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Topical Calcipotriol (MC 903) for Psoriasis: A Clinical Study

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Calcipotriol, a non-calcemic vitamin D3 analogue, inhibits the proliferation and is necessary for final differentiation of keratinocytes. The aim of the present study was to determine the efficacy and tolerability of calcipotriol ointment in patients treated for 6 weeks. Twenty patients with chronic plaque-type psoriasis were treated twice daily with calcipotriol ointment 50 ng/g. After 6 weeks' treatment there was a marked and statistically significant decrease in the PASI score values for 17 patients, no improvement was seen in 1 patient and local adverse events occurred in 2. Hypercalcemia or other laboratory abnomalities did not develop in any patient. ***Key words: vitamin D3; psoriasis; calcipotriol.***

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Psoriasis is a very common skin disorder with increased epidermal cell proliferation and incomplete terminal differentiation of the keratinocytes.

Recent studies have shown that 1,25(OH)2-D3, the hormonally active form of Vitamin D3, inhibits the proliferation and is necessary for final differentiation of keratinocytes (1, 2). The systemic and topical administration of 1,25(OH)2-D3 may however cause a high frequency of side effects on calcium/phosphorus metabolism (hypercalcemia and/or hypercalciuria) (3, 4).

Calcipotriol (MC 903) is a Vitamin D3 analogue which is at best 1/100th as active as 1,25(OH)2-D3 in causing hypercalcemia and hypercalciuria, even though it seems to act through the same mechanism and has the same clinical efficacy (5–8).

The aim of the present clinical study was to evaluate the efficacy and tolerability of topical Calcipotriol in patients with chronic plaque-type psoriasis.

PATIENTS AND METHODS

Twenty patients (13M/7F) with psoriasis vulgaris, mean age 52 years (range 20–67) were studied. The mean duration of the disease was 10 years (range 1–26 years). All the patients had slight or moderate chronic plaque-type psoriasis with PASI (Psoriasis Area and Severity Index) scores between 5.1 and 17.1 (mean 9.53). Exclusion criteria were: pustular and erythrodermic psoriasis or a rapidly worsening type; patients who had been treated with systemic, intralesional or ultraviolet irradiation therapy in the last 2 months or with topical therapy except bland emollients in the last 2 weeks before therapy; pregnancy or lactation; patients with basal serum hypercalcemia or abnormalities of liver and kidney function. No patients was taking calcium and/or Vitamin D tablets.

After a wash-out period of 2 weeks, the patients were treated twice daily for 6 weeks with topical calcipotriol ointment (50 μg/g) (Formenti, Milan, Italy). The psoriasis was evaluated by the same physician at weeks 0, 2, 4, 6, 10 and routine blood analyses (plus calcemia, phosphoremia) and evaluations of the PASI scores were done at each visit. Overall evaluation of efficicacy and tolerability of the medication was made at each visit by both the physician and patients as: 3 = very good, 2 = good, 1 = moderate, 0 = poor, −1 = very poor.

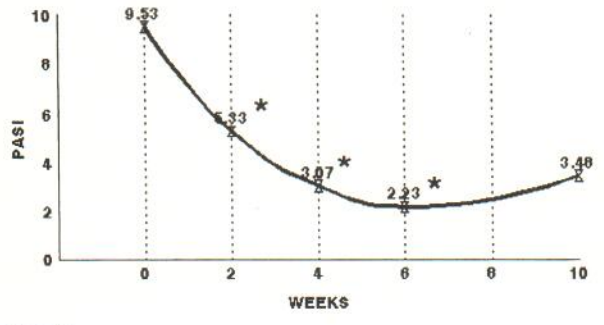
At the end of the treatment the condition of the patients was evaluated after a follow-up period of 4 weeks.

RESULTS

18 of 20 patients (90%) completed the study. 2 patients interrupted the treatment, one because of aggravation of the skin lesions and another because of increased erythema and development of vescicles where the drug was applied.

Treatment with Calcipotriol ointment resulted in a marked and statistically significant ($p < 0.0005$) decrease in the PASI score (Fig. 1) (mean PASI score 9.53 at TO to 2.23 at T6) in 17/18 patients. No improvement of the skin lesions was seen in 1 patient after 6 weeks.

During the therapy, progressive reduction of desquamation was noted, followed by decreased erythema and infiltration (Fig. 2). After 4 weeks of follow-up (T10), PASI score values were



*, p < 0.0005

Fig. 1. Calcipotriol (MC903) for Psoriasis. PASI.

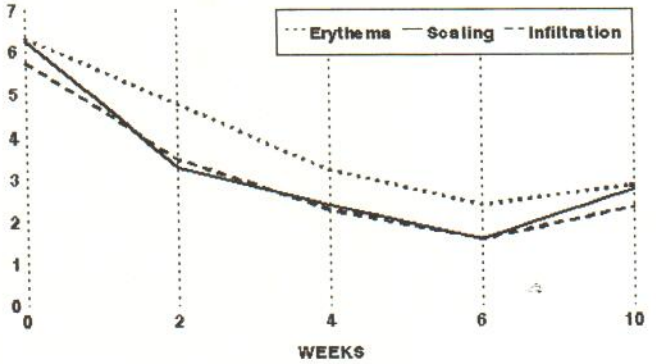


Fig. 2. Calcipotriol (MC903) for Psoriasis. Erythema, Scalling, Infiltration.

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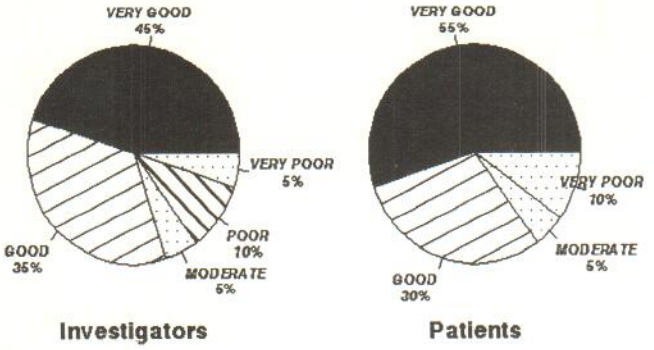

Fig. 3. Calcipotriol (MC903) for Psoriasis. Efficacy and Tolerability Evaluation.

slightly higher (T10=3.48) than at T6 (2.23). Although there was a slight increase in the PASI scores during the follow-up period, the decrease at T10 from T0 was still markedly and statistically significant.

The investigator's assessment of efficacy and tolerability was: very good for 9 cases (45%), good for 7 (35%), moderate in 1 case (5%), poor in 2 cases (10%) and very poor in 1 case (5%). The patient's assessment was: very good in 11 cases (55%), good in 6 (30%), moderate in 1 case (5%), but very poor in 2 cases (10%) (Fig. 3).

No patient had significant changes in routine blood analyses, calcemia or phosphoremia.

DISCUSSION

Our data confirm the efficacy of topical calcipotriol treatment for chronic plaque-type psoriasis. Positive results were obtained in 85% of the patients, unsatisfactory results in only 15%. One patient did not respond to the treatment and 2 developed local side effects (erythema and aggravation of the dermatosis).

The assessment of efficacy and tolerability by the investigator was: positive in 85% of the cases, while the patients' assessments were: positive in 90% of the cases.

No patient showed any systemic side effects.

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