A randomized double-blind placebo-controlled pilot study to assess the efficacy of a 24-week topical treatment by latanoprost 0.1% on hair growth and pigmentation in healthy volunteers with androgenetic alopecia

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Background: Latanoprost is a prostaglandin analogue used to treat glaucoma. It can cause adverse effects, such as iridial and periocular hyperpigmentation, and eyelash changes including pigmentation and increased thickness, length, and number. Latanoprost has been used to treat eyelash alopecia, but knowledge on its effects on human scalp hair growth is not available.

Objective: The primary objectives were to assess the efficacy of latanoprost on hair growth and pigmentation. The secondary objectives were to assess the effect on scalp pigmentation; investigate the treatment duration needed to affect hair growth, hair pigmentation, and scalp pigmentation; and assess safety of latanoprost.

Methods: Sixteen men with mild androgenetic alopecia (Hamilton II-III) were included. Latanoprost 0.1% and placebo were applied daily for 24 weeks on two minizones on the scalp. Measurements on hair growth, density, diameter, pigmentation, and anagen/telogen ratio were performed throughout the study.

Results: At 24 weeks, an increased hair density on the latanoprost-treated site was observed compared with baseline (n = 16, $P < .001$) and placebo-treated site ($P = .0004$).

Limitations: Only young men with mild androgenetic alopecia were included. The results may not be applicable to other patient groups. Choice of investigational site may have affected the results.

Conclusions: Latanoprost significantly increased hair density (terminal and vellus hairs) at 24 weeks compared with baseline and the placebo-treated area. Latanoprost could be useful in stimulating hair follicle activity and treating hair loss. (J Am Acad Dermatol 2012;66:794-800.)

Key words: androgenetic alopecia; hair density; hair growth; hair pigmentation; latanoprost; scalp pigmentation.

The prostaglandin F2α analogue latanoprost is widely used in treating open-angle glaucoma and ocular hypertension as ophthalmic solution (0.005%) because of its efficacy and minimal systemic adverse effects.[1,2] Latanoprost may induce local adverse effects, eg, iridial and periocular pigmentation,[3-7] erythema, and telangiectasia.[8] Increased eyelash thickness and length, extra

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eyelash rows, conversion of vellus hairs into terminal hairs, pigmentation,[9] curvature,[10] and eyelash ptosis have also been observed.[11]

Latanoprost has been used as eye drops to stimulate eyelash growth in alopecia areata. Case reports have documented minimal eyelash growth 3 to 4 weeks and pronounced growth 8 weeks after treatment onset.[12,13] In all, 17.5% of patients with eyelash alopecia treated with 0.005% latanoprost experienced complete and 27.5% moderate regrowth.[14] To our knowledge, its effect on scalp hair growth has only been tested on animals. Hair regrowth was observed in latanoprost-treated macaque monkeys[15] and latanoprost-treated mice compared with untreated controls.[16]

CAPSULE SUMMARY

- When used to treat glaucoma, the prostaglandin analogue latanoprost may cause eyelash changes including pigmentation and increased thickness, length, and number, and has therefore potential to also stimulate scalp hair follicles.
- The effect of latanoprost on human scalp hair growth and pigmentation and the treatment duration needed were assessed in this study.
- Latanoprost increased vellus and terminal hair density and may be useful for stimulating hair follicle activity and treating hair loss.

The observations suggest that latanoprost may be used for treating hair loss and canities. As much of the relevant literature appears in ophthalmologic journals, dermatologists may not be familiar with the promising effects.[17] Furthermore, the follicles and growth cycles of scalp hair and eyelashes are not identical.[18] It remains unknown whether latanoprost induces hair growth and pigmentation in intermediate and terminal androgen-dependant hair, and if so, which concentration and treatment duration are necessary.

The main objectives were to assess the efficacy of latanoprost on hair growth and pigmentation. The secondary objectives were to investigate the effect on scalp pigmentation, the treatment duration needed, and the safety of latanoprost. Latanoprost was chosen as a medically licensed representative of prostaglandin F2α analogues, with the intention to prove the concept that prostaglandins are potential promising agents for influencing hair growth.

METHODS

Study design

This was a monocenter, double-blind, randomized pilot study to assess the efficacy of a 24-week topical treatment with latanoprost 0.1% on hair growth and pigmentation in healthy volunteers. The subjects were randomized on location: each subject applied latanoprost on one investigational site and placebo on the other. The trial was conducted at the Clinical Research Center for Hair and Skin Science at the Charité-Universitätsmedizin Berlin, Germany, in 2003 in accordance with the Declaration of Helsinki principles, Good Clinical Practices, and local regulatory requirements (No. 1842/Si.260).

Subjects

Subjects were 16 healthy male volunteers, aged 23 to 35 years, with dark blond to light brown hair and of phototype III to IV, presenting a recently developed frontotemporal alopecia (Hamilton stage II-III). After written informed consent, a general clinical examination and an interview on medical history and concomitant therapies were performed. Exclusion criteria included female sex; scalp atrophy and/or canities on frontotemporal regions; any skin affection on the investigational areas; any ophthalmic pathology; allergy or hypersensitivity to any colorant, medicinal product, or component of the investigational product; a history of skin cancer; acute or chronic illness interfering with the trial conduct; physical treatments on the head within the last 6 months; using depigmenting or propigmenting products on the scalp or head during the last 3 months; planned ultraviolet sessions or sun exposure of the head during the study period; and using topical or systemic drugs or cosmetics that could interfere with the study assessments in the last month.

Investigational products

The investigational product was latanoprost 0.1% ternary solution (50% ethanol, 20% propylene glycol, water) packaged in droppers (flasks), compared with placebo packaged in identical droppers. The dose was considered to pose no risk, being 3.6 times less than the dose reportedly tolerated intravenously. Each subject received both products with the dose of one drop (~50 μL) daily for 24 weeks on two symmetric locations on the scalp according to randomization. The first topical application was performed on site by the investigator and for the first 4 weeks, 5 days a week, by a site technician. After ensuring correct application, each subject applied the products at home for the following 20 weeks. At the end drug accountability was performed for controlling compliance and total drug application.