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EFFECTS ON HUMAN HAIR AND BEARD GROWTH BY TOPICAL APPLICATION OF A CALIBRATED BLEND OF BOTANICAL EXTRACTS (*)



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Effects on human hair and beard growth by topical application of a calibrated blend of botanical extracts(*)

Paolo U. Giacomoni, Insight Analysis Consulting, Madison, AL, USA Élan Rose International, Tustin, CA, USA

(*) Auxina Tricogena® (Vevy Europe, Genova, Italy)

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ABSTRACT

A blend of hydro-alcoholic extracts from plants with pharmaco-gnostic evidence of healing cutaneous diseases and sores (Tussilago farfara L, Achillea millefolium L and Chincona officinalis), contains high levels of tocopherol, nicotinamide, riboflavin, glucose, ascorbic acid and tannins. Tested on the scalp of human male volunteers affected by paraphysiological alopecia, it nearly restores the anagen-catagen/telogen ratio as in healthy individuals after six weeks of daily application. Tested on the cheeks of male human volunteers with impaired beard growth, it restores beard growth in 60 days of twice daily application.

Introduction

A remarkable segment of the personal care market is represented by personal care products for men. It has been estimated that this market (~4 bn \$ in the USA alone in 2013 and perhaps six-seven times larger, worldwide) is comparable, in size, to the budget of the National Insitutes of Health (~32 bn \$).

Deodorants and fragrances, shaving creams and foams, after shave products and shampoos play a non-negligible role in this market, a large share of which is represented by topical products aimed at stimulating hair growth.

Finding substances able to stimulate hair growth is a formidable task for several reasons: the lack of pertinent laboratory models, the complexity of the biochemistry and genetics of hair growth regulation, the different forms of alopecia and hair loss encountered in humans, the ethical hurdles to experimenting on humans with xenobiotics or other interventions having drastic effects on specific metabolic pathways, etc.

This notwithstanding, serendipity and accurate analyses of the side effects of drugs prepared to tackle other pathologies have allowed the pharmacological industry to pinpoint a few molecules with a positive, albeit limited, effect on hair growth.

In this paper, the results of some experiments will be summarized, that describe the safety and efficacy of a calibrated blend of botanical hydro-alcoholic extracts on the growth of hair (on the scalp) and of beard in human male volunteers.

Results

Rationale and safety

Pharmacognosy is the science that observes and records the therapeutic action of natural substances, and pharmacology identifies the active principles.

Over the centuries, pharmaco-gnostic activity has allowed botanists and scientists to identify botanical species helpful in treating pathologies as various as tooth-ache-induced inflammation (by chewing the leaves of the weeping willow) or bacterial infections (by administering extracts of the fungus Penicillium notatum).

Nowadays, too, pharmacologists explore the botanicals used by Shamans in the rainforest, aiming at the identification of more active principles.

The calibrated blend of botanical extracts which will be described in this article, was prepared in order to generate a hair growth product with interesting properties. It consists of extracts from *Tussilago farfara L, Achillea millefolium L* and *Chincona officinalis*, three species traditionally used to treat cutaneous diseases, to fight scabies, ringworm, cradlecap and pimples (*T. farfara*) or to heal wounds and ulcers (*A. millefolium*) or to treat sores (*C. officinalis*) (1).

The calibrated blend is called Auxina Tricogena and consists of a mixture of hydro-alcoholic extracts from the three species above, with pH = 3.5-4, refractive index at 25 Celsius n= 1.3729, density d = 0.8998 and containing fitosterols (0.10%), quinolinic alkaloids (1.5%), flavonic glucosides (0.2%), salicinic glucosides (0.95%), Silicon salts (0.05%), Potassium salts (0.2%), glucose (0.9%), nicotinamide (2.5%), tocopherol (6%), ascorbic acid (0,26%), riboflavin (5.5%), tannins (0.1%), ether oils (0.1%) (2).

Safety

Clinical studies were undertaken between the sixties and seventies to test its safety (3). The results were that the intra-peritoneal toxicity of Auxina Tricogena in male mouse is 2.46 g/kg and the sub-acute or chronic toxicity in rat are nil.

Auxina Tricogena provokes hyperhemia in Draize test and in cutaneous test on rabbits; it is non-irritant in guinea pigs, non-teratogenic in rats, non-cancerogenic in mice.

Auxina Tricogena has no effect in Delayed Type Hypersensitivity and is non photo-toxic and non photo-sensitizing in guinea pigs.

Cutaneous efficacy test

30 days old Wistar albino rats were epilated and subdivided in 4 groups of 6 rats. The groups were subjected daily to: no treatment or topical application of Ethanol 75° or of 15% Auxina Tricogena in ethanol 75° or of 30% Auxina Tricogena in ethanol 75°.

For every group, the analyses were performed on three rats after 7 days treatment and on three other rats after 14 days treatment.

The endpoints of the clinical analyses were dictated by the outcome of the safety tests and were related to water content (to assess edema), histamine content (to address a possible inflammatory responses), mucopolysaccharides, hyaluronic acid, heparin and chondroitin sulfate (all these typical markers of the anagen phase) as well as to assess possible in-depth moisturizing effects.

Water content did not change, thus confirming the absence of edema. Histamine level in controls was 49.9 - 53.9 μ g/gram of cutis. In treated subjects at day 7 and day 14, histamine increased slightly to 57.4 - 66.5 μ g/gram cutis.

The topical application of Auxina Tricogena provoked the increase of Mucopolysaccharides from 150 to 190 μ g/ gram of cutis, and similar increase (20-30%) was observed for components such as heparin, hyaluronic acid and chondroitin sulfate (2).

As a serendipitous windfall profit, it was observed that hair regrowth in the epilated regions was larger in treated animals than in controls (2).

This observation could have been overlooked as not necessarily significant because rodent hair does not change with anatomical site whereas human hair characteristics heavily depend on the anatomical site in their shape and pigmentation as well as in response to testosterone.

Considering the presence in Auxina Tricogena of tocopherol, nicotinamide, riboflavin, glucose, vitamin C and tannins, it was understood that the blend might have positive physiological effects on hair growth, and so it appeared to be reasonable to explore its potential in inducing the growth of hair on the scalp and of beard on the cheeks of human male volunteers. This prompted the test of Auxina Tricogena on human volunteers.

Stimulation of hair and normalization of beard growth

A good indicator of the rate of hair growth is the fraction of hair in the telogen phase. In healthy hair, the anagen-catagen / telogen ratio is about 90 to 10.

Auxina Tricogena was applied daily on the scalp of 30 male volunteers affected by paraphysiological alopecia and the fraction of telogen and distrophic hair was assessed before the treatment and after 40 days of treatment, on 50 randomly plucked hair.

The results are reported below:

# of subjects	% telogen	% distrophic
7	28	3.1
23	37	4.7
17	13.7	1.7
6	14.8	2.5
7	31	3.9
	7 23 17	7 28 23 37 17 13.7 6 14.8

These results seem to indicate that Auxina Tricogena modulates the rate of growth by increasing the fraction of hair in anagen/catagen phases, in agreement with what is expected for a product able to stimulate hair growth. In addition, complete regrowth was observed in 26 panelists after 100 applications (and telogen fraction was below 15% in all of these 26 volunteers) (4).

Auxina Tricogena was also tested for its efficacy in normalizing beard growth (5), (6) in 25 males of age between 25 and 55 years.

The restoration of beard growth was assessed by a dermatologist according to a non-parametric (score from 0-no effect to 5-complete normalization) estimate. The experiment was double blind, insofar as the dermatologist was not told on what cheek Auxina Tricogena had been applied and the volunteers were given two lotions A and B, to be applied on the right cheek (A) and on the left cheek (B) without knowing which one was Auxina Tricogena and which one was the placebo.

Cheeks were treated every morning after shaving and every evening before bed time, for 60 days. According to the Dermatologist's assessment, after treatment with the placebo the "average" score (i.e. the score of beard growth for the majority of panelist) was 0-1, whereas for the treated cheeks the "average" score was 3.

Discussion

A great deal of scientific experimentation has been and is currently deployed to study the mechanisms of hair growth and hair loss. Inhibitors of the immune response have been suggested as treatment for hair loss by scientists having found evidences that hair loss might be the consequence of an auto-immune response.

The observation that testosterone injections, in WWI POW returning from the Near East battlefields, provoked total hair loss, suggested also the use of inhibitors of 5- α reductase (the crucial enzyme in the synthesis of testosterone) to fight hair loss or androgenic alopecia. The consequence to both these treatments might represent too high a price to pay in order to restore hair growth.

A commonly accepted working hypothesis is that hair growth can be stimulated by the use of topical products containing ingredients able to provoke vasodilation and increase the blood flow in and around the follicle.

Auxina Tricogena, among other substances of remarkable interest, contains nicotinamide and riboflavin, well known to increase blood flow and to be essential actors in the biochemical pathways of the intermediate metabolism and of the phosphorylative oxidation.

Auxina Tricogena appeared therefore as an excellent candidate to be tested in human hair growth experimentation.

The results obtained both on the anagen-catagen/te-logen ratio in the hair on the scalp and on the growth of hair on the cheeks indicate that Auxina Tricogena is by itself a good inhibitor of hair loss and a good stimulator of beard growth; it is therefore configured as an excellent tricostimulant in full respect of the anatomical structures of destination and of their physiological and biochemical aspects.

These results indicate that Auxina Tricogena is also an excellent candidate to be associated with other ingredients of not cosmetic relevance, having a proven effect on the growth of scalp hair, in specialized healing topical lotions.

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WHAT IS RELATA TECHNICA?

Starting from the beginning of the human story numberless substances have been applied on the skin to favour wound healing, for the management of skin diseases, or simply and perhaps more often for cosmetic aims. In sharp contrast, only in recent years, and with a great delay as compared with otherfields of pharmacology, the study of the effects of chemicals on the skin moved from art to science; now it is soundly based on a rational approach. Regulatory Authorities classify substances and formulations to be applied on the skin in two distinct categories: drugs and cosmetics. This in order to prevent that harmful or extremely active chemicals, contained in cosmetic preparations, are used without medical control.

Nevertheless, all pharmacologists know that in its widest meaning drug is every substance capable of modifying cell function, and it is difficult to admit that chemicals used in cosmetic preparations are devoid of any influence on biochemical mechanisms of epidermal cells, in particular in the case of long-term treatments. Thus dermopharmacology and cosmetology are at least overlapping disciplines, and there is no doubt that the same methodology should be employed in both fields.

Over the years Relata Technica has achieved a wide readership; at present its aim is to broaden the journal to make it a truly comprehensive dermopharmacology research journal in which articles in all of the most interesting and exciting areas of modern skin care have their forum. As a consequence, Relata Technica should attract manuscripts concerning the pharmacokinetic behaviour and the pharmacodynamic activity of old and new chemicals used to control skin diseases or to prevent skin aging, as well as studies providing insights on which to base rational development of new compounds for medicinal or cosmetic use.

Investigations on the various aspects of the interaction of chemicals with the skin can be analysed by the use of several experimental models: the intact animal, fragments of surviving skin, keratinocytes cultures or the more sophisticated in vitro reconstructed human skin, subcellular fractions and pure enzyme systems. The end point examined in the study may be the macroscopic appearance of the skin, its histological, histochemical or ultrastructural features, and a biochemical or molecular marker.

An important aspect of dermopharmacology, and even more of cosmetology, is safety assessment. Therefore the journal will be also very interested in publishing the results of research dealing with the local and systemic tolerability of new compounds. In this respect, one of the major goals of Relata Technica is to promote studies on the use and validation of the so called alternative assays which should have the final aim of substituting, at least for cosmetics, the use of laboratory animals in the assessment of systemic toxicity, local irritant activity and, in a broader sense, of any possible adverse effect.

Finally, Relata Tecnica should be the natural publication outlet for manuscripts concerning the formulation of dermopharmaceutical and cosmetic preparations, and in particular for those which analyse the influence of the vehicle and other ingredients on the efficacy and tolerability of the active substance.

It is essential that the quality of papers published in Relata Technica be good and, on the other hand, it is important for the journal to process and publish papers promptly. We will make every possible effort to improve and shorten the review process, and I believe that Relata Technica will become a preeminent journal in the field of dermopharmacology.