

Original papers

Clinical study of sertaconazole 2% cream vs. hydrocortisone 1% cream in the treatment of seborrheic dermatitis

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ABSTRACT. Seborrheic dermatitis (SD) is an inflammatory skin disorder affecting the scalp, face, and trunk, however, there are controversies surrounding its treatment. The aim of the study is to compare the efficacy of sertaconazole 2% cream with hydrocortisone 1% cream in the treatment of seborrheic dermatitis. In total, 138 patients suffering from seborrheic dermatitis were studied. Sixty-nine patients received local sertaconazole 2% cream and they were recommended to use the cream twice a day and for 4 weeks. To create a control group, 69 patients received hydrocortisone 1% cream twice a day for four weeks. At the time of referral, and at 2 and 4 weeks after their first visit, the patients were examined by a dermatologist to check the improvement of clinical symptoms. The mean age of patients was 36.45 ± 13.23 . The highest level of satisfaction (85.1%) was observed 28 days after sertaconazole consumption: 76.9% was recorded for the hydrocortisone group. No relapse of the disease one month after stopping treatment was observed in either the sertaconazole 2% group or the hydrocortisone 1% group. Sertaconazole 2% cream may be an excellent alternative therapeutic modality for treating seborrheic dermatitis.

Key words: Seborrheic dermatitis (SD), *Malassezia*, Sertaconazole 2% cream, Hydrocortisone 1% cream

Introduction

Seborrheic dermatitis is a common skin disorder that mainly affects the scalp, causing scaly, itchy, red skin and stubborn dandruff [1,2]. Seborrheic dermatitis can also affect the face, upper chest, back and other oily areas of the body [3,4]. It has been reported to be triggered by stress, but no controlled data is available [5,6]. Patients with seborrheic dermatitis frequently report improvement after exposure to sunlight [7,8]. However, an increased prevalence of seborrheic dermatitis has been reported among mountain guides who have a high level of long term occupational exposure to solar ultraviolet radiation [9,10]. A precise explanation for developing seborrheic dermatitis is not known and can be different for adults and toddlers [11,12]. The condition can be connected to hormones, as sometimes the disorder is seen in infants and vanishes prior to puberty [13,14]. It is also believed

that a fungus known as *Malassezia* may also be responsible [15]. There are a few serious medical conditions, like Parkinson's disease, head injury and AIDS, which can also lead to seborrheic dermatitis, perhaps due to it being more difficult to take normal care of the skin during the course of these ailments [16]. On the other hand, most of the individuals suffering from seborrheic dermatitis do not suffer from any of these illnesses [17].

The treatment of seborrheic dermatitis depends on its location on the body. Treatment also depends on age [18]. Pharmacological treatment options for seborrheic dermatitis include antifungal preparations (selenium sulfide, pyrithione zinc, azole agents, sodium sulfacetamide and topical terbinafine) that decrease colonization by lipophilic yeasts, and anti-inflammatory agents (topical steroids) [19]. Corticosteroids are medicines used for reducing inflammation. Hydrocortisone is a corticosteroid, acting inside cells to decrease the

release of inflammatory substances. This reduces swelling, redness and itch [20]. Hydrocortisone acetate is a mild corticosteroid that can be applied to the skin to treat a wide variety of inflammatory detergents, as well as mild eczema [21].

Sertaconazole is a new imidazole antifungal agent which inhibits the synthesis of ergosterol, an essential cell wall component of fungi [22]. It is indicated in the EU for the treatment of superficial skin mycoses such as dermatophytosis (including tinea corporis, tinea cruris, tinea manus, tinea barbae and tinea pedis), cutaneous candidiasis, pityriasis versicolor and seborrhoeic dermatitis of the scalp, and in the US for tinea pedis only [23]. The present study compares the efficacy of sertaconazole 2% cream with that of hydrocortisone 1% cream in the treatment of seborrhoeic dermatitis

Materials and Methods

In this study, 138 patients, aged 4 to 75 years (mean 36.45 ± 13.23), with diagnosis of seborrhoeic dermatitis referred to the Dermatology department of the Sina Hospital of Tabriz were studied. This study was approved by the ethics committee of the Tabriz University of Medical Sciences. The patients were administered SD-developing drugs including methyl dopa, chlorpromazine and cimetidine, those who had used local or systemic anti-acne drugs either within one month before or at the time of referral to the center, and those suffering from systemic diseases were excluded from the study.

Before beginning the study and after obtaining a letter giving their written consent, every patient was clinically examined fully by a dermatologist. The type of lesion, either generalized (involvement of more than one area) or localized (involvement of one area), the descriptive position of the lesions and the number of inflammatory lesions were separately recorded for each patient, as was the presence of erythema, desquamation, itching and irritation.

To determine the severity of SD, the Scoring Index (SI) ranking system recommended by Koca et al. was used. According to this system, erythema, desquamation, itching and irritation of each area was ranked from zero to three: nonexistence=0, mild=1, moderate=2, severe=3. The sum of these amounts was regarded as an SD rank based on three ranges: 0–4 (mild), 5–8 (moderate) and 9–12 (severe). Accordingly, every patient was awarded a special SI before treatment.

Patients who satisfied the above criteria were

randomly divided into two groups. The first group received sertaconazole 2% cream (group A), and the other received hydrocortisone 1% cream (group B) in a double-blind manner. The content of the boxes was unknown to both the patients and the research team. The treatment consisted of two applications of the product twice a day for four weeks. At the time of referral and at 2 and 4 weeks after their first visit, the patients were examined by a dermatologist to identify any improvement of clinical symptoms or any drug side effects. The clinical findings were registered and again were awarded an SI.

The pretreatment and post-treatment rank were used to make a final evaluation of the recovery rate. Additionally, patient satisfaction with the drug was also evaluated at the end of treatment in four conditions: no-change (0), mild (1), moderate (2), and good (3).

SPSS version 16 was used for statistical calculations. The coupled T-test and Wilcoxon signed-rank non-parametric test were used to compare pretreatment and post-treatment results, and an analysis of variance for repeated measurements was used for data analysis. Cohen's Kappa coefficient and the Chi-square test were used to determine the satisfaction rate. A P-value of <0.05 was considered significant.

Results

The study enrolled 138 volunteers: sixty-nine were placed in the sertaconazole cream group and 69 in the hydrocortisone cream group. The demographics of the groups were similar and are summarized in Table 1. Most of the participants were women (59.4%), and the male/female ratio was similar between the groups. The mean age of all the subjects was 36.45 ± 13.23 , while the mean ages of sertaconazole and hydrocortisone groups were 34.56 ± 13.12 and 38.94 ± 11.23 , respectively. 59.4%

Table 1. Baseline demographics

Variable	Sertaconazole N (%)	Ketaconazole N (%)	P
Gender			
Men	29 (42.1)	27 (39.1)	
Women	40 (57.9)	42 (60.9)	
Age	34.56 ± 13.12	38.94 ± 11.23	0.27
Kind of lesion			
Localized	42 (60.9)	40 (57.9)	
Generalized	27 (39.1)	29 (42.1)	

Table 2. Frequency distribution in terms of SI before and after treatment

Days	Beginning day		14 th day		28 th day	
	Hydrocortisone N (%)	Sertaconazole N (%)	Hydrocortisone N (%)	Sertaconazole N (%)	Hydrocortisone N (%)	Sertaconazole N (%)
Mild	2(2.8)	2(2.8)	33(47.8)	36(52.2)	48(69.6)	53(76.9)
Moderate	51 (73.9)	55(79.7)	29(42.1)	26(37.7)	21(30.4)	16(23.1)
Severe	16 (23.3)	12(17.5)	7(10.1)	7(10.1)	0(0)	0(0)
Total	69(100)	69(100)	69(100)	69(100)	69(100)	69(100)

and 40.6% of patients had localized and generalized lesions, respectively.

In patients receiving the hydrocortisone 1% cream, a moderate SI was most commonly seen at the pretreatment stage (73.9%), while a mild SI was most commonly noted at the post-treatment stage (69.6%). In patients receiving the sertaconazole 2% cream, most cases (79.7%) were observed to have moderate SI at the pretreatment stage while the majority (86.9%) demonstrated a mild SI at the post-treatment stage (Table 2).

The statistical analysis demonstrated that a significant relationship existed between SI score measured on the 28th day for subjects receiving sertaconazole 2% cream ($P=0.007$), and this relationship was also significant for those taking hydrocortisone 1% cream ($P=0.012$). The frequency distribution of patient satisfaction after consumption of sertaconazole 2% cream and hydrocortisone 1% cream at 14 and 28 days of treatment is demonstrated in Table 3. The highest level of satisfaction (85.1%) was observed after 28 days' use of sertaconazole 2% cream. After twenty-eight days of hydrocortisone 1% cream consumption, the satisfaction level was about 76.9%. The chi-square test was used to identify any relationship between the sertaconazole 2% and the hydrocortisone 1% groups regarding patient satisfaction on the 14th day. No significant difference was observed between these two groups. The relationship between

patient satisfaction and sertaconazole 2% cream receive in 28th day was meaningful ($P=0.007$).

Discussion

The findings in the current study indicate that new anti-fungal agents, aside from fungal eradication, are also effective in the treatment of seborrheic dermatitis. Sertaconazole is an imidazole-type antifungal agent that has shown considerable in vitro activity against pathogenic fungi [24]. Various studies carried out in animal models, clinical and toxicology trials have confirmed the value of sertaconazole in the topical treatment of superficial mycoses in Dermatology [25,26].

In the present study, a moderate SI was most commonly recorded in the hydrocortisone 1% cream group at the pretreatment stage. However, most patients (69.6%) were noted as having a mild SI at the post-treatment stage. In accordance with Firooz et al. [27], our study confirms the efficacy of hydrocortisone 1% cream in the treatment of seborrheic dermatitis. Additionally, in patients receiving the sertaconazole 2% cream, 79.7% of cases were found to have a moderate SI at the pretreatment stage, while most patients registered a mild SI at the post-treatment stage.

Both treatments demonstrated statistically significant reductions in SI score and rapid, effective relief of disease signs and symptoms.

Table 3. Patient frequency distribution, considering satisfaction after treatment consumption in the 14th and 28th days of treatment

Level of satisfaction	Satisfaction with Sertaconazole		Satisfaction with Hydrocortisone	
	14 th day	28 th day	14 th day	28 th day
None	4(5.8)	0(0)	5(7.2)	0(0)
Mild	7(10.2)	4(5.7)	6(8.7)	4(5.7)
Moderate	14(20.2)	7(10.2)	18(26.2)	12(17.4)
Good	44(63.8)	58(85.1)	40(57.9)	53(76.9)
Total	69(100)	69(100)	69(100)	69(100)

The similarity between treatments also was evident in assessments of reduction of disease signs. Most participants in both treatment groups experienced significant improvement regarding the scaling and erythema of seborrheic dermatitis. According to Elewski and Cantrell [28] our study also confirms that the new antifungal agent (sertaconazole) in the cream form was effective in the treatment of seborrheic dermatitis.

The similar efficacies of the corticosteroid and nonsteroidal creams extend to the safety profiles of these agents. The differences between groups were not statistically significant, with overall safety rated as excellent for more than 98% of the individuals in each treatment group. In the present study, the highest level of satisfaction (85.1%) was observed 28 days after sertaconazole 2% cream consumption, while twenty-eight days after hydrocortisone 1% cream consumption, the satisfaction level was about 76.9%. The relationship between patient satisfaction and sertaconazole 2% cream receive in 28th day was meaningful ($P=0.007$), although this relationship was not statistically significant in the hydrocortisone group. This finding demonstrates the superiority of sertaconazole 2% cream to hydrocortisone 1% cream according to patient satisfaction.

In summary, these results suggest that sertaconazole 2% cream is a well-tolerated and effective treatment for seborrheic dermatitis.

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Received 30 April 2013

Accepted 3 July 2013