

Side Effects Related to 5 α-Reductase Inhibitor Treatment of Hair Loss in Women: A Review

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ABSTRACT

5 α-reductase inhibitors such as finasteride and dutasteride have been studied for the treatment of hair loss in men, with finasteride being the only Food and Drug Administration-approved treatment. Increasingly, in recent years, off-label use of these drugs has been employed in the treatment of female pattern hair loss (FPHL) and frontal fibrosing alopecia (FFA) in women. Side effects with 5 α-reductase inhibitors can include changes in sexual function, and recent publications have characterized an increasing prevalence of these in men. A review of 20 peer-reviewed articles found that very few side effects, or adverse events, related to sexual function have been reported in studies in which dutasteride or finasteride has been used to treat hair loss in women. Future publications should investigate not only the efficacy of these drugs in treating FPHL and FFA, but the side effect profile in patients as well.

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INTRODUCTION

Finasteride and dutasteride are 5 α-reductase inhibitors approved for use in treatment of benign prostatic hyperplasia (BPH0.[1,2] Finasteride is the only Food and Drug Administration (FDA)-approved treatment of male pattern hair loss (MPHL), and dutasteride is often used as an off-label treatment for MPHL.[1,2,13-16] Although both drugs are teratogenic to male fetuses, additional off-label use of finasteride and dutasteride has been employed in several treatment regimens for hair loss in women.[3,17-19]

Two of the most common forms of hair loss where finasteride and dutasteride are used include female pattern hair loss (FPHL) and frontal fibrosing alopecia (FFA). FPHL is a form of non-scarring hair loss that causes thinning of the hair behind the hairline on the frontal and vertex scalp. Up to 42 % of Caucasian women aged 70 and older are affected by FPHL,[4] with clinical signs manifesting as early as 20 to 29 years of age.[6] FPHL differs from MPHL because it usually does not transition from decreased hair density to complete baldness;[7] and the role of androgens in the pathogenesis of FPHL is not as well understood as in MPHL.[8] A variant of lichen planopilaris,[9] FFA is a form of scarring hair loss that frequently affects postmenopausal women and is marked by frontotemporal hairline recession.[10]

Treatment options for women suffering from FPHL and FFA include off-label use of 5 α-reductase inhibitors such as finasteride and dutasteride, among other treatments. The side effects, or adverse events (AEs), of these drugs have been established in men, and include sexual dysfunction, decreased libido, breast tenderness and enlargement, dizziness, allergic reactions, and depression;[11,12] but it is unclear if these AEs occur for women. The side effects related to men's sexual function have been published increasingly in recent years. A 2011 review by Traish et al reported that in randomized, placebo-controlled trials including only men taking 5 α-reductase inhibitors for BPH, alopecia, and prostate cancer, dutasteride and finasteride users consistently experienced drug-related reductions in or loss of libido, erectile dysfunction, depression, and gynecomastia.[5] Belknap et al also recently suggested that several studies may be underreporting or underdetecting sexual dysfunction in clinical trials of finasteride for the treatment for androgenetic alopecia in men.[23]

In contrast, many of the studies evaluating the efficacy or effectiveness of finasteride or dutasteride for FPHL or FFA do not report the existence of AEs related to sexual libido. Changes in sexual function are a major concern for many women, especially as they approach middle age. A 2008 study of 31,581 US adult women reported that 45% of women aged 45 to 64 and 80% of women aged 65 or older reported low desire, low orgasm, or low arousal.[24] With such a high prevalence in the same population that uses 5 α-reductase inhibitors for hair loss treatment, it is important to consider how side effects may impact existing sexual function problems. Since it is not clear which sexual side effects, if any, women may experience due to these drugs, as they become more widely used we aim to clarify what is known in this area. In this paper, we have reviewed 20 articles that report on the efficacy of finasteride and/or dutasteride in the treatment of FPHL or FFA, and the extent to which AEs, specifically those related to changes in libido or sexual function, were mentioned.

METHODS

A PubMed search was completed in July 2015 to find clinical studies and case reports using finasteride and/or dutasteride to treat FPHL or FFA. Keywords used for these searches included "finasteride," "dutasteride," "women," "hair loss," "frontal fibrosing alopecia," and "side effects." Articles were also selected by reviewing the references of articles from initial searches. Publications were classified by case study, clinical study, or retrospective review. Case studies were classified as such if they contained fewer than 10 study subjects and reported on treatment success after its completion. Clinical studies were publications that initiated, followed, and completed treatment in patients, and reported on its success or failure. Retrospective reviews reported on patients' treatment success or failure using past medical records.

Ioannidis and Lau provide a framework for evaluating the adequacy of drug safety reporting for clinical trials.[21] Belknap et al used this framework to evaluate the adequacy of AE reporting in clinical trials for finasteride in the treatment of androgenic alopecia in men.[22] Since our review includes both clinical studies and case reports, adequacy of AE reporting was adapted to investigate the degree of detail to which AEs are described in the literature for finasteride and dutasteride treatment of FPHL and FFA.

First we evaluated if the existence or non-existence of AEs of patients taking finasteride or dutasteride was reported at all in the study or case report. If a publication did not make mention of these events, it was classified as "inadequate." Those publications which reported that no AEs took place during treatment were classified as "none." Secondly, if authors reported the existence of AEs, we noted event reporting. If a publication reported the existence of AEs but did not specify which events occurred, it was classified as "partially adequate." In contrast, if a publication reported the existence of AEs and specified each, it was classified as "adequate." Thirdly, for clinical studies, we evaluated whether the authors reported if patients withdrew from the study or stopped treatment due to specific AEs during treatment. Finally, we investigated if any of the authors reported patients experiencing a change in libido or sexual function during their treatment with finasteride or dutasteride.

RESULTS

A total of 20 clinical studies and case reports were obtained from the PubMed searches using the previously listed keywords. Four publications were retrospective reviews, 8 were clinical studies, and 8 were case reports. Sixteen of the 20 publications noted the existence or non-existence of AEs (Table 1). Six publications were adequate in their description of adverse events, 3 were partially adequate, 4 were inadequate, and 7 publications reported no AEs (Table 1). Twelve publications had study populations of only postmenopausal patients, 6 had both postmenopausal and premenopausal patients, and 2 had study populations of only premenopausal patients (Table 1). Among the 8 studies that included premenopausal patients, 7 made note of the use of oral contraceptive use and 1 did not (Table 1). A total of 6 publications detailed the specific AEs experienced during treatment (Table 2). Two of the 6 publications evaluating dutasteride treatment for FFA or FPHL reported AEs. The other 4 publications reporting AEs used finasteride. Some of these AEs resolved during treatment while others were consistent throughout. Two clinical studies had patients withdraw (Table 2). The first clinical study had a patient withdraw because of nausea, and another patient withdrew due to colon cancer believed to be unrelated to treatment.[19] The second clinical study had a patient withdraw due to headaches.[35] Of all 20 publications, only 2 studies write that patients reported a change in libido during treatment with finasteride.[36,37]

> "With such a high prevalence in the same population that uses 5 α-reductase inhibitors for hair loss treatment, it is important to consider how side effects may impact existing sexual function problems."

DISCUSSION

Nine of 20 studies where women are treated with 5 α-reductase inhibtiors for hair loss made mention of the existence of side effects or adverse events due to finasteride or dutasteride treatment, and 3 of those studies did not meet the criteria set for being adequate in reporting side effects. The side effects listed in the finasteride package insert include an allergic reaction, breast tenderness, breast enlargement, breast lumps, nipple discharge, and changes in sexual dysfunction or libido. Dutasteride has a similar side effect profile listed on its package insert, with the addition of potential side effects including depression and dizziness. Nearly all of these side effects were reported in the publications we reviewed. Women using finasteride for hair loss report similar side effects to those reported by men using it for hair loss.[43,44] In contrast, women who use dutasteride for hair loss have a very different side effect profile than men who use it for the same purpose.[43,44] Researchers reporting on use of the 5 α-reductase inihibitors in women should note the side effects they observe so that clinicians are aware of these risks. Given the dearth of publications on the use of these drugs for these conditions, reporting additional information on side effects would assist patients in choosing the treatment that best meets their needs.

The 7 studies that reported the non-existence of AEs had dosing ranging from 2.5-5 mg/day for finasteride, and 0.5 mg/day

TABLE 1.

Adverse Event Reporting for Case Reports and Clinical Studies of Finasteride and Dutasteride for Female Pattern Hair Loss and/or Frontal Fibrosing Alopecia

Authors	Publication type	Condition treated	Participants	Pre, peri, postmenopausal	Drugs Used	Oral Contraceptives Used – Y/N	Existence of Adverse Events Noted – Y/N	Specific Adverse Events Mentioned – Y/N	Adequacy of Reporting
Shum et al, 2002[23]	CR	FPHL	4	2 postmenopausal, 2 premenopausal	Finasteride 1.25 mg/day	Yes	Yes	No	Partially adequate
Thai et al, 2002[25]	CR	FPHL	1	Postmenopausal	Finasteride 5 mg/day	No	Yes	No	None
Olzewska et al, 2005[20]	CR	FPHL	1	Premenopausal	Finasteride for 3 mos @ 1mg/day, then dutasteride 0.5 mg/day for 12 months	Yes	Yes	No	None
Moreno-Ramirez et al, 2005[26]	CR	FFA	7	Postmenopausal	Finasteride 2.5 mg/day	No	No	--	Inadequate
Hong et al, 2007[27]	CR	FPHL	1	Postmenopausal[a]	Finasteride 2.5 mg/day	No	No	--	Inadequate
Katoulis et al, 2008[28]	CR	FFA	1	Postmenopausal[a]	Dutasteride 0.5 mg/day	No	Yes	Yes	Adequate
Boychenko et al, 2012[29]	CR	FPHL	1	Postmenopausal[a]	Finasteride 1.25 mg/day	No	No	No	Inadequate
Perez-Rodriguez et al, 2013[30]	CR	FFA	1	Postmenopausal	Dutasteride 0.5 mg/day	No	Yes	Yes	Adequate
Price et al, 2000[19,c]	CS	FPHL	62	Postmenopausal	Finasteride 1 mg/day	35/62 were receiving hormone therapy	Yes	Yes	Adequate
Carmina et al, 2003[17]	CS	FPHL	48	12 postmenopausal	Finasteride 5 mg/day	No	Yes	Yes	None
Trueb et al, 2004[31]	CS	FPHL	5	Postmenopausal	Finasteride, 2.5-5 mg/day	No	No	--	None
Tosti et al, 2005[32]	CS	FFA	8	Postmenopausal	Finasteride 2.5 mg/day	No	No	--	Inadequate
Iorrizo et al, 2006[33]	CS	FPHL	37	Premenopausal	Finasteride 2.5 mg/day	Yes	Yes	None	None
Georgala et al, 2009[34]	CS	FFA	13	Postmenopausal	Dutasteride 0.5 mg/day	No	Yes	No	None
Yeon et al, 2011[35]	CS	FPHL	86	Pre- and postmenopausal	Finasteride 5 mg/day	Yes	Yes	Yes	Adequate
Oliveira-Soares et al, 2013[36]	CS	FPHL	40	Postmenopausal	Finasteride 5 mg/day	Not noted	Yes	Yes	Adequate
Kohler et al, 2007[37]	RR	FPHL	12 (6 alopecia)	Pre- and postmenopausal	Finasterid 5 mg/day	Yes	Yes	Yes	Adequate

TABLE 1. *Continued*

Adverse Event Reporting for Case Reports and Clinical Studies of Finasteride and Dutasteride for Female Pattern Hair Loss and/or Frontal Fibrosing Alopecia

Authors	Publication type	Condition treated	Participants	Pre, peri, postmenopausal	Drugs Used	Oral Contraceptives Used –Y/N	Existence of Adverse Events Noted –Y/N	Specific Adverse Events Mentioned –Y/N	Adequacy of Reporting
Ladizinski et al, 2012[38]	RR	FFA	19	Pre- and postmenopausal	Finasteride (1-2.5 mg/day w OCs), dutasteride (0.5 mg/day for 2 weeks, then 0.5 mg/wk)	Yes, if premenopausal & taking finasteride, oral contraceptives used	Yes	No	None
Boersma et al, 2014[39]	RR	FPHL	120	Pre- and postmenopausal	Finasteride (1.25 mg/day) and dutasteride (0.15 mg/day)	Yes, but contraceptives are unnamed	Yes	No	Partially adequate
Vano-Galvan et al, 2014[40]	RR	FFA	355	343 total women, pre- and postmenopausal[b]	Finasteride (2.5-5 mg/day) in 102 patients, dutasteride (0.5 mg/wk) in 18 patients	Not noted	Yes	No	Partially adequate

[a]Patients postmenopausal due to hysterectomy.
[b]46 patients postmenopausal due to hysterectomy.
[c]Study was a randomized, double-blind, placebo-controlled trial.
CR, case report; CS, clinical study; RR, retrospective review.

for dutasteride. The 7 studies that reported the existence of AEs also had a wide variation in dosing for both finasteride and dutasteride, suggesting that AEs during treatment may not be dose related. In contrast, it is of note that of these 7 studies, only 2 publications -- a clinical study and a retrospective review -- report that participants experienced changes in libido while taking finasteride for FPHL.[36,37] Both of these studies dosed patients with 5 mg of finasteride daily, for 12 and 18 months, respectively. Interestingly, none of the studies that used dutasteride as a treatment for FFA or FPHL reported decreased libido as a side effect. This is especially striking when one considers that dutasteride is considered the more potent 5 α-reductase inhibitor when compared with finasteride. Even more striking is the fact that post-finasteride syndrome in men has been recently added to the National Institutes of Health Genetics and Rare Diseases Information website.[45] This condition is characterized by "persistent sexual, neurological, and physical adverse reactions in patients who have taken finasteride…to treat hair loss… or enlarged prostate."[46] From currently published literature on the use of these drugs in women for hair loss, it is unclear if these patients experience a similar constellation of symptoms.

Oliveira-Soares et al reported that 4 out of 40 postmenopausal patients experienced reduced libido as a side effect of finasteride treatment for FPHL, but that this was not perceived as a sufficient reason to stop treatment. This may not be the case for other women being treated with 5 α-reductase inhibitors for hair loss. While postmenopausal women are often concerned with changing sexual function during this stage of life,[24,42] FPHL and FFA patients may be more willing to accept a decreased libido as a side effect of treatment if hair maintenance and potential regrowth are possibilities of treatment with 5 α-reductase inhibitors. This may be a factor causing infrequent reporting of this side effect. Furthermore, it is unclear if patients from the studies reviewed here were being asked about any changes in sexual function or libido during their course of treatment with finasteride or dutasteride, or if they self-reported without prompting. This idea of an underreporting or underdetection of AEs related to sexual function is in keeping with a recent publication from Belknap et al that recently reported that safety reporting for 34 clinical trials of finasteride for the treatment androgenetic alopecia in males was inadequate when graded according to Ionannidis and Lau.[22]

Some publications reviewed here did not include a list of all AEs that patients experienced. In this case, published reports may omit side effect information that clinicians may feel is important, leading to perpetuation of missed AEs. Women using 5 α-reductase inhibitors for hair loss should be encouraged to report any changes in sexual function after they begin treatment. Before starting treatment, clinicians should also tell patients that these changes are often influenced by other medical conditions, medications, and social factors,[47] and that they should be aware of the additional impact 5 α-reductase inhibitors can contribute to changes in sexual function. In addition, clinicians could present flibanserin, the recently

TABLE 2.

Specific Adverse Events and Reasons for Study Withdrawal From Finasteride or Dutasteride Treatment

Authors	Condition Treated	Drugs Used	Specific Adverse Events Mentioned – Y/N	Specific Adverse Events	Resolved on Treatment – Y/N	Resolved off Treatment – Y/N
Katoulis et al, 2008[27]	FFA	Dutasteride 0.5 mg/day	Yes	Constipation	Not noted	--
Perez-Rodriguez et al, 2013[29]	FFA	Dutasteride 0.5 mg/day	Yes	Hyperpigmentation	No	Yes
Price et al, 2000[19]	FPHL	Finasteride 1 mg/day	Yes	Nausea (2, 1 withdrawn), colon cancer (1, withdrawn), folliculitis, headache (5), depression (1)	Yes, folliculitis	Not noted
Yeon et al, 2011[34]	FPHL	Finasteride 5 mg/day	Yes	Headache (1), menstrual irregularity (1), dizziness (1), increased body hair (1)	Yes, menstrual irregularity, dizziness, increased body hair, headache (1)	Yes, headache (1)
Oliveira-Soares et al, 2013[35]	FPHL	Finasteride 5 mg/day	Yes	Maintained libido reduction (4), increased liver enzymes (1)	No	Yes, increased liver enzymes (1)
Kohler et al, 2007[36]	FPHL	Finasteride 5 mg/day	Yes	Decreased libido (1), dry skin (1), mild acne (1)	Not noted	Not noted

FFA, frontal fibrosing alopecia; FPHL, female pattern hair loss.

approved drug for hypoactive sexual desire disorder in premenopausal women,[48] as a pharmacological option to combat libido changes during treatment for hair loss with finasteride or dutasteride.

Future studies are needed to further elucidate the effectiveness of finasteride and dutasteride at a standardized dose for randomized, placebo-controlled trials for the treatment of both FPHL and FFA. These studies should also carefully report the nature of AEs for study participants, enabling more adequate reporting of the risks of treatment with these 5 α-reductase inhibitors.

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