MSR85

Psoriasis Symptoms and Impacts Measure: Identifying Key Items Reflecting Core Symptoms of Patients with Plaque Psoriasis

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Objective

This post-hoc statistical analysis aimed to identify a subset of items from the Psoriasis Symptoms and Impacts Measure (P-SIM) which reflect the core symptoms experienced by patients with plaque psoriasis. This would allow a quicker and less burdensome assessment of symptom severity and minimise redundancy with other measures used in routine practice, such as the Dermatology Life Quality Index (DLQI).

Background

- The 14-item P-SIM is a novel patient-reported outcome tool which captures key symptoms and life impacts of psoriasis.[1]
- While the full 14-item P-SIM allows for a comprehensive assessment, it may be perceived as too burdensome and time-consuming for clinical practice, and some of its content may overlap with other assessments such as the DLQI.
- Therefore, a shorter, symptom-focused form of the P-SIM may be useful for more frequent assessments and overall monitoring of patient-perceived symptom severity.

Methods

- Findings from previous literature reviews and qualitative patient interviews were used to identify key items of interest to patients.
- Using observed case data pooled across all treatment arms at Baseline and Week 16 of the BE VIVID, BE SURE and BE READY phase 3 trials,[2–4] inter-item correlations, principal component analysis and exploratory factor analysis identified items with considerable overlap, from which some items were removed.
- Removed items were regressed on the items retained, using the R-squared statistic to determine how much variability could be explained by retained items.

Results

- Previous findings from literature reviews and patient interviews identified itching, skin pain, scaling, redness and burning as key items of interest to prioritise for retention.
- Principal component analysis showed clear separation within the 14 items (**Figure 1**), which were grouped into:
  - 11 symptom items;
  - 2 impact items (embarrassment, choice of clothing);
  - 1 fatigue item.
- Given the objective of these analyses was to develop a short symptom-focused form, attention was restricted to the 11 symptom items, among which item overlap was analysed further.
- Following overlap analysis, cracking and dryness were retained, as they did not have considerable overlap with any other items (**Figure 2**).
- Due to having considerable overlap with other items, the following items were removed (**Figure 2**):
  - Thickening (overlap with scaling);
  - Irritation (overlap with burning and skin pain);
  - Sensitivity (overlap with burning and skin pain);
  - Lesions (overlap with redness).
- Factor loadings from the exploratory factor analysis provided further evidence for the above overlap and item removal (overlapping items had high loadings on the same factors; **Table 1**).
- At Baseline, regression analysis indicated the seven retained symptom items explained a high proportion of the variability of the removed thickening, irritation, sensitivity and lesions items (**Table 2**).
  - At Week 16, the variability explained by the retained symptom items remained high (**Table 2**).

Conclusions

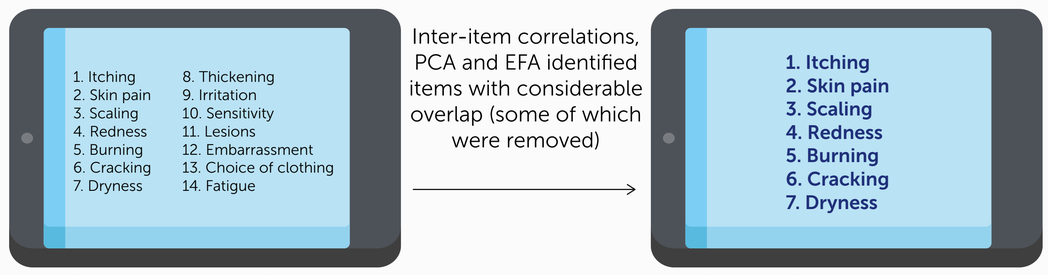
Seven P-SIM items reflecting the core symptoms experienced by patients with psoriasis were identified: itching, skin pain, scaling, redness, burning, cracking and dryness.

These items could trigger the development of a symptom short-form, allowing quick, valid and reliable assessment with minimised patient burden and inter-measure redundancy.

Summary

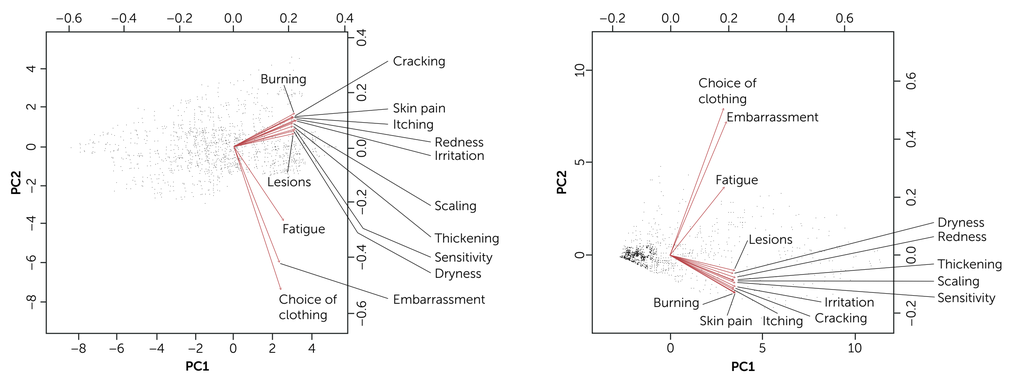
The P-SIM is a reliable, validated, **patient-reported outcome** tool which captures **key symptoms and life impacts** of plaque psoriasis[1]

Each P-SIM item is scored from 0–10:



Seven P-SIM items reflecting core symptoms experienced by patients with psoriasis were identified, which could trigger development of a **symptom short-form**. This may allow more frequent assessments and overall monitoring of **symptom severity** in **clinical practice**.

Figure 1 Principal component analysis at Baseline and Week 16 (14 items)



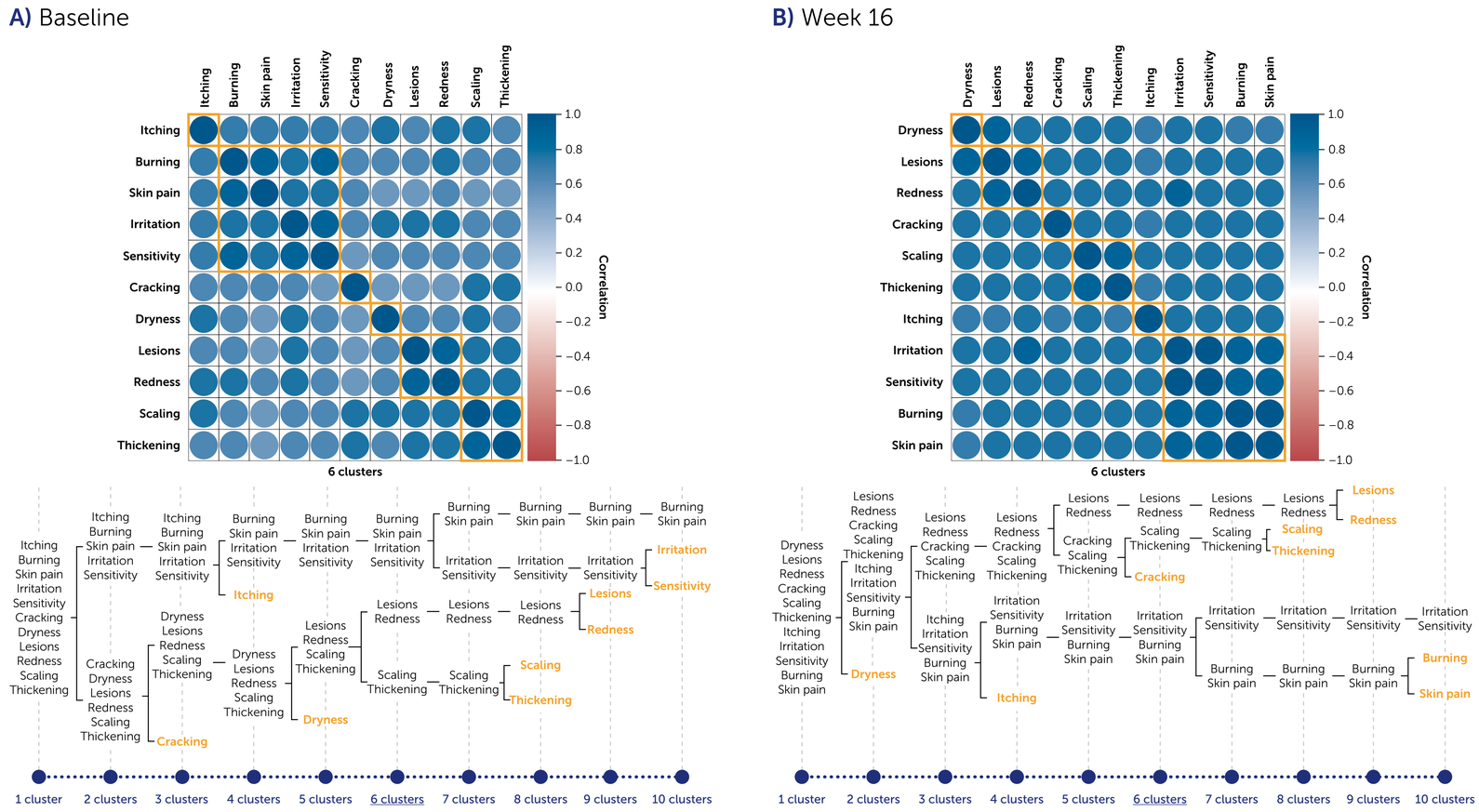
The first two principal components, PC1 and PC2, which explained the majority of the variance at Baseline (84%) and Week 16 (92%), displayed clear separation of the embarrassment, choice of clothing and fatigue items at each timepoint.

Table 2 Regression analysis: Variability of the removed symptom items explained by the retained items

	Removed symptom items			
	Thickening	**Irritation**	**Sensitivity**	**Lesions**
Variability explained by retained symptom items, %				
Baseline (N=1,227)	84.5	87.7	86.9	86.7
Week 16 (N=1,126)	94.2	94.3	92.2	92.6

Symptom items removed following overlap analysis were regressed on the seven retained symptom items. The R-squared statistic was used to determine variability explained.

Figure 2 Inter-item correlations with hierarchical clustering at Baseline and Week 16 (11 symptom items)



The choice to display inter-item correlations with six clusters here is arbitrary and not statistically driven. The number of hierarchical clusters were incrementally increased to see which items remained grouped and which were separated from each other. Clusters containing only one item are not displayed in subsequent steps in the schematics. Pearson correlation coefficients are presented for assessing the strength of correlations between each pair of items. The thickening (overlap with scaling), irritation (overlap with burning and skin pain), sensitivity (overlap with burning and skin pain) and lesions (overlap with redness) items were removed due to having considerable overlap with other items which had been prioritised for retention. Cracking and dryness were retained.

Table 1 Exploratory factor analysis at Baseline and Week 16 (11 symptom items)

A) Baseline — Highest loading for item

	Loadings			
	Factor 1	**Factor 2**	**Factor 3**	**Factor 4**
Itching	0.549	0.388	0.343	0.538
Skin pain	0.843	0.361	0.269	0.215
Scaling	0.356	0.665	0.415	0.383
Redness	0.446	0.424	0.648	0.366
Burning	0.803	0.352	0.337	0.226
Cracking	0.528	0.666	0.283	0.186
Dryness	0.406	0.549	0.411	0.380
Thickening	0.403	0.717	0.440	0.167
Irritation	0.632	0.395	0.416	0.257
Sensitivity	0.723	0.352	0.346	0.212
Lesions	0.383	0.482	0.719	0.171

B) Week 16 — Highest loading for item

	Loadings			
	Factor 1	**Factor 2**	**Factor 3**	**Factor 4**
Itching	0.482	0.650	0.424	0.337
Skin pain	0.703	0.404	0.447	0.344
Scaling	0.434	0.506	0.632	0.331
Redness	0.468	0.482	0.473	0.538
Burning	0.679	0.442	0.429	0.356
Cracking	0.545	0.396	0.585	0.349
Dryness	0.402	0.609	0.452	0.375
Thickening	0.475	0.404	0.635	0.400
Irritation	0.551	0.561	0.413	0.367
Sensitivity	0.594	0.555	0.365	0.332
Lesions	0.449	0.430	0.480	0.572

Only factors with SS loading >1 are presented. This table displays the loading of each item on the respective factor. The factors are given generic labels based on the size of their SS loading (i.e., factor 1 is the factor with greatest SS loading at the specific time point). Factors with the same label at the different time points may capture/reflect different underlying constructs. The vast majority of items removed via the overlap analysis loaded most heavily on the same factor as items which were prioritised for retention, further supporting their removal. The presented factors explained 87.4% of the variance of the items at Baseline and 93.9% of the variance of the items at Week 16.

DLQI: Dermatology Life Quality Index; **EFA:** exploratory factor analysis; **PC:** principal component; **PCA:** principal component analysis; **P-SIM:** Psoriasis Symptoms and Impacts Measure; **SS:** sum of squared.

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References: [1]Warren RB et al. Dermatol Ther (Heidelb) 2021;11:1551–69; [2]Reich K et al. Lancet 2021;397:487–98, NCT03370133; [3]Warren RB et al. N Engl J Med 2021;385:130–41, NCT03412747; [4]Gordon KB et al. Lancet 2021;397:475–86, NCT03410992. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **RBW**, **MA**, **RW**, **JL**, **BH**, **ABG**; Drafting of the publication, or reviewing it critically for important intellectual content: **RBW**, **MA**, **RW**, **JL**, **BH**, **ABG**; Final approval of the publication: **RBW**, **MA**, **RW**, **JL**, **BH**, **ABG**. **Author Disclosures: RBW:** Consulting fees from AbbVie, Almirall, Amgen, Arena, Astellas, Avillion, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly, GSK, Janssen, LEO Pharma, Novartis, Pfizer, Sanofi, and UCB Pharma; research grants to his institution from AbbVie, Almirall, Janssen, LEO Pharma, Novartis, and UCB Pharma; honoraria from Astellas, DiCE Therapeutics, GSK, and Union Therapeutics. **MA:** Consulting fees from AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Celgene, Centocor, Eli Lilly, GSK, Hexal, Janssen, LEO Pharma, Medac, Merck, MSD, Mundipharma, Novartis, Pfizer, Sandoz, UCB Pharma, and Xenoport. **RW:** Veramed statistical consultant for UCB Pharma. **JL**, **BH:** Employees and shareholders of UCB Pharma. **ABG:** Honoraria as an advisory board member and consultant for Almirall, Amgen, AnaptysBio, Avotres Therapeutics, Boehringer Ingelheim, Bristol Myers Squibb, DiCE Therapeutics, Eli Lilly, Highlight Therapeutics, Janssen, Novartis, Sanofi, UCB Pharma, and Xbiotech; research/educational grants from AnaptysBio, Bristol Myers Squibb, Highlight Therapeutics, MoonLake Immunotherapeutics, Novartis, and UCB Pharma (all paid to the Mount Sinai School of Medicine).

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