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Patient Satisfaction with Calcipotriol/ Betamethasone Dipropionate Cream in Psoriatic Patients Previously Treated With Foam Vehicle

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ABSTRACT

Introduction: Topical therapy is the first-line treatment for mild-to-moderate psoriasis, and guidelines recommend the combination of calcipotriene and betamethasone dipropionate (Cal/BD) as the preferred option, with its wide range of available formulations.

Objectives: The aims of this study were to assess the preference for Cal/BD cream in a group of patients previously treated with Cal/BD foam spray and to evaluate their satisfaction with the treatment.

Method: We conducted a prospective observational study on psoriatic patients treated with Cal/BD cream who had used Cal/BD foam in the previous three months. After four weeks of treatment, the comparison between the cream and the previous treatment with the foam was evaluated by a Patient Preference Questionnaire (PPQ) . Additionally, patient satisfaction was evaluated through Psoriasis Treatment Convenience Scale (PTCS) and the Topical Therapy Adherence Questionnaire (TTAQ).

Results: Thirty patients with mild-to-moderate psoriasis were enrolled. After 28 days of treatment, PASI, BSA, and DLQI scores showed significant improvement ($P<0.03$). According to the Patient Preference Questionnaire (PPQ), 24/30 patients found Cal/BD cream overall preferable to the Cal/BD foam formulation. Moreover, PTCS and TTAQ questionnaires found a very high level of satisfaction with the cream.

Conclusion: These findings suggest that Cal/BD cream represents a valuable therapeutic option for patients starting topical treatment thanks to its high cosmetic acceptability.

Introduction

Psoriasis is a chronic relapsing inflammatory skin disease that affects approximately 1–5% of the Western population and represents a well-documented source of reduced physical and psychological well-being for patients [1]. The choice of treatment is primarily based on the assessment of disease severity, which is evaluated, both in clinical practice and in trials, using scoring systems that evaluate the characteristics and the extent of the skin involvement (Psoriasis Area and Severity Index (PASI) and Body Surface Area (BSA)) and the impact on quality of life (Dermatology Life Quality Index (DLQI)) [2].

In recent years, there has been growing interest in the treatment of psoriasis, largely driven by the relatively recent introduction of systemic biologic agents for the management of severe disease forms. While these therapies are essential for the optimal control of extensive psoriasis and for mitigating the burden of well-known systemic comorbidities, topical medications often remain the first-line approach for patients with mild-to-moderate manifestations and are highly valuable in synergistic combination with systemic therapies to manage residual manifestations [1,3,4]. Topical therapies for psoriasis include a wide range of solutions, including emollients, keratolytics, coal tar derivatives, which were historically used but have largely been abandoned in clinical practice, topical calcineurin inhibitors (TCIs), topical Roflumilast (not available in Italy), Tapinarof 1% cream (not available in Italy), vitamin D derivatives (VDs), corticosteroids (CS), and fixed combinations of corticosteroids and vitamin D derivatives (CS/VD) [1,5,6]. In particular, the fixed combination of 0.005% calcipotriene hydrate, a synthetic vitamin D3 analog, and 0.064% betamethasone dipropionate (Cal/BD), a synthetic corticosteroid, is currently very common in clinical practice and highly recommended by several guidelines as first choice topical treatment because it has been particularly proven to be effective and safe in clinical trials [7,8].

Recently, a new technology called polyaphron dispersion (PAD™) has made it possible to encapsulate these active ingredients in microscopic lipid droplets suspended in an aqueous vehicle [9]; a new Cal/BD formulation in a cream base was then developed [10]. Although this technology appears promising in terms of patients' cosmetic preference for treatment, direct comparative trials with other Cal/BD vehicles are lacking, although some authors have performed indirect or split-body comparisons [11,12,13].

Objectives

The aims of this study were to assess the preference for Cal/BD cream in a group of patients previously treated with Cal/BD foam spray and to evaluate their satisfaction with the treatment.

Methods

We conducted a prospective observational study including adult patients diagnosed with mild-to-moderate psoriasis starting a topical monotherapy with Cal/BD cream at the clinics of the Institute of Dermatology and Venereology of the A. Gemelli University Hospital Foundation IRCCS, Rome. Additionally, patients had to have applied Cal/BD foam in the previous three months, with a 30-day wash-out period.

Patients with palmoplantar, inverse, erythrodermic, guttate psoriasis, or scalp psoriasis were not eligible to participate. Furthermore, females who were pregnant or planning a pregnancy as well as patients with disabilities or other motor issues that may complicate self-medication were excluded.

Enrolled patients were prescribed Cal/BD cream for 28 consecutive days and were instructed to complete a clinical diary to confirm the daily application of the medication.

Clinical and demographic characteristics of the patients were collected (age, sex, BMI, comorbidities, family history of psoriasis, disease duration, previous treatments). Patients were clinically evaluated at baseline and after four weeks of treatment using the PASI, the BSA, and the Dermatology Life Quality Index (DLQI) to assess the impact on quality of life. After four weeks of treatment, cosmetic preference and tolerability were assessed using some questionnaires. In detail, the comparison between the cream and the previous treatment with the foam was evaluated by Patient Preference Questionnaire (PPQ) [14]. This consists of 10 items, with items 1–5 focusing on comparisons with previous topical therapies and items 6–10 addressing comparisons with systemic therapies. For this study, we analyzed only the results related to the first five questions, investigating the preference for various aspects (effectiveness, ease of use, side effects, tolerability, and overall preference) of the current topical therapy over the previous one. Each item could be rated as follows: 0 = "not at all true," 1 = "not entirely true," 2 = "somewhat true," 3 = "completely true," or marked with an additional checkbox labeled "not applicable." For the interpretation of this questionnaire, responses rated as 2 and 3 were cumulatively classified as 'agreement'.

Additionally, patient satisfaction with the treatment was evaluated through Psoriasis Treatment Convenience Scale (PTCS) and Topical Therapy Adherence Questionnaire (TTAQ) questionnaires [14, 15]. The PTCS questionnaire comprises six questions addressing different aspects of product use: ease of application (Question 1), the greasy sensation during application (Question 2), emollient properties (Question 3), the greasy sensation after application (Question 4),

the extent to which product application interferes with daily activities (Question 5), and overall satisfaction (Question 6). Patients rate each question on a scale from 1 (not satisfied) to 10 (very satisfied).

The TTAQ questionnaire comprises 59 items divided into three sections: "benefits for the patient," "knowledge, communication, and relationship with the physician," and "therapeutic satisfaction." Each item, which highlights various positive aspects of the undertaken therapy and the physician's communication regarding it, can be rated as follows: 0 = "not at all true," 1 = "not entirely true," 2 = "somewhat true," 3 = "completely true," or marked with an additional checkbox labeled "not applicable."

Throughout the treatment period, patients were monitored for any side effects.

Continuous variables are expressed as median with interquartile range (IQR), while categorical variables are reported as absolute frequencies, expressed as fractions, and relative frequencies, expressed as percentages.

Comparison of clinical scores (PASI, BSA and DLQI) between baseline and after four weeks of treatment was performed with the Wilcoxon signed-rank test. The results were considered statistically significant at $P< 0.05$. STATA/BE 18.0 Software (StataCorp, Texas) was used for the analysis.

The present study was conducted in accordance with the principles outlined in the Declaration of Helsinki (WMA, 2013) and received approval from the Institutional Ethics Committee of Lazio Area 3 with protocol ID n.6131. The patients included in the study signed a written informed consent and were able to withdraw their consent at any time.

Results

We enrolled 30 patients with psoriasis who met the inclusion and exclusion criteria. The study population consisted of 17 males and 13 females, with a median age of 57.0 years (IQR 44.0 – 64.8), a disease duration of 15.0 years (9.0 – 21.0), and a median BMI of 25.8 kg/m² (23.2 – 28.2). At baseline, the PASI was 6.0 (4.2 – 10.0), the BSA was 5.0 (3.0 – 7.0), and the DLQI was 4.0 (2.8 – 8.3), while the most frequently affected body areas were the knees (n = 17) and elbows (n = 12). None of the patients had significant comorbidities in their medical history.

After 28 days, the treatment was generally well-tolerated, with only one patient (n=1) reporting skin burning at the application site as an adverse event. According to the clinical diary, the median number of applications was 25.0 (22.0 –26.0) days. At the end of this period, the median PASI, BSA, and DLQI statistically improved ($P<0.0001$, $P<0.001$, $P<0.03$, respectively). All demographic characteristics and their respective clinical scores before and after therapy are reported in Table 1.

Table 1. Clinical and Demographic Characteristics Before and After Cal/BD Cream Application. Data are expressed as sample median with interquartile range.

	Baseline	At week 4
Age (years)	57.0 (44.0 – 64.8)	
Disease duration (years)	15.0 (9.0 – 21.0)	
BMI (kg/m²)	25.8 (23.2 – 28.2)	
PASI	6.0 (4.2 – 10.0)	2.0 (0.0 – 4.5)
BSA	5.0 (3.0 – 7.0)	2.0 (0.3 – 3.5)
DLQI	4.0 (2.8 – 8.3)	2.0 (1.0 – 6.5)

Abbreviations: BMI: body mass index; BSA: body surface area; DLQI: Dermatology Life Quality Index; PASI: Psoriasis Area and Severity Index.

Table 2. Patients' Preference for the Cal/BD Cream Treatment Over the Previous Treatment With Foam by PPQ Items.

PPQ Item	Patients in agreement/ strong agreement n/N (%)
Cal/BD cream treatment versus previous foam treatment	
1 – 'More effective'	22/30 (73.3)
2 – 'Easy to use'	25/30 (83.3)
3 – 'Fewer side effects'	19/30 (63.3)
4 – 'Better tolerability'	22/30 (73.3)
5 – 'Overall preference'	24/30 (80.0)

Abbreviation: PPQ : Patient Preference Questionnaire.

The PPQ questionnaire showed that 24 out of 30 enrolled patients overall preferred the cream to the previous treatment with foam (Table 2). This preference was because patients found the cream "easier to use" (25/30 patients), "more effective" (22/30), and with "better tolerability" (22/30). Minor differences among the two vehicles were found by patients for side effects (19/30 patients preferred the cream).

Moreover, PTCS questionnaire found a very high level of "overall satisfaction" with the cream, as shown by a median score 9.0 (6.3–10.0) for question 6 (Figure 1). This is due mainly to its ease of application (median score 10.0 (9.0–10.0) for Question 1) and a very low impact on daily activities (median score 10.0 (7.3–10.0) for Question 5).

Finally, the median total score for the TTAQ was 123.5 (100.3–143.3), with a mean response per question of approximately 2.1 ± 0.45, corresponding to an agreement with several statements reporting a preference for the treatment.

Discussion

Topical therapies are the mainstay treatment for mild-to-moderate psoriasis [16]. However, these therapies are often

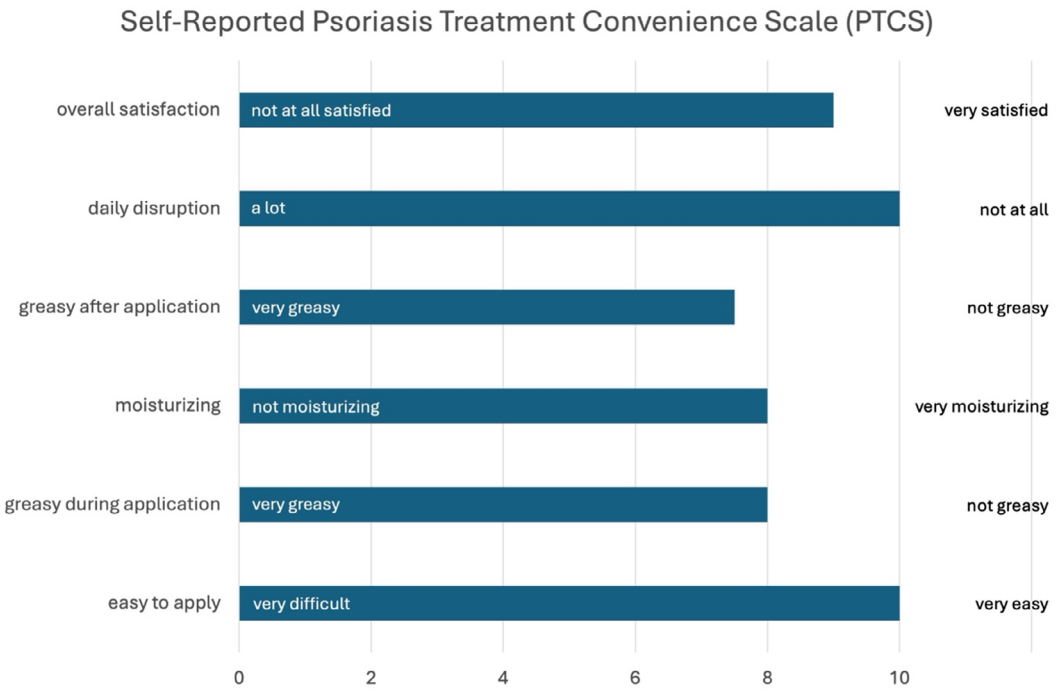

Figure 1. Psoriasis Treatment Convenience Scale (PTCS) median values.

associated with poor patient adherence, both during active disease and maintenance phases, leading to decreased clinical outcomes and reduced quality of life [17,18]. Adherence is influenced by multiple factors, including related to the patient, to the physician, and to the treatment characteristics. In this context, understanding patient preferences regarding the vehicle of the topical medication—both in terms of its pleasantness and its impact on daily activities—is a crucial factor for the prescribing physician to achieve a satisfactory therapeutic response. The key characteristics of topical products that patients consider most important include strong emollient properties, quick drying/absorption without leaving residues, a non-greasy or oily texture, and being fragrance-free [19].

Our primary objective was to assess patient preference for Cal/BD cream over a previous treatment with the Cal/BD foam using the PPQ questionnaire. As highlighted, the majority of patients preferred the cream vehicle over the foam because they considered it more effective, easier to use, and more tolerable.

At present, randomized clinical trials directly comparing Cal/BD cream and foam formulations are lacking. Indirect analyses have been conducted, such as in the study by Reich A et al., where overall treatment satisfaction after one week of application was significantly higher for the Cal/BD cream vehicle compared to Cal/BD foam. Statistically significant differences were observed, as in our study, for the PTCS items "easy to apply," "non-greasy," and "perceived as emollient."[20]

In a single-blind split-body study by Kircik LH et al., foam or cream was applied once to one side of the body of the participants. Data derived from questionnaires indicated an overall preference for the cream formulation, with higher scores for 'ease of application' and 'skin feel.' Notably, consistent with our study in terms of PTCS scores, the investigators observed a preference for the items 'easy to apply,' 'moisturizing,' and 'overall satisfaction.' However, contrary to our findings, they reported a preference for the foam in terms of 'greasy during application.' It should be noted, however, that these results are based on a single application and not on continuous use over time [12].

The superior cosmetic acceptability of the Cal/BD cream may be attributed to PAD technology, an innovative oil-in-water formulation with a drug delivery system consisting of a lipid core surrounded by a multilayered shell made of lipids, surfactants, and water. This contrasts with traditional emulsions, which require higher levels of surfactants [9]. In fact, we found that patients reported a minimal perception of greasiness both during and after application, as indicated by the PTCS questionnaire. This characteristic could promote product use and improve treatment adherence. The data collected through the TTAQ and PTCS regarding mainly the ease of application, moisturizing properties, and overall satisfaction are encouraging and highlight how patients provide positive feedback on the Cal/BD cream [21].

Consistent with patient preferences, the effectiveness and adherence data in our patients are highly positive, showing a significant reduction in PASI and BSA after four weeks and a high rate (>80%) of days with topical treatment application.

Limitations

This study has some limitations. Firstly, the comparison between the cream and foam vehicles was not conducted in a double-blind manner but relied on patients' retrospective experience. Another limitation of the study is that efficacy was not assessed for both vehicles; therefore, no direct comparison between them was performed. Additionally, although the analyzed sample is representative of the general population, its size remains limited. Therefore, further studies with a larger sample are needed to strengthen the findings.

Conclusions

In conclusion, our findings confirm that the Cal/BD cream is well-tolerated, effective, and appreciated by patients, making it a valid alternative to the foam vehicle. However, we believe that there is no single best vehicle to prescribe, and a wide range of available vehicles allows for a more personalized approach. To identify the most suitable topical treatment for each patient will make it possible to improve adherence and, ultimately, to achieve treatment success.

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