

Cyberspace Chat

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The Treatment of Men with Finasteride: Scientific and Anecdotal Evidence



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(*JC*) How do we manage the very young patient with a strong family history of androgenic alopecia, who is advancing to a NW 5 at a young age? In such individuals, hair transplant surgery is not an optimal option. Medical therapy is the obvious answer, but what should we consider when medical therapy fails? We all know the clinical studies, but what is our personal experience and how does personal experience govern our decision making progress?

(*BW*) Edwin Epstein presents a well-written and well-referenced lead article in this issue, "Update on Efficacy of Generic Finasteride," that explores scientific evidence concerning finasteride. But does our knowledge end there? Of course not. Physicians have been prescribing finasteride in one form or another for 23 years during which time much anecdotal evidence has accumulated. Anecdotal evidence (information passed along by word-of-mouth but not documented scientifically) leaves verification dependent on the credibility of the party or parties presenting the evidence. We leave it to you to assess the credibility of the information based on those presenting the evidence.

The Scientific Evidence

(*BW*) From the original Merck studies: Investigator assessment was based on a 7-point scale evaluating increases or decreases in scalp hair at each patient visit. This assessment showed significantly greater increases in hair growth in men treated with Propecia® compared with placebo as early as 3 months ($p < 0.001$). At 12 months, the investigators rated 65% of men treated with Propecia as having increased hair growth compared with 37% in the placebo group. At 2 years, the investigators rated 80% of men treated with Propecia as having increased hair growth compared with 47% of men treated with placebo. At 5 years, the investigators rated 77% of men treated with Propecia as having increased hair growth, compared with 15% of men treated with placebo.¹



Figure 1. Pre-treatment (left) and after 7 years of Propecia (right).



Figure 2. Pre-treatment (left) and after 8 years of Propecia

If women were told that there is a medication that 65-80% of the time could stop the aging of their faces for at least 5 years with minor side effects, how popular would that drug be? The scientific evidence suggests that finasteride is a miracle drug that prevents most men from prematurely losing hair that is genetically programmed to die. Our patients should be encouraged not to outlive their hair! (See Figures 1-4.)

(*JC*) With this in mind, Jim Vogel recently presented the case of a 22-year-old male who lost hair following an 11-month course of generic 1mg finasteride (Figure 5).

What would you do and which questions would you ask? What percentage of men are non-responders to finasteride? What would your next course of action be? These questions triggered an interesting debate.

The Anecdotal Evidence

Ed Epstein pointed out that his experience with finasteride was similar to the Merck study mentioned above. This seems to be a similar experience for Jerry Wong, Jim Vogel, and Bill Parsley. Ron Shapiro feels that 70-80% respond with no progression or more hair. Bob Haber feels that at the very least finasteride slows down the progression of hair loss. Personally, a large percentage of my patients refuse to take any form of medication. In those men who take Propecia, I (*JC*) see about an 80% response.

Years ago, Bill Parsley studied his patients' response to Rogaine®. He was unable to find a single patient who had demonstrated clinical improvement on Rogaine alone. Vance Elliott points out that Rogaine is very beneficial in his female patients. Personal experience (anecdotal evidence) indeed seems to govern our treatment protocols. Dr. Parsley states that "the true gold standard is how it works in your hands and in your office."

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Figure 5. Dr. Vogel's patient before (left) and 11 months after (right)

Bill Parsley, Ron Shapiro, Brad Wolf, and Bob Haber pointed out a concern we are seeing with the generic finasteride. Vance Elliott stated that he's had only one patient who has NOT lost hair when switched to generic finasteride, so he strongly advocates the brand name (Propecia). Men who did respond to Propecia at times fail on the generic version of finasteride. Therefore, if a patient fails to respond to finasteride, make sure you give him a trial of name-brand Propecia or quartered 5mg finasteride. Bill Parsley points out that, while he has seen no problems with 5mg generic finasteride, he would not start a patient on generic 1mg finasteride or generic minoxidil in the first year. Bill and many others have found that the combination of minoxidil and finasteride is much better than finasteride alone.

In his article, Ed Epstein lists the manufacturers of generic finasteride and reminds us that we should report finasteride failures to the FDA. Is this an industry-wide issue or company specific? John Gillespie notes that many widely prescribed drugs including metformin, Synthroid, Norvasc, and Amoxil are dispensed in generic form, so it does not make sense when men are failing on generic finasteride. Ed points out that generic manufacturer applications are required to show 80-125% bioavailability. The question remaining is what percentage of counterfeit generics has filtered into the marketplace.

Then there is the concern about compliance. How frequently did they take the medication? Many men stop suddenly because they see no improvement. Others may take the product sporadically because they see little improvement. It is also possible that finasteride slows the progression of hair loss in some who appear to be non-responders. Russell Knudsen pointed out that there is an "aggressiveness index" in some patients who will not have a complete cessation in balding while on finasteride when they are experiencing significant and rapid balding. Bill Parsley noted that some young male patients really want a hair transplant so they will pretend to take the medication, appear to fail treatment, and then seek a hair transplant. Some physicians recommend that patients start on finasteride 3-4 months prior to surgery to improve the donor area. Why, when there are supposedly no receptors for DHT in the donor area?

Editor's note (RHT): Yes, it appears to make no sense to prescribe finasteride for the donor area. But I can think of one reason: if you know you are harvesting from an area that you

think will probably be affected by progression of balding, putting such patients on finasteride helps to promote the longevity of follicles transplanted from outside the "safe zone."

Russell Knudsen referred to a case where the patient continued to lose hair on finasteride, but he had significant recovery when dutasteride, 0.5mg per week, was added to his medical regimen. Of course, as Jim Vogel points out, another option is to switch your patient to dutasteride. Jerry Wong reflected that he has at least 3 patients who did really well on dutasteride after they failed finasteride.

A Closer Look at Finasteride

(BW) The potential side effects of chronic finasteride use should be completely explained to all patients who begin treatment. This can be accomplished by verbal and/or written instructions. Some physicians choose to have their patients read and sign a document specifying the mechanism of action and the known side effects of chronic finasteride use. Finasteride should not be administered to men who have an elevated prostate specific antigen (PSA). It is recommended that men over 49 years old have a PSA level drawn prior to starting finasteride.

Other important points to be considered when prescribing finasteride include: it takes an average of 6-12 months after starting to see results and 6-12 months to lose the effects after stopping treatment, always have the patient take photos before initiating finasteride treatment for objective comparison, and success is dependent upon the number of existing anagen and miniaturized hairs present at the time of initiation of treatment.

The following forms of finasteride are currently available: Brand finasteride 1mg (Propecia), generic finasteride 1mg, brand finasteride 5mg (Proscar), generic finasteride 5mg. Benefits and negatives are listed below:

Brand 1mg (Propecia)

Benefits: The gold standard, no counterfeits, optimal results seen as soon as possible, no pill cutting necessary for therapeutic dose, can dose in 1mg increments or less, private practice can dispense from the office.

Negatives: Most expensive alternative.

Generic 1mg

Benefits: Approximately one-third of the cost of Propecia and will decrease in price in the future, can dose in 1mg or less increments.

Negatives: Manufactured off shore by generic makers with reported poor quality control/counterfeits, difficult to dispense from physicians' offices, many reported treatment failures.

Brand 5mg (Proscar)

Benefits: None

Negatives: Same as for generic 5mg—more expensive than generic, no greater efficacy than generic.

Generic 5mg

Benefits: Inexpensive alternative for treatment, consistent good results, available at pharmacies in the United States for as little as \$10 per prescription, no reports of treatment failure.

Negatives: Must divide for therapeutic dose, variable amount of finasteride in each fragment, loss of ingredient with cutting, smallest dose is 1.25mg, if taken every day—higher chance of side effects.

My Anecdotal Experience

(BW) Based on my experience prescribing finasteride to men since it became available in 1992, I use the following criteria to determine which form to prescribe:

Brand name 1mg (Propecia): I prescribe this to patients who can afford it and, given the alternatives, request it to avoid the chance of treatment failure. I dispense it from my office at a reduced price compared to retail pharmacies. When starting treatment, it is the gold standard to determine the initial response to the recommended therapeutic dose (1mg/day).

Generic 1mg: This became available in 2013 and is a popular alternative due to its reduced price. As reported by others, I have seen multiple scenarios in which its use has led to treatment failure. This includes men who have been on Propecia for a long time and noticed shedding and/or thinning after taking the 1mg generic for 3-6 months. In some instances, the generic is substituted for Propecia by the pharmacist unbeknownst to the patient. They usually see a cessation of shedding/thinning with resumption of Propecia. Patients who have originated treatment with generic 1mg have seen no results and subsequently have seen results when switched to Propecia. I have a patient who had good results with one generic but was switched to another generic by his pharmacy and saw shedding/thinning. This resolved with resumption of the original 1mg generic. If patients are started on or switched to 1mg generic, I inform them that they should be aware of either no results or shedding/thinning in 3-6 months and should switch to Propecia. I do recommend generic 1mg for men who have been on brand name 1mg for 6-12 months who want reduced price. These patients are warned to look for shedding/thinning and change to brand name 1mg or ¼ generic 5mg immediately.

Finasteride 5mg: The brand name (Proscar) and generic have the same effect, so I therefore see no need to use Proscar. For some reason, generic 5mg finasteride has not suffered the same pains as generic 1mg finasteride. When originating treatment with quartered generic 5mg finasteride (at most 1.25 mg/day), I have never had a treatment failure or a patient complain of shedding/thinning when switched to generic 5mg. Generic 5mg finasteride would seem to be the ideal option, but when informed of all the options, some patients choose not to use generic 5mg for three reasons: 1) they prefer not to split pills, 2) they do not want to risk ineffectiveness by having the active ingredient unevenly distributed in the tablet, and 3) they don't want to risk the increased chance of side effects by taking 0.25 mg/day more than recommended. These are patients who want the highest chance of success without regard to cost and choose to use Propecia.

Reduced Dosing

Anecdotal evidence has shown that doses of less than 1 mg/day are as effective as 1mg/day. Russell Knudsen may have been the first to report dosing less than 1mg/day, prescribing rather 1mg three times a week. Bill Parsley often starts patients on ¼ mg per day, a 1mg tablet quartered. I have been using reduced doses for a number of years. I start men who choose to use quartered 5mg finasteride on at most ¼ tab (1.25mg) every other day, which is 2.5mg every three days. If patients who are 40 years old and older choose Propecia (1mg), they are started on 1mg every other day. Any patient who is overly concerned about side effects are started on a reduced dose. I often recom-

mend that patients 50 and older take 1mg Propecia or 1.25mg generic finasteride every third day. If patients experience side effects and are concerned, it is recommended that they reduce their dosage by half or stop the medication altogether. It is puzzling to me that the dosage reductions described above have not led to complaints of shedding or thinning in patients, some who had taken 1mg finasteride/day for 10 years or more. Why is this? If testosterone in men decreases with age, is there a concomitant decrease in dihydrotestosterone (DHT), making decreasing finasteride doses effective?

As patients age, the side effects from finasteride, decreased libido and/or erectile dysfunction, are common without ingesting finasteride. As men get older, their testosterone level gradually declines—typically about 1% a year after age 30. Testosterone peaks during adolescence and early adulthood. It is important to determine in older men if a low testosterone level is simply due to the decline of normal aging or if it is due to a disease (hypogonadism).²

Testosterone decline is not inevitable with age, according to Australian scientists. Older men in excellent health can maintain their hormone levels. Two study centers in Australia recruited 325 men over the age of 40 (median age 60) who had self-reported excellent health and no symptom complaints. To test blood testosterone levels, the researchers took blood samples from the men nine times over three months. They excluded men from the study who took medications that affect testosterone. Age had no effect on testosterone level: "The modest decline in blood testosterone among older men, usually coupled with nonspecific symptoms, such as easy fatigue and low sexual desire, may be due to symptomatic disorders that accumulate during aging, including obesity and heart disease. It does not appear to be a hormone deficiency state."³

Examining the scientific and anecdotal evidence, in conjunction with years of experience, leads each to his or her own rationale for prescribing finasteride. There is no doubt that it has proven to be an effective medication.

References

1. Merck prescribing information: http://www.merck.com/product/usa/pi_circulars/p/propecia/propecia_pi.pdf
2. See <http://www.mayoclinic.org/healthy-living/sexual-health/in-depth/testosterone-therapy/art-20045728>
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