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**What is the Efficacy of Finasteride Therapy in Reducing or Reversing Hair Loss?**

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the requirements For

The Degree of Masters of Science

In

Health Science- Physician Assistant

Department of Physician Assistant Studies  
Philadelphia College of Osteopathic Medicine  
Philadelphia, Pennsylvania

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## Abstract

**OBJECTIVE:** The objective of this selective EBM review is to determine whether or not Finasteride is effective in reducing/reversing the symptoms of androgenic alopecia.

**STUDY DESIGN:** Reviewed three English primary studies published in 2006, 2008, and 2009.

**DATA SOURCES:** All Studies were randomized controlled trials comparing Finasteride to placebo or other hair loss treatments were found using PubMed, EBSCO, MEDLINE, and Cochrane research databases.

**OUTCOME MEASURED:** Overall reduction in size of balding area based on measurements of total hair counts. Measurements were based on macrographical analysis of test subjects' balding area, as well as global photographic analysis carried out by the investigators of each trial study. Test subjects were given self assessment questionnaires to gather subjective views of the treatment.

**RESULTS:** All three randomized controlled trials included in this review indicated that oral Finasteride therapy of 1-5mg demonstrated measurable reversal of hair loss in men suffering androgenic alopecia.

**CONCLUSION:** Based on the three RCT's reviewed in this study, there is measurable evidence to indicate the use of Finasteride in the reduction and reversal of androgenic alopecia. This review only analyzed the effect of Finasteride on test subjects before and after treatment. Further tests would need to be done to determine if Finasteride is a medication that must be taken daily as preventative therapy, or if it can be discontinued once hair regrowth is obtained.

**KEY WORDS:** Finasteride; androgenic alopecia; hair loss; male pattern hair loss.

## INTRODUCTION

The value that society places on hair is high, which can have a significant effect on quality of life and psychosocial impairment when an individual develops alopecia. Androgenic alopecia—also known as male pattern baldness (MPB)—is a disorder whereby there is a progressive shrinking of the hair follicles resulting in visible loss of hair on the scalp. MPB has been found to be genetically linked predisposing 50% of males by the age of 40 to the disorder; with white males being affected most commonly. Little is known about the true cost an individual will spend annually on medications or hair products to halt the recession/loss of hair; or, the number of annual healthcare visit seen in regards to hair loss. This may possibly be due to embarrassment felt by the individual over losing hair, attempts to self treat with over the counter remedies, or the fact that most insurance companies will not pay due to MPB being classified as a cosmetic condition.

Fortunately research has identified the causative process behind androgenic alopecia. The process is as a result of increased levels of 5-alpha-reductase enzymes, which convert testosterone into its active form of dihydrotestosterone (DHT). DHT is what is responsible for the symptoms of androgenic alopecia: shrinking follicles, thinning hair, and receding hair line. MPB has been shown to be absent in patients deficient in 5-alpha-reductase enzyme identifying DHT as a major factor in the disorder. Using this information, pharmacotherapy has been initiated as a first line treatment for individuals suffering from androgenic alopecia. Topical and oral forms of Minoxidil or Finasteride have been the standard medications for treatment of androgenic alopecia. Surgical hair grafts are also available, but are considered a last line of treatment.

While the treatments above have been initiated as suitable medications to counteract MPB, no pharmacologic therapy has been shown to completely cure the results of MPB. Surgical intervention as listed above is an effective way, but costly treatment approach not easily accessible for everyone suffering from this disorder. Additionally, it does not affect the primary issue of increased levels of DHT. While further studies are done to find a more effective treatment to androgenic alopecia, this study will focus on one of the current medications—such as Finasteride—and assess its efficacy in reducing or reversing the effects seen in MPB.

## **OBJECTIVE**

The objective of this selective EBM review is to determine whether or not Finasteride is effective in reducing/reversing the symptoms of androgenic alopecia. Finasteride has been tested in many randomized controlled trials (RCT) indicating positive effect on hair growth and reduction in hair loss in men suffering from androgenic alopecia.

## **METHODS**

The studies reviewed in this article used test subjects between the ages of 18 and 45 testing oral Finasteride therapy to either a placebo or other hair loss medications. One study compared 1mg Finasteride to placebo taken daily for one year. Another study compared 5mg Finasteride to varying potencies of Dutasteride as well as a placebo taken daily for 24 weeks. The third study compared oral 1mg Finasteride taken daily to topical 1% finasteride gel applied twice a day over 6 months. At the end of each study, the results were analyzed using overall reduction in size of balding area based on measurements of total hair counts using macrophotographical analysis. All three studies reviewed in this article were randomized controlled trials.

The three randomized controlled trials reviewed in this article were found using PubMed, EBSCO, MEDLINE, and Cochrane research engines entering in key words such as Finasteride, androgenic alopecia, hair loss, and male pattern hair loss. Articles used were selected based on their relevance to the question posed, as well as having contained outcomes in the form of patient oriented evidence that mattered (POEM) relevant to patients suffering from androgenic alopecia. All articles were presented in English, and published in peer-reviewed journals from 2006 to 2009. These articles met inclusion criteria if they were published after 1996, were RCT's, and contained POEM's. Articles excluded from review in this article were systematic reviews and articles discussed in systematic reviews that posed the same question this article aims to investigate. To obtain significance in the outcome of the study, dichotomous data collected from each article was interpreted using p-value and numbers needed to treat (NNT).

**Table 1: Demographics and Characteristics of Reviewed Studies**

Study	Type	Number of Patients	Age	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Hajheydari, 2009	RCT	45	≤30	Males under age 30; hair loss duration <5 years; max hair density 20 hairs/cm <sup>2</sup> ; max diameter of bald area <10cm; complete physical and psychological health.	Male alopecia previously under treated; patients with baseline disease causing hair loss.	7	Randomized into two groups to receive either topical finasteride (1%)+ placebo pill, or topical placebo + finasteride pill (1mg).
Kaufman, 2008	RCT	1553	18-41	Hamilton-Norwood Stages II-V.	Norwood/Hamilton Classification Stage I.	813	Randomized into two groups to receive either 1mg finasteride orally or a placebo.
Olsen, 2006	RCT	416	21-45	Hamilton-Norwood stages III-V.	Hamilton-Norwood stage I and II; use of a 5 alpha-reductase inhibitor; any medication for alopecia within 6	42	Randomized into 6 groups to receive either dutasteride (.05, .1, .5, or 2.5 mg) finasteride (5mg), or a placebo.

					months of study; significant health problems; androgen/anti-androgen drug use within 6 months.		
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### Outcomes measured

The outcomes measured from these studies were in the form of POEM's and evaluated by both investigators and test subjects. The investigators of each study utilized macrographical and photographic analysis of test subjects' balding areas to assess total hair counts. This method allowed for an enhanced view of the patient's scalp making it easy to count individual hairs, and note any increases in total hair counts from pretreatment analyses. Test subjects in each study were given patient self assessment questionnaires to analyze if they noticed any change after the given treatment.

### Results

All three articles were presented as RCT's. Hajheydari et al conducted a double blind RCT comparing topical 1% Finasteride gel to 1mg finasteride oral tablet. There were 45 subjects suffering from androgenic alopecia enrolled into this study that were selected from private clinics and the dermatology department of the City of Sari in Iran. Seven were excluded due to incomplete or discontinuation of the entire study period. In the Study, test subjects were randomized into two groups and either given a placebo gel to apply twice a day along with 1mg Finasteride tablet taken daily; or, 1% Finasteride gel applied twice a day with a placebo tablet taken daily. The study was conducted over six months and subjects analyzed at the end of each month. Data obtained indicated a relatively similar therapeutic response of between the two test groups with a moderate response of 54.5% increase in hair counts in the Finasteride gel group and a 56% increase in hair counts in the Finasteride Tablet group. This yielded a p-value of .643,

which indicates no significance or superiority over administering Finasteride topically versus orally; however, in regards to this article, it does prove a general therapeutic benefit of administration of Finasteride for treatment of androgenic alopecia, which can also be seen after evaluation of the data collected in Table 2.

		Before Therapy	After Therapy	P-Value in Each Group	P-value Between Groups
Hair Counts	Gel	139.74 ± 34.21	147.80 ± 33.91	0.000	0.642
	Tablet	137.89 ± 35.33	153.56 ± 36.28	0.000	
Number of Terminal Hairs	Gel	108.42 ± 37.60	113.27 ± 39.74	0.001	0.661
	Tablet	105.58 ± 39.33	118.61 ± 37.49	0.000	

\*(Hajheydari et al, "Comparing Therapeutic Effects of Finasteride")

Kaufman et al conducted a multicenter RCT in which 1553 men were selected using the Norwood/Hamilton Classification Scale—which classifies severity of MPB from I to V—were enrolled for a one year trial, which continued for four consecutive years. Test subjects were randomized into one of two groups: 1mg Finasteride or placebo daily for one year. During the subsequent four year extension studies, patients were re-randomized into experiment and control groups, leaving only 713 test subjects that maintained the same therapy from the start of the study till the end (645 on Finasteride and 68 on placebo). This article will only analyze the data from the 713 test subjects. The data collected from this study evaluated data collected in the form of incidence rates and percent decrease in likelihood of developing further visible hair loss assessed by global photographic assessment expressed in events per patient-years. The study concluded that out of 100 patient-years 26 events of further hair loss would occur in the placebo group versus 3.1 in the Finasteride group. Photographical assessment of the Finasteride group yielded a 93% decrease in continued hair loss with an 89 to 96% confidence interval and p-value of .001. What this is indicating is that there is clinical significant in treating androgenic alopecia with Finasteride.



**Table 3: Incidence rate and percent decrease in likelihood of developing further hair loss.**

Placebo		Finasteride		Percent Decrease in likelihood with Finasteride 1mg relative to Placebo (95% CI)
N (%)	Incidence Rate (Event/100 Patient-years)	N (%)	Incidence Rate (Event/100 Patient-years)	
68 (100)	26.0	645 (100)	3.1	93% (89,96)

\*(Kauffman et al, "Long-term Treatment with Finasteride")

In Olsen et al enrolled 416 men into a RCT study who were suffering from mild to moderate MPB using the Norwood-Hamilton classification III to V. The study aimed to compare Finasteride 5 mg to placebo and Dutasteride 0.05, 0.1, 0.5, and 2.5 mg carried out over 24 weeks. For this article review, we will only focus on the Finasteride treatment as it compares to the placebo. Efficacy was determined by hair counts measured using macrophotographical evidence. Data in this study was in the form of continuous data. Data was converted into dichotomous form to fit the results of the previous studies. At the end of the 24 weeks, there were 68 participants still left in the Finasteride group, and 50 in the controlled placebo group. In comparison, 41% of test subjects in the Finasteride group saw at least a 10% increase in hair counts compared to 0% in the control group.

Table 4 analyzes the data collected from each study in an attempt to confirm the efficacy of experimental Finasteride to the control group. In Kaufman et al and Olsen et al studies comparing Finasteride to a placebo, one sees the significance of administration of Finasteride for treatment of androgenic alopecia in the low NNT. What this number is identifying is that in order to see a reduction of reversal of MPB in one person, you would need to treat 4 or 3 people respectively suffering from MPB with Finasteride, which again is clinically significant. In Hajheydari et al study comparing topical to oral Finasteride therapy, you see a high NNT, which indicates no real significance of administering oral Finasteride over topical. However, as we stated above and presented in Table 2, there is clinical evidence that identified an increase in hair

counts after administration of oral Finasteride, which further proves clinical significance of using Finasteride for reduction of androgenic alopecia.

<b>Table 4: Analysis of Data From Each Study in Relevance to RBI/ABI/ NNT</b>					
	Controlled Event Rate (CER)	Experimental Event Rate (EER)	Relative Benefit Increase (RBI)	Absolute Benefit Increase (ABI)	Numbers Needed to Treat (NNT)
<i>Hajheydari et al</i>	54.5%	5%	0.0275	0.015	67
<i>Kaufman et al</i>	74%	96.9%	0.309	0.229	4
<i>Olsen et al</i>	0%	41%	0	.41	3

Each study in this article comments on adverse events experienced during the Study.

Hajheydari et al recorded one complaint of erythema with topical Finasteride, and one complaint of decreased libido with oral Finasteride. Kaufman et al recorded 1.8%, 1.3%, and 1.2% of test subjects who experienced decreased libido, erectile dysfunction, and ejaculation disorder respectively. Olsen et al recorded 11 subjects who experienced adverse events; however, adverse events were not explained in this study. Only Olsen et al documented compliance, measured by pill counts, which was between 94% and 99%.

## **Discussion**

Across all three studies analyzed in this article, there has been positive evidence to agree that Finasteride therapy is beneficial in slowing or reversing MPB. All three studies noted increased hair counts by the sixth month, including the five year study conducted by Olsen et al. Kaufman et al noted a need for larger sample sizes and longer assessment periods, but aside from her notes, there appeared to be no other limitations that were identified, nor that the studies noted. All participants were double blinded and randomized for the trials.

Finasteride can be a simple routine therapy for the treatment of androgenic alopecia. Finasteride pills are easily tolerated, only interacting with one other drug—nevirapine—which may increase speed of clearance from the body. Contraindications to medication use are seen in

pregnant or lactating women due to known teratogenicity, and individuals with hepatic impairment or hypersensitivity. Adverse effects, as stated prior, such as decreased libido, ejaculate volume decrease, and erectile dysfunction have been seen. Sold under the brand name Propecia, this hair loss medication requires a prescription from your physician. Unfortunately, MPB is seen as a cosmetic disorder, which results in essentially no coverage or defrayment of cost by most health insurances. Out of pocket expense for Finasteride averages \$184.99 for a 90 day supply (roughly \$2.06 per pill). This would not be a poor investment if alopecia was halted or reversed permanently; however, if the medication is discontinued, hair loss will resume within 12 months. Even though surgical interventions such as hair grafts may be more costly, it may be a better long term alternative to taking Finasteride pills daily for life as the results of hair grafts are permanent.

### **Conclusion**

After a review of the three studies in this article, we can confirm that there is efficacy behind the administration of Finasteride for the treatment of androgenic alopecia. All studies appeared to have taken appropriate precautions to prevent any flaws or bias in the experiments. Duration of studies may have been an issue with two of the studies lasting only six months; however, the Kaufman et al study was carried out for one year, with a four year extension covering long term therapy and efficacy of treatment. Given that this article aimed to evaluate the efficacy of only Finasteride, future studies should aim to compare other medications utilized to treat androgenic alopecia—as is seen in the Olsen et al study.

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