

# Clinical Efficacy of Oral Administration of Finasteride at a dose of 2.5mg/Day in Women with Female Pattern Hair Loss

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## ABSTRACT

**Aim:** To find clinical efficacy of oral administration of finasteride at a dose of 2.5mg/day in women with female pattern hair loss.

**Study design:** Descriptive cases series

**Place and duration of study:** Department of Dermatology, Unit II, Mayo Hospital Lahore from 01-10-2019 to 31-03-2020.

**Methodology:** A total of 137 cases were taken. Trichoscopy was performed at enrollment and after 5 months. At the standardized resolution of each image, ratio of terminal to vellus hair measured at two sites of the scalp. Clinical efficacy was determined as per operational definition at 5th month of treatment.

**Results:** Patients ranged between 40-70 years of age with mean age of 49.5±6.9 years. Pre-menopause women were 99 (72.3%) while post-menopause were 38(27.7%). Mean duration of FPHL was observed 4.4±1.3 months. Out of 137 cases, 92 women (67.2%) belonged to Ludwig scale-I and remaining 45 women (32.8%) belonged to Ludwig scale-II. Clinical efficacy of finasteride 2.5mg/day was found in 85 women (62%). Stratification for age, duration of FPHL, menopause status, and baseline Ludwig scale was also carried out. Four to six months duration of FPHL, premenopausal women and lower Ludwig scale showed significant effect of finasteride ( $p < 0.001$ ,  $p = 0.010$  and  $p = 0.003$ , respectively).

**Conclusion:** In conclusion, the efficacy of administration of finasteride at a dose of 2.5 mg/day for patients with female pattern hair loss was recorded 62%, and it was also observed that finasteride revealed better effect on hair growth in patients having lower Ludwig score.

**Keywords:** Female pattern hair loss; Finasteride, Efficacy, Oral administration.

## INTRODUCTION

Female pattern hair loss (FPHL) presents with diffuse thinning over the mid-frontal scalp, for which various treatment modalities have been tried.<sup>1,2</sup> FPHL affects approximately 40% of women by age 50, and management can be challenging.<sup>3</sup> FPHL or female androgenetic alopecia is the main cause of hair loss in adult women and has a major impact on patients' quality of life. It evolves from the progressive miniaturization of follicles that lead to a subsequent decrease of the hair density, leading to a non-scarring diffuse alopecia, with characteristic clinical, dermoscopic and histological patterns<sup>4</sup>.

Diagnosis is usually made clinically. Recent advances in digital image analysis has increased the use of dermatoscopy in the diagnosis of FPHL and as a consequence, reduced the need for doing skin biopsies.<sup>5</sup> Current medical treatments for FPHL include topical minoxidil (available in 2%, 5% solutions or 5% foam), finasteride, dutasteride, topical ketoconazole, anti-androgens, estrogens (for FPHL), PRP, stem cell transfer and follicular unit transplantation<sup>6</sup>. Oral finasteride 5mg/day seems to be a safe treatment of FPHL in premenopausal women. One in each five patients had side effects e.g. headache, menstrual irregularity, dizziness and hirsutism 3 months after beginning finasteride. However, they were mild and most of them reversible, even with maintenance of treatment.<sup>7</sup> Finasteride is a competitive and specific inhibitor of 5  $\alpha$ -reductase II and prevents the conversion of testosterone into dihydro-testosterone. This article mainly reviews the use of Finasteride in FPHL<sup>8</sup>.

A study reported using global photographs that 33(29.5%) of the 112 patients studied who used finasteride showed slight improvement, 73(65.2%) showed significant improvement, whereas no change was recorded in 6 (5.4%)<sup>1</sup>. The current study is planned to find clinical efficacy of oral administration of finasteride at a dose of 2.5mg/day in women with FPHL as there is no study available in local population and a study reported high

clinical efficacy with its use i.e. 65.2%<sup>1</sup>. This study is imperative to be done to generate local evidence and if we find higher clinical efficacy then in future, such females will be treated with finasteride at a dose of 2.5mg/day.

The objective of the study was to find clinical efficacy of oral administration of finasteride at a dose of 2.5mg/day in women with female pattern hair loss.

## MATERIALS AND METHODS

A total of 137 cases meeting inclusion criteria were included in this study after getting approval from hospital ethical committee. An informed consent from cases or attendants were obtained. Patients were enrolled through OPD of department of dermatology Mayo Hospital Lahore. After enrollment patient's contact information, demographic and clinical history was noted. Finasteride at a dose of 2.5mg/day was given to all cases for 5 months. Trichoscopy was performed at enrollment and after 5 months. At the standardized resolution of each image, ratio of terminal to vellus hair was measured at two sites of the scalp. Clinical efficacy was determined as per operational definition at 5th months of treatment. All data were collected on attached proforma by researcher herself. All collected data were entered and analyzed using SPSS version 22. Descriptive statistics like age, was presented in form of mean±S.D. Qualitative data like clinical efficacy were presented in frequency and percentage. Data were stratified for age, duration of FPHL, menopause status and baseline Ludwig scale. Post stratified Chi-square test was applied to taking. P-value  $\leq 0.05$  was considered as significant.

### Inclusion Criteria

- Females aged 40-70 years
- Females having normal testosterone levels (cut off <0.4ng/ml)
- Cases diagnosed with FPHL having Ludwig scale I, II (annexure-I attached)
- Duration of FPHL not more than 6 months

### Exclusion Criteria

- Patients who used other FPHL treatment modalities including topical minoxidil, oral anti-androgens (on clinical record).

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- Hb level < 11.5
- Deranged thyroid function tests
- Those diagnosed with any systemic illness within the previous 6 months e.g. enteric fever, PUO, HIV, CRF, secondary syphilis, SLE, dermatomyositis etc.

**RESULTS**

Patients ranged between 40-70 years of age with mean age of 49.5±6.9 years. Pre-menopause women were 99 (72.3%) while post-menopause were 38(27.7%). Mean duration of FPHL was observed 4.4±1.3 months. Out of 137 cases, 92 women (67.2%) belonged to Ludwig scale-I and remaining 45 women (32.8%) belonged to Ludwig scale-II. Clinical efficacy of finasteride 2.5mg/day was found in 85 women (62%). Four to six months duration of FPHL, premenopausal women and lower Ludwig scale showed significant effect of finasteride (p<0.001, p=0.010 and p=0.003, respectively).

Table1: Distribution of patients by age (n=137)

Age (years)	No.	%
40-55	110	80.3
56-70	27	19.7
Total	137	100.0
Mean±SD	49.5±6.9	

Table2: Distribution of patients by menopause status

Menopause	No.	%
Pre-menopause	99	72.3
Post-menopause	38	27.7

Table 3: Distribution of patients by duration of FPHL duration (month)

Duration (Months)	No.	%
1-3	30	21.9
4-6	107	78.1
Mean±SD	4.4±1.3	

Table 4: Distribution of patients by baseline

Baseline Ludwig scale	No.	%
Ludwig scale-I	92	67.2
Ludwig scale-II	45	32.8

Table 5: Distribution of patients by clinical efficacy of Finasteride 2.5mg/day

Clinical efficacy	No.	%
Yes	85	62.0
No	52	38.0

Table 6: Stratification for age with clinical efficacy

Age	Efficacy		Total	P value
	Yes	No		
40-55	70	40	110	0.438
56-70	15	12	27	
Total	85	52	137	

Table 7: Stratification for duration of FPHL (month) with clinical efficacy

Duration	Efficacy		Total	P value
	Yes	No		
1-3	27	3	30	<0.001
4-6	58	49	107	
Total	85	52	137	

Table8: Stratification for menopause status Menopause

Menopause	Efficacy		Total	P value
	Yes	No		
Pre-menopausal	68	31	99	0.010
Post-menopausal	17	21	38	
Total	85	52	137	

Table 9: Stratification for baseline Ludwig scale

Baseline Ludwig scale	Efficacy		Total	P value
	Yes	No		
Ludwig scale	65	27	92	0.003
Ludwig scale-II	20	25	45	
Total	85	52	137	

**DISCUSSION**

Female pattern hair loss the most common form of hair loss, affects up to 50% of women during their life.<sup>9</sup> Although hair thinning in women with FPHL may be diffuse, 3 different clinical patterns have been described: the Christmas tree pattern<sup>10</sup> the Ludwig pattern and the Hamilton pattern.<sup>11</sup> Patients who experience hair thinning complain of social anxiety and embarrassment. If left untreated, FPHL may be rapidly progressive. Treatment for FPHL consists mainly of topical minoxidil, which is effective<sup>13</sup> but sometimes is not well accepted by the patient. The efficacy of oral antiandrogens is not well established. Although cyproterone acetate is prescribed in Europe to treat FPHL<sup>14</sup> its efficacy is still controversial. A controlled 12-month randomized trial<sup>15</sup> compared the effects of cyproterone acetate, 52mg/d with 2% topical minoxidil in FPHL. All the patients took oral contraceptives. After 6 months of treatment, minoxidil was effective in women with a low body mass index and the absence of hyperandrogenism. Cyproterone was effective when other signs of hyperandrogenism were present and when body mass index was high.

Finasteride is a 5 α-reductase type II inhibitor currently approved to treat male androgenetic alopecia at a dosage of 1mg/d. Because of the potential risk of teratogenicity in a male fetus<sup>16</sup>, finasteride is contraindicated in women of childbearing potential. A multicenter, double-blind, placebo-controlled, randomized study<sup>17</sup> of finasteride, 1mg/d, in postmenopausal women with FPHL showed negative results in increasing hair growth and slowing the progression of hair thinning. After 12 months of treatment, patients in the finasteride and placebo groups had a modest decrease in hair count from baseline. Scalp biopsies also revealed no differences in the anagen-telogen ratio and the terminal hair–miniaturized hair ratio. In this study, the lack of efficacy of finasteride may have been related to the older age of the patients. Hair thinning may not be androgen dependent in senescent scalps. Moreover, in this study with negative findings, finasteride was administered at a dosage of 1 mg/d, which might be inadequate for FPHL<sup>17</sup>.

In our study, clinical efficacy of finasteride 2.5mg/day was found to be 62%. Our findings are comparable with the study carried out by Won et al.<sup>1</sup> Some other studies<sup>18,19,20,21</sup> also demonstrated that finasteride therapy effective in premenopausal and postmenopausal women. Camacho<sup>19</sup> reported hair regrowth using finasteride, 2.5mg/d, in 41 women with FPHL and SAHA (seborrhea, acne, hirsutism, and alopecia) syndrome. Thai and Sinclair<sup>20</sup> administered finasteride at a dosage of 5mg/wk (<1mg/d) to a 67 year-old postmenopausal woman without signs of hyperandrogenism and with Ludwig FPHL. After 12 months of treatment the patient showed a significant increase in hair density.

**CONCLUSION**

In conclusion, the efficacy of administration of finasteride at a dose of 2.5 mg/day for patients with female pattern hair loss was recorded 62%, and it was also observed that finasteride revealed better effect on hair growth in patients having lower Ludwig score.

**Conflict of interest:** Nil

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