

Patient Preference for Calcipotriene and Betamethasone Dipropionate Cream Versus Foam for the Topical Treatment of Psoriasis: A Pilot Study

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ABSTRACT

Background: The well-established sequential use of topical calcipotriene and topical betamethasone dipropionate in combination has been shown to provide greater benefit than either monotherapy. A newer topical fixed combination formulation of calcipotriene 0.005% and betamethasone dipropionate 0.064% in a cream base (Cal/BD cream) is effective with high patient ratings for convenience and tolerability. The current study compares patient satisfaction between Cal/BD foam and Cal/BD cream formulations.

Study Design and Patient Demographics: This is a single-use, split body, open label study involving 20 subjects. Ten subjects additionally had scalp psoriasis. Study treatments were applied by the investigator in a randomized manner and patients completed questionnaires to assess treatment preferences.

Findings: Both Cal/BD formulations provided rapid and significant improvement in symptoms of pruritus, stinging, burning, and pain; with no statistically significant difference in response between the 2 treatments. Overall, Cal/BD cream outperformed Cal/BD foam on several key measures for vehicle features and patient satisfaction. For non-scalp application, 55% of subjects preferred Cal/BD cream over Cal/BD foam. For the scalp, 60% of subjects preferred Cal/BD cream over Cal/BD foam. No adverse events were reported during the study.

Conclusion: Results of this current study indicate high levels of patient satisfaction with Cal/BD cream and a preference for the cream base over foam for the treatment of body and scalp psoriasis.

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INTRODUCTION

The sequential use of the topical vitamin D analog, calcipotriene, and the topical corticosteroid, betamethasone dipropionate, is well established for the treatment of psoriasis; and the 2 agents used in combination have been shown to provide greater benefit than either monotherapy.^{1,2,3}

Fixed combinations of calcipotriene and betamethasone dipropionate (Cal/BD) are available in ointment, foam, and topical suspension formulations. A Cal/BD aerosol foam formulation (Enstilar, LEO Pharma) is well established in the market. In clinical trials for psoriasis, Cal/BD aerosol foam was significantly more effective than either Cal/BD ointment or the individual active ingredients, providing greater and faster reduction in disease severity. Cal/BD foam was also associated with rapid itch reduction.⁴ Based on a review of data across studies, a panel of experts has suggested that Cal/BD aerosol foam presents an effective, safe, and cost-effective option for management of psoriasis that is beyond mild.⁵

A newer topical fixed combination formulation of calcipotriene 0.005% and betamethasone dipropionate 0.064% in a cream base (Wynzora® Cream, EPI Health/MC2 Therapeutics) is now available on the market. It features a specialized multimolecular technology (Polyaphron Dispersion [PAD™] Technology) that encapsulates the active ingredients in microscopic oil droplets suspended in an aqueous vehicle. In clinical trials, Cal/BD cream outperformed Cal/BD topical suspension (TS) in terms of Physicians Global Assessment (PGA) and mean psoriasis area and severity index (PASI) improvement at week 8. Cal/BD cream was well tolerated, with no adverse event reported with a frequency greater than 1%.⁶ In the pivotal trials, patients expressed a preference for the Cal/BD cream formulation, indicating that it was more convenient than the topical suspension.⁷

The current study is intended to investigate comparative patient satisfaction between Cal/BD foam and Cal/BD cream formulations.

Trial Design

This was a single-use, split body, open label study. Of the 20 subjects, 10 subjects were randomized to apply Cal/BD cream to the right side of the body and Cal/BD foam to the contralateral side; the remaining 10 subjects were randomized to apply Cal/BD cream to the left side of the body and Cal/BD foam to the contralateral side. Ten subjects with scalp involvement applied study drugs to the scalp in a bilateral manner and answered questionnaires specific to scalp psoriasis. Study treatment was applied to each area bilaterally at the same time by the study coordinator. Prior to application, subjects completed the Dermatology Life Quality Index (DLQI) assessment and SCALPDEX assessment, which analyzed 3 quantitative subscale scores for symptom, emotional, and functional impact.

Immediately after application, subjects completed symptom assessments (pruritis, stinging, burning, pain), Patient Preference Questionnaire, Vehicle Preference Measure (VPM), Psoriasis Treatment Convenience Scale (PTCS), Non-scalp and Scalp Questionnaires, and a Final Preference questionnaire analyzed as a binary variable.

Patient Demographics

Twenty subjects with moderate to severe psoriasis vulgaris were enrolled; 10 subjects had scalp involvement. Fifty percent (10) were male and 50% (10) were female. Patients ranged in age from 35 to 74 with a mean of 56 (SD=10). Ninety percent (18) of subjects were white, and 10% (2) were black. All subjects were of non-Hispanic ethnicity.

No subjects withdrew from the study and all 20 that enrolled in the study were included in the data analysis.

RESULTS

Patients were well-matched between randomization groups in terms of assessed symptoms and impact of body and scalp psoriasis. There was no difference in DLQI scores between the 2 randomization groups ($P=0.97$). Among patients with scalp involvement, there were no significant differences in subscale scores for pruritis, stinging, burning, and pain between the randomization groups ($P>0.24$).

Both Cal/BD formulations provided rapid and significant improvement in symptoms of pruritus, stinging, burning, and pain. There was no statistically significant difference in response between the 2 treatments.

Overall, Cal/BD cream outperformed Cal/BD foam on several key measures for vehicle features and patient satisfaction. Responses to the Patient Preference Questionnaire overall tended to indicate a preference for Cal/BD cream. Subjects were significantly more likely to rate Cal/BD cream higher than Cal/BD foam for measures of soft skin, moisturizing, spreadability, and non-stickiness ($P<0.05$).

Cal/BD cream outperformed Cal/BD foam for residue, absorbs quickly, easy to apply, and fragrance-free items; but the difference was not significant.

There was substantial variability in Vehicle Preference Measure (VPM) scores. Cal/BD cream had significantly higher scores than Cal/BD foam on the VPM ($P=0.04$). Twelve of 20 subjects (60%) scored the VPM higher for Cal/BD cream than Cal/BD foam.

Cal/BD cream scored significantly higher than Cal/BD foam on the Psoriasis Treatment Convenience Scale (PTCS). The mean PTCS score for Cal/BD cream was 39.1, while the mean score for Cal/BD foam was 33.0 ($P=0.02$).

The majority of subjects indicated a final preference for Cal/BD cream over Cal/BD foam. For non-scalp application, 11 of 20 (55%) subjects preferred Cal/BD cream over Cal/BD foam. For the scalp final preference, 6 of 10 (60%) subjects preferred Cal/BD cream over Cal/BD foam.

No adverse events were reported during the study.

DISCUSSION

Fixed combination Cal/BD formulations are an established option for the safe and effective treatment of plaque psoriasis. Results of the current study indicate that both Cal/BD cream and Cal/BD foam provided rapid and significant improvements in key symptoms of psoriasis. Both scored favorably in key measures of patient preference, although Cal/BD cream performed significantly better on certain key measures.

Accumulating research in psoriasis has suggested that patient preferences for topical treatment vehicles vary widely.⁸⁻⁹ One analysis looking only at creams, gels, and ointments for the topical management of psoriasis found a preference for the latter to treat small areas of involvement, while creams and gels were preferred for larger areas. Of note, the analysis also found that more than 75% of subjects were non-adherent with topical therapy.¹⁰ Other research suggests low levels of adherence and treatment satisfaction with topical therapy. A large, systematic review of topical and systemic treatments for psoriasis found that overall patient satisfaction with available treatments was low.¹⁰

In light of these findings, it is incumbent on prescribers to select a treatment that is most likely to meet the patient's preference and potentially support long-term adherence. Findings from this current study show notable levels of patient satisfaction with the unique base of the studied Cal/BD cream, even for the treatment of the hair-bearing scalp. The innovative, water-based cream with PAD Technology has key features that facilitate the combined delivery of the actives while enhancing the application experience.

CONCLUSION

Topical therapy continues to be a mainstay of psoriasis treatment.¹¹ Selection of an appropriate treatment depends on multiple factors, including severity of symptoms, extent of disease, previous treatment experience, and patient preference. With continued innovations in formulations, prescribers should assess patient preference and reconsider conventional notions that suggest certain vehicle bases are suitable only for certain treatment sites.

Results of this current study indicate high levels of patient satisfaction with Cal/BD cream and a preference for the cream base over foam treatment for the treatment of both trunk and scalp psoriasis. Additionally, large-scale studies are indicated to validate the current findings.

DISCLOSURES

Dr. Kircik has served as an investigator, speaker, and consultant for LEO Pharma and EPI Health, and Novan. Charles Kircik has no conflicts of interest to declare.

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