Calcipotriol Open Trial in Psoriasis in Dammam Central Hospital (D.C.H.) Eastern Province (E.P.), Kingdom of Saudi Arabia (K.S.A.)

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SUMMARY

Twenty-five patients with psoriasis whose PASI score varied between 21.6 and 0.8 were treated with topical calcipotriol (Daivonex, Leo). Forty-eight percent had excellent results and 36% had very good to good response. The side effects reported such as erythema, itching and soreness are less than those reported with other topical treatments. Calcipotriol proved to be safe and effective in treatment of localized plaque type psoriasis.

Introduction

The prevalence of psoriasis in Western Europe varies between 1.3-3%. In Norway, it is 4.8% and reaches 2% in the United Kingdom (U.K).[1] The hospital attendance for psoriasis in eight different centres in U.K. showed an average of 5.6%.[2]

The diagnosis of psoriasis is simple because of its classic presentation. Invariably clinicians face some difficulty in diagnosing early erythrodermic, arthropathic, and pustular psoriasis. Psoriasis is sometime confused with seborrhoeic dermatitis, candidiasis, tinea, lichen planus, chronic eczema, drug eruption, and secondary syphilis. Current thoughts about aetiopathogenesis of psoriasis deal with its genetic aspects, the provocating factors, the pathophysiology, the nature of the primary defect, the effect of cytokines and the role of activated keratinocytes.[3]

The interaction between T-lymphocytes and keratinocytes together with the close relationship between the epidermis and dermal vascular endothelium have central role in psoriasis pathophysiology.[4]

In Dammam Central Hospital, an open trial to treat psoriatic patients was carried out using Daivonex ointment. This ointment contains calcipotriol which is a vitamin D3 analogue (Mc903) developed for topical application in the concentration of 50 McG/ML. Calcipotriol ointment proved effective and safe in treating psoriasis.

Patients and Methods

Thirty-three psoriatic patients were included in the trial which was carried out from November 1991 till April 1992.

Eighty-four percent of the patients who completed the trial responded with a variable degree of improvement. Each patient had a first, second and third visit sheet. In the first visit, the patients' condition was assessed and the degree of psoriasis was estimated according to psoriasis area and severity index (PASI score).

Daivonex was applied twice daily and was not combined with any other psoriasis therapy whether local or systemic. The ointment was not applied to the face or flexures and the amount used per week did not exceed 100 grams. In every visit, patient's opinion about effectiveness of treatment, any side effects of the drug, PASI score measurement, and the percentage of improvement were all recorded. Patients were encouraged to check weekly in order to discover any side effects early. Some patients continued to come for follow up for 14 to 18 weeks.

Results

The 33 patients who entered the trial were 21 males (63.6%) and 12 females (36.4%). Twenty-five patients completed the trial (15 males and 10 females). Eight failed to report (six males and two females).

In the first week, 31.8% responded to the treatment, while 22.7% responded in the second week, and by the fourth week 81.7% of the patients showed improvement (Table 1). Twenty patients of the 22 who responded (90%) had maximal response between first and eight weeks. Two patients (10%) had their maximal response between fourth and eleventh weeks or eighth and 12th weeks respectively.

Tabel 1. Week of early response

Week of treatment	Patient with early response	
	No.	Percentage
1	7	31.8
2	5	22.7
3	1	4.5
4	5	22.7
5	1	4.5
6	1	4.5
7	1	4.5
Between 4 & ll	1	4.5
Total	22	99.7

Table 2. Percentage of improvement

Percentage of Improvement	Number of patients and their percentage to the total		Male	Female
	No.	%		
90-100	12	48	7	5
80-89	4	16	2	2
70-79	-	-	-	-
60-69	3	12	1	2
50-59	2	8	1	1
40-49	1	4	1	-
0	3	12	4	-
Total	25	100	15	10

The following scale was used to assess the response to treatment:

90-100%: excellent, 60-89%: very good, 50-59%: good, 40-49%: poor, 0: no response. The degree of maximal response varied. Forty-eight percent had excellent results, 28% had very good response, 8% had good result, and 4% poor results. The total excellent to good resuls comprised 84% of the group (Table 2). Three patients (12%) failed to respond (Table 3).

Among the patients who came for follow up, five patients (22.7%) were free till 12th week. Three patients (13.6%) were free at 14th week. Two patients (9.11%) were free at 18th week. 22.7% of the patients got recurrence while off treatment between the seventh and twelfth weeks.

The main side effects were erythema in 40%, itching in 20% and soreness in 12% of the patients.

Discussion

Local treatment of psoriasis includes tar

Table 3. Non responders

Serial No. of patients	Age in Years	Sex	Psoriasis duration in years	Site affected	PASI SCORE	Main side effect
4	45	M	2	Lower Limb	.8	Pain, redness, itching
20	13	M	1	Scalp, upper limb, trunk, lower limb	2.4	None
24	45	M	20		24.4	None

therapy, dithranol and corticosteroides. Topical cytostatic agents were used as nitrogen mustard 0.01-0.05% which causes contact dermatitis in 80% of cases. Thiotepa 0.4% under occlusion carries the risk of leukaemia. Fluorouracial 5% can clear psoriasis but may produce necrolysis of the epidermis or cause dermal inflammation. Topical methotrexate gel containing penetration enhancer has been tried.

Other local treatment includes phototherapy using UVB or local PUVA. Occlusive dressing alone has been also recommended with good results.

Calcipotriol is vitamin D analogue and has an affinity for vitamin D receptors of the epidermal keratinocytes. It is as effective as the active form of Vitamin D (1, 25 dihydroxycholecalciferol i.e. 1,25 dihydroxy vitamin D3), but it has a very low calcemic effect in vivo. It is 200 times less active than vitamin D3 in raising calcium level in serum and urine because calcipotriol is rapidly metabolized into products of reduced biological activity. Calcipotriol has been shown ot inhibit DNA synthesis.[5,6] Calcipotriol is believed to inhibit proliferation and induce differentiation of keratinocytes. It is a potent inhibitor of human interleukin-1-induced proliferation.[7] Calcipotriol does not affect functions produced by interleukin-2 and tumor necrosis factor.[8]

Calcipotriol has been shown to be superior to betamethasone 17-valerate ointment for treatment of mild to moderate psoriasis.[9]

In the present study, 25 patients whose PASI score varied between 21.6 and 0.8 were treated with topical calcipotriol. The drug was effective and well tolerated. Forty-eight percent had excellent results and 36% had very good to good response. The side effects reported such as erythema, itching and soreness are less than those reported with other topical treatments. Calcipotriol used over the course of one year was safe and provided effective control of psoriasis with no significant laboratory abnormality.[10] In our opinion, this drug is a step forward in topical therapy of psoriasis, particularly localized plaque type, where it proved to be safe and effective.

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