0.001$ ). Acne was reported by 8 patients (20%) during the therapy. There were no other side effects.

**Conclusion:** Finasteride cream is an efficient and harmless therapy in patients with idiopathic hirsutism.

### Introduction

Hirsutism is defined as excessive facial or/and body terminal hairs in women in a male-like distribution which affects between 5-15% women [1, 2]. Although of minor importance clinically, hirsutism has a significant negative impact on psychosocial development and severely affects the quality of life [2].

Hirsutism is androgen-dependent in 70 to 80% of cases, and androgen-independent in 6 to 17%. Idiopathic hirsutism (IH) is defined as presentation of hirsutism, regular ovulation and normal androgen levels which is caused by increased sensitivity of poliseba-

ceous unit to normal circulating androgen levels, presumably caused by increased peripheral 5 $\alpha$ -reductase (5 $\alpha$ -R) activity [3, 4, 5].

Different medical therapies, alone and in combination have been used to treat IH. Suppressive (oral contraceptives) and anti-androgen therapy (spironolactone, cyproterone acetate and flutamide) inhibits ovarian or adrenal androgen production and androgen activity either by blocking androgen cytochrome P450 receptors or by inhibiting 5 $\alpha$ -R activity. In addition cosmetic hair-removing procedures (camouflage by bleaching and various mechanical ways such as shaving, plucking and using depila-

tory creams) achieve the desired result for only a brief period [6, 7].

Finasteride is a 5 $\alpha$ -R inhibitor which can be used systemic or local. Finasteride decreases hair growth by causing less exposure of hair follicles to androgen stimulation [8, 9].

Although the efficacy of systemic finasteride has been reported in different studies, there is a few articles in which the efficacy and tolerability of topical finasteride as facial cream has been evaluated. The aim of this study was to examine the efficacy and tolerability of a 6-month course of topical finasteride in female with idiopathic hirsutism.

## Materials and Methods

We evaluated all the referred women complaining of hirsutism to endocrinal institute affiliated to Iran University of Medical Sciences (IUMS) from February to October 2006. To be eligible for this study, women were selected if they had below conditions to be considered as idiopathic hirsute patients:

*Ferriman-Gallwey* Score > 8 [10]

Normal serum androgen (total testosterone, free testosterone, androstenedione and DHEA-S)

Normal serum level of thyroid hormone, prolactin and cortisol.

No chemical or biochemical evidence of polycystic ovarian syndrome which is ruled out by regular menstrual cycles, normal ultrasound exam, serum LH/FSH ratio < 1 and normal serum SHBG.

Normal basal and ACTH-stimulated serum 17-hydroxyprogesterone level

Absence of chronic renal disease, diabetes mellitus and hepatic disease.

56 women with the mean age of  $32 \pm 3.5$  years with the mean BMI of  $22.67 \pm 1.7$  were enrolled in the study. This study was approved by the ethical committee of Iran University of medical sciences and our institutional review board. All the patients gave informed consent for their participation in our study after reading the protocol of this experiment. They had not used any other therapy for idiopathic hirsutism for at least the six previous months. They were told that finasteride could affect a male fetus and consequently pregnancy was contraindicated during the treatment and so effective contraceptive must be used. They were also informed that potential side effects of finasteride were unknown in women and they should report any possible side effects during the medication. The patients were explained not to use any other drug for IH at the

same time. Moreover electrolysis, waxing and plucking were not permitted during the treatment whereas shaving was permitted for subjective evaluation of hair growth by patients. The degree of hirsutism in the chin area was determined by *Ferriman-Gallwey* score. The scale is form 0 (absence of terminal hairs) to 4 (extensive terminal hair growth). Premature scores were determined by 2 examiners and mean scores were calculated for each patients. Three hairs of the chin area were plucked from each patient. Each hair was then fixed on a slide with a transparent resin that solidifies with air and was covered with another slide. Hair caliber was measured with a micrometer applied to an optical microscope (x 10 magnification). Then they received finasteride cream 0.25% on their chins twice a day for 6 months. They were explained to clean the chin area before usage and to avoid using powder, lotions, and sprays two hours after cream. The finasteride cream consists of 15 tablets of ministered (5 mg each) triturated and then wetted with 2 ml of propylene glycol. The mixture was incorporated into Farabi base (Razi laboratories, Ins.).

The patients were seen in consultation at 3 months intervals. Questions were asked about the side effects, menstrual abnormalities and also patients self evaluation of the clinical effects of the treatment. After six months, the mean caliber of three plucked hairs and the *Ferriman-Gallwey* score of the chin area was assessed again.

Data are presented as mean  $\pm$  SD or percentage. Statistical analyses were performed using spss software version 15:0:0 and paired T-Test for comparison of quantitative variables was used to compare the hair caliber before and after medication. P values less than 0.05 were statistically significant.

## Results

Out of fifty six participants, sixteen were excluded because they stopped the medication. The forty remained patients with the mean age of  $36 \pm 3.5$  continued the medication throughout the 6-month study period. None of the women reported any systemic problems with irregularity of menstrual periods, nausea, vomiting, diarrhea, abdominal pain or headache. Acne was the only problem reported in 8 patients (20%) on the chin area where the drug was applied. By subjective evaluation all the patients noted a diminished rate of hair growth (fewer times needed for shaving) and a decrement in the thickness of hairs on the chin area. By objective evaluation, mean hair thickness decreased from  $49.0 \pm 1.2$  micrometer before medication to  $37.4 \pm 0.7$  micrometer

after medication that was statistically significant ( $p < 0.001$ ). The *Ferriman-Gallwey* score of the chin area statistically decreased from  $3.2 \pm 0.41$  to  $2.2 \pm 0.76$  after a 6-month finasteride cream therapy ( $p < 0.001$ ). By *Pearson* correlation test, no significant correlations were found between BMI and hair thickness or *Ferriman-Gallwey* score changes before and after medication.

## Discussion

In this study, tolerability of finasteride and its efficacy on the decrement of facial hair growth and thickness were evaluated in female with IH. Finasteride is a  $5\alpha$ -R inhibitor, with no androgenic, anti-androgenic, steroid hormone-related properties and affinity for androgen receptors, which is indicated for prostatic disease and male balding [7]. More recently finasteride has been shown to be effective on clinical aspects of hirsutism in women [11]. Hyperactivity of  $5\alpha$ -R in the skin is considered a major mechanism of excessive hair growth in hirsute women with normal levels of serum androgens. Thus the use of finasteride for the treatment of hirsutism is rational because of its specific effect on  $5\alpha$ -R, the enzyme responsible for sensitizing the hair to testosterone [9, 12].

In previous studies, orally administered finasteride has been successfully used in the treatment of hirsutism. *Castello et al* [13] reported that *Ferriman-Gallwey* scores in 14 women with idiopathic hirsutism were significantly decreased during a 1-year course of finasteride therapy. In addition, *Faloia and colleagues* [14] observed a 33% reduction in clinical scores of hirsute patients after six months usage of finasteride. Notably there have been fewer investigations about topical application of finasteride. In fact its effects as an topical drug in the treatment of hirsutism are still debated. In a previous study, *Lucas* [9] showed a significant reduction in mean hair counts and the thickness of the hairs in eight women with hirsutism, treated with finasteride cream, whereas in the study performed by *Price et al* [8] nine hirsute women with IH showed no significant difference after six months therapy with topical finasteride, based on the hypothesis that topical application of finasteride did not result in significant systemic

absorption. The current study, designed to assess the clinical effects of finasteride cream on facial hirsutism, showed significant improvement in the area treated by topically applied finasteride.

Adverse effect of finasteride reported in other investigations includes; minimal gastrointestinal disturbances, headaches, dry skin and decreased libido and feminization of a male fetus [1, 15]. In our study no adverse effect except acne in 20% was reported. This indicates that topical finasteride is a promising therapy for IH with less side-effect in comparison with orally administered one.

As the possible side-effects of long-term finasteride therapy are unknown, thus further investigation in this regard is required. One of the deficits of this investigation was the lack of placebo group, which could make it possible to assess the efficacy of finasteride cream more exactly by comparing the placebo group with finasteride one.

In conclusion, topically applied finasteride is well tolerated and significantly decreased hair growth and thickness in hirsute women with minimum side-effects.

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