Clinical studies on the effects of oral finasteride, a type 11 5(x-reductase inhibitor, on scalp hair in men with male pattern baldness

Introduction

Ever since the clinical observations of James Hamilton over fifty years ago, investigators have sought the identification of the specific androgens responsible for the development of male pattern baldness (Androgenetic Alopecia). In 1974, the description of men with genetic deficiency of type II 5a-reductase shed further light on this issue. These men were found to have low serum dihydrotestosterone, normal or slightly elevated serum testosterone, and no prostate enlargement or male pattern baldness. This led to the search for 5a-reductase inhibitors as potential pharmacologic agents for treatment of disease in man.

Clinical studies

Finasteride, an orally-active type 11 5a-reductase inhibitor, was the first such agent developed for clinical use in man. Clinical trials conducted for the treatment of men with benign prostatic hyperplasia established the excellent safety profile of this compound. Studies were subsequently initiated for the treatment of men with male pattern baldness. Concurrently, finasteride administration was shown to result in increased hair growth in the stumptail macaque, and to lower scalp skin dihydrotestosterone in balding men.

We conducted two separate, placebo-controlled clinical trials to evaluate the safety and efficacy of finasteride in men age 18 to 35 years old with Hamilton classification III vertex and IV male pattern baldness. Finasteride 5 mg/day or placebo was administered orally for 12 months in one study, while finasteride 1 mg, 0.2 mg, or 0.01 mg/day or placebo was administered for 6 months in a second study.

Materials and methods

Objective improvement in hair growth in men with male pattern baldness was determined by analysis of haircounts from macrophotographs taken of a 1

inch diameter circle (5.1 cm) of scalp hair centered at the leading edge of the vertex bald spot.-

Subjective improvement was determined by analysis of:

1) a self-administered patient hair growth questionnaire (HGQ);
2) investigator clinical assessment (ICA) of hair growth; and
3) assessment of global photographs (GPA) by a panel of expert dermatologists.

Results

Table 1 summarizes the results of these studies. Patients treated with finasteride at 5 mg, 1 mg or 0.2 mg/day showed improvement in hair growth at 6 months (M6) or at 12 months (M12), while treatment with 0.01 mg/day was similar to the placebo. Serum dihydrotestosterone (DHT) was reduced to castrate levels in patients receiving finasteride at 5 mg, 1 mg or 0.2 mg/day, while serum testosterone (T) remained in the normal range. No significant safety issues were identified in patients receiving finasteride at any dose.

Table 1.
Summary of results

Hair Growth	Placebo	**0.01 mg**	**0.2 mg**	**1 mg**	Placebo	**5 mg**
Assessment	M6	M6	M6	M6	M12	M12
(Change from baseline)	(N=86)	(N=93)	(N = 84)	(N=95)	(N=80)	(N=74)
Haircount (1 inch circle)	-7	-3	61 *	77 *	-10	95 *
HGQ (% improved appearance)	32%	36%	48% *	54% *	29%	71% *
ICA (916 increased hair) '	53%	49%	70% *	75% *	47%	76% *
GPA (% increased hair)	15%	15%	41% *	58% *	2%	51% *
DHT (median 176 change)	-3.9%	-10.8% *	-61.7% *	-68.7% *	0.0%	-69.2% *
T (median 76 change)	8.8%	13.2%	23.9% *	21.5% *	-2.8%	23.0% *

*p < 0. *05 vs placebo*

Conclusions

In these studies, oral treatment with finasteride at doses from 0.2 to 5mg/day resulted in clinically significant improvement in hair growth in men with male pattern baldness. These studies are currently ongoing at the 1mg dose of finasteride to obtain longer-term data.