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Topical Finasteride in the Treatment of Androgenetic Alopecia in Men and Women: A Systematic Review

Dutra Duque*

Department of Pharmaceutical Sciences, Universidade Federal de São Paulo–UNIFESP, Rua São Nicolau, 210, Centro, Diadema - SP, Brazil

Abstract

Oral finasteride is a wellestablished treatment for men with androgenetic alopecia (AGA), but patients do not always tolerate longterm therapy. A topical finasteride formulation has been developed to reduce systemic exposure by targeting hair follicles specifically. To compare the efficacy and safety of topical finasteride to placebo, as well as the systemic exposure and overall benefit to oral finasteride. This 24-week randomised, doubleblind, doubledummy, parallelgroup study in adult male outpatients with AGA was conducted at 45 sites across Europe. The efficacy and safety of the treatment were assessed. Finasteride, testosterone and dihydrotestosterone (DHT) levels were determined.

Keywords: Alopecia • Androgenetic alopecia • Dutasteride • Hair loss • Topical finasteride • Therapy

Introduction

To treat FPHL, various treatment options have been tried. Topical minoxidil is the only agent approved by the US Food and Drug Administration (FDA). Low-level laser therapy, fractional laser therapy, platelet-rich plasma, human follicle stem cells and hair transplantation are currently available treatment options. Nonetheless, some patients' treatment outcomes may be unsatisfactory. Finasteride, an inhibitor of type II 5-reductase enzyme, is currently approved for the treatment of AGA in men. It's becoming more popular as an off-label treatment for FPHL. Despite the possibility of teratogenicity, several studies on finasteride in FPHL have yielded positive results. As a result, the purpose of this review is to summarise the pharmacology, therapeutic efficacy and safety of oral finasteride for the treatment of FPHL.

Description

The preliminary results of topical finasteride application for the treatment of AGA were encouraging. Higher follicular density and anagen:telogen ratios were observed in the group treated with topical finasteride 2% solution in a testosteroneinduced alopecia albino mouse model. 15 Mazarella and colleagues investigated topical finasteride application for the treatment of AGA in a study involving 52 patients (28 males) with AGA. Beginning at 6 months, there was a progressive and significant reduction in the rate of hair loss in the topical finasteride vs. placebo group, with no significant differences in plasma levels of total testosterone, free testosterone and DHT between treatment groups [1].

Because there is no data for specific agents, the use of chlorhexidine, benzoyl peroxide and zinc pyrithione is supported by expert opinion. Resorcinol 15% cream, a keratolytic and antiseptic, was studied in 12 women with Hurley stage I or II disease; it reduced pain and duration of abscesses, but irritant dermatitis was common. Clindamycin 1% solution was the only topical antibiotic studied. 1,2 A 12-week randomised, placebo-controlled trial of 27 people with Hurley stage I or II disease found that it reduced pustules but had no effect on inflammatory nodules or abcesses. The patient's self-evaluation improved. In a double-blind comparative trial of 46 patients with mild-to-moderate disease, topical clindamycin performed similarly to tetracycline [2].

Mazarella et al. completed the first human study on topical finasteride in 1997 as a single-blind, placebo-controlled study involving 28 males and 24 females with AGA. For 16 months, subjects were randomly assigned to receive either 1.0 mL topical FNS 0.005% solution or placebo twice daily to the affected scalp. The pharmacodynamic data revealed no significant difference in total testosterone, free testosterone, or DHT plasma levels between the groups. Researchers observed a significant decrease in the rate of hair loss in the topical FNS group compared to the placebo group at six months. Patients' perceptions of treatment effectiveness were generally positive in the FNS group, with 73% of treated patients reporting "high effectiveness" and 60% of placebo patients reporting "no effect."

Used a randomised, parallel-group design in a follow-up study to investigate the dose-dependent effects of topical FNS. The first part of this study compared applying 1 mL of topical FNS 0.25% solution to the scalp once or twice daily to administration of an oral FNS 1 mg tablet once daily for seven days to 18 male patients. Two participants had an increase in alanine aminotransferase, pollakiuria and testicular pain. In the second part, 32 men were randomly assigned to either a placebo or a 100 L (0.2275mg), 200 L (0.455 mg), 300 L (0.6285 mg), or 400 L (0.91 mg) topical FNS 0.25% solution to apply to the scalp once daily for seven days [3,4].

Finasteride is a synthetic 4-azasteroid compound that inhibits type II 5-reductase, preventing testosterone conversion to dihydrotestosterone (DHT) in the skin, liver and prostate gland. According to one study, oral finasteride reaches its maximum plasma concentration approximately 1-2 hours after ingestion and reaches steady-state within three days. In patients with AGA, finasteride reduces scalp DHT levels by 43% after 28 days and up to 65% after 42 days of treatment with finasteride 5 mg daily. To the best of our knowledge, no study has been published that examines the changes in scalp DHT in women with FPHL. Finasteride has an 80% bioavailability and is not significantly influenced by food. Doses of 100 L (0.2275 mg) and 200 L (0.455 mg) topical FNS 0.25% solution applied daily appear to be the most efficacious concentration and frequency at this time, with consistent inhibitory effects on scalp DHT levels while minimising systemic effects on serum DHT.

There have been no reports of serious side effects from the use of topical FNS; however, there have been reports of scalp irritation manifesting as erythema and contact dermatitis, as well as cases of increased liver enzymes, bed-wetting, testicular pain, headaches, presyncope and oropharyngeal pain.

***Address for Correspondence:** Dutra Duque, Department of Pharmaceutical Sciences, Universidade Federal de São Paulo–UNIFESP, Rua São Nicolau, 210, Centro, Diadema - SP, Brazil; E-mail: marcelo.duque010@unifesp.br*

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Although current evidence indicates that patients are satisfied and that the drug is well-tolerated, we believe that large cohort studies examining the drug's potential adverse effect profile are warranted [5].

Conclusion

AGA is a debilitating chronic condition that causes significant psychological morbidity and lower patient quality of life. The preliminary results of the use of topical FNS for the treatment of AGA are encouraging. Current evidence suggests that topical FNS may have therapeutic potential in the treatment of AGA while minimising unwanted systemic side effects associated with oral use. When compared to systemic FNS, topical FNS appears to be non-inferior for hair regrowth. Combination therapies with topical FNS, MNX, or dutasteride may be more effective than topical FNS alone. Despite its proven efficacy and lack of side effects, topical FNS is not widely used, most likely due to a lack of evidence-based research.

Acknowledgement

None.

Conflict of Interest

The authors declare that there is no conflict of interest associated with this manuscript.

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