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High-dose finasteride is an effective treatment modality for androgenic alopecia in postmenopausal women

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ABSTRACT A critical appraisal and clinical application of Oliveira-Soares R, Silva JE, Correia M, André M. Finasteride 5 mg/day treatment of patterned hair loss in normo-androgenetic postmenopausal women. *International Journal of Trichology*. 2013;5(1):22-25. doi: [10.4103/0974-7753.114709](https://doi.org/10.4103/0974-7753.114709).

Keywords: androgenic alopecia, female pattern hair loss, finasteride, balding

Clinical Context

Linda Jones (pseudonym), a 68-year-old Caucasian woman with a past medical history of hypertension and hypercholesterolemia, presented to her primary care physician's office for her annual well-visit. During the interview, Linda expressed feelings of low self-esteem and dissatisfaction of her appearance, particularly in relation to her hair. The patient's hair had been thinning around the crown of the head over the last 5 years, and while she tolerated her appearance previously it had now become unbearable to her. On physical exam, decreased hair density was apparent around the crown of the head to the extent that scalp was visible. The patient's hair density is consistent with Ludwig stage 1 of female pattern hair loss (FPHL), showing a generalized thinning of crown hair starting 1-3cm behind the frontal hairline. Stage 2 and 3 of the Ludwig scale describe a more global diffuse thinning and complete loss of hair on the crown, respectively.¹ Linda had not been treated clinically for hair loss before, however her husband used minoxidil years previously but stopped due to a perceived lack of hair growth and thickening. This prompted the discussion of treatment with Minoxidil 2% solution in addition to other non-FDA approved treatment modalities. Finasteride, a 5 alpha-reductase inhibitor, currently FDA approved for male androgenic alopecia (AGA) at a dose of 1mg/day also fills a controversial role in FPHL treatment at high dose of 5mg/day, due to the 1mg/day being found insufficient to produce results.^{2,3} Linda was skeptical about the overall efficacy of the available treatment options for her after seeing her husband's past dissatisfaction in treatment and was concerned that starting a new medication would lead to experiencing potential side effects such as irritation or contact dermatitis, and hypertrichosis, without clinical improvement in her hair density.⁴ Because of this, Linda wished to defer treatment at the current time until having a discussion with her dermatologist for a second opinion about starting a medication for treatment of FPHL.

Clinical Question

Is high dose, 5mg/day, finasteride a safe and effective treatment modality for FPHL in postmenopausal women?

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Research Article

Oliveira-Soares R, Silva JE, Correia M, André M. Finasteride 5 mg/day treatment of patterned hair loss in normo-androgenetic postmenopausal women. *International Journal of Trichology*. 2013;5(1):22-25. doi: [10.4103/0974-7753.114709](https://doi.org/10.4103/0974-7753.114709)

Related Literature

PubMed was searched using the term, “Finasteride female androgenic alopecia women,” yielding 85 citations. 8 studies were selected for further assessment. Among the relevant articles was a review article of FPHL by Fabbrocini et al., “Female pattern hair loss: A clinical, pathophysiologic, and therapeutic review.”⁴ The review discussed topical and systemic therapeutic options for FPHL such as minoxidil, ketoconazole, prostaglandin analogs, and finasteride. The article noted that other entities outside of the more historically targeted aspects like genetics and hormones need to be further investigated for their role in the pathogenesis of FPHL before more effective therapies can be developed.

The Won study from 2018, a large retrospective analysis of pre and postmenopausal women from the years of 2012-2016 who were prescribed finasteride at a dose of 2.5mg/day.⁶ The patients’ ages ranged from 30-73 years of age at their initial visit with a mean age of 54.1 years as well as a FPHL onset at the age of 17-61 years. Analysis was performed using chart review and images captured of the scalp at 3-month intervals and assessed for global change on a three-point scale by two dermatologists (no response, slightly improved, significantly improved). Despite the size of the study, it was not selected due to the study design being retrospective via chart review, a less reliable method of analysis than a prospective case series like the Oliveira-Soares study. Their design lends itself to increased difficulty to control for bias, confounding variables, and being reliant on records kept by others. Additionally, the analysis of their results was not stratified by age groups making it difficult to draw conclusions for our 68-year-old patient.

The Whiting study from 1999 examined the effects of 1mg/day finasteride in 44 postmenopausal women for 12 months and showed no significant change in hair growth.⁷ This paper was excluded as the appraisal topic due to the subtherapeutic dosage of finasteride used in addition to a sample size that was smaller than comparable studies.

The Trueb study from 2004 evaluated the effects of 2.5 and 5.0mg/day doses of finasteride in 5 postmenopausal women with evaluations at 6, 12, and 18 months.⁸ The study showed significant improvement in hair growth but was excluded as the appraisal topic due to the small sample size.

The Thai and Sinclair study from 2002 followed one participant that used 5mg weekly doses of finasteride after having failed trials of spironolactone and cyproterone acetate due to side effects of dizziness and malaise over a 12-month.⁹ The study showed improvement in alopecia but was excluded due to the very small sample size.

The Price study from 2003 evaluated the effects of 1mg/day finasteride over the course of 12 months in 62 postmenopausal women and showed no significant improvement in alopecia.² The study design was high quality, being a double-blind and placebo controlled. Additionally, the study was performed in the United States. However, it was excluded because the dosage of finasteride used was not the 5mg/day “high dose”. Instead it used a 1mg/day dosage, and only included women aged 41-60 which did not include our patient’s age demographic.

The Yeon study from 2011¹⁰, used 5mg/day finasteride in 87 normoandrogenic pre and postmenopausal Asian women with FPHL. Their results yielded significant improvement in hair density and thickness after 12 months of therapy. However, this study was not selected due to the differences in ethnic demographic when compared to our patient as well as its inclusion of both pre and postmenopausal women.

Ultimately, a 2013 study by Oliveira-Soares was selected for critical appraisal.⁵ The study was a prospective case series and was selected because it is one of the larger studies available, at 40 participants, and was a prospective analysis. The study only included normoandrogenic postmenopausal women, similar to our patient, and utilized a high, 5mg/day, dosage of finasteride. Additionally, the study separated results based on age ranges (<60, 60-70, >70) and utilized both subjective and objective analysis through measures patient satisfaction and global photograph analysis by dermatologists, respectively.



Critical Appraisal

The study by Oliveria-Soares, et al.⁵ was a prospective case series that studied normoandrogenic postmenopausal women with FPHL who had not received any hair restoration treatment within the last six months. According to the Strength of Recommendation Taxonomy (SORT) criteria, this study could be classified as Level 3, as it is a case series.¹¹ Normoandrogenism was considered to be normal levels of total testosterone, free testosterone, dehydroepiandrosterone (DHEA), delta-4-androstenedione, and 5 α -dihydrotestosterone (DHT). The treatment consisted of taking oral finasteride at a dose of 5mg/day for 18 months. Efficacy criteria included patient satisfaction categorized as impairment, none, moderate, or highly satisfied with the results. Efficacy criteria also included photograph assessment by two independent dermatologists with responses categorized as impairment, moderate or no improvement, or major. Upon starting treatment patients were medically evaluated and Ludwig score was performed for each patient (Ludwig 1 of 15 patients, Ludwig 2 of 16 patients, and Ludwig 3 of 9 patients). Efficacy was evaluated at 6, 12, and 18 months as well as a safety evaluation looking at symptomatology, complete blood count, aspartate aminotransferase, alanine transaminase, total bilirubin, alkaline phosphatase, blood glucose, urea, creatinine, iron, 17 β -hydroxyprogesterone, cortisol, prolactin luteinizing hormone (LH), follicle-stimulating hormone, as well as the normoandrogenic criteria stated previously. Additionally, efficacy was stratified by age: below 60 (22 patients), 60-70 (13 patients) and over 70 (5 patients).

After 6 months of finasteride therapy, 22 patients reported significant improvement, 12 moderate improvement, and 6 no improvement.⁵ Using global photo assessment, 16 patients showed significant improvement, 16 showed moderate improvement, and 8 showed no improvement. Slight improvement was seen overtime from 6 to 12 to 18 months, but most improvement was seen at 6 months. The percentage of patients with major improvement was greater in the below 60 group (12 of 20) than patients 60 to 70 (4 of 13) and above 70 (0 of 5). Over the course of the study, the only side effects experienced were an elevation in liver enzymes for one patient, which normalized without discontinuation of treatment and libido reduction in 4 patients who continued treatment. The authors considered these effects tolerable, given the success with treating alopecia.

A main limitation of this study was that there was no placebo group due to most patients failing previous treatments for FPHL and wanting to receive treatment. Additionally, there was no blinding of patient and examiners which could increase the risk of performance and detection biases where patients or examiners alter responses knowing they have an expectation of a certain result. The voluntary nature of patient recruitment for this study also increased the likelihood of participation bias by potentially having more severe or refractory cases of FPHL seek out treatment in this study. An additional limitation of this study was its analysis not producing data in reference to number needed to treat (NNT) or number needed to harm (NNH) using a 5mg/day dose of finasteride. Another aspect to consider is that the Oliveria-Soares study was conducted in Portugal, not using a US demographic. Although the patient's ancestry is European, this may provide differences physically and culturally with regard to hair characteristics views on FPHL. In an effort to eliminate changes in patient satisfaction or dermatological assessment secondary to factors other than finasteride treatment all patients were asked to maintain hair color, style, and length throughout the 18 months of therapy.

Clinical Application

The Oliveria-Soares et al. study is applicable to our patient because it includes a demographic similar to her in age, postmenopausal state, as well as a shared European ancestry.⁵ This study provides evidence that at a dose of 5mg/day finasteride is an effective treatment option for postmenopausal FPHL. There was significant improvement based on patient satisfaction and dermatological analysis and should be considered in clinical decision making for initial or refractory cases. An additional point of consideration, however, is that the group that found the greatest benefit with treatment was not our patients age group of 60-69 years old, it was the <60 years of age group. Because of this, additional consideration should be made when treating older patients with regard to the expectations of treatment results.

Limited numbers of studies have been done looking at the benefits of finasteride therapy at dosages above 1mg/day, the recommend dosage for treatment of male AGA. However, studies at levels of 2.5mg/day 3.8 and 5mg/day 5,¹⁰ provided data supporting its efficacy in the treatment of postmenopausal women and its use as a clinical treatment modality with minimal, if any, side effects. Based on Linda's skepticism of minoxidil's efficacy the research suggesting that 5mg/day finasteride is well tolerated and improves FPHL, finasteride is a viable therapeutic recommendation for her.



Learning points:

1. Finasteride at a dose of 5mg may be effective in treating FPHL in postmenopausal females, with efficacy displayed at doses as low as 2.5mg/day.
2. Those who seek treatment early and present with alopecia at a younger age are associated with a more positive response to treatment.
3. FPHL is a complex condition that potentially involves elements outside of genetics and hormones which need to be examined in greater detail before treatment for FPHL can be optimized.

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