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EFFICACY OF TOPICAL CALCIPOTRIOL IN THE MANAGEMENT OF CHRONIC PLAQUE PSORIASIS

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Abstract:

Introduction *Calcipotriol ointment (DAIVONEX) has been shown to be effective in the treatment of chronic plaque psoriasis.*

Aim: *To evaluate the efficacy and safety of calcipotriol ointment (50 µg / g) in the treatment of chronic plaque psoriasis.*

Patients and Methods: *A prospective, non-controlled, open clinical trial of calcipotriol ointment (50µg/g) was conducted in the department of Dermatology, Bahawal Victoria Hospital, Bahawalpur for one-year duration from July 2019 to July 2020. A total of 61 patients (39 male, 22 females, aged 18 to 76 years) with chronic plaque psoriasis were enrolled in an open-label, prospective study. 51 completed the study. Calcipotriol ointment was applied twice daily for up to 6 weeks to the lesion area, after a 2-week washout phase with liquid paraffin. Efficacy, as measured by the Psoriasis Severity Index (PASI), and safety were assessed at 2, 4 and 6 weeks.*

Results: *The reduction in PASI was statistically highly significant at all visits. Mean PASI decreased from 10.47 to 2.18 over 6 weeks ($p < 0.001$). An analysis of the patient evaluation after 6 weeks showed total body clearance in 8% of patients and a marked improvement in 71% of patients. Serum calcium levels remained unchanged.*

Conclusion*: Topical application of 50 µg / g calcipotriol ointment was found to be effective and safe in the treatment of chronic plaque psoriasis.*

Key words: *Calcipotriol (DAIVONEX), psoriasis treatment, PASI*

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INTRODUCTION:

Calcipotriol is a synthetic vitamin D3 analogue which has high affinity for the calcipotriol cell receptor; is a potent regulator of cell differentiation and an inhibitor of cell proliferation in human keratinocytes2. It is effective as a topical treatment for chronic plaque psoriasis. It is as effective or even more effective than 0.1% betamethasone 17-valerate ointment5,6 and more effective than short-term dithranol therapy in plaque psoriasis. The aim of this study was to evaluate the therapeutic efficacy, local and systemic safety. and tolerance of the application of calcipotriol ointment 50 µg / g twice daily in the treatment of chronic psoriatic plaque on the skin.

PATIENTS AND METHODS:

A prospective, non-controlled, open clinical trial of calcipotriol ointment (50µg/g) was conducted in the department of Dermatology, Bahawal Victoria Hospital, Bahawalpur for one-year duration from July 2019 to July 2020. Sixty-one outpatients (39 men, 22 women), aged 18-76 (mean age 41.10) who suffered from chronic plaque psoriasis and completed the study. Patients were required to submit a signed consent. The exclusion criteria were: acute guttate, pustular or erythrodermic psoriasis, unstable washout psoriasis, systemic anti-psoriasis treatment or ultraviolet therapy in the 16 weeks prior to the study, pregnancy, willingness to become pregnant during the study period or a nursing mother, concomitant treatment with> 400 iu vitamin D daily, calcium tablets or other medications that may influence the course of the disease (e.g. lithium, beta-blockers, captopril, thiazide diuretics), renal and hepatic dysfunction and hypercalcemia. The first phase of the study was a 2-week washout period during which patients used white soft paraffin as emollient twice daily. If psoriasis remained stable, patients continued to apply topical calcipotriol ointment twice daily for up to 6 weeks to the injured area except the head and skin folds. The maximum quantity allowed is 100gm / week. Topical use of low-potency steroids has been recommended to treat lesions of the head or skin folds. Patients were assessed at study start and every two weeks during the treatment phase. At each visit, the investigator assessed the extent (grade 0-6) and severity of psoriasis (grade 0-4) with scaling using a modified Psoriasis Area and Severity Index (PASI) 8 scoring system (Table 1). The assessed areas are the trunk and limbs. The head was excluded from the evaluation. Overall efficacy assessments were made by the investigator and the patient after 2, 4 and 6 weeks of treatment using a six-point scale (Table 1). The overall cosmetic acceptability assessment was performed by the patient at week 6 (Grade 1-5; Table 1). Blood samples for serum calcium levels were assessed at the beginning and end of treatment.

RESULTS:

Sixty-one patients (39 men, 22 women) entered the study. The mean age was 41.1 years (range 18 to 76 years). Ten patients withdrew from the study (4 default, 3 unacceptable responses, 3 adverse events). There was a statistically significant reduction in the mean (+ SD) PASI, which fell from 10.47 + 4.24 at the start of treatment to 2.18 + 0.54 at the end of treatment ($p < 0.001$).

Table 1 Parameters assessed in this study

Assessment of extent of psoriasis	
0.	No involvement
1.	< 10%
2.	10-29%
3.	30-49%
4.	50-69%
5.	70-89%
6.	90-100%
Assessment of severity of psoriasis (erythema, thickening, scaling)	
0.	Absent
1.	Slight
2.	Moderate
3.	Severe
4.	Very severe
Overall efficacy assessment	
1.	Worse
2.	No change
3.	Minimal improvement
4.	Moderate improvement
5.	Marked improvement
6.	Cleared
Assessment of acceptability	
1.	Very poor
2.	Poor
3.	Acceptable
4.	Good
5.	Excellent

Of the patients who completed the study, complete clearance of psoriasis (PASI score reduced to zero from baseline) was achieved in 8% of patients after treatment discontinuation. Clear, moderate, and minimal improvement was observed in 71%, 9%, and 7% of patients, respectively.

Table 2 PASI score during the 6 weeks of treatment phase

Baseline	10.47 ± 4.24
2 weeks	5.92 ± 3.12
4 weeks	3.15 ± 1.42
6 weeks	2.18 ± 0.54

Exacerbation of psoriatic lesions in 3% and no psoriasis in 2% of patients. The cosmetic tolerance of calcipotriol ointment was found to be good or excellent in 88% of patients. Fifteen patients reported side effects, the most common of which was local irritation (8 patients), which was mild and transient. After the end of treatment, all patients had normal calcium levels.

DISCUSSION:

Twice daily 50 µg / g calcipotriol ointment for 6 weeks resulted in complete resolution of psoriasis (PASI score reduced to zero from baseline) at the end of treatment in 8% of patients. Our results showed that there was a marked improvement in lesions in approximately 71% of patients (Fig. 1). These results are similar to those obtained previously. There was a very significant reduction in the mean PASI at each

visit compared to baseline. The fastest reduction occurred within the first 2 weeks of treatment (Fig. 2 and Table 2), which is comparable to other studies. The maximum reduction in mean PASI found after 6 weeks, which was also noted by other investigators. No serious adverse events have been reported or observed. Some skin irritations with lesions and cuts were not uncommon. In our study, approximately 16% of patients experienced irritation, which was also noted in other studies. Psoriasis exacerbation during treatment in three patients and no change in psoriasis lesions in one patient (Fig. 1). In the present study, ten patients withdrew from the study; four failed, three were unacceptable responses, and three had adverse events. At the end of treatment, overall acceptance was good to excellent in 88% of patients. Serum calcium levels remained within the normal range for all patients in our study, and no significant changes in serum calcium levels were noted in numerous studies. Studies with calcipotriol have shown that there is no risk of hyperglycaemia with up to 100 g (50 µg / g) per week. In summary, this open-label study showed that administering calcipotriol ointment at 50 µg / g twice daily is safe and well-tolerated in the treatment of chronic plaque psoriasis.

REFERENCES:

1. Ara, Shamim, Mohammad Rafiqul Mowla, Mansurul Alam, and Md Ismail Khan. "Efficacy of oral methotrexate monotherapy vs oral methotrexate plus narrow band UV-B phototherapy in palmo plantar psoriasis." *Dermatologic Therapy* (2020): e13486.
2. Bahramizadeh, Mahdiyeh, Maryam Bahramizadeh, Bita Kiafar, Amir Hossein Jafarian, Amin Reza Nikpoor, Mahdi Hatamipour, Habibollah Esmaily et al. "Development, characterization and evaluation of topical methotrexate-entrapped deformable liposome on imiquimod-induced psoriasis in a mouse model." *International journal of pharmaceutics* 569 (2019): 118623.
3. Afreen, Humaira, AKM Shariful Islam, Mohd Nurul Alam, Farzana Afroz, and Tahmina Sultana. "A comparative study of once daily tazarotene versus combination of tazarotene and betamethasone valerate in the treatment of plaque psoriasis." *Journal of Pakistan Association of Dermatology* 29, no. 1 (2019): 93-100.
4. Boutin, Joël, Marie-France Côté, Martin Perreault, René C. Gaudreault, and Stéphane Gobeil. "Chapitre 3. PcAU-1003 improves the psoriatic phenotype in a human reconstituted skin model of psoriasis and in an imiquimod-induced psoriasis mouse model." *Contribution à l'étude des phényl cycloalkylurées, une nouvelle classe de molécules anti-inflammatoires à potentiel anti-psoriasique*: 120.
5. Stone, P. Michael. "The Skin, Selected Dermatologic Conditions, and Medical Nutrition Therapy." In *Integrative and Functional Medical Nutrition Therapy*, pp. 969-1002. Humana, Cham, 2020.
6. Thandar, Yasmeen, Rivesh Maharajh, Firoza Haffejee, and Anisa Mosam. "Treatment of cutaneous lichen planus (Part 1): A review of topical therapies and phototherapy." *Cogent Medicine* 6, no. 1 (2019): 1582467.
7. Gaikwad, Juilee, Sanjay Sharma, and Ketan V. Hatware. "Review on Characteristics and Analytical Methods of Tazarotene: An Update." *Critical Reviews in Analytical Chemistry* 50, no. 1 (2020): 90-96.
8. Hicks, Siobhan. "Examination of the Skin, Hair, and Nails." *Physical Assessment for Nurses and Healthcare Professionals* (2019).
9. Menaa, Farid. "Recent Highlights and Expert Opinion on Psoriasis Management." *J Dermatol Res*.
10. Türsen, Ümit, and Belma Türsen. "Retinoids in Keratinization Disorders." *Retinoids in Dermatology* (2019): 43.
11. Alinaghi, Farzad, Monika Calov, Lars Erik Kristensen, Dafna D. Gladman, Laura C. Coates, Denis Jullien, Alice B. Gottlieb et al. "Prevalence of psoriatic arthritis in patients with psoriasis: A systematic review and meta-analysis of observational and clinical studies." *Journal of the American Academy of Dermatology* 80, no. 1 (2019): 251-265.
12. Schoch, Jennifer J., Jordan Russell, Nicole Miranda, Eric W. Triplett, J. Lauren Ruoss, and Josef Neu. "Society for Pediatric Dermatology 44th Annual Meeting Poster Presentations July 2019| Austin, Texas." (2019).
13. Martinez, José L., Amner Muñoz-Acevedo, and Mahendra Rai. "ETHNOBOTANY." (2019).
14. Carreño-Gayosso, Ehekatzin Arturo, and Marco Antonio Rodríguez-Castellanos. "Porokeratosis: an update." *Dermatología Revista Mexicana* 63, no. 4: 373-387.
15. Carreño-Gayosso, Ehekatzin Arturo, and Marco Antonio Rodríguez-Castellanos. "Poroqueratosis: actualización." *Dermatología Revista Mexicana* 63, no. 4 (2019): 373-387.