Efficacy and Safety of a New Nutritional Supplement in Androgenetic Alopecia

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Introduction

Androgenetic alopecia (AGA) is the most common form of hair loss affecting up to 80% of men and 50% of women and is a very common reason for dermatology consultation. The first sign of male pattern hair loss is often a recession of the hairline at the temples. In women, hair loss presents with thinning in the central region of the scalp. The first sign of female pattern baldness is widening of the central part, which is often more evident at the hairline.

The purpose of this study is to report the effectiveness of a new oral supplement containing antioxidants and botanical 5-alpha reductase inhibitors in patients with AGA.

Methods

Ten patients 18 to 65 years of age were included in the study. Inclusion criteria were androgenetic alopecia (Sinclair 2 for women and Hamilton III for men). Subjects with evidence of hair loss for reasons other than AGA were excluded from the study. Use of oral or topical hair growth products was not allowed in the 6 months preceding the study and during the study. The nutritional supplement (Forti5®) was administered at a dosage of 2 tablets a day for 24 weeks. Clinical evaluation was performed at baseline and at 24 weeks. The following efficacy measures were used:

1. Hair Mass Index (HMI) measured by Cross Section Trichometer. HMI was measured using the Cross Section Trichometer, a mechanical device that measures the cross-sectional area of a bundle of hair selected from a specific area of the scalp, which is recognized with a special template (trichometer tab). The HMI was obtained at baseline and 24 weeks.

2. Trichogram. Approximately 50 hairs were plucked from the parietal scalp at baseline and 24 weeks. Anagen to telogen ratio was defined as the percentage of plucked hairs in the anagen stage. The telogen to anagen ratio was calculated from the following formula: (the number of telogen hairs x 100)/the number of anagen hairs. Anagen to telogen ratio was defined as the percentage of plucked hairs in the anagen stage.

3. Investigator Global Photography Assessment. The investigator scored changes in hair density evaluated from global photographs. Standardized photographs of a vertex view of the whole scalp, with hair parted in the center and combed away were taken at baseline and week 24. Global images taken at week 24 were compared with baseline photographs. Efficacy was assessed using the following 7-point scale (-3 = greatly decreased, -2 = moderately decreased, -1 = slightly decreased, 0 = no change, +1 = slightly increased, +2 = moderately increased, +3 = greatly increased).

4. Dermoscopy. A selected area was chosen using the trichometer tab.

Statistical analysis: The Wilcoxon signed-rank test was used to determine if there was a statistically significant difference before and after 24 weeks of supplementation.

Results

This pilot study showed a positive response after 24 weeks of supplementation with Forti5®. The investigator global assessment photography showed that 80% (8/10) of subjects were rated as improved at the final visit (mean change of +1.4 = slightly-to-moderately increased). There was significant improvement in terminal hair count (mean increase of 5.9% or 4.2 more terminal hairs in the area examined, p=0.014) and in HMI (mean increase of 9.5% or 4.5 higher HMI, p=0.003) after 24 weeks.

Discussion

AGA is caused by a progressive reduction in the diameter, length and pigmentation of the hair. Hair thinning results from the effects of the testosterone metabolite dihydrotestosterone (DHT) on androgen-sensitive hair follicles. Androgen sensitivity is genetically determined and depends on DHT production through the 5-alpha reductase enzyme.

Forti5® is a nutritional supplement designed to improve thinning caused by AGA via antioxidants and botanical 5-alpha reductase inhibitors. The supplement combines key ingredients that have each individually been shown to reduce shedding, thinning or otherwise improve hair growth. The key ingredients include melatonin, cholecalciferol, beta-sitosterol, soy isoflavones, green tea extract and omega 3 and 6 fatty acids.

This small pilot study of men and women with moderate AGA showed a statistically significant improvement in several efficacy measures of hair regrowth after 24 weeks of supplementation. The supplement was well tolerated by study subjects without major side effects.

Conclusion

Forti5® is a new nutritional supplement that combines key antioxidants and botanical 5-alpha reductase inhibitors that may be a useful adjunct in the treatment of AGA in both men and women.

References