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Short Term and Long-Term Efficacy of Calcipotriene/ Betamethasone Dipropionate Foam Combination

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Abstract: Psoriasis is a well-known chronic disease characterized by the development of erythematous, indurated, scaly, pruritic plaques on the skin with cycles of remission and symptom flare-ups. The management of patients with chronic plaque psoriasis has been more challenging since the Covid-19 pandemic as health care professionals have had to adapt to remote consultations for some patients, and patients have had to adapt to the changing health landscape. The rapid resolution of psoriasis symptoms especially those with a substantial impact on quality of life can improve patient satisfaction and adherence, making it an important factor in successful treatment. Cal/BD foam contributes to improved patient adherence and treatment outcome through its rapid action and superior efficacy versus Cal or BD monotherapy, Cal/BD ointment and gel and clobetasol cream in the short-term flare treatment of psoriasis. Moreover, the benefits of proactive long-term management of psoriasis compared to reactive management and its favourable safety profile are higher efficacy and a better health-related quality of life. Cal/BD foam should be considered an effective topical treatment for short-term flare treatment and long-term control of adult psoriatic patients.

Keywords: psoriasis, adherence, proactive management, quality of life

Introduction

The short paper below will address the content of 2 industry hubs presented at the virtual EADV 2021, focusing on the holistic management of psoriasis with topical treatments, treating flare-ups in the short term and controlling disease relapses in the long term.

Management of patients with chronic plaque psoriasis is optimal when it is patient-centric. The holistic management of psoriasis with topical combination Calcipotriol/Betamethasone (Cal/BD) treatments, treating the flare-ups in the short term and controlling disease relapses in the long-term is both patient-centric and a helpful alternative in light of changes in consultation since the Covid 19 pandemic. Cal/BD foam formulation presents two main advantages compared to other topical treatments: firstly, its rapid onset of action which can be attributed to the foam formulation leading to fast resolution of symptoms with a positive impact on quality of life (QoL) and the potential improvement of patients' adherence and thus the outcome; secondly, the superior efficacy of proactive long-term management with Cal/BD foam versus the reactive management of psoriasis.¹⁻³

Discussion

Psoriasis is a well-known chronic disease characterized by development of erythematous, indurated, scaly, pruritic plaques on the skin with cycles of remission and symptom flare-ups. The treatment depends on the severity of the disease; mild or moderate psoriasis, represented by 80% of patients, is managed with topical treatments.⁴

However, despite the large range of available products, treatment adherence remains low, leading to suboptimal disease resolution and then poor QoL by the presence of the plaques with physical symptoms such as itching (64–97% of patients with psoriasis suffer from itching), itch-related sleep loss, and psychological and social well-being consequences.^{1,2,5,6} The Global Burden of Disease project revealed that skin and subcutaneous disorders are the 4th most important cause of non-fatal disease burden with a deterioration of health-related QoL similar to cancer and cardiovascular disease.^{1,6} Recent studies have shown that for almost 75% of patients their psoriasis has a moderate to large impact on their QoL, 34% experiencing sleep disorders and more than 5% suicidal ideation.^{1,2,7} Effective improvement on outcomes linked to QoL and rapid onset of action is a key factor for treatment success and has the potential to improve adherence to treatment.^{1,6}

Short Term Efficacy

Findings across pooled analysis of Phase II/III studies revealed that Cal/BD foam has a rapid onset of action, provides fast resolution of psoriasis symptoms with visible results as early as week 1, particularly those shown to have a significant impact on QoL versus Cal/BD gel or foam vehicle, and has the potential to improve adherence and thus patient outcomes in psoriasis.^{8,9}

A pooled analysis of three Phase II/III studies assessing efficacy and health-related QoL outcomes showed a rapid reduction in itching as early as Day 3 through Week 4 associated with significant improvements in itch-related sleep loss and sleep quality for patients treated with Cal/BD foam versus foam vehicle.¹⁰

In addition, a second post-hoc, pooled analysis of three Phase II/III trials described a rapid mode of action with Cal/BD foam, and a greater proportion of Cal/BD foam-treated patients achieving absolute mPASI targets and improving QoL outcomes as early as week 1 versus foam vehicle treated patients.⁹

Cal/BD foam has also shown superior efficacy to its individual components, calcipotriol and betamethasone dipropionate, Cal/BD gel and ointment formulations as well as clobetasol cream.^{11–14}

In one study, the percentage of patients achieving treatment success after 4 weeks, defined by a PGA score is higher in the Cal/BD foam group than in the Cal/BD ointment group (54.6% vs 43%).¹³ In a second study, 52.1% of patients receiving Cal/BD foam achieved PASI75 after 4 weeks, compared with 24.3% receiving Cal/BD gel.¹²

Cal/BD foam has also demonstrated superior effectiveness to clobetasol cream, along with higher levels of patient satisfaction.¹⁴ In a recent interventional investigator-initiated Phase IV study, more patients treated with Cal/BD foam achieved a total clinical score of 1 or less, indicating better clinical resolution than with clobetasol.¹⁴ Cal/BD foam induced a significantly faster response than clobetasol, with 80% of patients achieving a meaningful reduction in total clinical score, versus 43.4% at 4 weeks.¹⁴ Despite the increased penetration of calcipotriol and betamethasone, no increased AEs or negative safety outcomes has been observed.¹⁵

The rationale for the superior efficacy of Cal/BD foam can be explained by the association of the two components and the foam formulation:

In combination, calcipotriol and betamethasone dipropionate have complementary, synergistic effects that help controlling psoriasis inflammation.¹⁶

Propellants contained in the foam formulation evaporate rapidly and lead to the formation of a thin supersaturated layer on the skin increasing the penetration and the bioavailability of active ingredients Cal/BD.^{17,18}

In addition to data showing the superiority of Cal/BD foam over its individual components and Cal/BD ointment and gel formulations, the early efficacy of Cal/BD foam was demonstrated in the treatment of psoriasis flare-ups.

In the lead-in open label Phase of the PSO-LONG 52-week study, 80% of patients (n=521) achieved treatment success, measured by PGA clear and almost clear, with at least a 2-grade improvement from baseline after 4 weeks of treatment. Of these responders, 21.1% and 78.9% had a PGA score of clear and almost clear, respectively. The mean change from baseline in mPASI score at Week 4 was 82.1%, with a mean change in body surface area of 56.6%.¹⁹

In the Phase III, randomised PSO-FAST study, Cal/BD foam was shown to improve the health-related QoL (primarily driven by pain/discomfort and anxiety/depression) for moderate to severe psoriasis patients receiving it after 4-weeks, with most of them experiencing clinically meaningful improvements (DLQI and EQ-5D scores) and almost 50% reporting no impairment to QoL at all (DLQI = 0/1) (Figure 1). For itching, one of the main symptoms responsible

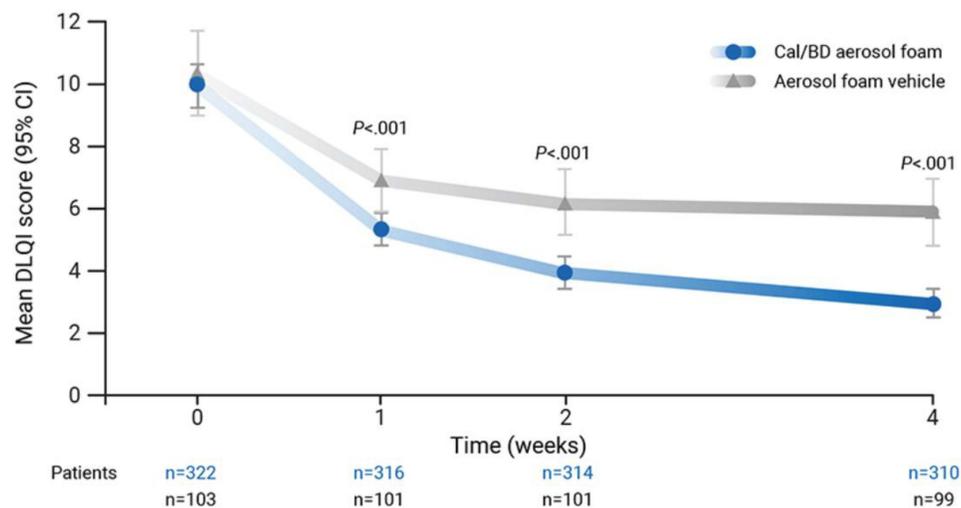


Figure 1 Mean dermatology life-quality index score by visit (observed cases). Phase III randomized PSO-FAST study (N=426).

for the discomfort, 84% of patients receiving Cal/BD foam achieved at least a 70% reduction in itching by Week 4. The correlation between itching and DLQI has been shown to be strong, suggesting the substantial impact of itching on QoL, and the importance of prioritising this symptom during treatment.²

Data from 5 different real-world studies in more than 1400 patients across the US and Europe (Greece, Germany and Spain-2 studies) show similar improvements in effectiveness, QoL (PGA, change in BSA, PASI and DLQI), patient-reported outcomes, and confirmation of the safety profile of Cal/BD foam established in randomised controlled trials.^{20–24}

In the Spanish studies, adherence to treatment with Cal/BD foam was high (100% and 73.8% of patients after 4 and 12 weeks respectively) and the percentage of patient satisfaction (completely satisfied) was 84.6%. 93% of physicians believed that using Cal/BD foam had a quite good or a very good influence on adherence.^{22,23}

Cal/BD foam was shown to induce rapid, effective responses, resolve troublesome symptoms like itch, improve QoL and was well tolerated. Thus, patients and physicians were satisfied with treatment leading to high levels of product acceptability and adherence.^{20–24}

Long-Term Efficacy

Leading experts in psoriasis identified an unmet need for longer-term solutions for flare control in patients treated through topical therapy.⁴

Despite the availability of several treatments' options, many patients do not achieve complete and sustained disease resolution in the long term with negative impact on patients' QoL. Long-term management of psoriasis is challenging because of the relapsing and remitting, chronic nature of the disease, delayed treatment responses and poor adherence.^{6,25} Currently, it relies on a reactive approach to treat disease relapses rather than a proactive approach to maintain remission.

However, relapse is common as underlying residual lesion can remain following initial skin clearance and lesions tend to recur after therapy has been discontinued.^{6,26–28}

The randomised, Phase III PSO-LONG study provides evidence of the benefits of long-term, proactive management of Cal/BD foam (twice weekly) in treating psoriasis and the superiority to reactive management (flare treatment once daily for 4 weeks), increasing time to first relapse (+26 days), and reducing the number of relapses (risk of experiencing first relapse reduced by 46% and lower predicted number of relapses per year of exposure) and increasing days in remission (+41 days).³

The side effects of steroid-based topicals are considered a major barrier to long-term use. This aspect was approached by a sub-analysis of the Phase III PSO-LONG which assessed the safety of long-term proactive management with Cal/BD foam over 52 weeks in patients with more severe psoriasis (PGA \geq 3 and affected BSA 10–30%). These patients may be more susceptible to corticosteroid-induced HPA-axis suppression and a higher risk of corticosteroid-induced systemic toxicity.^{6,29}

However, no clinically significant HPA-axis suppression in either the reactive or proactive treatment groups was found, no new safety signals were detected and the safety profile was similar for both proactive and reactive treatments.²⁹

Similarly positive results were seen in a recent analysis of PSO-LONG by Kircik et al, which looked at skin atrophy and local tolerability of long-term treatment with Cal/BD foam. Regarding skin disorders, assessments done at visits where the patient was not starting or ending a relapse, or in a relapse, low levels of dryness, erosion, erythema, oedema or burning or pain were reported. At the start and end of relapses, local skin reactions and burning or pain were present at slightly higher levels than non-relapse-related visits but were absent for around 90% of patients in both treatment groups, with cases usually mild. Skin atrophy was not reported by investigators at any point, in either treatment group.³⁰

Added to the primary efficacy results from PSO-LONG study, a recent post-hoc analysis of this study shows data supporting these primary outcomes. In this post-hoc analysis, authors projected the clinical course of patients over a 1-year period using a multistate model, which assessed four different states; remission (after the open-label lead-in phase and re-entered if they achieved clear or almost clear skin defined by a PGA <2 after 4 weeks of relapse treatment), relapse (confirmed relapse, or a PGA ≥2), end of treatment (day of premature withdrawal and the completion of the study) and treatment failure (no achievement of clear or almost clear skin after 4 weeks of relapse treatment). The estimated mean stay in the remission state was 81.3 days for proactive management versus 48.9 days for reactive management. Patients in the proactive management group had an estimated 36 more total days in remission and 34 less total days in relapse compared to reactive management and they were also expected to have fewer relapses than patients in the reactive management group – 2 versus 3.2 relapses, respectively.³¹

Two other post-hoc analyses from PSO-LONG investigated the quality-of-life benefits after long-term management with Cal/BD foam, focussing on the impact of treatment on patient reported outcomes such as perceived symptom severity and health-related QoL. In both analyses there were significant advantages of a proactive, twice-weekly, management approach with Cal/BD foam versus reactive flare treatment, with patients reporting better and more sustained health-related QoL outcomes. In the first analysis, patients showed sustained improvement in DLQI, PSI and EQ-5D scores with significantly greater improvement in the proactive group during both the open-label and maintenance phases (DLQI and PSI 15% lower in proactive group vs reactive group).³² In the second analysis, proactive management using Cal/BD foam prolongs time with health-related QoL improvement compared with reactive management: the risk of patients losing DLQI benefit (0/1) was reduced by 48% in the proactive group and the median time to lost response was almost 3.5 times longer for the proactive group (Figure 2).³³

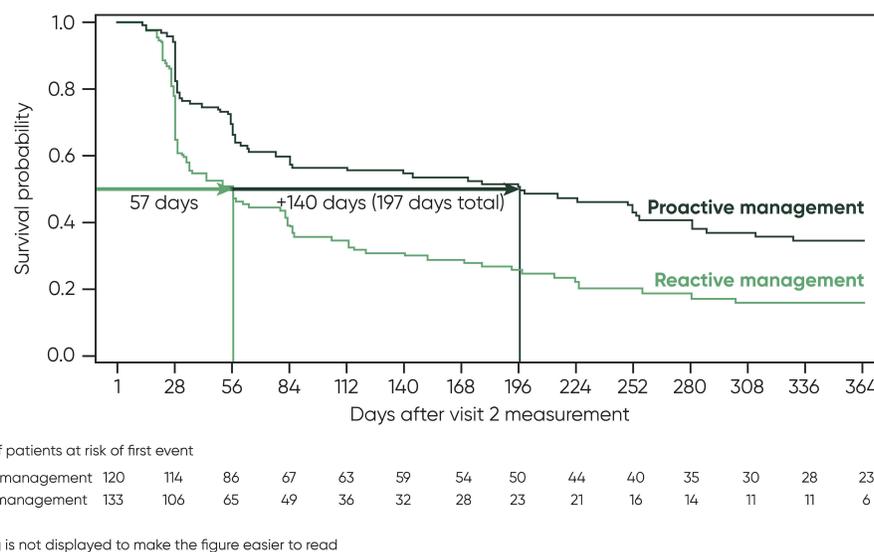


Figure 2 Estimated survival curve for time to first DLQI > 1. PSO-LONG study.

Conclusion

Rapid resolution of psoriasis symptoms especially those with a substantial impact on quality of life can improve patient satisfaction and adherence, making it an important factor in successful treatment. Cal/BD foam contributes to improve patient adherence and treatment outcome by its rapid onset of action and its superior efficacy versus Cal or BD monotherapy, Cal/BD ointment and gel and clobetasol cream in short term flare treatment of psoriasis. Moreover, the benefits of proactive long-term management of psoriasis are the superiority in term of efficacy and improvements in health-related quality of life compared to reactive management and its favourable safety profile.

Cal/BD foam should be considered an effective topical treatment for short term flare-up treatment and long-term control of adult psoriatic patients.

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