CLINICAL EVALUATION OF THE EFFICACY OF A BARRIER CREAM CONTAINING POLYVINYLPYRROLIDONE IN CHRONIC HAND ECZEMA

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The management of chronic hand eczema is usually difficult. The aim of this open-label study is to assess the effectiveness and 'steroid-sparing' activity of a barrier cream containing polyvinylpyrrolidone in patients with chronic hand eczema. Rescue treatment with topical corticosteroids (TCs) was permitted in the event of eczema worsening, whereas preventive measures were maintained unchanged with respect to those adopted by patients in the past. Among the 207 participants, the main diagnosis was irritant contact dermatitis, followed by allergic contact dermatitis and atopic dermatitis. Nearly half of the patients (49%) applied the barrier cream once or twice a day, while the remaining patients used it three or more times per day. Regardless of rescue therapy with TCs, regular use of the barrier cream caused a progressive significant improvement of eczema severity, as indicated by dermatologists' and patients' assessments. A significant reduction in the amount of the TC applied in the last 3 months and in the number of TC treatment days during the previous 4 weeks was found at the end of 12-week treatment with the barrier cream as compared with baseline. The product was also well-tolerated and accepted by the majority of patients. The results of this study suggest that a barrier cream containing polyvinylpyrrolidone can represent a useful tool in the management of chronic hand eczema and may show steroid-sparing effects.

Hand dermatitis is a common skin condition which often has a chronic relapsing course and may represent a relevant socioeconomic burden. This disorder can be influenced by genetic and environmental factors, such as daily habits, occupational activities, and climatic factors. Hand dermatitis actually corresponds to a heterogeneous group of skin disorders with different etiology and clinical presentations. The most frequent clinical entity affecting the hands is eczema, mainly consisting in irritant contact dermatitis (ICD), contact allergy (CA) and atopic dermatitis (AD). Hand eczema has sometimes a multifactorial nature, with exposure to irritants and/or allergens acting in concert with endogenous factors. This multifactorial origin can be responsible for the chronic course of hand eczema, as well as for its refractoriness to treatment (1-2). Therapeutic management of hand eczema is usually complex and frustrating because of difficulties in adopting effective prevention

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strategies and in adhering to these preventive measures in the long term. Regular use of a barrier cream can substantially protect the hands against irritation and may prevent skin breakdown. The aim of this open-label prospective experience is to assess the effectiveness and steroid-sparing activity of a barrier cream containing polyvinylpyrrolidone in patients with chronic hand eczema.

MATERIALS AND METHODS

The study population consisted of 207 patients, 129 females and 78 males, aged 9 to 84 years (mean age, 37.9). They had active hand eczema with a chronic course defined by a duration of at least 3 months. The main diagnosis was ICD (n= 102), followed by CA (n= 58), and AD (n= 47). The general characteristics of hand eczema among the study participants are summarized in Table I.

Exclusion criteria were concomitant skin disorders, including infections, capable of affecting the study evaluations, as well as the presence of acute oozing hand lesions, and any disease which could require active treatments interfering with the study procedures and results. Patients were asked to apply the study product (Vicutix mani® cream, Sirton Medicare, Villa Guardia, Como, Italy) one or more times per day on an 'as needed' basis. Subjects who were receiving intermittent short-term treatments with topical corticosteroids (TCs) within the last three months were instructed to continue the prescribed regimen and to apply TCs as rescue medications throughout the study period, limiting their use in the event of relevant worsening of hand eczema. The TC recommended as rescue therapy had to be identical to the preparation already used by the patient before the study entry in order to obtain reliable data regarding the effect of the barrier cream on TC usage. For the same reason, the patients had to maintain unchanged the preventive measures previously adopted in the last months. Patients who never used TCs for their eczema were instructed to contact the dermatologist in the case of eczema flare before starting any type of treatment different from the barrier cream. The consumption of TCs within the 12 weeks before the study and over the study period was registered and reported as both weight of consumed TCs and treatment days.

Visits were performed at baseline (D0) and after 4 and 12 weeks of treatment (W4 and W12, respectively). At each visit, global assessment of disease severity was rated by the dermatologist using a four-point scale (0= absent, 1= mild, 2= moderate, 3= marked). At the same time, the patients independently evaluated the severity of their condition by means of a 100-mm visual analog scale (VAS). At D0 and W12, detailed information about treatment with TCs relative to the previous three months were collected from each patient. At the end of the 12-week treatment, patients were questioned on their assessment of the treatment, rating its tolerability and acceptability as insufficient, modest, fair, good or excellent. Any adverse events were recorded and monitored.

As for the statistical methods, the variation of numerical parameters during the study period was analysed using the Wilcoxon matched-pairs signed-ranks test. Descriptive analysis was also used, as appropriate. Significant differences corresponded to p values less than 0.05.

RESULTS

Of the 207 eligible patients who gave their consent to participate in the trial, 205 were visited at W4, and 190 at W12. Premature discontinuations occurred because of administrative reasons (n= 7), poor adherence to study treatment and procedures (n= 5), prohibited treatments (n= 3), and adverse reactions (n= 2).

Nearly half of the patients (49%) applied the study product once or twice a day, 23% of patients an average of three times per day, and 28% four times or more.

Regardless of the rescue therapy with TCs, treatment with the barrier cream caused a progressive significant amelioration of hand eczema, as indicated by the dermatologists' and patients' assessments of disease severity (Table II). There were no relevant differences in the degree of improvement in dependence on either the clinical diagnosis or the frequency of application of the barrier cream (data not shown). A total of 93 patients never received TCs to manage their hand eczema over the three months preceding the study start, whereas 114 patients had undergone intermittent courses of TCs during the few weeks before the study start. The first group of patients showed at the baseline an eczema less severe than that of the latter group (patient-reported VAS, 45.8 *vs* 65.1 mm; physician's assessment mean score, 1.5 *vs* 2.1). There was a significant improvement of eczema severity over the 3-month study period in both these groups, irrespective of the use of TCs, with a trend towards a greater improvement in the patients who never used TCs, although the difference between the groups did not reach any

Table I. *General characteristics of hand eczema in the study population (n= 207).*

Diagnosis (n)	
Irritant contact dermatitis	102
Allergic contact dermatitis	58
Relevant contact allergens:	
Nickel sulphate	30
Potassium dichromate	12
Cobalt chloride	10
Paraphenylenediamine	5
Myroxylon pereirae resin	3
Methylchloroisothiazolinone/methylisothiazolinone	2
Carba mix	2
Thiuram mix	1
Atopic dermatitis	47
Duration of hand eczema (n)	
3 to 6 months	89
7 to 12 months	52
> 12 months	66
Risk factors (n)	
Work-related duties	95
Hyperhidrosis	67
Personal atopic diathesis	39
Familial history of atopic disorders	42

Of the 207 patients with chronic hand eczema, the most frequent diagnosis was irritant contact dermatitis, followed by allergic contact dermatitis (culprit allergens are shown) and atopic dermatitis. Duration of hand eczema and risk factors for the disease are also specified.

statistical significance (data not shown). Among the patients who did not undergo recent courses of TCs, only 13 patients (14%) were treated with TCs throughout the study period, despite application of the barrier cream. Regarding TC treatment during the study in previous or current users of TCs, 77 of these (67.5%) progressively reduced the TC usage in terms of treatments days and/or amount of applied TCs, with complete discontinuation of TCs until the end of the study in 50 cases (44%). Moreover, 13 of these patients (11.5%) continued to use TCs at a rate comparable to that registered before the study entry, while 14 patients (12%) increased the TC usage as compared with the past consumption, and 10 patients (9%) experienced an initial transient increase in the TC usage with a dramatic reduction during the final month. Despite the absence of a statistically significant change in TC treatment days over the entire study period as compared with the three months preceding the study, the amount of the TC applied in the last three months was found to be significantly decreased, as well as the number of treatment days during the 4 weeks preceding the evaluation at D0 and W12 (Table III).

The tolerance to the barrier cream was good in most cases. Adverse reactions at the site of application occurred only in six patients. A mild transient burning sensation or pruritus, regarded as unrelated to the study product, was reported by four patients. A moderate burning associated with eczema worsening was observed in 2 patients; the correlation with the study product was considered as possible, and the event required treatment discontinuation in both cases.

At W12, nearly 80% of patient judged either the tolerability or the cosmetic acceptability of treatment as good or excellent (Fig. 1).

DISCUSSION

Therapeutic management of hand eczema is directed to the prevention against causative factors, as well as to the repair of skin changes and relief of symptoms (1-4). TCs are widely used to control inflammation during the flares of the disease, but they should be avoided for chronic long-term treatment because of the development of dependency, tachyphylaxis and risk of untoward effects, such as skin atrophy (5-8). In most cases of irritative forms, moisturizers may cause great improvement of the subjective discomfort (3, 9). Cosmetic products with moisturizing and/or emollient properties may play a true therapeutic role and can exhibit a steroid-sparing activity in eczema and skin disorders associated with impairment of barrier functions (10-

Table II. *Dermatologist's and patient's global assessment of disease severity.*

	Day 0	*Week 4*	*Week 12*
Dermatologist's assessment			
Mean value	1.86	1.05*	0.7**
Disease severity (%)			
Absent	0	18.5	36
Mild	27.5	58	58
Moderate	59	23	6
Severe	13.5	0.5	0
Patient's assessment			
Mean value	58.4	30.4*	16.7**

Dermatologist's assessment was rated by means of a 4-point scale (ranging from 0= absent to 3= severe), and results are reported as both total mean score and proportions of patients with different degree of severity. Patient's assessment was made using a 100-mm VAS. There was a statistical significant reduction of the severity mean score reported by both the dermatologist and the patient ($p < 0.01$ vs day 0; ** $p < 0.001$ vs day 0 and < 0.05 vs week 4).*

Table III. *Use of TCs over the study period.*

Visit	**TCs used in the previous 3 months** (grams)	**TC treatment days in the previous 3 months**	**TC treatment days in the previous 4 weeks**
Day 0	38.0	16.2	6.9
Week 12	21.6*	15.9**	4.1*

Consumption of topical corticosteroids (TCs) is reported as amount of the topical drug used in the previous 3 months, as well as treatment days in both the last 3 months and the last 4 weeks preceding the visit.
*Week 12 vs day 0: * $p < 0.01$; ** non significant difference ($p > 0.05$)*

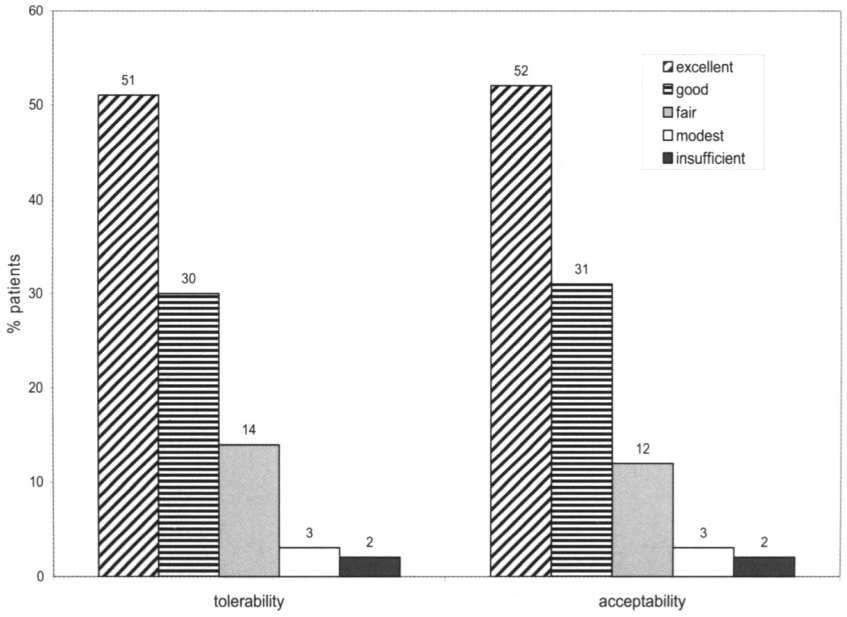

Fig. 1. *Patients' assessment of tolerability and cosmetic acceptability. Both parameters were rated by patients according to a 5-point scale (as insufficient, modest, fair, good or excellent) at the end of the 12-week treatment..*

15). Some evidence supports the usefulness of some barrier creams for the prevention of ICD and, to a lesser extent, of CA manifestations (3, 16-17).

The results of this study demonstrate that the use of a barrier cream containing polyvinylpyrrolidone (Vicutix mani®) is effective in patients with chronic hand eczema.

The protective properties of this preparation were studied using a real-life setting, with TC rescue treatment permitted in the event of relevant worsening of hand dermatitis, and preventive strategies kept unchanged in order to avoid interference with the interpretation of results. The product showed a steroid-sparing activity, as an indirect confirmation of its effectiveness. In fact, among TC users, a gradual incremental reduction of TC usage in terms of treatment days and/or amount of applied TC was observed in nearly two-thirds of them, with a complete withdrawal from TC treatment in 44%. A significant reduction in the amount of the TC applied in the last 3 months and in the number of treatment days in the previous 4 weeks was found at the W12 assessment as compared with baseline. An increase of TC use in comparison with the past consumption or an *ex novo* treatment in patients naïve to TCs was registered in a minority of patients despite application of the barrier cream. A trend towards a greater improvement of eczema severity, even if without statistical significance, was noted in patients who had not undergone recent courses of TCs, possibly because their hand dermatitis was less severe than the eczema of patients requiring TCs.

The product was also well tolerated and accepted by the majority of patients, and this has important implications for compliance issues.

In conclusion, this study suggests that a barrier cream containing polyvinylpyrrolidone is a useful tool in the management of chronic hand dermatitis, providing a steroid-sparing effect in most patients.

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