EFFICACY AND SAFETY OF CLOBETASOL PROPIONATE SHAMPOO IN THERAPY OF PSORIASIS OF THE SCALP

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ABSTRACT

Objectives: to evaluate the efficacy and safety of clobetasol propionate shampoo in patients with psoriasis lesions of the scalp in the acute phase. Materials and methods: Sixty patients with psoriasis of the scalp were enrolled and treated with 0.05% clobetasol propionate shampoo. All patients applied shampoo once daily for 15 minutes during 28 days. Evaluation of effectiveness was made on visit day 0, 7, 14, 21 and 28 using mPASI; TSS and the intensity of pruritus indexes. Safety of therapy was judged by the frequency of occurrence of any adverse effects. Results: It was shown that a daily 15-minute application of clobetasol propionate shampoo for 28 days promotes regression of psoriatic efflorescence of the scalp, decreasing of lesions area involvement approving statistically significant dynamics of dermatological index - mPASI; TSS; itching. A distinct therapeutic effect and absence of adverse effects promoted to a good compliance in patients with psoriasis of the scalp.

KEYWORDS: psoriasis, therapy, clobetasol propionate, efficacy, safety.
INTRODUCTION

Nowadays psoriasis is one of the most common dermatoses. At the same time nearly 70% - 80% of all patients with this disease have clinically significant manifestations on the skin of the scalp\(^1,2\) and almost half of them have complains on emotional discomfort, social problems that effect on health and quality of life.\(^3,4\)

This problem is so urgent that in 2009 the European Academy of Dermatology and Venereology adopted a specific consensus on psoriasis of the scalp, in which modern classification of severity and approaches to the treatment of patients with this pathology were reflected. Currently, there are three degrees of severity of psoriasis of the scalp, which differ in the affected area, severity of erythema, infiltration and desquamation. In cases of mild disease efflorescence occupy less than 50% of the anatomical region of the skin and is characterised by slight erythema, infiltration and itch. Moderate and severe forms of psoriasis of the scalp affect more than 50% of a skin of the scalp, accompanied by intensive erythema, infiltration and pruritus.\(^5\)

It is obvious that the defeats of the scalp have their own specific characteristics that distinguish them from efflorescence on other sites of the skin and influence on the choice of methods of treatment. Presence of hair on the skin of the scalp restricts the usage of such common forms as ointments, creams and pastes. Rich vascularization of the scalp is an unfavorable factor contributing to drug resorption, which can lead to the development of a number of systemic adverse events in the patient’s organism (e.g., for corticosteroids - suppression of gipotalyamo-pituitary-adrenal system, for synthetic vitamin D analogues - systemic immunosuppression and hypercalcemia). It is also known that regular use of very potent topical corticosteroids can cause iatrogenic rosacea, glaucoma and steroid acne.\(^6\)

On the other hand, topical therapy compliance is largely determined by the cosmetic appeal of the drug to patients themselves. Ointments, creams and gels having a fatty basis significantly limit their use in patients with psoriasis of the scalp. This group of patients usually prefers the use of drugs with a light texture, such as lotions, foams and shampoos. Given topical forms have cosmetically acceptable properties and contain different active topical substances such as tar or corticosteroids.\(^7\)

More than thirty years topical drugs on the basis of corticosteroids form the basis of topical treatment of psoriasis of the scalp, as highly effective and fast-acting substances.
Corticosteroids are used in different topical forms - ranging from shampoos to ointments. An important advantage is the ability to use them in combination with other compounds, such as salicylic acid, tar and derivatives of vitamin D.

As mentioned earlier the European Academy of Dermatology and Venereology Consensus (2009) emphasizes that those topical corticosteroids as shampoos can be used daily to relieve the symptoms of psoriasis of the scalp in the acute phase or 1 - 2 times per week in remission for its prolongation.\(^5\)

Today in Russia registered a shampoo containing very potent topical corticosteroid 0.05% clobetasol propionate. In the federal guidelines for the management of patients with psoriasis (2013) written that the use of this shampoo allows to achieve a significant improvement in reduction or stabilization of psoriatic process on the skin of the scalp. A method of short applying of shampoo on dry scalp daily with an exposure for 15 minutes followed by washing allows on one hand - to achieve high safety of treatment, to avoid the development of local and systemic adverse events with regular use of a very potent topical corticosteroids, and to provide cosmetic acceptability to patient on the other hand. Long proactive therapy of patients with psoriasis of the scalp with 0.05% clobetasol propionate shampoo twice weekly effectively prevents the development of the next exacerbation of dermatosis.\(^8\) The above data on both short- and long-term use of the shampoo have a high level and degree of evidence what was proved by double-blind, randomized, placebo-controlled, multicenter clinical studies.\(^9,10\)

**Objectives** to evaluate the efficacy and safety of 0.05% clobetasol propionate shampoo in patients with acute phase of psoriasis of the scalp.

**MATERIAL AND METHODS**

The study included 60 patients (29 men and 31 women) with psoriasis of the scalp in phase of progression; the mean age of the study population was 31.6 ± 4.1. Written informed consent was obtained from all study subjects, prior to participation in the study, which was approved by the Ethics Committee of Saratov State Medical University. The study was conducted in accordance with the guidelines of the Helsinki Declaration of 1975, as revised in 1983.

Duration of psoriasis ranged from 6 months to 20 years. The duration of this relapse in 27 patients was 2-3 weeks, 14 people - up to 3 months, in 10 patients - up to 6 months, 9 patients - more than 1 year. Vulgar form of psoriasis had 45 patients, 15 - exudative, with a primary
lesion on the scalp (more than 50% of the area). All patients had progressive phase of psoriasis. The total PASI index ranged from 8 to 34 (mean 15.6 ± 1.2). Moderate form of psoriasis of scalp was diagnosed in 42 patients; in 18 - severe. Absolute values of mPASI index which is specific to the scalp were between 9 and 26 (mean 19.6 ± 0.8). The values of the standard index of global assessment of severity of psoriasis TSS have ranged from 3 to 5 (mean 3.85 ± 0.4).

Itch was evaluated by a scale, where 0 - absence of the symptom; 1 - slight itch; 2 - moderate pruritus; 3 - intensive itching. The absolute value of this index was 2.1 ± 0.4.

Observed patients received standard systemic therapy (hepatoprotectors; emollients – except scalp area). At the same time all patients received 0.05% shampoo Etrivex (manufactured by Laboratoires Galderma, France; active ingredient - 0.05% solution clobetasol propionate) on the scalp once daily for 28 days (first 10 days in complex therapy, later in monotherapy). The drug was applied on dry skin of the scalp for 15 minutes and then foamed and washed with pure water. After this procedure, any further indifferent shampoos were not used. The clinical efficacy of treatment was performed on visit day 7, 14, 21 and 28 by dynamics of mPASI; TSS; and itch indexes. Safety of therapy was judged by the frequency of adverse events. Data processing and statistical analyses were performed using software packages Statistica 6.0 (StatSoftInc.), SPSS 13.0 for Windows (SPSS Inc.), Microsoft Office Excel 2010. For assessing the significance of differences standard parametric Student t-test was used.

RESULTS AND DISCUSSION

During treatment with clobetasol propionate shampoo in patients with psoriasis reduction of erythema, infiltration and desquamation, as well as decrease of affected area were noted (Fig. 1 - 2). In first two weeks positive dynamics of erythema and infiltration was seen more distinct. Desquamation and reduction of the size of psoriatic elements to visit day 28 were more vivid. Dynamic calculation of the absolute values of mPASI index recorded its statistically significant decreasing (Fig. 3).

With a global assessment of the severity of psoriasis researchers noted a clear statistically significant reduction of TSS index (Fig. 4).

Along with positive dynamics from psoriatic efflorescence decreasing of intensity of itch was also recorded (Fig. 5). Moreover, the most distinct statistically significant reduction of this
index was on the 7th day of therapy. In terms of 8-28 days the dynamics to declining of the intensity of pruritus persisted, although it was less pronounced. Two patients during first week of therapy had complains on feeling of "dryness" in affected areas, occurs immediately after shampooing the skin of the scalp (connection of this adverse event with topical application of testing shampoo is probable but did not require discontinuation of the drug, and (or) additional drug exposure). At the same time, objective examination of the skin of the scalp didn’t show any signs of irritation. From 8 to 28 day of topical therapy with clobetasol propionate shampoo subjective sensations were not observed. However, I.Puig et al. (2010) in commentary of Spanish Academy of Dermatology and Venereology emphasize that corticosteroid shampoos containing alcohol and foaming agents don’t cause adverse effects such as dryness and itching while applying to the scalp and other areas of the skin.[11] The above statement is confirmed by the results of randomized trials.[12] A detailed analysis of the data of adverse events in our patients has been made; it was found out that both patients previously washed their hair once weekly. Probably a doctor's recommendation for more frequent, daily use of shampoo caused the short-term occurrence of the above-mentioned sensations in the first week of therapy. Any other local or systemic adverse events were not observed. All patients highly estimated cosmetically acceptability of this drug form and demonstrated a willingness to continue the ongoing topical therapy.

CONCLUSIONS
Clobetasol propionate shampoo is an effective topical treatment of psoriasis of the scalp in the acute phase. Usage of this drug on a regular basis during 28 days not only helps to reduce the incidence and severity of psoriatic efflorescence on the skin of the scalp, but also safety. Topical drug in the form of shampoo promotes good compliance in therapy of patients with psoriasis of the scalp.
Figure 1 Patient D, 63 y.o. Psoriasis of the scalp a) before treatment; b) 28 day of therapy with clobetasol propionate shampoo
Figure 2 Patient D, 63 y.o. Psoriasis of the scalp a) before treatment; b) 28 day of therapy with clobetasol propionate shampoo

![Image](b)

Figure 3 Index mPASI (p<0.05) in patients with psoriasis of the scalp on 0-21 days of clobetasol propionate shampoo therapy (ED)

Figure 4 TSS (p<0.05) in patients with psoriasis of the scalp on 0-21 days of clobetasol propionate shampoo therapy (ED)
Figure 5 Intensity of itch ($p<0.05$) in patients with psoriasis of the scalp on 0-21 days of clobetasol propionate shampoo therapy (ED)

REFERENCES
