Real world experience with calcipotriene and betamethasone dipropionate foam 0.005%/0.064% (Cal/BD foam) in the treatment of adult psoriasis itch from retrospective chart review

Jashin J. Wu, MD[1]; Karen A. Veverka, PhD[2]; Minyi Lu PhD[2]; and April W. Armstrong, MD[3]

[1]Department of Dermatology, Kaiser Permanente Los Angeles Medical Center, Los Angeles, CA; [2]LEO Pharma Inc., Madison, NJ; [3]Department of Dermatology, Keck School of Medicine of University of Southern California, Los Angeles, CA, USA.

Introduction

- Despite a reported global prevalence of pruritus ranging from 64% to 97%[1], the real-world data on the impact of topical medications on itch in psoriasis patients has not been widely reported.
- Treatment with the foam formulation of calcipotriene 0.005%/betamethasone dipropionate 0.064% (Cal/BD) foam is a topical treatment for chronic adult plaque psoriasis with efficacy and safety established in clinical trials.[2-5]
- We assessed the clinical characteristics, treatment patterns, and other physician and patient characteristics, adverse events, and resource utilizations in patients using Cal/BD foam to treat plaque psoriasis.
- The results of our study uniquely provide real-world practice data for topical psoriasis therapy with Cal/BD foam including impact on itch.

Materials & Methods

Study Design

- Retrospective, observational, medical chart review conducted at clinical practice sites in US
- Psoriasis vulgaris (n=105) patients ≥18 years who initiated Cal/BD foam between Jan 1, 2016 and Oct 31, 2016 were included.
- Patients were required to have baseline visit and at least 3 months of available data after treatment initiation, and no history of psoriatic arthritis.
- HCPs who abstracted records reported being experienced in treating psoriasis and in prescribing Cal/BD foam, and were balanced for geographical representation. (**Figure 1**)
- The healthcare providers were asked to complete a survey to assess attitudes towards Cal/BD foam.

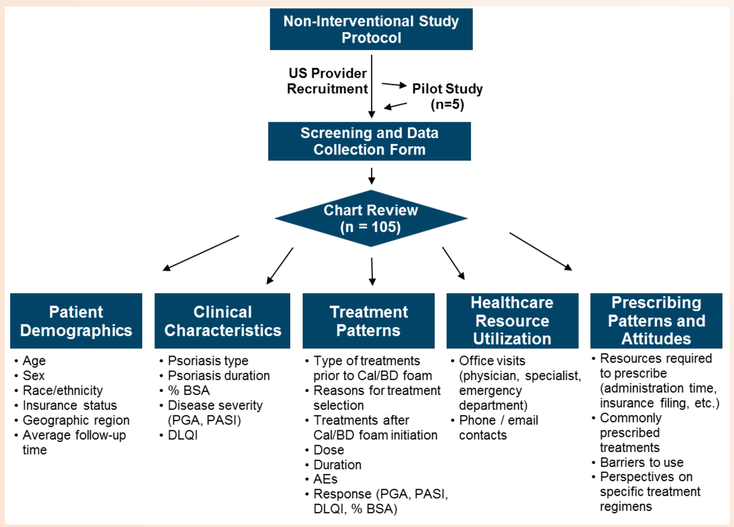

Figure 1: Study Flow Diagram

Results

Table 1. Patient Baseline Demographics

	Patients (N=105) n (%)
Age, years	41.7
Sex	
Female	46 (44%)
Male	59 (56%)
Race	
White	92 (88%)
Black	2 (2%)
Asian	5 (5%)
American Indian or Alaska Native	0 (0%)
Native Hawaiian or Other Pacific Islander	1 (1%)
Other	5 (5%)
Ethnicity	
Hispanic	9 (9%)

Table 2. Baseline Disease Characteristics

	Patients (N=105) n (%)
History of plaques affecting:	
Scalp	24 (22%)
Facial seborrheic	5 (5%)
Trunk	30 (29%)
Upper Extremities (excluded: elbows)	20 (19%)
Elbows	39 (37%)
Lower extremities	27 (26%)
Knees	45 (43%)
Genitals	3 (3%)
Palms/soles	5 (5%)
Nails	4 (4%)

Patient Demographics

- 59 men and 46 women; mean age at Cal/BD foam initiation 41.7 years **(Table 1)**
- Most of the patients are White (88%); 9% of Hispanic ethnicity
- 60% patients diagnosed with psoriasis before Cal/BD foam initiation
- 91.4% with ≥1 follow-up visit after Cal/BD foam initiation

Baseline Disease Characteristics

- Patients had a history of plaques affecting knees, n=45 (43%); elbows n=39 (37%); trunk n=30 (29%), lower extremities n=27 (26%), scalp n=24 (22%), and upper extremities n=20 (19%). **(Table 2)**
- The median BSA plus scalp was 5.0% and ranged from 1%-85%. **(Figure 2)**
- 45.7% of patients complained of itch and itch affected the quality of life of 60.4% of the patients who experienced itch at baseline. **(Table 3)**
- Clinical measures of disease severity (e.g., PGA, PASI) were not recorded in patient charts and therefore were not available.

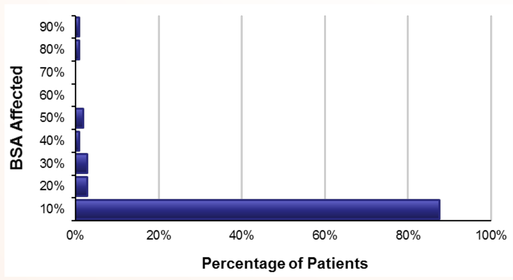

Figure 2. Distribution of BSA Plus Scalp Affected at Cal/BD Foam Initiation

Table 3. Baseline Disease Characteristics

	Patients (N=105) n (%)
BSA, %	5 (1-85)
PGA	*Not recorded*
PASI	*Not recorded*
Itch	87 (82.6%)
Complained of itch	48 (55.2)

Treatment Response: Plaque Areas

- There were a total of 177 plaque areas treated with Cal/BD foam in the study.
- Cal/BD foam was prescribed to use once-daily (n=124/177 treated plaques; 70.1%) for 4 weeks (n=69/177 treated plaques; 39.0%).
- 126/177 plaque areas were evaluated for which response could be attributed to Cal/BD foam, and of those, 113 were mild-moderate-severe before treatment initiation. **(Table 4)**
- After treatment with Cal/BD foam:
  - 70.6% of plaques classified as mild/moderate/severe at baseline were ‘clear’ or ‘almost clear’.
  - 55.7% of plaques classified as mild/moderate/severe at baseline were ‘clear’ or ‘almost clear’ with 2-grade improvement.

Table 4. Response of Plaques to Cal/BD Foam

	Plaque areas (N = 177)
# plaque areas evaluated with response to Cal/BD foam	126
# plaque areas at mild-mod-sev	113/126
# plaque areas at mild-mod-sev that were ‘clear’ or ‘almost clear’ at time of best response	80
# plaque areas at mild-mod-sev that were ‘clear’ or ‘almost clear’ at time of best response with 2 grade improvement	63

Table 5. Response of Itch to Cal/BD Foam

	Plaque areas (N=177)
Response to Cal/BD foam (n)	128
Itch (n), prior to Cal/BD foam treatment	64/128
No itch (n), prior to Cal/BD foam treatment	64/128
Itch resolved (n), after Cal/BD foam treatment	58
Itch not resolved (n), after Cal/BD foam treatment	6

N = # plaque areas

Treatment Response: Pruritus

- Treatment response was also reported for itch. Of the plaques for which the presence of itch was recorded at baseline and time of best response to treatment with Cal/BD foam **(Table 5)**:
  - 50% of treated areas (n=6+58) had itch at baseline and 50% did not (n=64)
  - Itch resolved for 90.1% (58/64) of plaques with itch at baseline (i.e., no itch after treatment with Cal/BD foam)
  - All areas (100%) with no itch at baseline did not have itch after treatment.

Safety and tolerability

- Adverse events (skin irritation on the knees and the palms/soles) were reported in n = 1/105 (1%) patients in this real-world study.

Conclusions

- **Itch is present for an overwhelming majority of mild-moderate patients before initiation of topical treatment.**
- **Itch is a bothersome symptom; 55.2% of patients complained about itch to their provider as was documented in their medical chart, and itch affected quality of life for 60.4% of the patients who complained about itch.**
- **Based on this chart review study, adult psoriasis patients treated topically with Cal/BD foam for up to 4 weeks realized significant improvements in treatment response of plaque lesions. Lesions were ‘clear’ or ‘almost clear’ and with important corresponding reductions of itch.**
- **These data help extend results reported from clinical trials with Cal/BD foam.**

Disclosures

- Wu JJ and Armstrong AW have been advisors with/without funding to LEO Pharma, Inc.
- Lu M and Veverka K are employed by LEO Pharma, Inc.
- The analysis of data was conducted by RTI, Inc. and A+A, sponsored solely by LEO Pharma, Inc.
- Editorial support provided by Dharm Patel, PhD at LEO Pharma, Inc.

References

1. Reich A, Szepietowski JC. Clinical Aspects of Itch: Psoriasis. In: Carstens E, Akiyama T, editors. Itch: Mechanisms and Treatment. Boca Raton (FL): CRC Press/Taylor & Francis; 2014. Chapter 4. Available from: https://www.ncbi.nlm.nih.gov/books/NBK200930/
2. Paul C et al. *J Eur Acad Dermatol Venereol*. 2017 Jan;31(1):119-126.
3. Lebwohl M et al. *J Clin Aesthet Dermatol*. 2016; 9(2): 34-41.
4. Koo J et al. *J Dermatol Treat*, 2016; 27(2):120-127.
5. Leonardi C et al. *J Drugs Dermatol*. 2015; 14(12):1468-1477.

Poster presented at the 2018 Winter Clinical Dermatology Conference in Maui, HI; January 12-17th, 2018.