



## FINASTERIDE AND DUTASTERIDE EFFECTS ON WOMEN WITH ANDROGENETIC ALOPECIA OVER A PERIOD

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### ABSTRACT

There has been controversy regarding the effectiveness of finasteride and dutasteride in the treatment of androgenetic alopecia in women. In a study on women with androgenetic alopecia, finasteride and dutasteride were evaluated for their effects on hair loss. We selected 30 women from a database of 3500 women treated with finasteride 1.25 mg or dutasteride 0.15 mg whose data had been systematically retrieved to obtain data on the treatment of androgenetic alopecia. The sample was stratified for age and medication type. The thickness of the three thinnest hairs was measured by standardized microscopic images at the beginning of treatment and after 3 years of continuous medication intake. Three dermatologists/hair experts independently evaluated the macroscopic images. An image displaying superior density of hair had to be identified for diagnosis. Based on signed rank tests, it was found that hair thickness increased statistically significantly for both age categories over the 3-year period when finasteride and dutasteride were used. Finasteride resulted in an increase in hair thickness for 49 (81.7%) of the women and dutasteride resulted in an increase for 50 (85.6%) of the women. Dutasteride was rated superior to finasteride by 118 (66.7%) and 124 (69.8%) post-treatment images on average. The results of a statistical comparison between dutasteride and finasteride at the central and vertex sites of the scalp in the age category below 50 years were significantly better with dutasteride. In studies involving women suffering from androgenetic alopecia, finasteride 1.25 mg and dutasteride 0.15 mg were shown to be effective in increasing hair thickness and preventing further hair loss

**Key words:** Women, Androgenetic alopecia, dutasteride, effectiveness

### INTRODUCTION

Generally occurring in women over the age of 40, androgenetic alopecia is characterized by female pattern hair loss. Women over 70 years of age are more likely to develop this disease [1], and adolescents may already be affected [2]. A significant psychological problem as well as a cosmetic inconvenience is perceived by the majority of women with a bald head as a major cosmetic inconvenience [3]. A series of prospective randomized controlled trials (RCTs) have examined the effectiveness of finasteride in treating androgenetic alopecia in women, with all findings concluding that the drug is ineffective [4 6]. According to a Cochrane systematic review, these three

RCTs are highly biased and cannot be used as clinical guidelines for treating androgenetic alopecia in women [7]. The studies were also short in duration and that their effect measure was hair density, which further diminishes their value as a support for clinical decision making. The Cochrane review did not include studies with other designs than randomized controlled trials, despite the fact that these publications provide evidence that finasteride and dutasteride are effective and safe [8 12].

Clinical trials on finasteride and dutasteride have not been able to demonstrate their effectiveness.

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The Cochrane Review recommends the conducting of new well-designed randomized trials so that the issue can be clarified, but no new randomized trials have been conducted after the publication of the study referred to above. During the course of our research, we conducted a study of women in a dermatological clinic that specializes in hair disorders on the effectiveness of finasteride and dutasteride.

## **METHODS**

### **Population of patients**

Approximately 3500 women who were diagnosed with androgenetic alopecia and who gave their written informed consent to receive the prescribed medication were observed to receive finasteride 1.25 mg or dutasteride 0.15 mg daily after they were given written informed consent to receive them. As a result of an internal dose finding study that was conducted within the company, the doses were chosen. There were 16-84 age participants in the study. Blood samples were analyzed yearly and a general clinical examination was performed. A combination of finasteride and dutasteride was prescribed to premenopausal women. A standardized global photo was taken of the scalp at every patient visit, and microscopic images were taken at the vertex centre, midline center, and center of the frontal hairline. A reproducible image of the scalp could be produced at every visit using the imaging system. Microscopy images were used to measure hair thickness with a software tool. After three years of continuous medication intake, we measured the hair thickness of three thinnest hairs at three sites on the scalp using standardized microscopic images. A priori consent by an ethics committee was not possible because of this study's retrospective design. Every researcher involved in the study was given information about the patients' identities.

### **Sampling**

This study included the following criteria:

It has been determined that the patient has grade 1 or grade 2 androgenetic alopecia based on the microscopic appearance of thin hair.

The analysis was conducted on a stratified random sample of 60 patients with finasteride and 60 patients with dutasteride who have taken a continuous course of treatment for at least three years. It is important to mention that both groups included 30 patients who were under the age of 50 and 30 patients who were over the age of 50.

### **Thickness of hair**

Each site was measured by two trained analysts to determine the thickness of the three thinnest hairs. Duplicate measurements of 20 cases were used to assess intraobserver reliability. A three-year gain in haircut thickness was determined by subtracting pretreatment

haircut thickness from post-treatment haircut thickness. As long as hair thickness increased by a factor equal to or greater than 0, the treatment was considered effective.

### **Hair structure and scalp coverage**

Independent evaluation of scalp centers and vertex images by three European hair experts. A total of 20 duplicate cases were used to determine the intraobserver reliability. Images taken before and after treatment were compared. Pretreatment images were positioned left or right based on randomly assigned sequence numbers, while posttreatment images were positioned on the other side. Pretreatment images displaying superior scalp coverage and structure were scored as one if they showed better coverage and structure than posttreatment images. In the case of inequalities of scalp coverage and structure between pre- and posttreatment images, a score of 0 was assigned, whereas a score of +1 was awarded where the posttreatment image displayed better scalp coverage and structure. Using the center and vertex regions of the scalp as the indices, one patient score was calculated. Those with scores of zero or greater were considered to be receiving effective treatment.

### **Statistical analysis**

A paired Student t-test and Pearson correlation coefficients were used to test differences between original and duplicate measurements of hair thickness. For comparison of the effects of finasteride and dutasteride, signed rank tests were conducted in order to determine whether the increase in hair thickness was different from zero. According to Cohen's kappa statistic, the intraobserver reliability of hair experts' scalp coverage scores is expressed between the original and duplicate images. Statistically significant differences between the patient scores and zero were determined by signed rank tests.

## **RESULTS**

The graphs below demonstrate the effects of finasteride 1,25 mg and dutasteride 0.15 mg on hair thickness after three years. As a result of the two analysts' paired student t-test, hair thickness measurements by the original and duplicate analysts were not statistically significant ( $P = 0.86$ ); linear correlations were high (Pearson correlation coefficients were 0.89 and 0.96, respectively), indicating a high degree of intraobserver reliability. Finasteride increased hair thickness in 49 (81.7%) and dutasteride increased it in 50 (83.3%) of the women in each group. There were no age-related differences [Table 1]. There was statistically significant difference between 0 and 100% in both age categories and at all scalp sites when compared to 0 (Signed rank test,  $P 0.05$ ), except for dutasteride at the frontal site in those over 50 years. As demonstrated by the results of the Signed rank test, dutasteride users in the age group under 50 years

experienced significantly greater hair thickness increases at the center of the scalp and vertex. These results indicate a higher efficacy of dutasteride in these two areas [Table 2]. Based on Cohen's kappa statistics, the subjective scalp coverage and structure measurements of the three hair experts were 0.50, 0.70, and 0.70, respectively, indicating

fair intraobserver reliability. According to three hair experts, 124 image pairs associated with improved hair density were associated with finasteride (68.9%) and 118 with dutasteride (65.6%). [Table 3] For finasteride, its effectiveness was highest in older adults, while for dutasteride, its effectiveness was highest in younger adults.

**Table 1: At the start and after three years of treatment, the thickness of hair (HTI) and effectiveness of finasteride 1.25 mg were measured in 120 women.**

Treatment	Age category (%)	HTI<0 mm (n)	HTI≥0 mm (n)	Effectiveness %
Finasteride 1.25 mg	Less than 50 years	4	24	82.4
	≥50 years	5	23	79
	All ages	10	48	80.6
Dutasteride 0.15 mg	<50 years	4	24	82.6
	≥50 years	4	24	82.6
	All ages	9	49	82.6
	Overall	20	98	81.4

**Table 2: Based on age category and measurement site, delta hair thickness increase differs between the dutasteride and finasteride groups. Brackets indicate 95% confidence intervals.**

Site (Age)	Delta HTI (mm) (Age)	
	More than 50 years	More than 50 years
More than 50 years	More than 50 years	More than 50 years
More than 50 years	More than 50 years	More than 50 years
More than 50 years	More than 50 years	More than 50 years

**Table 3: A study of 120 women with hair loss checked by three hair specialists (360 cases) at the begin and at the end of 3 years of treatment, investigating the efficacy of finasteride 1.25 mg compared with dutasteride 0.15 mg on their hair loss.**

Treatment	Age category (%)	SCHS<0 (n)	SCHS≥0 (n)	Effectiveness %
Finasteride 1.25 mg	<50 years	29	57	64.9
	≥50 years	24	63	71.3
	All ages	54	122	67.8
Dutasteride 0.15 mg	<50 years	24	62	70.3
	≥50 years	34	52	59.0
	All ages	60	116	64.7
	Overall	116	238	66.3

**DISCUSSION**

It has been well established that finasteride is effective in preventing hair loss in men [13], and it is now commonly prescribed to balding males. Dihydroxytestosterone (DHT) in serum, prostate, and scalp is decreased by about 65% when finasteride is used as an inhibitor of type II 5αphereductase. As a result of dihydroxytestosterone (DHT) inhibition by dutasteride, the serum level of DHT is reduced by about 90%, and it has highly proven effectiveness in treating androgenetic alopecia in men [14,15]. As a result of finasteride/dutasteride use in this area, finasteride and dutasteride prescriptions should increase.

As a result of finasteride and dutasteride treatment for over 1 year, the size of hair follicles, the thickness of hair, and the growth of hair have been shown to increase considerably, which explains the choice of choosing hair

thickness as a measure of the treatment's effectiveness. Additionally, Olsen questioned the theory that hair loss is androgen-dependent, which is supported by the increased thickness of the thinnest hair observed in this study [16]. Hair thinning occurs slowly over years in women suffering from androgenetic alopecia. Hair thickness and density can be improved through medical treatment. Regrowth of thicker hair can only be achieved with prolonged treatment, since it takes years instead of months to regrow thicker hair. As well, a successful treatment does not only entail improving hair thickness and length, but also preventing further hair deterioration. 68.9% and 65.6% of the cases were able to be improved by finasteride or dutasteride after three years of treatment, respectively, based on subjective evaluations after the treatment period. A statistically significant 81.7% and 83.3% increase in hair thickness was determined by objective measurements. The

effect size of finasteride and dutasteride is well aligned with studies on male effectiveness of these medications [13,17].

According to this theory, women's hair loss is caused by the same mechanism as that of men. A 5-alpha-reductase inhibitor could stop or reverse hair loss in women suffering from androgenetic alopecia, as it does in men.

Finasteride or dutasteride clinical effectiveness was measured using hair thickness in this study for the first time. As there are no scientific details on the number of hairs per unit in women under 50 years of age, we chose not to use hair density as an effect measure. As measured at the center of the midline and vertex, dutasteride 0.15 mg appears significantly more effective than finasteride 1.25 mg. Consequently, younger women are preferred to be prescribed dutasteride. As a precaution, finasteride or dutasteride are only recommended for women who are unable to become pregnant or do not want to become pregnant. Doctors should ensure that patients comply with contraceptive measures prescribed to them by the latter group. Female pattern hair loss women often preserve their frontal hairline, which may explain the lack of a significant

dissimilarity finasteride and dutasteride at the frontal line. Dihydroxytestosterone (DHT) does not seem to affect hair growth along the frontal hairline. A major disadvantage of retrospective studies compared to controlled clinical trials is that placebos are not administered to control groups. A second source of bias is a lack of double-blind data collection. It was also possible to introduce bias in this study by limiting participants to women who have been taking finasteride or dutasteride continuously for three years, thus excluding women who discontinued the medication within three years due to perceived or ascertained weak, adverse effects, financial reasons, gestational plans, or prediction for other treatment alternatives. It was, however, a prospective study, where data were systematically collected for all patients in the clinic. A retrospective study may have some disadvantages, but our results may be useful in assisting with the debate regarding the efficacy of finasteride and dutasteride as prescriptions under field conditions in women with androgenetic alopecia, and in determining whether a new randomized controlled trial should be conducted.

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