Clinical efficacy of oral administration of finasteride at a dose of 2.5 mg/day in women with female pattern hair loss

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Abstract
Female pattern hair loss (FPHL) presents with diffuse thinning over the mid-frontal scalp, for which various treatment modalities have been tried. Although currently, oral 5α-reductase inhibitors such as finasteride are being used, their clinical efficacy remains controversial. We retrospectively investigated 544 premenopausal or postmenopausal patients with FPHL who were prescribed finasteride at a dose of 2.5 mg/day. Our study excluded patients with a follow-up period of <3 months and patients who were prescribed other FPHL treatment modalities including topical minoxidil. Finally, 112 patients were evaluated based on their medical records and clinical photographs. Based on assessment using the Ludwig scale at the time of their initial visit, among 112 patients studied, 59 patients were classified as belonging to grade I, 47 were grade II, and 6 were grade III. Using global photographs, we found that 33 (29.5%) of the 112 patients studied showed slight improvement, 73 (65.2%) showed significant improvement, whereas no change was recorded in 6 (5.4%). We could demonstrate efficacy of administration of finasteride at a dose of 2.5 mg/day for patients with FPHL and also found that finasteride has a better effect on hair growth when patients had a lower Ludwig score and an older age at onset.

KEYWORDS
androgenetic alopecia, female pattern hair loss, finasteride

1 | INTRODUCTION

Pattern hair loss is the most common cause of hair loss in both men and women. Pattern hair loss in women (female pattern hair loss [FPHL]), which presents with diffuse thinning over the central portion of the scalp, spares the frontal hairline and is characterized by a wider midline part of the crown than on the occipital scalp (Shapiro, 2007). In approximately 50% of women, FPHL can develop at any time during their lifetime after the onset of puberty and the prevalence increases with age (Boersma et al., 2014; Price, 2003).

Various treatment strategies including use of topical minoxidil, oral anti-androgen agents, and 5α-reductase inhibitors including finasteride and dutasteride have been tried as treatment for FPHL (Blumeyer et al., 2011). However, the only treatment for FPHL approved by the U.S. Food and Drug Administration is use of topical minoxidil.

Finasteride is a competitive and specific inhibitor of type II 5α-reductase and prevents the conversion of testosterone to dihydrolestosterone (DHT), the latter known to play a role in causing hair follicle miniaturization (Levy & Emer, 2013). Large-scale studies have proved that intake of 1 mg/day of finasteride reduces hair loss, and additionally increases the total and anagen hair count in men with male pattern hair loss (Kaufman et al., 1998; Leyden et al., 1999). Therefore, administration of oral finasteride at a dose of 1 mg/day is recommended to improve and/or prevent progression of androgenetic alopecia (AGA) in male patients (Blumeyer et al., 2011). However, clinical efficacy of finasteride use in FPHL remains controversial. A large-scale, multicenter, randomized, placebo-controlled trial investigating the effects of daily administration of 1 mg of finasteride in women showed no significant effect on hair growth (Price et al., 2000). However, case reports have shown that administration of finasteride at a dose of 5 mg/day for women led to a significant change in mean hair density and thickness but was associated with several adverse effects (Kohler, Tschumi, Bodmer, Schneiter, & Birkhaeuser, 2007; Oliveira-Soares, E Silva, Correia, & André, 2013; Yeon et al., 2011).

Although a study has demonstrated the beneficial effects of finasteride at a dose of 2.5 mg/day, the number of patients studied was small, and the study included only premenopausal women (Iorizzo, Vincenzi, Voudouris, Piraccini, & Tosti, 2006). Therefore, we
TABLE 1  Baseline characteristics and their association with improvement in scalp hair appearance in 112 patients who were retrospectively studied

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Significant improvement (+2) (n = 73)</th>
<th>Mild improvement (+1) (n = 33)</th>
<th>No change (0) (n = 6)</th>
<th>Mean score</th>
<th>Spearman’s correlation coefficient</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age ± SD (range)</td>
<td>53.8 ± 7.4 (38–73 years)</td>
<td>54.1 ± 8.1 (30–69 years)</td>
<td>57.8 ± 5.8 (51–67 years)</td>
<td>–</td>
<td>−0.092</td>
<td>.335</td>
</tr>
<tr>
<td>Mean age at onset ± SD (range)</td>
<td>43.3 ± 9.9 (17–59 years)</td>
<td>37.7 ± 10.8 (20–61 years)</td>
<td>26.8 ± 6.4 (17–35 years)</td>
<td>–</td>
<td>0.348</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Mean duration of FPHL ± SD (range)</td>
<td>10.5 ± 8.3 (1–33 years)</td>
<td>16.4 ± 9.8 (4–41 years)</td>
<td>31.0 ± 6.4 (21–41 years)</td>
<td>–</td>
<td>−0.452</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Mean duration of treatment ± SD (range)</td>
<td>8.0 ± 3.4 (4–59 months)</td>
<td>16.1 ± 11.8 (3–40 months)</td>
<td>8.0 ± 3.4 (4–12 months)</td>
<td>–</td>
<td>0.192</td>
<td>.044</td>
</tr>
<tr>
<td>Ludwig scale</td>
<td>2.9 (3)</td>
<td>2.9 (3)</td>
<td>2.9 (3)</td>
<td>–</td>
<td>−0.331</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>I (n = 59)</td>
<td>47</td>
<td>9</td>
<td>3</td>
<td>1.75</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>II (n = 47)</td>
<td>25</td>
<td>20</td>
<td>2</td>
<td>1.49</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>III (n = 6)</td>
<td>1</td>
<td>4</td>
<td>1</td>
<td>1.00</td>
<td>–</td>
<td>–</td>
</tr>
</tbody>
</table>

FPHL = female pattern hair loss.

retrospectively reviewed charts for post and premenopausal women (those who did not plan to get pregnant) to investigate the clinical efficacy and safety of daily administration of 2.5 mg of finasteride in this population.

2 | PATIENTS AND METHODS

2.1 | Patient population

We retrospectively investigated 544 patients with FPHL who presented to our clinic between January 2012 and April 2016 and had been prescribed finasteride 2.5 mg/day. All of the patients were either postmenopausal women or premenopausal women without a plan to get pregnant. Other inclusion criteria were normal androgen, iron, and ferritin levels, as well as normal thyroid function test results. We excluded patients with a follow-up period of < 3 months, patients who were prescribed other FPHL treatment modalities including topical minoxidil, oral anti-androgens, and those diagnosed with any systemic illness within the previous 6 months. Finally, 112 patients were included and evaluated based on their medical records and clinical photographs.

2.2 | Efficacy assessment

Global photographs were taken using a digital camera (Canon EOS 70D). We took pictures at the time of the patient’s first visit and subsequently at every 3-month follow-up visit. Two expert panels of dermatologists compared pictures obtained at the time of their first visit with those obtained at the time of their last follow-up. A 3-point scale was used to grade the change in scalp hair appearance as follows: no response or aggravation (0), slightly improved (1), and significantly improved (2).

2.3 | Statistical analysis

Data were expressed as means ± SDs. Statistical analysis was performed using the SPSS statistical package (SPSS® 20.0 for Windows; SPSS Inc., Chicago, IL). Spearman’s Rho correlation test was used to evaluate the relationship between improvement of scalp hair appearance and patient characteristics including age, age at the time of onset of this condition, duration of FPHL, and Ludwig grade. The level of statistical significance was set at p = .05.

3 | RESULTS

3.1 | Baseline characteristics

The patients’ mean age at initial visit was 54.1 ± 7.5 years (range, 30–73 years). Mean age of onset was 40.7 ± 10.8 years (range, 17–61 years), mean follow-up duration was 17.6 ± 12.9 months (range, 3–59 months), and mean duration of FPHL was 13.4 ± 9.5 years (range, 1–41 years).

3.2 | Global photographs assessment

Results of baseline characteristics and improvement in scalp hair appearance are shown in Table 1. Among the 112 patients studied, 33 (29.5%) showed slight improvement, 73 (65.2%) showed significant improvement, whereas no change was recorded in 6 (5.4%) (Figure 1). A negative association was observed between the duration of FPHL and improvement of scalp hair (Spearman’s correlation coefficient = −0.452, p < .001). A positive association was seen to exist between age of onset, duration of treatment, and improvement of scalp hair (Spearman’s correlation coefficient = 0.348, 0.192, p < .001, p = .044). Namely, an older age of onset and a longer duration of treatment were associated with better hair growth. Among 112 patients studied, 59 patients belonged to grade I, 47 belonged to grade II, and 6 belonged to grade III based on Ludwig scale assessment performed at the time of their initial visit. We found that a lower Ludwig grade was associated with better hair growth (Spearman’s correlation coefficient = −0.331, p < .001).
3.3 | Safety

No patient reported adverse effects such as headache, menstrual irregularity, and/or dizziness.

4 | DISCUSSION

FPHL is the most common cause of alopecia in women and differs from male pattern baldness in terms of epidemiology, clinical presentation, and management (Sinclair et al., 2011). The pathogenesis of FPHL has not yet been completely understood. Although androgens are considered to play a role in women who demonstrate features of hypergonadism, most women with FPHL have normal androgen levels (Schmidt, Lindmaier, Trenz, Schurz, & Spona, 1991). Additionally, the fact that patients demonstrate varied responses to various treatment modalities suggests that FPHL is a condition that arises from an interplay of multiple pathogenetic mechanisms.

Several medications including topical minoxidil, oral finasteride, and oral anti-androgens are widely used to treat FPHL. The U.S. Food and Drug Administration has approved 2% topical minoxidil use for the treatment of FPHL. Usually, anti-androgens including spironolactone, and cyproterone acetate have been used in women with FPHL with concomitant signs of androgen excess (Olsen et al., 2005; Sinclair & Dawber, 2001). Finasteride is a competitive and specific inhibitor of type II 5α-reductase and prevents the conversion of testosterone into dihydrotestosterone (DHT), the latter known to play a role in causing hair follicle miniaturization (Levy & Emer, 2013).

Several reports pertaining to treatment of FPHL using oral finasteride have shown variable efficacy (Boersma et al., 2014; Boychenko, Bernstein, & Schweiger, 2012; Carmina & Lobo, 2003; Hong, Chiu, Chan, Chen, & Lin, 2007; Iorizzo et al., 2006; Kohler et al., 2007; Kim, Song, Ko, Kim, & Kim, 2012; Oliveira-Soares et al., 2013; Price, 2003; Shum, Cullen, & Messenger, 2002; Thai & Sinclair, 2002; Trüeb, 2004; Whiting, Waldstreicher, Sanchez, & Kaufman, 1999; Yeon et al., 2011) (Table 2). A large-scale, multicenter, randomized, placebo-controlled trial comprising 137 postmenopausal women with FPHL demonstrated that finasteride at a daily dose of 1 mg did not increase hair growth or slow the progression of hair thinning in postmenopausal women with FPHL (Price et al., 2000).

However, Shum et al. (2002) have reported a series of four women with hyperandrogenism showing characteristic female or male pattern hair loss responding to a 1.25 mg daily dose of finasteride. Boersma et al. (2014) have also shown a statistically significant increase in hair thickness from baseline with use of a 1.25 mg daily dose of finasteride over a 3-year period. Yeon et al. (2011) report a study performed on 87 normoandrogenic premenopausal and postmenopausal women with FPHL, which demonstrated efficacy of 5 mg/day of finasteride. However, four patients experienced adverse events with headache, menstrual irregularity, dizziness, and hirsutism. A study performed on 37 premenopausal women has shown that administration of a combined regimen using 2.5 mg/day of finasteride and oral contraceptive containing drospirenone and ethinyl estradiol is associated with a significant effect on hair growth (Iorizzo et al., 2006).

In our study, most premenopausal or postmenopausal patients with FPHL who had been treated > 3 months responded to 2.5 mg/day of finasteride. Oral finasteride at a dose of 2.5 mg/day was generally well tolerated by patients without any adverse effects. Finasteride is observed to produce a good response with longer duration of treatment. A positive correlation was demonstrated between the age of onset of this condition and improvement in hair growth. Patients with Ludwig grade I showed a higher mean score of improvement than those with Ludwig grade II and III. However, based on literature reported by Yeon et al. (2011), patients with a higher Ludwig grade had better effects of finasteride on hair growth. Maybe, this is due to a somewhat lesser quantity of Ludwig III patients studied in our study.

Limitations of our study are: (a) Ours was a retrospective study based on chart reviews. Therefore, the reliability of the data may be less than that of the prospective studies. (b) We did not measure...
changes in hair thickness using a phototrichogram. Efficacy of drug administration was measured only by comparing global photographs, which is a subjective assessment. However, our study reviewed the largest number of patients among several studies that have evaluated the efficacy of finasteride for FPHL and showed efficacy similar to use of finasteride at 5 mg daily (Boersma et al., 2014; Boychenko, Bernstein, & Schweiger, 2012; Carmina & Lobo, 2003; Hong, Chiu, Chan, Chen, & Lin, 2007; Iorizzo et al., 2006; Kohler et al., 2007; Kim, Song, Ko, Kim, & Kim, 2012; Oliveira-Soares et al., 2013; Price, 2003; Shum, Cullen, & Messenger, 2002; Thai & Sinclair, 2002; Trüb, 2004; Whiting, Waldstreicher, Sanchez, & Kaufman, 1999; Yeon et al., 2011).

On the basis of our study, it can be concluded that use of finasteride at a dose of 2.5 mg daily for FPHL achieves the same safety and efficacy as a daily dose of 5 mg of this drug.

CONFLICT OF INTEREST
The authors have no conflict of interest to declare.

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Kohler, C., Tschumi, K., Bodmer, C., Schneider, M., & Birkhaeuser, M. (2007). Effect of finasteride 5 mg (Proscar) on acne and alopecia in TABLE 2 Clinical studies evaluating efficacy of finasteride to treat patients demonstrating female pattern hair loss

<table>
<thead>
<tr>
<th>Authors</th>
<th>Finasteride dosage</th>
<th>Duration (Months)</th>
<th>Efficacy</th>
<th>Participants</th>
<th>Country</th>
<th>Pre/postmenopausal</th>
<th>Adverse effects</th>
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</thead>
<tbody>
<tr>
<td>Whiting et al. (1999)</td>
<td>1 mg daily</td>
<td>12</td>
<td>No significant difference</td>
<td>44</td>
<td>United States</td>
<td>Postmenopausal</td>
<td>No</td>
</tr>
<tr>
<td>Trüb (2004)</td>
<td>2.5 or 5 mg daily</td>
<td>6, 12, 18</td>
<td>Improvement</td>
<td>5</td>
<td>Switzerland</td>
<td>Postmenopausal</td>
<td>No</td>
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<td>Price (2003)</td>
<td>1 mg daily</td>
<td>12</td>
<td>No significant difference</td>
<td>62</td>
<td>United States.</td>
<td>Postmenopausal</td>
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<td>Shum et al. (2002)</td>
<td>1.25 mg daily</td>
<td>24–30</td>
<td>Improvement</td>
<td>4</td>
<td>U.K.</td>
<td>Premenopausal and Postmenopausal</td>
<td>No</td>
</tr>
<tr>
<td>Thai and Sinclair (2002)</td>
<td>5 mg weekly</td>
<td>12</td>
<td>Improvement</td>
<td>1</td>
<td>Canada</td>
<td>Postmenopausal</td>
<td>No</td>
</tr>
<tr>
<td>Carmina and Lobo (2002)</td>
<td>5 mg daily</td>
<td>12</td>
<td>No significant difference</td>
<td>12</td>
<td>Italy</td>
<td>Premenopausal</td>
<td>No</td>
</tr>
<tr>
<td>Iorizzo et al. (2006)</td>
<td>2.5 mg daily</td>
<td>12</td>
<td>Improvement</td>
<td>37</td>
<td>Italy</td>
<td>Premenopausal</td>
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<td>Kohler et al. (2007)</td>
<td>5 mg daily</td>
<td>–</td>
<td>Improvement</td>
<td>6</td>
<td>Switzerland</td>
<td>Premenopausal and postmenopausal</td>
<td>No</td>
</tr>
<tr>
<td>Kim et al. (2012)</td>
<td>1.25 mg daily</td>
<td>7</td>
<td>Partial improvement</td>
<td>14</td>
<td>Republic of Korea</td>
<td>Premenopausal</td>
<td>No</td>
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<tr>
<td>Hong et al. (2007)</td>
<td>2.5 mg daily</td>
<td>10</td>
<td>Improvement</td>
<td>1</td>
<td>Taiwan</td>
<td>Postmenopausal</td>
<td>No</td>
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<tr>
<td>Yeon et al. (2011)</td>
<td>5 mg daily</td>
<td>12</td>
<td>Improvement</td>
<td>87</td>
<td>Republic of Korea</td>
<td>Premenopausal and Postmenopausal</td>
<td>Yes</td>
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<tr>
<td>Oliveira-Soares et al. (2013)</td>
<td>5 mg daily</td>
<td>18</td>
<td>Improvement</td>
<td>40</td>
<td>Portugal</td>
<td>Postmenopausal</td>
<td>Yes</td>
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<td>Boychenko et al. (2012)</td>
<td>1.25 mg daily</td>
<td>3.5</td>
<td>Improvement</td>
<td>1</td>
<td>United States</td>
<td>Postmenopausal</td>
<td>No</td>
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<tr>
<td>Boersma et al. (2014)</td>
<td>1.25 mg daily</td>
<td>36</td>
<td>Improvement</td>
<td>60</td>
<td>Netherlands</td>
<td>Premenopausal and Postmenopausal</td>
<td>No</td>
</tr>
</tbody>
</table>
female patients with normal serum levels of free testosterone. Gynecological Endocrinology, 23(3), 142–145.


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