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A novel, fixed-dose calcipotriol and betamethasone dipropionate cream for the topical treatment of plaque psoriasis: Direct and indirect evidence from phase 3 trials discussed at the 30th EADV Congress 2021

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REVIEW ARTICLE

A novel, fixed-dose calcipotriol and betamethasone dipropionate cream for the topical treatment of plaque psoriasis: Direct and indirect evidence from phase 3 trials discussed at the 30th EADV Congress 2021

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Abstract

Four posters about the novel, fixed-dose calcipotriol and betamethasone dipropionate cream (CAL/BDP cream) based on Poly-Aphron Dispersion (PAD) Technology were presented at the 30th European Academy of Dermatology and Venereology (EADV) Congress 2021 and are summarized here. CAL/BDP cream was compared in two randomized, phase 3 trials to vehicle and active comparator (CAL/BDP gel/topical suspension [TS]) in adults with plaque psoriasis (NCT03802344 and NCT03308799). Pooled data from both trials demonstrated significant greater efficacy in favour of CAL/BDP cream for all efficacy endpoints, including PGA treatment success, mPASI, and mPASI75 compared to CAL/BDP gel/TS. CAL/BDP cream was well tolerated and comparable to CAL/BDP gel/TS with no adverse drug reactions with a frequency >1%. In the NCT03308799 study, CAL/BDP cream demonstrated a substantial improvement in the proportion of participants achieving a minimum 4-point improvement on the peak pruritus numeric rating scale (NRS) score compared with vehicle at Weeks 1, 4 and 8. CAL/BDP cream also improved quality of life (QoL), as assessed through the Dermatology Life Quality Index (DLQI), and the EQ-VAS at Week 8 compared with active comparator. Treatment convenience of CAL/BDP cream, as measured by the Psoriasis Treatment Convenience Scale, was superior to CAL/BDP gel/TS at all studied timepoints, including questions addressing formulation's greasiness and overall treatment satisfaction. Finally, an indirect comparison following the Bucher's method of adjusted indirect comparison and the difference-in-differences method was conducted to compare CAL/BDP cream and CAL/BDP foam, as both therapies have been compared to CAL/BDP gel/TS. Indirect evidence showed that treatment with CAL/BDP cream was associated with a trend for greater QoL improvement than CAL/BDP foam when DLQI improvement was assessed at the recommended treatment duration of 8 weeks for CAL/BDP cream and 4 weeks for CAL/BDP foam. CAL/BDP cream was statistically superior versus CAL/BDP foam in four out of five treatment satisfaction domains.

INTRODUCTION

Psoriasis has a negative impact on patients' quality of life (QoL), affecting them both physiologically and psychologically.[1,2] The fixed-dose combination of calcipotriol (CAL), a vitamin D analogue, and betamethasone dipropionate (BDP), a potent topical corticosteroid, is recommended by European, Canadian and American psoriatic societies as first-line treatment in mild-to-moderate psoriasis.[3] However, the current marketed therapeutic options with the CAL/BDP fixed-dose combination are sticky, greasy and inconvenient to many patients.[3] In order to improve the adherence to topical psoriasis treatments, it is important to increase the patient satisfaction with the drug vehicle.[4] Thus, there is a need to develop a more patient-friendly topical treatment for psoriasis with the CAL/BDP combination.[3]

Calcipotriol and betamethasone dipropionate (50 mcg/g CAL and 0.5 mg/g betamethasone as dipropionate, BDP) cream (CAL/BDP cream) is a novel topical treatment for plaque psoriasis. This cream is based on Poly-Aphron Dispersion (PAD) Technology, which allows for a stable, fast absorbing and easy to apply aqueous formulation of CAL/BDP, despite the known pH-related instability of CAL and BDP when combined in the presence of water.[3]

CAL/BDP cream was evaluated in two head-to-head, Phase 3, randomized, multicentre, investigator-blind, parallel-group trials comparing CAL/BDP cream to vehicle and an active comparator (50 mcg/g CAL and 0.5 mg/g betamethasone as dipropionate, BDP gel/topical suspension [TS]) in adults with plaque psoriasis conducted in Europe (NCT03802344) and the United States (NCT03308799).[3] Eligible patients were adults with a clinical diagnosis of plaque psoriasis involving the trunk and/or limbs. Additional key inclusion criteria included a treatment area involving between 2% and 30% of the body surface area and a physician global assessment (PGA) score of mild or moderate disease severity. Patients were randomly assigned into three treatment groups with a ratio of 3:1:3 for treatment with CAL/BDP cream, matching vehicle and CAL/BDP gel/TS. Patients were instructed to apply the treatment topically once daily to affected areas for up to 8 weeks.[3]

The 30th Congress of the European Academy of Dermatology and Venereology (EADV) was held virtually between the 29th September 2021 and the 2nd October 2021. A total of four posters about the CAL/BDP cream were presented, focused on its efficacy and safety (P1447),[5] improvement of itch (P1388),[6] patient reported outcomes (PROs) (P1445)[7] and the indirect comparison of QoL and treatment satisfaction versus foam (P1382).[8] This article summarizes the main results of the four posters about the CAL/BDP cream that were presented at the 30th EADV congress.

EFFICACY AND SAFETY (P1447)[5]

This analysis of pooled data from the two Phase 3 trials investigated the efficacy and safety of CAL/BDP cream for the topical treatment of psoriasis. Statistical analyses were based on a modified intention-to-treat population (n = 1271), which included all randomized participants who had at least one efficacy assessment after the baseline visit.

The percentage of patients achieving PGA treatment success at Week 8 was significantly higher in the CAL/BDP cream group compared with the CAL/BDP gel/TS group (43.2% vs. 31.9%, $p < 0.0001$). Moreover, these significant differences were observed as early as Week 4 (p = 0.0001). In the European trial (NCT03802344), the PGA success rate on scalp psoriasis was statistically superior for CAL/BDP cream compared with vehicle at Week 4 (p = 0.005) and Week 8 (p = 0.0002).

The mean percent reduction in mPASI score from baseline to Week 8 was statistically greater for CAL/BDP cream than CAL/BDP gel/TS (−64.6% vs. −56.4%, $p < 0.0001$), with the difference being significant as early as Week 1 (p = 0.0009).

In addition, the proportion of subjects obtaining mPASI75 was greater in the CAL/BDP cream group than in the CAL/BDP gel/TS group from Week 4 (p = 0.0004) to the end of treatment at Week 8 (p = 0.0011).

The mean Dermatology Life Quality Index (DLQI) improvement from baseline, at Week 8, was significantly greater for CAL/BDP cream compared with CAL/BDP gel/TS (6.5 vs. 5.6 points, $p < 0.0001$).

Regarding safety, CAL/BDP cream was well tolerated and comparable to CAL/BDP gel/TS with no adverse drug reactions observed at a frequency >1% associated with the CAL/BDP cream.

IMPROVEMENT OF ITCH (P1388)[6]

In the Phase 3 study conducted in the United States (NCT03308799), itch was evaluated on an 11-point peak pruritus numeric rating scale (NRS). In this analysis, itch reduction was assessed by the absolute change in peak pruritus NRS score from baseline and by a responder analysis defining itch treatment success as at least four points improvement in peak pruritus NRS score from baseline.

The trial enrolled 796 patients at 55 clinical sites across the United States. A total of 626 (78.8%) patients had a peak pruritus NRS score of at least 4 at baseline.

Mean (SD) baseline peak pruritus NRS score was similar across treatment groups: 5.9 (2.7), 6.0 (2.8) and 5.6 (2.8) in the CAL/BDP cream, CAL/BDP gel/TS and vehicle group, respectively.

CAL/BDP cream demonstrated superior reduction of least square mean (LSM) peak pruritus NRS score compared with vehicle at Week 4 (3.5 vs. 1.1 points of improvement; $p < 0.0001$). CAL/BDP cream also demonstrated significant reduction in LSM peak pruritus NRS score compared with vehicle at Weeks 1 and 8 ($p < 0.0001$) and compared with CAL/BDP gel/TS at Week 8 ($p < 0.05$).

Among patients who had a peak pruritus NRS score ≥4 at baseline, a higher proportion of participants achieved a clinically relevant improvement (≥4 points) from baseline to

Weeks 1, 4 and 8 in the CAL/BDP cream group compared with vehicle. Furthermore, a significantly greater proportion of participants randomized to CAL/BDP cream compared with CAL/BDP gel/TS achieved a clinically relevant improvement in peak pruritus NRS score during the first week of treatment (44.0% vs. 36.9%; $p < 0.05$) (Table 1), thereby underlining the rapid onset of action of CAL/BDP cream on itch relief.

Consistent improvement in plaque psoriasis and associated itch was observed across 8 weeks of treatment with CAL/BDP cream (Figure 1).

PATIENT REPORTED OUTCOMES (P1445)[7]

The objective of this pooled analysis was to analyse the combined PROs data from the two Phase 3 trials. Statistical analyses were based on the modified intention-to-treat population ($n = 1271$).

TABLE 1 Percentage of patients achieving a ≥4-point clinically relevant improvement in peak pruritus NRS score

Timepoint	CAL/BDP cream (%)	PAD cream vehicle (%)	CAL/BDP gel/TS (%)
Week 1	44.0*†	20.7	36.9
Week 4	60.2*	21.4	55.8
Week 8	66.1*	26.6	62.7

Note: Adapted from Stein Gold et al.[6] (30th EADV Congress 2021, P1388).

Abbreviations: BDP, betamethasone dipropionate; CAL, calcipotriol; NRS, numerical rating scale; PAD, poly-aphron dispersion; TS, topical suspension.

*$p < 0.0001$; CAL/BDP PAD cream versus PAD cream vehicle.

†$p < 0.05$; CAL/BDP PAD cream versus CAL/BDP gel/TS.

The level of PGA treatment success was confirmed by the Subject Global Assessment (SGA) success, defined as the proportion of patients who had at least a 2-grades improvement to clear or very mild disease. At Weeks 4, 6 and 8, the SGA success was significantly higher in the CAL/BDP cream group as compared with the CAL/BDP gel/TS group (Week 8, 44.2% vs. 27.9%, $p < 0.0001$).

A DLQI score of 0 or 1 (i.e. the psoriasis disease did not affect the patient's life) at Week 8 was obtained by 43.8% in the CAL/BDP cream group and 34.2% in the CAL/BDP gel/TS group ($p = 0.0005$). A significantly higher proportion of patients ($p < 0.05$) achieved a clinically important improvement of at least four points in DLQI for CAL/BDP cream (>60% of patients from Week 4) compared to CAL/BDP gel/TS (Table 2).

Mean EQ-VAS value at baseline was comparable across the treatment groups. EQ-VAS improved in all treatment groups, with a significantly better improvement at Week 8 in the CAL/BDP cream treatment group as compared to active comparator group (mean change from baseline of 6.6 vs. 6.1, $p = 0.0158$).

Treatment convenience of CAL/BDP cream, as measured by the Psoriasis Treatment Convenience Scale (PTCS), was superior to the CAL/BDP gel/TS at all studied timepoints, including questions addressing greasiness of the formulation and overall satisfaction of treatment.

QUALITY OF LIFE AND TREATMENT SATISFACTION: INDIRECT COMPARISON VERSUS FOAM (P1382)[8]

The objective of this study was to assess how the use of CAL/BDP cream impacted patients' QoL and treatment satisfaction compared with CAL/BDP foam. As both topical

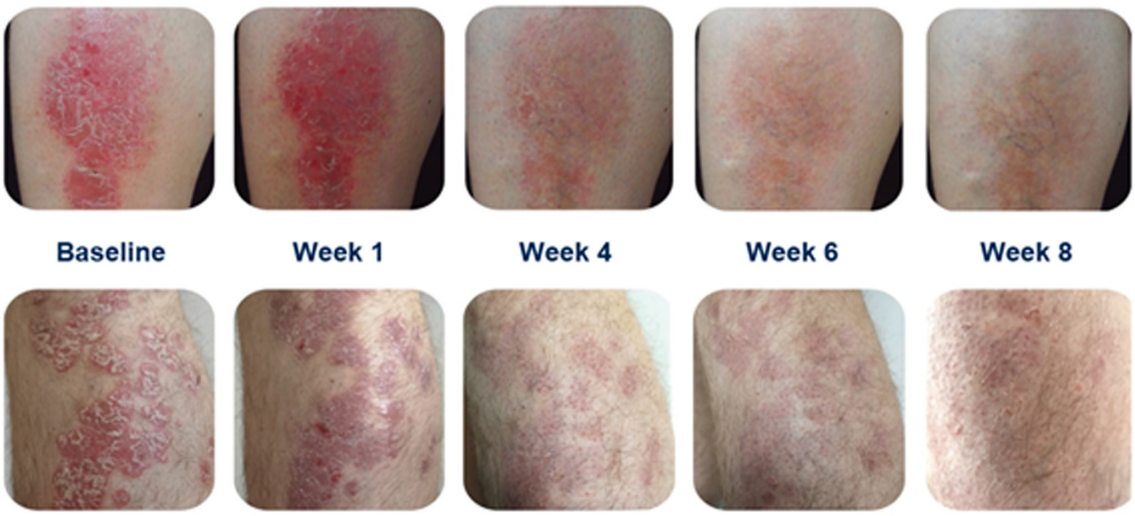

FIGURE 1 **Visualization of treatment with CAL/BDP cream**. Pictures from phase 3 trial (NCT03308799). Consent to publish pictures has been obtained from patients. Adapted from Stein Gold et al.[6] (30th EADV Congress 2021, P1388). BDP, betamethasone dipropionate; CAL, calcipotriol

therapies had been previously compared to CAL/BDP gel/TS, an indirect comparison analysis following the Bucher's method of adjusted indirect comparison and the difference-in-differences method could be performed.

The QoL and treatment satisfaction of CAL/BDP cream versus CAL/BDP gel/TS were assessed through the DLQI improvements and PTCS in the two previously mentioned phase 3 trials (NCT03802344 and NCT03308799).[3] Regarding CAL/BDP foam versus CAL/BDP gel/TS, DLQI improvement was evaluated in the PSO-ABLE trial[9] while treatment satisfaction was assessed through the Topical Product Usability Questionnaire (TPUQ) in the PSO-INSIGHTFUL trial.[10] The six PTCS questions were matched with TPUQ questions covering five treatment satisfaction domains. TPUQ values were converted to PTCS values taking the different scale ranges into account. The mean difference (MD) between CAL/BDP cream and CAL/BDP foam was estimated with the difference-in-differences method applying the common comparator CAL/BDP gel/TS. The characteristics of the studies populations were identified as similar.

Treatment with CAL/BDP cream was associated with significant improvement of overall treatment satisfaction versus foam (MD for CAL/BDP cream vs. foam: 0.62; 95% CI: 0.13, 1.12; $p = 0.01$). Furthermore, treatment satisfaction analyses at Week 1 showed significant differences in favour of CAL/BDP cream on the following treatment satisfaction domains: ease of application ($p < 0.001$), not greasy ($p < 0.001$) and felt moisturizing ($p = 0.01$) (Figure 2).

Treatment with CAL/BDP cream showed a trend for greater improvement on DLQI compared to CAL/BDP foam (MD for CAL/BDP cream vs. foam: −1.00; 95% CI: −2.20, 0.20; $p = 0.10$) when assessed at recommended treatment duration of 8 weeks for CAL/BDP cream and 4 weeks for CAL/BDP foam. CAL/BDP cream was similar to CAL/BDP foam on DLQI improvement at Weeks 4 and 8 (Figure 2).

Finally, after the EADV Congress 2021, the indirect comparison of CAL/BDP cream and foam was published,[11] including results for efficacy endpoints, PGA treatment success and PASI75 response. The results of both treatments were on par when assessed at the recommended treatment duration of 8 weeks for CAL/BDP cream and 4 weeks for CAL/BDP foam.

TABLE 2 Percentage of DLQI 4-point improvement responders

Timepoint	CAL/BDP cream (%)	PAD cream vehicle (%)	CAL/BDP gel/TS (%)
Week 1	45.2*	29.4	38.1
Week 4	61.3*	31.6	54.5
Week 8	65.7*	34.8	58.8

Note: Adapted from Pinter et al.[7] (30th EADV Congress 2021, P1445).

Abbreviations: BDP, betamethasone dipropionate; CAL, calcipotriol; DLQI, Dermatology Life Quality Index; PAD, poly-aphron dispersion; TS, topical suspension.

*$p < 0.05$; CAL/BDP PAD cream versus CAL/BDP gel/TS.

CONCLUSIONS

CAL/BDP cream shows a unique combination of high efficacy, favourable safety and convenience of treatment in a

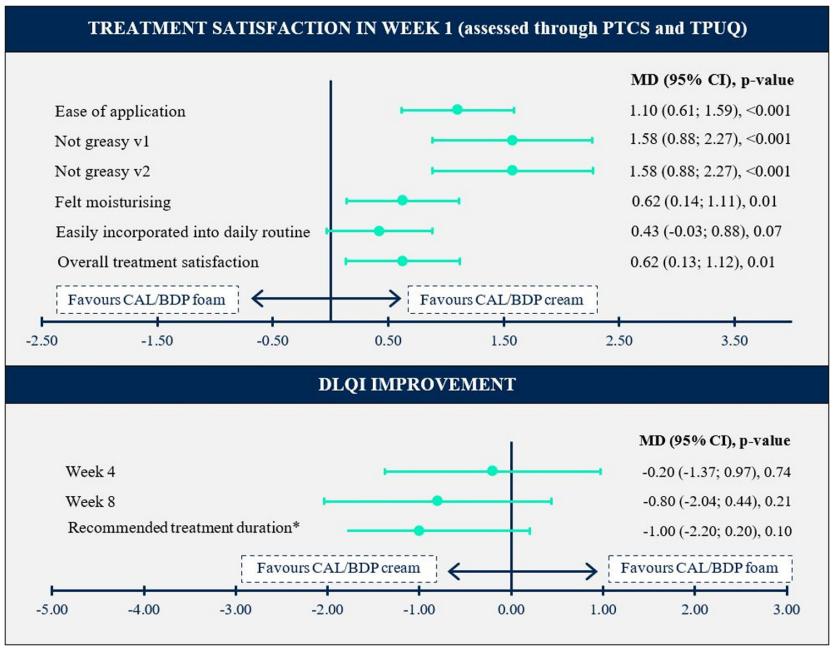

FIGURE 2 **Indirect comparison of treatment satisfaction and DLQI improvement between CAL/BDP cream and foam with the common comparator CAL/BDP gel/TS**. Adapted from Reich et al.[8] (30th EADV Congress 2021, P1382). *8 weeks for CAL/BDP cream and gel and 4 weeks for CAL/BDP foam. 95% CI, 95% confidence interval; BDP, betamethasone dipropionate; CAL, calcipotriol; DLQI, Dermatology Life Quality Index; MD, mean difference; PTCS, Psoriasis Treatment Convenience Scale; TPUQ, Topical Product Usability Questionnaire; TS, topical suspension; v#, version number.

single product. Pooled data from two phase 3 trials demonstrated significant greater efficacy in favour of CAL/BDP cream compared with CAL/BDP gel/TS and a comparable safety profile between the two products, with no adverse drug reactions observed at a frequency >1% for CAL/BDP cream. Data from the phase 3 trial conducted in the United States also demonstrated a substantial and clinically meaningful improvement of itch in patients with psoriasis. Through PAD Technology, this novel topical treatment for psoriasis also offers excellent QoL and treatment satisfaction for patients. CAL/BDP cream has high cosmetic acceptance and overall treatment satisfaction, which can be expected to optimize patient adherence and treatment outcomes in clinical practice. An indirect comparison of CAL/BDP cream versus CAL/BDP foam showed that CAL/BDP cream tends to improve QoL and significantly improves overall treatment satisfaction compared with CAL/BDP foam.

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CONFLICT OF INTEREST

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICAL APPROVAL

The patients in this manuscript have given written informed consent to the publication of their case details.

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