

EVALUATION OF TREATMENT WITH SICORTEN CREAM BY DAY AND SICORTEN OINTMENT AT NIGHT IN PATIENTS WITH CHRONIC PSORIASIS

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SYNOPSIS

In an open non-comparative trial forty ambulant patients with chronic psoriasis vulgaris were treated with non-occlusive application of Sicorten® cream twice by day and Sicorten® ointment once at night for up to 30 days. This combined regimen yielded good (marked improvement) to very good (complete clearance) results in 92.5% of the patients treated. The onset of therapeutic effect was observed within 3 days of starting the treatment in 95% of the patients. All forty patients tolerated Sicorten® topicals well and no adverse effects due to either local skin intolerance or the transcutaneous systemic absorption of the corticoid were observed in this trial, nor were any instances of skin atrophy reported.

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INTRODUCTION

Halometasone is a new synthetic dermatocorticoid, possessing pronounced anti-inflammatory, antiepidermoplastic, anti-exudative and antipruritic properties. Sicorten® ointment contains 0.05% halometasone in solute form in an anhydrous hydrocarbon lipid base to which propylene glycol, sodium chloride and hypo-allergenic acetylated wool fat have been added. Sicorten® cream contains 0.05% halometasone in micro-crystalline form suspended in a hydrophilic oil-in-water emulsion with a slightly acidic pH which accords well with the physiological acidity of the skin. Both Sicorten® cream and ointment do not contain parabens or perfume.

In international clinical trials carried out by dermatologists in six European countries, Sicorten® topicals have displayed good tolerability and were, with respect to the overall success rate, more effective than Ultralan cream (p=0.002), Ultralan® ointment (p=0.0001), Diprosone® cream (p=0.04), Diprosone® ointment and Synalar® ointment in patients with eczematous dermatoses. (1-3) A combined regimen comprising Sicorten® cream (without a dressing) once by day and Sicorten® ointment with occlusive dressing once at night, have yielded good to very good results in 93% of patients with psoriasis. (4)

In long-term studies extending up to 90 days and performed with Sicorten® ointment in patients with chronic recalcitrant dermatoses, neither skin atrophy nor any systemic adverse effect due to transcutaneous absorption of halometasone was observed. (5, 6) In view of these encouraging results, a trial was carried out using Sicorten® cream twice by day and Sicorten® ointment once at night in patients with chronic plaques of psoriasis, at the Department of Dermatology, Beilinson Medical Centre, Tel Aviv University Medical School in Israel.

PATIENTS AND METHODS

The evaluable trial population consisted of 40 patients (25 males and 15 females) suffering from chronic plaques of psoriasis covering less than 20% of the total body surface and suitable only for topical therapy. Their ages ranged from 13 to 70 years (Table 1).

TABLE 1 CHARACTERISTICS OF TRIAL POPULATION

Characteristics	Patients	
	n	%
Number of patients	40	100
Sex: Males	25	62.5
Females	15	37.5
Age: 13 to 40 years	5	12.5
41 to 60 years	29	72.5
61 to 70 years	6	15
Total duration of psoriasis:		
up to 4 years	4	10
5 to 10 years	11	27.5
more than 10 years	25	62.5
Severity of psoriasis:		
Severe	12	30
Moderate	22	55
Mild	6	15
Severity of pruritus:		
Severe	3	7.5
Moderate	6	15
Mild	6	15
Nil	25	62.5

The average duration of the present attack was 12 weeks, with a range between 2 and 24 weeks. The total duration of psoriasis ranged from 1 to 30 years. The trial population included 12 severe, 22 moderately severe and 6 mild cases. Pruritus was absent in most of the patients. (Table 1)

In this open, non-comparative trial, an ointment containing 10% salicylic acid was applied to the lesions twice daily for the first 2 or 3 days to remove scales. Then all patients were treated with Sicorten® cream twice by day and Sicorten® ointment once in the evening for up to 30 days. During this period no occlusive dressings were permitted and no concomitant therapy that could influence psoriasis was given. Onset of action, i.e the first sign of improvement (observed by the investigator and/or the patient, and adverse effects due to the trial preparations were recorded. At the end of the trial treatment a global assessment of therapeutic effect was made by the investigator according to the following 4-point scale:

1. very good : complete clearance of psoriasis plaques
2. good : more than 60% clearance of the plaques
3. moderate : 30% to 60% clearance of the plaques
4. poor : less than 30% clearance of the plaques

The patients opinion on the cosmetic acceptability and ease of application of the trial preparations was also recorded. After the first examination, visits were scheduled at 10-day intervals.

RESULTS

According to the investigator's judgement, this treatment regimen yielded an overall success rate (good to very good results) of 92.5% (Table 2). The onset of therapeutic effect was observed within 3 days of starting treatment with Sicorten® topicals in 38 (95%) of the 40 patients. The first visible sign of improvement was the thinning of the psoriatic plaque. Duration of treatment was 30 days in 12 patients, 11 to 20 days in 22 patients and less than 11 days in 6 patients. All forty patients tolerated Sicorten® topicals well and no adverse effects, due to either local skin intolerance or the transcutaneous systemic absorption of the corticoid, were observed in this trial, nor were any instances of skin atrophy reported. Cosmetic acceptability and ease of application of Sicorten® cream and ointment were considered by most of the patients as very good or good. Six patients claimed that the ointment was rather greasy and three of these patients also felt that the cream had drying effect on their psoriatic skin.

DISCUSSION

Since 1953 corticosteroid topicals, used alone or in combination with salicylic acid, dithranol, tar and urea,

TABLE 2 THERAPEUTIC EFFECT AND ADVERSE REACTIONS

Total No. of patients	Therapeutic effect				Adverse effect
	very good	good	moderate	poor	
40	18	19	3	0	0

have been playing a significant role in the treatment of psoriasis. Psoriasis, affecting approximately 2% of the world population, presents a major therapeutic problem in dermatology. Corticosteroid topicals have been reported as the most commonly used form of therapy, given to 88.5% of psoriatics in Denmark (Foged and Schmidt). (7)

In our trial the combined regimen comprising non-occlusive application of Sicorten® cream twice by day and Sicorten® ointment once at night, yielded a very satisfactory success rate of 92.5% in patients with chronic plaque-type psoriasis. This form of psoriasis is more refractory even to retinoids than the pustular and erythrodermic types (Voorhees and Orfanos). (8) The high success rate and rapid onset of action reported in this trial could be due to the high potency and optimum intracutaneous penetrability of the active ingredient in Sicorten® cream and ointment.

Following complete clearance of the lesions, either hypopigmentation (psoriatic leucoderma) or residual hyperpigmentation was observed on the treated areas in some patients. The most recalcitrant plaques were located on the hands and feet. Although psoriatic plaques on the other parts of the body had healed, some lesions persisted on palms and soles in five patients. The refractory plaques in four of these five patients were treated successfully by application of Sicorten® cream (without a dressing) twice during the day and Sicorten® ointment (with an occlusive dressing) overnight for 4 to 7 days. One patient did not respond even to this modified treatment schedule.

Treatment of psoriatic plaques with highly potent dermatocorticosteroids, e.g. Sicorten® topicals, should not be discontinued abruptly. Even after the complete clearance of psoriatic lesions, the patients should be treated further for about 8 to 10 days with a once-daily application of a moderately potent dermatocorticosteroid, e.g. Locasalen® ointment, which contains 0.02% flumethasone pivalate and 3% salicylic acid. Such a step-down therapy is advisable to prevent relapses.

Psoriatic plaques are usually treated with corticosteroid ointments and such formulations are greasy,

sticky and unpleasant to use by day. All patients admitted to our trial pointed out that Sicorten® cream used during the day was a quite acceptable form of treatment, especially during working hours, because it was easy to apply and did not soil their clothes.

Based on the results of this trial, the combined regimen with Sicorten® cream and ointment may be considered as most suitable for treating patients with chronic plaques of psoriasis.

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