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CASE REPORT

Calcipotriol/betamethasone foam for proactive management of plaque psoriasis: four case reports

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Abstract

Psoriasis is a chronic inflammatory disease affecting about 100 million people worldwide. Around 80% of patients can be treated with topical agents, most commonly corticosteroids and vitamin D analogues. A topical foam formulation of calcipotriol (50 µg/g) and betamethasone dipropionate (0.5 mg/g) (Cal/BD foam; Enstilar®) is approved for the daily treatment of psoriasis for up to 4 weeks and twice-weekly thereafter as maintenance treatment (after initial 4-week treatment success). Long-term proactive maintenance with Cal/BD foam for plaque psoriasis has been shown to prolong the time to first relapse, reduce the number of relapses and increase days in remission in the PSO-LONG trial. Four case studies of proactive management with Cal/BD foam for the treatment of plaque psoriasis for up to 12 months from initial presentation are described. These case studies provide real-world evidence on the long-term effectiveness of proactive management with Cal/BD foam as well as the improvement and maintenance of health-related quality of life. Cal/BD foam was well tolerated.

Keywords: aerosol foam, betamethasone dipropionate, calcipotriol, psoriasis.

Citation

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Introduction

Psoriasis is a chronic inflammatory disease that may affect the skin, nails and joints.[1] An estimated 100 million people worldwide are affected by the condition, and the prevalence of psoriasis continues to rise. In many developed countries, prevalence is between 1.5% and 5%.[2,3]

Chronic plaque psoriasis is characterized by scaly, erythematous plaques, and about 80% of patients are commonly treated with topical agents. Clinical practice guidelines recommend treatment with topical corticosteroids and vitamin D analogues as first-line for initial and long-term therapy.[4] A topical foam formulation of calcipotriol (50 µg/g) and betamethasone dipropionate (0.5 mg/g) (Cal/BD foam; Enstilar®) is approved for the once-daily treatment of psoriasis for up to 4 weeks and twice-weekly long-term treatment thereafter (for patients with treatment success in first 4 weeks).[5,6] Randomized clinical trials have demonstrated the efficacy and safety of Cal/BD foam. The PSO-FAST study showed superior efficacy of Cal/BD foam over vehicle during 4 weeks of treatment,[7] and in the PSO-ABLE trial, Cal/BD foam treatment for 4 weeks had greater efficacy compared with a Cal/BD gel formulation administered over 8 weeks.[8] In the 4-week open-label lead-in phase of PSO-LONG, Cal/BD foam was highly efficacious and well tolerated.[9] Long-term benefits of Cal/BD foam treatment for plaque psoriasis were shown in the PSO-LONG randomized clinical trial in which proactive management with Cal/BD foam (administered twice weekly over 52 weeks) had superior efficacy compared with reactive management: prolonging the time to first relapse, reducing the number of relapses, increasing days in remission and reducing the body surface area affected by psoriasis.[10] Efficacy of long-term proactive management with Cal/BD foam was maintained in patients with moderate-to-severe plaque psoriasis undergoing hypothalamic–pituitary–adrenal axis testing, with no new safety signals.[11] Furthermore, proactive management with Cal/BD foam significantly improved health-related quality of life (HRQoL) measures compared with reactive management.[12] Finally, proactive management of plaque psoriasis with Cal/BD foam was more cost-effective compared with reactive management.[13]

Cal/BD foam has a rapid onset of action,[14] is well tolerated and has a low incidence of adverse events — the most commonly reported were nasopharyngitis and application site pain.[15,16]

Real-world data can provide valuable evidence for the treatment of patients in routine clinical practice. Here, we report four case studies of proactive use of Cal/BD foam for the treatment of plaque psoriasis for up to 12 months. Patients provided written informed consent for the use of their data and clinical images for scientific aims and publication.

Methods and consent

All four patients were treated over the course of routine clinical management, and no information is reported that could identify them. Patients were informed about the publication of the case reports and provided consent. This manuscript, prepared according to CARE guidelines, is a summary of individual case reports and does not involve a research protocol requiring approval by a relevant institutional review board or ethics committee.

Case reports

Case report 1

The patient is an 18-year-old man who had been diagnosed with plaque psoriasis 1 year previously, who was treated with 0.05% clobetasol lotion. Lesions were localized on his scalp (Figure 1a) and legs. He had a Psoriasis Area and Severity Index (PASI) score of 6, Physician Global Assessment (PGA) score of 2, pruritus Visual Analogue Scale (VAS) of 6 and a Dermatology Life Quality Index (DLQI) score of 9. Both the physician's and patient's goals for treatment were initial control of disease activity (PGA of 0/1 and pruritus VAS of 0) and prolonged disease-free intervals following proactive management. The patient was treated with Cal/BD foam once daily for 4 weeks and then maintenance treatment with Cal/BD foam, twice per week.

At 4 weeks, he had a PGA of 1, pruritus VAS of 0 and a DLQI of 3, and his scalp lesions were resolved (Figure 1b). At 6 months, PGA of 1 and pruritus VAS of 0 were unchanged, but the DLQI was further reduced to 2 (Figure 1c). The patient had adhered to the twice-weekly proactive management with Cal/BD foam. At 12 months, the psoriasis severity was unchanged. The PGA remained at a score of 1, pruritus was rated as 0 (VAS scale) and DLQI was 2. During the 12 months, no relapse occurred.

Case report 2

Case 2 is a woman, aged 35 years, with a family history of psoriasis (her mother). She had a 5-year history of psoriasis and comorbid Hashimoto disease (thyroiditis). Previous treatment was 50 mg/g calcipotriol monohydrate + 0.5 mg/g betamethasone dipropionate gel, 1 mg/g mometasone furoate ointment, and coal tar shampoo. Concomitantly, she received thyroxine for Hashimoto thyroiditis. Examination revealed scalp psoriasis with dandruff-like skin flaking (Figure 2a). At presentation, her PASI was 10 and the DLQI was 15. Both the physician's and patient's goals for treatment were complete skin clearance. Initially, the patient received topical treatment with Cal/BD foam once daily for 4 weeks, followed by proactive management with Cal/BD administered twice per week.

After 4 weeks of Cal/BD foam treatment, both PASI and DLQI were reduced to 0, and scalp psoriasis was resolved (Figure 2b). After 5 months of long-term management, the DLQI remained at 0 and PASI had increased to 3 and was accompanied by the re-appearance of some dandruff-like skin flaking (Figure 2c). During the first 5 months of long-term treatment, the patient did not experience any relapse. However, she stated that she had some difficulties with fully removing the product from her thick hair. As the previous treatment was effective, the patient was not 100% adherent and tolerated the reappearance of some dandruff. Twelve months after initial presentation, PASI was 1 and DLQI was 2–5 (corresponding values for scalp

Figure 1. Case 1: At presentation (a); after 4 weeks treatment with calcipotriol (50 µg/g)/betamethasone dipropionate (0.5 mg/g) (Cal/BD) foam (once daily) (b); and after 5 months Cal/BD foam (twice weekly) (c).

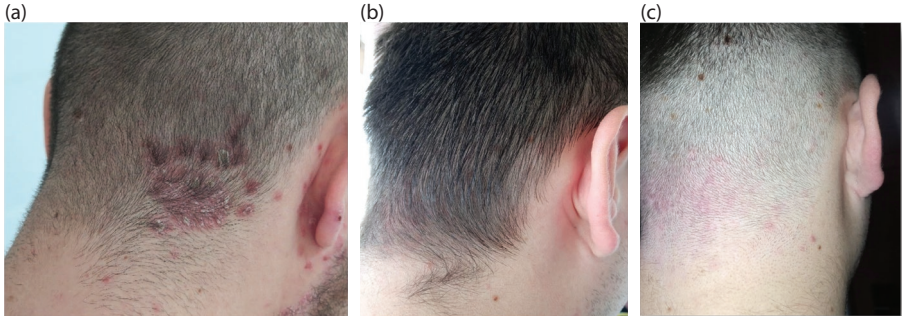
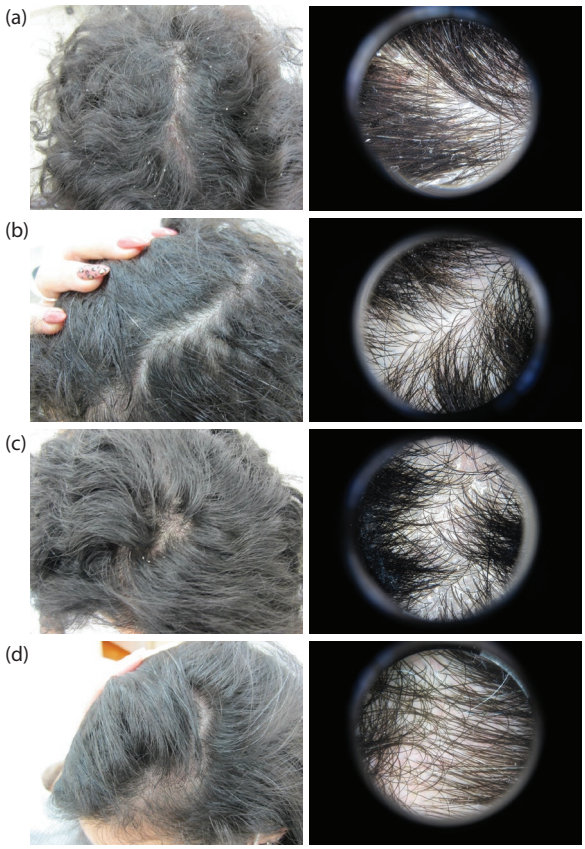


Figure 2. Case 2: at presentation (a); after 4 weeks treatment with calcipotriol (50 µg/g)/ betamethasone dipropionate (0.5 mg/g) (Cal/BD) foam (once daily) (b); and after proactive management with Cal/BD foam (twice weekly) for 5 months (c) and 11 months (d).

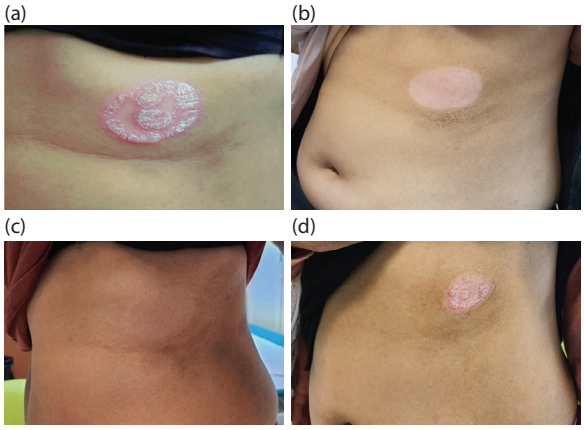


psoriasis were 0 and 0–1, respectively). The dandruff-like skin flaking on the scalp had disappeared (Figure 2d). The patient has been adherent to treatment since the last visit, and no relapses have occurred.

Case report 3

Case 3 is a 40-year-old woman with a 10-year history of psoriasis not previously treated with systemic/biological therapy. She presented with trunk lesions (Figure 3a) and had a PGA of 3 and a DLQI of 6. Following 4 weeks of treatment with Cal/BD foam (once daily), she exhibited persistent vitiligous lesions in the area of former trunk lesions (Figure 3b), with a reduction of PGA score to 1 and DLQI to 0. Proactive management with Cal/BD foam (twice per week) for 4 months reduced PGA to 0 and DLQI remained at 0, with the disappearance of the vitiligous lesion (Figure 3c). Treatment adherence was good in initiation and long-term treatment. After 4 months of proactive management, the patient decided to stop any treatment and, after 2 months, presented herself

Figure 3. Case 3: at presentation (a); after 4 weeks treatment with calcipotriol (50 µg/g)/ betamethasone dipropionate (0.5 mg/g) (Cal/BD) foam (once daily) (b); after 4 months Cal/BD foam (twice weekly) (c); and after 2 months without any treatment (d).



with a flare (PGA of 2) at the physician's office. The patient's reason for stopping the treatment was that she had observed a high effectiveness in the initial therapy phase in the first period of long-term treatment and thought that this effectiveness would be maintained even without treatment (Figure 3d).

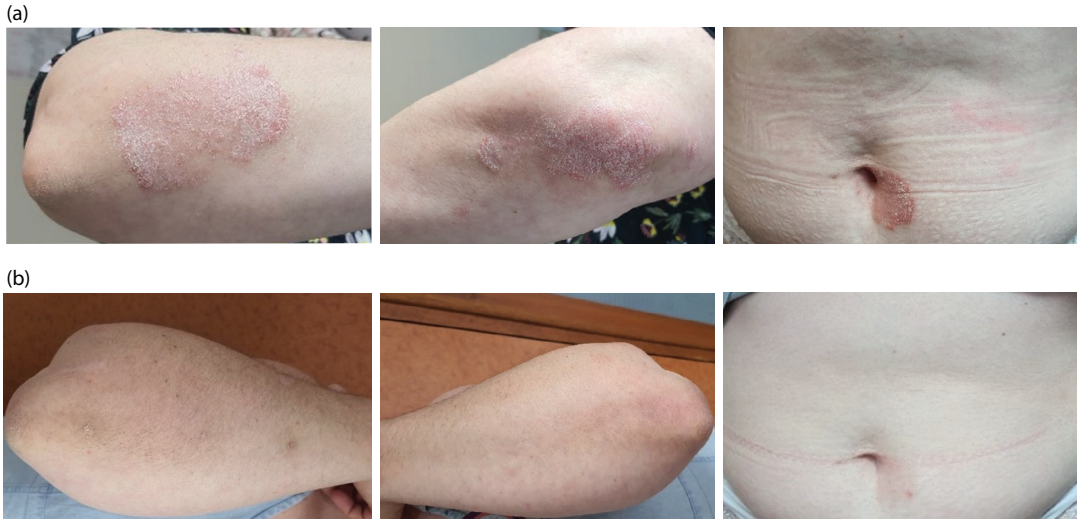
Case report 4

The patient is a 72-year-old woman with a 20-year history of chronic psoriasis only treated with topical corticosteroids and no history of systemic/biologic therapy. At presentation, she had a PASI of 4.2 and DLQI of 6, with lesions present on both elbows and trunk (Figure 4a). Before 3 months of proactive management with Cal/DB foam, she applied Cal/BD foam once daily for 1 month. Lesions were resolved following daily treatment and maintained during proactive management (Figure 4b) and were accompanied by reductions of both PASI and DLQI to 0. Treatment adherence was good at initiation and during long-term management.

Discussion

These individual case reports of four patients presenting with lesions localized solely on the scalp or trunk, scalp and legs, or trunk and elbows, showed that Cal/BD foam reduced signs and symptoms of psoriasis within 4 weeks of starting treatment in all cases and was also associated with a marked improvement in HRQoL. Proactive management with twice-weekly Cal/BD foam generally maintained or improved symptoms for up to 12 months from presentation. This included two patients (Cases 3 and 4) with mild psoriasis and only isolated plaques

Figure 4. Case 4: at presentation (a) and at 4 months after initial presentation [initial therapy: 4 weeks' treatment with calcipotriol (50 µg/g)/betamethasone dipropionate (0.5 mg/g) foam (once daily), followed by proactive maintenance therapy: 3 months Cal/BD foam (twice weekly)] (b).



with no history of using systemic or biologic treatments, for which the treatment was reported for a time span of 4 months.

The findings of these four individual case reports reflect results from the recent PSO-LONG trial demonstrating that 12-month proactive management had superior efficacy to reactive management by prolonging the time to first relapse, reducing the number of relapses and increasing days in remission in adults with psoriasis vulgaris.[10] As psoriasis is a chronic disease, topical long-term maintenance therapy has been widely recommended as a preventive measure.[4] However, Cal/BD foam is the only topical formulation with a specific recommendation and approved label for both reactive treatment of relapse and regular (twice weekly) maintenance use.[17] In our view, the foam formulation is a good choice for the long-term treatment of plaque psoriasis given that it is easy and convenient to apply and generally well accepted by patients.

Psoriasis has a negative impact on the HRQoL of patients, which was reflected in initial DLQI scores at presentation ranging from 6 to 15.[1] In our patients, at 4 weeks, Cal/BD foam markedly improved HRQoL in all cases, reducing DLQI scores to 0 (no impact of skin disease on quality of life) in 3 of 4 cases. At up to 6 months, proactive management maintained or further improved 4-week DLQI scores. This reflects the findings from a post hoc analysis of the PSO-LONG trial, where Cal/BD foam significantly improved HRQoL during the 4-week open-label and 52-week maintenance phases of the study.[12] The benefit of Cal/BD foam in improving HRQoL was also shown in a previous observational study and two clinical trials (PSO-FAST and PSO-ABLE) following 4–12 weeks of treatment.[18–20]

Patient adherence was good during initiation and long-term treatment. Similarly, a single-centre prospective observational study of Cal/BD for mild–moderate plaque psoriasis reported good adherence with 73.8% of patients showing high adherence at 12 weeks.[21] Additionally, in a recent real-world, multicentre, 4-week observational prospective cohort study, patient self-reported adherence to treatment was complete but not 100%.[22] As part of the chronicity of the disease, it has been shown that psoriatic skin has a lesional memory, which is described by reappearance of lesions in previously psoriatic skin.[23] Therefore, proactive, long-term management strategies should be included in treatment regimens for psoriasis patients as they may help to optimize adherence.[24]

It is therefore important that physicians educate their patients about the disease characteristics as well as the proper use of topical dermatological products, including Cal/BD foam; as observed in Case 2, the patient experienced some inconvenience after application of the foam for the treatment of scalp psoriasis and it is important to follow correct application and hair washing procedures to maximize cosmetic acceptability.[25]

High levels of adherence to topical anti-psoriatic drugs are important as poor adherence limits treatment effectiveness.[26] Adherence is strongly influenced by the safety/tolerability profile of topical preparations. In this regard, a combination of Cal/BD was better tolerated and had a wider safety margin than the individual components when applied in a unique ointment or aerosol foam formulation.[27,28] The importance of maintaining a proactive treatment regimen can be especially seen in Case 3, who had been in remission for 4 months when

adhering to the proactive long-term treatment regimen but developed a flare 2 months after discontinuation of treatment.

In the second patient, reappearance of some dandruff-like scales was reported. As skin plaques were not present on the scalp during the second examination, it is possible that this was not a recurrence of mild psoriasis but an exacerbation of seborrheic dermatitis. The coexistence of psoriasis and seborrheic dermatitis is quite common. The pathogenesis of seborrheic dermatitis generally involves species of Malassezia (formerly known as Pityrosporum) fungi and treatment includes the use of antifungal shampoos in addition to topical corticosteroids.[29]

Whilst real-world findings, such as these case reports, provide important observations concerning the effectiveness of Cal/BD foam in daily clinical practice and add to the results obtained from controlled clinical trials, case reports have several limitations that need to be recognized. These include the lack of generalizability, the inability to establish cause–effect relationships (in contrast to controlled trials) and the danger of overinterpretation of a single case report.

In conclusion, these case studies provide real-world evidence on the long-term effectiveness and improvement in HRQoL of proactive management with Cal/BD foam. Cal/BD foam was well tolerated and no safety concerns were described.

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