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Conclusions of the Multicentre International Trial to Assess Topical Application of a Preparation Containing Capixil BG and Poliplant Capillar Complex in Patients with Alopecia Areata

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Abstract

Hair disorders represent an extraordinarily exhaustive and serious chapter in dermatology. In many patients they cause serious mental and health problems. Alopecia areata is one of the most frequent types of hair loss. The therapy uses topical and systemic preparations as well as various combinations thereof. The paper comments on the result of a Multicentre International Trial to assess topical application of a preparation containing Capixil BG and Poliplant Capillar complex in patients with alopecia areata.

Keywords: Alopecia Areata; Topical Therapy

Introduction

Alopecia is one of the most common hair diseases nowadays. It is a problematic condition that is hard to influence, with more and more complicated cases appearing among young age groups (such as total alopecia in children). The past 15 years have been marked with an exceptionally significant increase in the cases of androgenetic alopecia in women [1, 2, 6, 9, 12]. Its aetiology is in many cases (despite the effort made by physicians and the quality of examination techniques and laboratory testing) impossible to identify. A certain role may be played by focal infections, severe infections diseases, uncorrected eyesight problems, neurologic problems (headache, back pain, etc.), stress, severe endocrinopathy, systemic drug therapy, childbirth or abortion, etc.. An antibody study has been carried out lately to determine (PL) gliadin and reticulin antibodies in patients with various types of alopecia. Obtained results have surprisingly verified anti gliadin and reticulin antibody positivity in nearly 40% out of the 100 tested patients [1- 6, 11, 13, 14, 17]. Clinically, we distinguish between reversible alopecia (curable, followed by hair re-growth) and irreversible alopecia (incurable, with no hair re-growth on the affected foci), for example in some severe scarring skin diseases (Systemic lupus erythematosus, scleroderma and so on), or caused due to trauma. Among the disputable causes of some types of alopecia (subject of intense research) there is chemisation and environmental pollution, and the influence of UV and other types of radiation. Hair loss in the course of life is physiological. Every hair follicle goes through the hair cycle 10 to 20 times during the life of a human being. The duration of single phases and the amount of hair in each phase is genetically determined.

Alopecia

They affect all age categories and differ according to case. Sometimes patients have no difficulties and only find out about their hair loss accidentally. In other cases hair loss is the source of severe mental distress and social issues. The most often diagnosed types of alopecia include alopecia areata, alopecia diffusa, alopecia totalis, alopecia caused by malnutrition or certain drugs, endocrine disorders, atrophic alopecia – Pseudopelade Brocq, traction alopecia, trichotillomania, and others. Clinical examination of hair loss is not a simple procedure and it cannot be performed in a superficial manner (by assessing the most obvious morphological changes).

Alopecia areata

It was described two thousand years ago by Celsi and is thus known as Area Celsi. It affects all age categories and all races, whereby 38% of first manifestations occur before the age of 20 years.

Specific characteristics of alopecia areata

The clinical picture of alopecia areata is very characteristic, with round or oval areas with no hair without any subjective problems. Hair loss may affect any hairy body part – the scalp, moustache, eyebrows, etc

The course of disease is very individual and it is always necessary to count with progression. In most patients the first episode is benign, with no other foci appearing. However, there is no guarantee that the condition will not relapse and have an even more severe course. In some cases patients develop a confluent type of alopecia, or universal alopecia called alopecia maligna. Children typically develop ophiasis affecting the temporal area and occipital areas on the head. Hair loss may be accompanied by dystrophic nail changes (in more than 60% of cases with alopecia) and affected eye lens, leading to sub capsular cataract [1- 6, 8, 11, 14].

Alopecia therapy is divided into the following groups:

- I. elimination of possible cause of hair loss
- II. topical therapy
- III. internal therapy
- IV. surgical therapy
- V. physical therapy
- VI. supportive therapy

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Topical preparations in the therapy of various types of alopecia accelerate the process of hair growth on the foci as well as the quality and thickness of hair. At present, there are many preparations - cosmetic as well as pharmaceutical products. Cosmetics contain herbal extracts (nettle, soy oil, AHA acids, birch extract, arnica, extracts from peppers, jojoba oil). The quality and density of hair may also be influenced by extracts of oats, millet, malt, and caffeine. Application forms of course are equally important. Available products include shampoos, balms, concentrated solutions, creams, sprays and lotions and tonics. The most up to date product is hyaluronic acid, the basic component of healthy skin. Until recently intrafocal injections to support vascularisation of alopecic foci and the hair follicle were used to treat alopecia areata [2, 3, 7, 10, 11, 14, 15]. Products of pharmaceutical companies most often include vitamin B and E (very widely used panthenol and pyridoxine) salicylic acid, resorcinol, tincture chinae, tint, capsici, corticoids, minoxidil, aminexil, and so on. In some product age (they are not to be used in children), pregnancy, lactation, allergies and rebound phenomenon are a contraindication. A common mistake is topical use of panthenol foam, which is to be used in burns and not hair loss. Products in the therapy of alopecia include original preparations, or preparations freshly prepared in the pharmacy based on a prescription.

Surgical therapy

Hair transplantation (with various procedures and techniques) is very popular and effective, but also very expensive. The results are not always predictable and undesired reactions may occur.

Physical therapy

It includes a variety of therapeutic procedures, which are very efficient at the end in individual patients. Old procedures include iontophoresis, where electrodes are used to transport active substances into the skin via electric impulses. The method is not painful, and very efficient in some cases. Class IIIB biostimulation lasers are used with great success. Cryotherapy is the application of liquid nitrogen in form of cryospray or massage. In severe cases of the so called alopecia maligna, other sources are used, such as UV radiation, phototherapy, soft lasers, biostimulating lamps and combs that not only vibrate, but also irradiate the skin with special diodes. Surprising results may be achieved in some individuals with acupuncture and acupressure.

Material and Methods

The clinical trial was carried out in three centres in the Czech and Slovak Republic (Brno, Svidník, Žilina) to verify the effects of a special topical preparation to stimulate hair growth, containing natural substances such as amino acids, vitamins and oligoelements. The resulting percentage of every ingredient of this preparation was determined considering the final effect of reactivating and stimulating the hair follicle. The product is designed for patients with hair growth disturbances of varying aetiology, in all age groups including children aged more than 3 years. It is a complex preparation without allergens, with the content of Capixil BG and the Poliplant Capillar complex, hyaluronic acid, salvia extract, and so on. The patients enrolled into the trial included 40 males and females aged 18 to 45 years diagnosed with alopecia areata in varying locations on the scalp. The control group (with patients of the same age, gender, age and condition) applied minoxidil. The results achieved in the control group are not subject of the paper

Trial duration

December 2011 – May 2012

Inclusion criteria

- Moderate to severe Alopecia Areata
- Outpatient status
- Age of 18 to 45 , female and male gender
- Voluntary participation in the trial
- Signed informed patient consent form
- One-time participation in the trial

Exclusion criteria

Specific exclusion criteria

- Usage of other systemic preparation which might influence the final assessment
- Usage of hormonal contraception in females
- Known allergy to the tested preparation
- Disease focus infection manifestations (superinfection requiring therapy)
- Immunosuppressive therapy
- Cancer
- Malignancies
- Usage of other topical preparation or substance to treat alopecia

General exclusion criteria

- Alcohol and drug abuse
- Painkiller abuse
- Participation in another clinical trial within the past 90 days
- Simultaneous participation in any other clinical trial
- Other reasons excluding the patient from the trial
- Restricted ability of the patient to follow therapy instructions
- Other physical or mental disorders disturbing the trial plan
- Possible consent withdrawal, presumed patient unreliability
- Topical application 2 times a day, after an indifferent shampoo

Recommended daily hygiene

Non irritating preparations having no influence on the therapy process.

Other medication

Only the medication necessary for the basic comfort of the patient, administered exclusively based on recommendation by other medical expert. Women should discontinue hormonal contraceptives at least 3 months prior to enrolment.

Other therapeutic procedures: Excluded in all centres

Basic laboratory screening

Not part of the trial, however, it was performed in every patient for monitoring purposes by the investigators), strictly followed glycaemia, HT, blood fat and mineral levels, blood count + dif, FW, urine)

Documentation: Working protocol, Quality of Life Questionnaire

Visits: On day 0, 30 60 and 90 – or on exclusion day

Basic examination: Clinical examination and objective assessment of the finding

Basic examination: Multi Skin Test Center®, by Courage + Khazaka, number of hairs in given locality, anagen/telogen/catagen ratio in all centres, trichology, Hair microphotography

Photodocumentation: Pictures taken 4 times in selected patients [Figures 1-4]

Special examination: Histological examination – in selected patients – centre Žilina [Figures 5 and 6]

Final assessment: Upon exclusion from the trial

Assessment of therapy effect on alopecia made by the investigator

grade scale I – 4

1. Excellent, 80 – 100% excellent re-growth of quality hair, excellent aesthetic effect
2. Satisfactory, 70% satisfactory re-growth and improved quality of hair and lanugo, satisfactory aesthetic and cosmetic effect
3. Insignificant improvement, 30% re-growth and improved quality of hair and lanugo
4. Unsatisfactory condition, finding in original extent

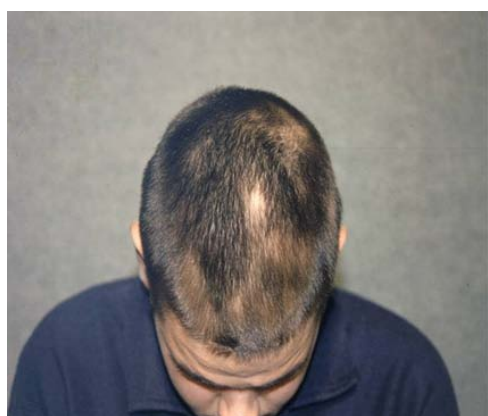


Figure 1: Alopecia Areata – clinical picture.



Figure 2: Alopecia Areata clinical picture.



Figure 3: Alopecia areata – before therapy.



Figure 4: Alopecia areata, the same patient – after therapy.

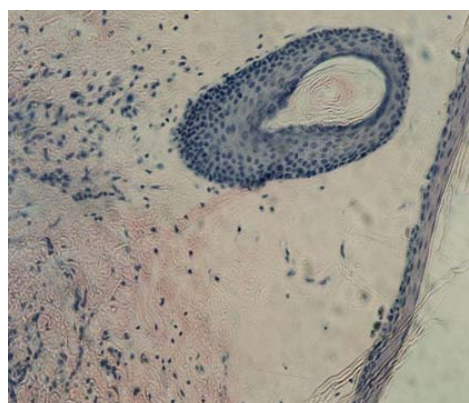


Figure 5: Alopecia Areata, the same patient, histology – hair follicle atrophy.

Subjective assessment therapy effect alopecia made by the patient: 1-4

1. Excellent aesthetic and cosmetic effect, no undesired effects
2. Satisfactory aesthetic effect
3. Insignificant improvement, unsatisfactory effect
4. Unsatisfactory effect

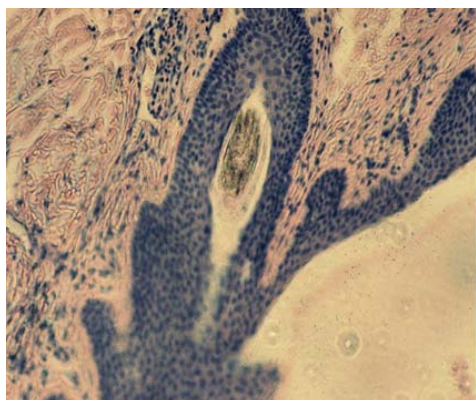


Figure 6: Alopecia areata, the same patient, histology – hair follicle atrophy.

Results

In total the trial monitored 40 trial participants with the ratio of 7 male and 33 female patients and with the average age of 30, 6 years, the youngest patient was 18 and the oldest patient was 45 years old. Prior to enrolment all patients were ingesting vitamins, minerals, and antioxidants (methionin, B vitamins, zinc), whereby 50% of patients were applying topical corticoids (Alpicort, Alpicort F), 20% minoxidil (Neocapil), and 30% patients used natural preparations (nettle extracts) or aminexil. They ceased applying the said products 3 months prior to trial enrolment (inclusion criterion). Manifestations of alopecia lasted from 17 to 52 months, the shortest period of 17 months. In all Centres the trial participants underwent a trichology examination at the beginning and at the end of trial, 2 trial participants underwent histological examination. The application period in all Centres comprised 90 days. Undesired effects were recorded. Manifestations were only transient and posed no reason for trial discontinuation. Trial participants only applied the product one time a day when they noticed erythema, dry skin, or pruritus. 4 patients had dry skin, 4 patients had mild erythema, and 2 patients had mild pruritus. There were no serious complications.

Efficacy of product with was assessed by the investigator as

Excellent	18 trial participants (45%)
Satisfactory	18 trial participants (45%)
Insignificant improvement	4 trial participants (10%)
Trial participants assessed the efficacy even more significantly:	
Excellent	24 trial participants (60%)
Satisfactory	13 trial participants (32.5 %)
Insignificant improvement	3 trial participants (7.5%)

Tolerability of alopel® foam catalysis S.L. madrid was assessed by the investigator as

Excellent	35 trial participants (87.5 %)
Satisfactory	5 trial participants (12.5 %)
Dissatisfaction	0
Dissatisfactory condition	0

Trial participants assessed the tolerability as follows:

Excellent	27 trial participants (67,5 %)
Satisfactory	10 trial participants (25 %)
3 trial participants (7,5 %) were dissatisfied with the application	
Dissatisfactory condition 0	

The application of product with Capixil BG and the Poliplant Capillar complex, hyaluronic acid, salvia extract requires a lot of patience and thorough patient education. First results – growing lanugo – appear already after 30 days of application. After 10 days the quality of hair starts improving, the hair is stronger and more resilient and the styling is easier. On the average, it takes around 6 weeks until the foci are covered with first white and later pigmented newly grown hair.

Discussion

The therapy of alopecia poses a serious challenge for the therapist and a permanent aesthetic and mental problem for the patients affected. We see an increasing incidence of alopecia areata in children and male patients with affected beard and moustache, which is very stressful for them. In all patients it is necessary, apart from performing all basic tests, to focus on the examination of focal infections or vision problems, neurological problems, and possible mental distress. There are patients who are unbelievably fixed at their problem and it is necessary to refer them to a psychologist or a psychiatrist. Another interesting finding is the fact that often there is a verified presence of antibodies to prove hypersensitivity to cow's milk, gliadin, and reticulins. When the diet is adjusted the process of healing accelerates. We have performed examinations in our patients, which is subject of this report. Due to this many atopic conditions, contact dermatitis, fungal infections, psoriasis and acne alopecia and other forms of alopecia occur very frequently and are very difficult to treat. They may rightfully be considered civilisation diseases. Similarly, androgenetic alopecia in female patients shows an increasing incidence and there are still not enough preparations on the market to therapeutically influence this condition. Application of various external agents to foster hair growth is problematic in patients of all age groups since for example topical corticoids cause secondary skin atrophy, minoxidil only acts during the application period and is followed by the rebound phenomenon upon discontinuation. It is therefore necessary to have products which would successfully replace corticoids and minoxidil and have an even more prominent therapeutic effect. There are many well known natural substances in the therapy of alopecia which for centuries have been used in natural medicine – extracts of salvia, nettle, rosemary, ivy, etc. The product assessed within the trial contains a number of various active substances which block hair loss and stimulate hair growth. Their optimum concentrations also play a role in the excellent final effect. The patented substance Capixil is a biomimetic peptide composed of amino acids which stimulate hair growth through their direct effect on hair follicles. Compared with minoxidil it shows a more significant effect and is assessed as more efficient also by experts. Poliplant capillar complex contains *Arctium majus*, *Arnica montana*, *Calendula officinalis*, *Citrus limonum*, *Hedera helix*, *Matricaria recutita*, *Nasturtium officinale*, *Pinus sylvestris*, *Rosmarinus officinalis*, *Salvia officinalis*, *Tropaeolum majus*, *Lamium alba*. All components stimulate hair growth and have an anti-seborrheic effect as well.

Conclusion

The multicentre trial carried out on 40 trial participants with alopecia areata has supported the use of product with Capixil BG

a komplex Poliplant Capillar (Alopel® foam Catalysis S.L. Madrid) in the said indications.

Results

The effect of application which was 90% (excellent or very good) may be considered a great result. The product is very well tolerated and has a very good texture and application form. Alopel® foam Catalysis S.L. Madrid was used also in three children outside of the trial cohort, one of them a little girl of three years with complete alopecia. The results were extraordinarily good and especially the parents very much appreciated the advantages and the effects of the product. There were no undesired effects observed or reported. Outside the trial, we treated 10 female and 5 male patients with alopecia androgenetica. We observed moderate hair thickening on the crown and above the receding hairline, as well as a change in hair quality. Patients with androgenetic alopecia are to be followed within the next trial. The given product with Capixil BG and Poliplant Capillar complex is efficient and suitable to be part of the portfolio to treat Alopecia Areata.

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