



CASE SERIES

# Efficacy of Calcipotriol/Betamethasone Dipropionate Fixed-Combination Aerosol Foam in the Treatment of Localized Scalp Psoriasis: A Real-Life Case Series from Switzerland

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## ABSTRACT

**Introduction:** Scalp psoriasis is one of the most common and challenging manifestations of plaque psoriasis for general practitioners, dermatologists, and patients, as successful topical management requires the choice of effective ingredients, an appropriate formulation, and clear application instructions to patients. To date, only limited experience is available for the calcipotriol (50 µg/g)/betamethasone dipropionate (0.5 mg/g) aerosol foam formulation (Cal/BD foam) in the treatment of scalp psoriasis.

**Methods:** In this Swiss real-world patient case series, we asked 10 consecutive patients with active scalp psoriasis to apply the Cal/BD foam once daily before bedtime for a period of 4 weeks. Clear application and rinse-off instructions were provided.

**Results:** A total of 10 consecutive adult patients were treated between April and May 2019. Two patients suffered from mild, five from moderate, and three from severe scalp psoriasis. In eight out of the 10 patients, scalp psoriasis was the

only manifestation of disease. All patients had received previous topical treatments, mainly topical corticosteroids (TCS), tar shampoo, and salicylic acid. After 4 weeks of treatment with Cal/BD foam, the scalp psoriasis improved in all 10 patients by  $\geq 2$  points on a 5-point severity assessment scale. Eight out of 10 patients achieved clear/almost clear skin after 4 weeks of treatment, with no further keratolytic treatments needed. Adverse events were not observed in any of the patients. Overall, patients were very satisfied with the ease of use, the efficacy, and the safety of the Cal/BD foam.

**Conclusion:** Our case series confirms that Cal/BD foam is a rapid, effective, and convenient treatment for localized scalp psoriasis in a nonselected real-world patient cohort refractory to TCS or other local treatments. Clear application instructions are crucial for treatment success and cosmetic acceptance, however.

**Keywords:** Aerosol foam; Calcipotriol; Betamethasone; Patient instruction; Scalp psoriasis

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### Key Summary Points

Topical management of localized scalp psoriasis is challenging with regards to the choice of ingredients, formulation, and application instructions.

This case series of 10 consecutive patients with mild, moderate, and severe scalp psoriasis mainly refractory to topical corticosteroids (TCS) represents the first data on calcipotriol/betamethasone (Cal/BD) foam use in a nonselected, real-world patient cohort.

Once-daily application of the Cal/BD foam over a period of 4 weeks resulted in rapid, effective, and convenient treatment, with eight out of 10 patients achieving clear/almost clear skin in different severity types of scalp psoriasis.

Clear application and rinse-off instructions were given, as they are crucial for treatment success and cosmetic acceptance.

Further real-world evidence is needed to confirm the efficacy and safety of Cal/BD foam in this patient cohort.

## INTRODUCTION

Psoriasis is a chronic immune-mediated inflammatory skin disease [1] with a worldwide prevalence of up to 2% of the population. Up to 50–79% of patients with psoriasis have scalp involvement [2], and often the scalp is the first or sole manifestation site of psoriasis. Scalp psoriasis presents clinically as varying degrees of erythematous, thick, crusted plaques with dry, silvery scales which are solitary, multiple, or confluent and commonly extend over the hairline [3]. Lesions on the scalp are often difficult to hide, causing patients, embarrassment. In addition, itching, scaling, and loss of hair

have a significant impact on patients' self-esteem and quality of life [2–4].

Topical treatment of scalp psoriasis can be rather challenging [2] due to inaccessibility of the scalp, its proximity to facial skin, cosmetic aspects such as sticky or greasy formulations, and its time-consuming application, impacting patients' adherence [3, 5, 6]. In addition, topicals are usually applied on the scalp overnight only and rinsed off with shampoo in the morning, which can undermine efficacy as well [5].

Current guidelines and consensus papers on the topical management of psoriasis recommend a fixed combination of calcipotriol (50 µg/g) and betamethasone dipropionate (0.5 mg/g) (Cal/BD) (gel or foam formulations) or topical corticosteroids (TCS) of classes III and IV (shampoo or foam formulations) as first-line therapy for mild-to-moderate scalp psoriasis [5, 7, 8].

In Switzerland, the Cal/BD fixed combination is available as an ointment (Daivobet<sup>®</sup>), gel (Daivobet<sup>®</sup> gel, Xamiol<sup>®</sup>), or aerosol foam (Enstilar<sup>®</sup>) formulation. The gel formulation has shown superior efficacy compared to the ointment as well as to each of the components alone in scalp psoriasis [9–11]. The foam formulation was developed with the aim of being more cosmetically acceptable and easier to handle than the ointment and gel. In addition, the supersaturation of fully dissolved active ingredients in the aerosol foam led to increased skin penetration and local bioavailability in the skin, which might enhance efficacy [12].

In psoriasis affecting the trunk and the limbs, the Cal/BD foam has already proven to be superior in its onset of action and efficacy after 4 weeks of treatment compared to both the gel and the ointment formulations, and showed improved application comfort [4, 13–15]. However, only limited evidence is available from a small subset affected with scalp psoriasis in a phase 2 study [4]. Another small case series in three patients with hyperkeratotic scalp psoriasis revealed that descaling with keratolytic agents before the initiation of Cal/BD foam is not necessary [6]. Its easy application and fast and effective onset of action in other psoriasis manifestations predestine the Cal/BD

foam for use in scalp psoriasis as well, but to date only very few case reports corresponding to real-life conditions have been published.

## METHODS

This is a real-world patient case series from a dermatological practice in Switzerland of patients diagnosed with scalp psoriasis. Informed patient consent was obtained from all patients for the anonymized use of patient data and photographs. As all patient files were handled in a completely anonymized form and all data/information were generated in the context of individual patient management, this case series was comparable to a so-called “practice experience report”, for which ethics committee approval was not required in Switzerland.

- *Consecutive patient selection.* All patients with psoriasis and scalp involvement who visited our private practice between April 19 to May 19 and consented to treatment were selected for treatment with the Cal/BD foam. Patients with psoriasis lesions of the scalp of different severity degrees and with various previous topical treatment regimens were chosen to be eligible for Cal/BD foam. Patients requiring systemic treatment were not elected for this case series cohort.
- *Severity assessment* was done using a 5-point grading system (clear, almost clear, mild, moderate, severe) for scalp psoriasis:
  - Clear (0): no signs of psoriasis (post-inflammatory hyperpigmentation may be present)
  - Almost clear (1): only minimal signs of psoriasis (minimal erythema, scaling, no plaque elevation)
  - Mild (2): slight plaque elevation, scaling, and/or erythema
  - Moderate (3): marked plaque elevation, scaling, and/or erythema
  - Severe (4): very marked plaque elevation, scaling, and/or erythema.
- *Treatment instructions* on using the Cal/BD foam:

- Patients were asked to apply Cal/BD foam once a day before going to bed over a 4-week period.
- Clear instructions were given to apply the foam with a finger directly to the localized affected scalp areas and not to spray the foam directly onto the plaques.
- When rinsing off the following morning, patients were told to apply the shampoo to their dry hair first and emulsify before rinsing with water.

## RESULTS

### Patient Characteristics

We enrolled 10 consecutive cases between April and May 2019. Nine out of 10 patients were female, and the mean age was 52 years (range 33–76 years). All patients had received previous topical treatment, including diverse TCS, tar shampoo, or salicylic acid. None of the patients had received systemic psoriasis treatments before inclusion. At inclusion, two patients suffered from mild, five from moderate, and three from severe scalp psoriasis. In eight out of 10 patients, scalp psoriasis was the only manifestation of psoriasis. Further patient characteristics are given in Table 1.

### Efficacy

After 4 weeks of treatment with Cal/BD foam, the scalp psoriasis improved in all 10 patients by  $\geq 2$  points on the 5-point severity scale. Eight out of 10 patients had clear/almost clear skin of the scalp after 4 weeks of treatment, with no further keratolytic treatment needed.

### *Case Series 1: Two Patients with Mild Scalp Psoriasis*

Two female patients with mild scalp psoriasis lesions were treated with Cal/BD foam (Table 1). They were previously treated with zinc pyrithione shampoo or (TCS). After 4 weeks of treatment, clear skin was achieved in both patients.

**Table 1** Characteristics, affected body areas, and outcomes of patients with localized scalp psoriasis before and after 4 weeks of treatment with Cal/BD foam

#	Scalp affected	Other body regions affected	Former treatments	Scalp-PGA week 0	Scalp-PGA week 4
1	X		TCS	Mild	Clear
2	X		Zinc pyrithione shampoo	Mild	Clear
3	X	X	TCS, ciclopiroxolamine shampoo	Moderate	Clear
4	X		Clobetasol, salicylic acid	Moderate	Clear
5	X		TCS, tar shampoo	Moderate	Clear
6	X		TCS	Moderate	Clear
7	X		Ciclopiroxolamine shampoo	Moderate	Clear
8	X	X	TCS, zinc pyrithione shampoo	Severe	Moderate
9	X		Salicylic acid, tar shampoo	Severe	Almost clear
10	X		TCS, selenium disulfide shampoo	Severe	Mild

PGA Physician Global Assessment, TCS topical corticosteroids

### **Case Series 2: Five Patients with Moderate Scalp Psoriasis**

Almost all of the five moderate scalp-psoriasis patients received TCS prior to treatment with the Cal/BD foam—the majority in combination with tar or ciclopiroxolamine shampoo or salicylic acid. Only one of the moderate patient group received only ciclopiroxolamine shampoo before treatment. After 4 weeks of treatment, all patients showed clear skin of the scalp (Fig. 1).

### **Case Series 3: Three Patients with Severe Scalp Psoriasis**

Three female patients with severe scalp psoriasis were previously treated with a combination therapy consisting of TCS or salicylic acid and a tar, zinc pyrithione, or selenium disulfide shampoo. After 4 weeks of treatment with the Cal/BD foam, psoriasis improved by at least 2 points in all those patients, with two of them achieving an almost clear or mild disease status (Fig. 1); only one was still moderate.









### **Safety and Convenience**

Adverse events were not observed in any of the patients. Overall, the patients were very satisfied with the ease of use, efficacy, and safety of the Cal/BD foam.

## **DISCUSSION**

This case series of 10 consecutive patients with mild, moderate, and severe localized scalp psoriasis mainly refractory to previous TCS treatment represents the first data on the use of Cal/BD foam in a nonselected, real-world scalp psoriasis patient cohort. Rapid, effective, and convenient treatment success was observed, with eight out of 10 patients achieving a clear/almost clear scalp after 4 weeks of treatment.

Though the Cal/BD foam formulation may be predestined for use on the scalp, to date, only 66 out 100 patients with psoriasis affecting the trunk, limbs, and scalp have been investigated in a phase 2 program on the Cal/BD foam formulation [4], and none have been investigated in a phase 3 program [14]. Patients with scalp psoriasis as the sole manifestation (eight out of

(A) Before Tx	(B) After 4 weeks Cal/BD foam	Case information
		<p><b>Case #3</b>  <b>Former Tx:</b>                      TCS, Ciclopiroxolamine shampoo  <b>Severity:</b>                      (A): moderate                      (B): clear</p>
		<p><b>Case #4</b>  <b>Former Tx:</b>                      Clobetasol, salicylic acid  <b>Severity:</b>                      (A): moderate                      (B): clear</p>
		<p><b>Case #5</b>  <b>Former Tx:</b>                      TCS, tar shampoo  <b>Severity:</b>                      (A): moderate                      (B): clear</p>
		<p><b>Case #10</b>  <b>Former Tx:</b>                      TCS, Selenium disulfide shampoo  <b>Severity:</b>                      (A): severe                      (B): mild</p>

**Fig. 1** Photodocumentation obtained before (A) and after (B) 4 weeks of treatment with Cal/BD aerosol foam in selected cases from Table 1. *TCS* topical corticosteroids, *Tx* treatment

10 patients in our population) have not been enrolled in any randomized controlled trial (RCT) on the Cal/BD foam so far. With regard to real-world evidence, a German case series of three patients with mild-to-severe scalp psoriasis has been published [6], but those patients were selected specifically for treatment with Cal/BD foam and were not enrolled consecutively, as was done in our case series.

Therefore, this case series of 10 patients is representative of a nonselected, typical real-world patient cohort of scalp psoriasis patients who randomly visit a dermatological practice in Switzerland. In addition, it represents the first data on patients with scalp psoriasis as the sole manifestation who were treated with the Cal/BD foam under daily practice conditions.

In this case series, we showed that scalp psoriasis improved in all 10 patients by  $\geq 2$  points on a 5-point severity assessment scale. Eight out of 10 patients achieved clear/almost clear skin after 4 weeks of treatment, with no further keratolytic treatments needed. These results confirmed observations of German cases [6] in which the Cal/BD foam was also found to be associated with a significant reduction in scalp lesion severity at week 4, with no descaling necessary in advance, but our results revealed a better clinical response than that observed in the phase 2 program, where only 53% of patients with scalp psoriasis achieved treatment success (defined as a PGA of “clear/almost clear” in cases with a moderate/severe disease status or “clear” in cases with a mild disease status at baseline) after 4 weeks of treatment with the Cal/BD foam (vs. 48% in BD- and 36% in Cal-foam-treated patients) [4].

This difference might be related to the clear application instructions we provided to our patients. They had to apply the foam once a day before going to bed to ensure sufficient soaking time overnight. We instructed them to first spray the foam onto the hand and then to apply it onto their plaques with their fingers. It was necessary to emphasize that the foam should not be sprayed directly onto the scalp, as this would result in a greasy, cosmetically unattractive film on the hair and would not allow sufficient direct contact of the foam with the skin. To rinse off the foam the next day, they were

instructed to apply the shampoo directly onto the dry hair and then emulsify before rinsing off with water. We think that these clear instructions were key to achieving and maintaining treatment success, patient satisfaction, as well as cosmetic acceptance. They might also be the reason for the better clinical results in a real-life situation than those observed in the phase 2 studies.

A Cochrane review (2016) of topical agents for the treatment of scalp psoriasis revealed equivalence of the Cal/BD combination and TCS [3]. Also, in the phase 2 program, the response rates of the Cal/BD foam group and the BD foam group did not statistically significantly differ in the scalp psoriasis cohort [4].

In our real-life patient cohort, seven out of 10 patients were previously treated with TCS (the majority in combination with keratolytic agents or antifungal shampoos), but their scalp psoriasis was not sufficiently controlled. Our case series suggests that, in real-life situations, patients who are not responsive to TCS monotherapy can benefit from switching to the Cal/BD foam combination.

Overall, the patients were very satisfied with the ease of use, the efficacy, and the safety of the Cal/BD foam. However, due to the daily practice setting, we measured neither satisfaction nor quality of life with standardized questionnaires, as the completion of, e.g., a Dermatological Life Quality Index (DLQI) questionnaire is only required when biological treatment, not topical treatment, is considered in routine care in Swiss daily practice. A recent 4-week Italian real-life observational study of 256 psoriasis patients (36.7% with scalp involvement) confirmed that 90% of the patients assessed that the Cal/BD foam was more effective, easier to use, and better tolerated compared to previous topical treatments, based on a patient preference questionnaire [16]. This is in line with the qualitative observation we made for this case series, but specific data on the impacts on quality of life and patient satisfaction are still missing for this specific scalp-affected psoriasis cohort.

Though this case series represents the first data on Cal/BD foam use in a nonselected, real-world scalp psoriasis patient cohort, data are

limited by the small sample size of patients enrolled. In addition, more standardized questionnaires assessing the severity of scalp psoriasis symptoms, the impact on quality of life, and patient satisfaction in a larger, more representative real-world patient cohort are needed to further confirm the effectiveness and safety of Cal/BD foam in this patient cohort and to guide physicians and patients on its optimal use in scalp psoriasis.

## CONCLUSION

This case series confirmed that application of the Cal/BD foam once daily over 4 weeks was an effective and convenient treatment for localized scalp psoriasis of all severity degrees in a non-selected real-world patient cohort refractory to TCS or other local treatments. Clear application instructions are crucial for treatment success and cosmetic acceptance, however.

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**Author Contributions.** Ralph M. Trüeb developed the concept, designed, and analyzed this case series and drafted the concept of the manuscript. Both Ralph M. Trüeb and Antonia Régnier contributed equally with regard to patient information and instruction, data collection, and revising the manuscript.

**Disclosures.** Ralph M. Trüeb served as a speaker for LEO Pharma at the 24th World Congress of Dermatology, Milan, Italy. Antonia Régnier has nothing to disclose. At the time of

the study, she was an employee of the Center for Dermatology and Hair Diseases.

**Compliance with Ethics Guidelines.** Informed patient consent was obtained from all patients for the anonymized use of patient data and photographs. As all patient files were handled in a completely anonymized form and all data/information are generated in the context of individual patient management, this case series was comparable to a so-called "practice experience report," for which it was not required to obtain ethics committee approval in Switzerland.

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