Response of patients with moderate plaque type psoriasis to calcipotriol – a Sri Lankan experience

D Bandara[1] and D N Atukorala[2]

Sri Lanka Journal of Dermatology, 1999 - 2000, **4**, 28-30

Introduction

Many studies have shown that topical application of calcipotriol is an effective option for the treatment of mild to moderate psoriasis[1,2]. It has been shown to be significantly superior to a placebo[1] and to topical dithranol[1,3], and of equal efficacy to betamethasone[4,5]. The chief adverse effects reported has been lesional, perilesional and facial irritation[4,5]. In studies from the west these events occured in around 20% of patients[5]. In a previous study done in Sri Lanka, calcipotriol was found to be an effective therapy for mild to moderate psoriasis and it was at least as effective as topical dithranol[6]. This study did not show any irritant reactions to calcipotriol.

Objectives of the study

Very few studies are available about the efficacy and the adverse effects of topical Calcipotriol on the pigmented skin. This study was undertaken as a part of a similar study being done in various centres to:

A. investigate the efficacy of calcipotriol ointment (50ug/g) in patients of Indian and Sri Lankan origin with psoriasis vulgaris

B. investigate the safety and tolerability of calcipotriol ointment.

Methods

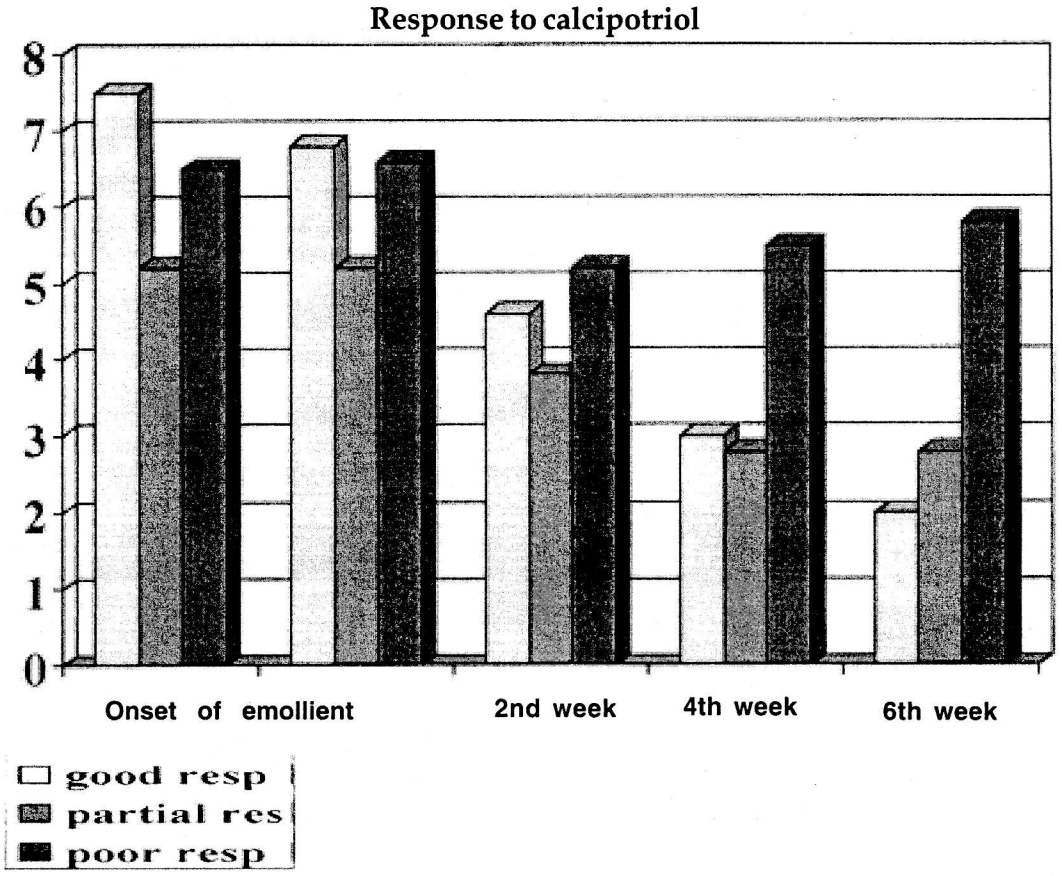
This was undertaken as a prospective, open non-controlled study of treatment with calcipotriol ointment (50ug/g). 50 patients with mild to moderate psoriasis vulgaris, of over 18 years, were recruited to the study from the patients presenting for treatment at the skin clinic at the National Hospital of Sri Lanka. Those on active systemic therapy for psoriasis, and those with marked lesions on the skin folds, face, and scalp, were not included in the study. There was an initial wash out phase of 2 weeks where an emollient ointment was used as the only therapy. This was followed by an open treatment phase were calcipotriol ointment was applied twice daily. During this phase the patients were assessed at 2 weekly intervals and at each visit the severity of the patient's psoriasis was assessed using the Psoriasis Area and Severity Index (PASI). All adverse events during the period of assessment were noted as mild, moderate or severe. The patients were withdrawn from the study, on a voluntary basis, for deterioration of the condition, or unacceptable side effects. A single investigator assessed the patients at each visit.

Results

Only 38 patients completed the study, the others having abandoned the study voluntarily. The ages of the patients ranged from 21 to 72 years, with a mean age of 48. There were 30 males and 20 females. It was made certain that none of the females were pregnant by doing a pregnancy test prior to the trial proper.

24 patients (63%) had a good response to therapy, the PASI score mean falling from a mean of 7.6 (range 18.9 to 3.6) to 1.8 (range 7.6 to 1.8). This was also clinically evident by a marked reduction of the area of involvement and the redness, scaling and thickness of the lesions. 6 patients (15.7%) showed a partial response their mean PASI score falling from 5.0 range (range 7.5 to 3) to 2.7 (range 3.9 to 1.2). 8 patients (21%) showed no improvement at all, the PASI score mean changing only from 5.9 (range 12.6 to 2.7) to 5.5 range 11.5 to 1.8). [Table 1].

[1]*Senior Registrar*, [2]*Consultant Dermatologist, Department of Dermatology, National Hospital, Colombo.*



17 patients (44%) developed adverse reactions in the form of burning or irritation and erythema of the lesional and perilesional skin and in 9 of these the reaction was considered severe. In patients (21%) the treatment had to be terminated due to the severity of the reaction. 1 patient developed a severe pustular and erythematous dermatitis in the lesional and perilesional skin.

Discussion

63% of the patients showed clearing or a good response to therapy with six weeks of topical calcipotriol. Clearing of lesions or a good response was obtained in 40.2% of the patients on twice daily applications of calcipotriol in a comparative study by Kragballe[7], and in 78% of the patients by Beth-Jones[3]. In both these studies the duration of therapy was 8 weeks as compared to the 6 weeks in our study. In the previous Sri Lankan study, which was also over a period of 6 weeks, the mean PASI score fell from 13.77 to 2.06 in the patients treated with calcipotriol[6]. 21% of the patients in this study showed no respone or a worsening of the lesions. The Beth-Jones' study showed a slight or no change response in 13.5% of the patients[3].

44% of the patients in this study developed burning or irritation of the lesional and perilesional skin. This is a known adverse effect with calcipotriol. 34.3% of patients in the study by Kragballe[7] and 20% of patients in the Beth-Jones' study[3], had similar irritant reactions. The figure in our study is particularly high, especially as the previous study from Sri Lanka[6], showed no adverse effects at all. It is difficult to explain the difference in adverse effects in these 2 studies. The irritant reactions were severe in 9 of the patients

and in 8 patients (21%), the reactions were severe enough to withdraw calcipotriol. Only 3.4% of patients in the calcipotriol group in the Kragballe study[7] and 1.2% in the same group in the Beth-Jones study[3], needed to be withdrawn from the studies due to the irritational adverse effects. One of the patients in this study developed a marked irritational reaction with a pustular dermatitis. Facial and flexural irritational reactions were encountered in this study as patients with significant disease in these areas were excluded from the study.

There are many inherent defects in this study. This was an open uncontrolled study. However the treatment responses and the adverse effects can still be considered valid. The drop out of 12 patients for voluntary reasons was far too high. Difficulties in travel and time for follow up, and disturbances in the health delivery system are some of the causes for this. This number of patients finally analysed is too small and the voluntary withdrawals of a number of patients casts doubts on the validity of the conclusions. The high adverse effect numbers need further studies to confirm.

Conclusions

78.7% of patients showed a good or partial response to Calcipotriol. This is in agreement with previous studies. However the irritant reactions of the lesional and perilesional skin was present in 44% of patients in this study compared to 20% and 34.3% in previous studies and no adverse effects in a previous study from Sri Lanka. The irritation was also more severe, 21% of the patients having to stop therapy in this study, compared to 1.2% and 3.4% in previous studies.

References

1. Kragballe K, Beck HI, Soggard H. Improvement of psoriasis by a topical vitamin D3 analogue (MC903). *Br J Dermatol* 1988; **119**: 223-230.

2. Kragballe K. Treatment of psoriasis by the topical application of cholecalciferol novel D analogue (MC903). *Arch Dermatol* 1989; **125**: 1647-1652.

3. Beth-Jones J, Chu AC, Dodd WAH et al. A multicentre, parallel-group comparison of calcipotriol ointment and short-contact dithranol therapy in chronic plaque psoriasis. *Br J Dermatol* 1992; **127**: 266-271.

4. Kragballe K, Gjertsen BT, de Hoop D et al. Double blind righ/left comparison of calcipotriol and betamethasone valerate in the treatment of psoriasis vulgaris. *Lancet* 1991; **337**: 193-196.

5. Cunliffe WJ, Beth-Jones J, Caludy A, et al. A multicentre comparative study of calcipotriol (MC903) ointment and betamethasone 17-valerate ointment in patients with psoriasis vulgaris. *J Am Acad Dermatol* 1992; **26**: 736-743.

6. Perera WDH, Dissanayake SD. Comparison of calcipotriol ointment and dithranol paste in the treatment of psoriasis - a pilot study. *Sri Lanka J Dermatol* 1995; **1**: 4-6.

7. Kragballe K, Barnes L, Hamberg KJ et al. Calcipotriol cream with or without concurrent topical corticosteroid in psoriasis: tolerability and efficacy. *Br J Dermatol* 1998; **139**: 649-654.