Patient Preference for Calcipotriene 0.005%/Betamethasone Dipropionate 0.064% Foam or Topical Suspension vs. Latest Topical Treatment in the PSO-INSIGHTFUL Study

Jennifer Soung, MD,[1] Lisa Tiu, PharmD,[2] Karen Veverka, PhD,[2] Chih-Ho Hong, MD[3]

[1]Southern California Dermatology; [2]LEO Pharma Inc; [3]University of British Columbia, Department of Dermatology and Skin Science and Probity Medical Research

Introduction

- Topical therapies are a mainstay in psoriasis vulgaris treatment and are used in combination therapy even in patients receiving systemic or biologic therapy
- Patient preference for vehicle formulation can impact adherence and, consequently, real-life effectiveness
- The PSO-INSIGHTFUL study was designed to assess patient-reported factors that influence preference following once-daily topical treatment with calcipotriene 0.005%/betamethasone dipropionate 0.064% (Cal/BD) foam and gel[1]
- Questionnaires (including Topical Product Usability Questionnaire, TPUQ; Comparison to Latest Topical Treatment, CLTT) were completed by patients at baseline and timepoints during the study to assess usability and preference differences

Materials & Methods

PSO-INSIGHTFUL Study Design

- PSO-INSIGHTFUL was a prospective, multicenter, Phase IIIb, open-label, randomized, two-arm crossover study including patients ≥18 years with mild-to-severe psoriasis of ≥6 months' duration involving 2-30% BSA and mPASI of ≥2 (Table 1)
- After 4-week washout, 213 patients were randomized 1:1 to once-daily Cal/BD foam for 1 week, followed by Cal/BD gel for 1 week, or vice-versa (Figure 1)

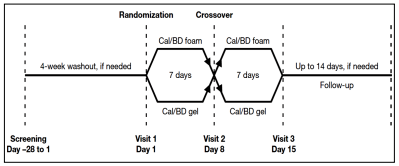

Figure 1: Schematic of study design of PSO-INSIGHTFUL, [NCT02310646] [2]

Study Assessments

- Patients completed questionnaires to assess therapy usability and preference differences
  - Topical Product Usability Questionnaire (TPUQ)
  - Comparison to Latest Topical Treatment (CLTT)

Statistical Analysis

- Full analysis set comprised all randomized patients who completed an on-study questionnaire
- LTT analysis set comprised all randomized patients who had used topical treatment within 3 months before baseline

Table 1. Patient Demographics and baseline characteristics (adapted from PSO-INSIGHTFUL)

	All patients n = 212 (%)
Age category, n (%)	
18 – 39 years	48 (22.6)
40 – 59 years	92 (43.4)
≥ 60 years	72 (34.0)
Male : Female, n (%)	133:79 (63:37)
BMI, n (%)	
< 25 kg/m²	37 (17.5)
25 – 30 kg/m²	73 (34.4)
> 30 kg/m²	102 (48.1)
PGA, n (%)	
Mild	61 (28.8)
Moderate	122 (57.5)
Severe	29 (13.7)
Duration of psoriasis, n (%)	
< 2 years	4 (1.9)
2 – 5 years	30 (14.2)
> 5 years	178 (84.0)
BSA, n (%)	
< 4%	93 (43.9)
4 – 6%	56 (26.4)
6 – 11%	38 (17.9)
11 – 15%	11 (5.2)
≥ 15%	14 (6.6)
mPASI, n (%)	
2 – 5	86 (40.6)
5.1 – 10	91 (42.9)
> 10	35 (16.5)
Mean DLQI	7.8
Localized:widespread distribution of psoriasis, %	62:38

BMI, body mass index; BSA, body surface area; mPASI, modified psoriasis and severity index; PGA, Physician's Global Assessment of disease severity

Topical Product Usability Questionnaire (TPUQ)

- Each patient assessed the extent to which they agreed with each of the 26 items using 5-point scale (-2 to 2), organized into four domains: "*application*", "*formulation*", "*container*", "*satisfaction,*" regarding product usability.
- Frequency:
  - Following randomization, the TPUQ was used to assess the LTT at baseline
  - During visits to the clinic at the end of weeks 1 and 2, patients completed TPUQ based on their treatment experience during the previous 7 days

Comparison to Latest Topical Treatment (CLTT)

- Patients stated whether they preferred their LTT or Cal/BD foam/gel, or had no preference
- Frequency:
  - During visits to the clinic at the end of weeks 1 and 2, patients completed CLTT based on their treatment experience during the previous 7 days

Results

Table 2. Mean TPUQ scores compared with LLT, by domain, for Cal/BD foam and topical suspension

	LTT (n=118)	Cal/BD foam (n=116)	Cal/BD topical suspension (n=115)
Application domain scores			
Ease of application	1.4	1.2	1.5
Ease of application on lesion only	1.3	0.9*	1.4
Ease of spreading	1.5	1.5	1.7*
Lack of mess	0.6	0.9	1.0**
Good for use on small areas	1.1	1.0	1.4*
Good for use on large areas	0.9	1.4***	1.5***
Quick to apply	1.2	1.5**	1.3
Total time spent acceptable	1.1	1.6***	1.4**
Easily incorporated into daily routine	1.0	1.5***	1.4***
Formulation domain scores			
Quickly absorbed	0.2	0.7**	0.6**
Dried quickly	0	0.5**	0.4**
Immediate feeling of relief	0.1	1.1***	0.7***
Felt soothing	0.6	1.3***	1.0**
Appealing to touch	0.2	1.0***	0.9***
Felt moisturizing	0.6	1.3***	1.2***
Not greasy	–0.5	0.2***	0.2***
Odourless	1.2	1.3	1.5**
No staining	0.4	0.9**	0.9***
Container domain scores			
Easy to get medication out of container	1.3	1.2	1.3
Easy to use	1.3	1.2	1.4
Easy to keep clean	1.1	1.3	1.3
Accurately dispense wanted amount	1.0	0.9	1.5***
Satisfaction domain scores			
Confidence in using	0.6	1.3***	1.2***
Would use regularly	0.9	1.4**	1.3*
Would recommend	0.4	1.3***	1.0***
Overall satisfaction	0.3	1.2***	1.1***

Range: –2, strongly disagree to +2, strongly agree
*P<0.05, **P<0.01, ***P<0.001 vs LTT. LTT included various corticosteroids (of different potencies) and combination products, with similar types of products in all categories (ointment, cream, 'other')

Table 3. Mean TPUQ scores, by domain, for Cal/BD foam and topical suspension

	Cal/BD foam (n=212)	Cal/BD topical suspension (n=212)	*P* value
Application domain scores			
Ease of application	1.1	1.5	**
Ease of application on lesion only	0.9	1.4	***
Ease of spreading	1.5	1.7	**
Lack of mess	0.8	1.0	NS
Good for use on small areas	1.0	1.4	***
Good for use on large areas	1.4	1.5	NS
Quick to apply	1.4	1.4	NS
Total time spent acceptable	1.5	1.5	NS
Easily incorporated into daily routine	1.4	1.5	NS
Formulation domain scores			
Quickly absorbed	0.7	0.7	NS
Dried quickly	0.5	0.5	NS
Immediate feeling of relief	1.0	0.7	**
Felt soothing	1.2	1.0	**
Appealing to touch	0.9	0.9	NS
Felt moisturizing	1.1	1.2	NS
Not greasy	0	0.3	*
Odourless	1.3	1.6	***
No staining	1.0	1.0	NS
Container domain scores			
Easy to get medication out of container	1.1	1.3	NS
Easy to use	1.1	1.4	***
Easy to keep clean	1.2	1.4	*
Accurately dispense wanted amount	0.9	1.5	***
Satisfaction domain scores			
Confidence in using	1.2	1.2	NS
Would use regularly	1.3	1.3	NS
Would recommend	1.2	1.1	NS
Overall satisfaction	1.1	1.2	NS

Range: –2, strongly disagree to +2, strongly agree
*P<0.05, **P<0.01, ***P<0.001

Cal/BD foam or Cal/BD topical suspension vs. LTT:

- Mean TPUQ domain scores were often significantly in favor of both Cal/BD foam and topical suspension compared with LTT
- Scores for Cal/BD topical suspension were generally higher than for LTT
- Most scores for Cal/BD foam were higher, although some related to ease of application and container items were comparable to LTT

Cal/BD foam vs. Cal/BD topical suspension:

- Mean application, container and satisfaction domain scores were high for both Cal/BD foam and gel
- Both Cal/BD foam and Cal/BD gel had very high application domain scores for:
  - Good for use on large areas
  - Total time spent acceptable
  - Quick to apply
  - Easily incorporated into daily routine
- Significant differences observed in favor of Cal/BD foam vs topical suspension in the domains of "immediate feeling of relief" and "soothing feeling"
- Significant differences observed in favor of Cal/BD topical suspension vs foam included:
  - Ease of application, ease of application on lesion only, and ease of spreading
  - Good for use on small areas
  - Odorless
  - Accurately dispensed wanted amount

Table 4. Difference in total formulation score (TPUQ) between study treatments by psoriasis distribution phenotype (FAS)

	All patients; foam-gel*
Localized (n = 128)	0.5 ± 8.8
Widespread (n = 78)	-2.1 ± 8.2
All patients (n = 204)	-0.5 ± 8.2

*Negative difference indicates preference for gel

Differences in TPUQ scores between study treatments by psoriasis distribution

- The forward selection procedure identified psoriasis distribution as a significant factor
- Trend towards more favorable scores for Cal/BD foam in patients with localized distribution and in favor of gel for patients with widespread distribution

Conclusions

- **Overall, patients from the PSO-INSIGHTFUL study had stronger preferences for either Cal/BD foam or gel as compared to their last topical treatment**
- **These results from the Topical Product Usability Questionnaire are further corroborated with the similar results in the Comparison to Latest Topical Treatment survey**
- **The significant differences observed in favor of Cal/BD foam as compared to the topical suspension formulation are related mainly to application and a "feeling of relief" which may be attributable to the vehicle**
- **These data provide insight into aspects of topical product usability, but more robust research is necessary to obtain a complete understanding**

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References

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