Psychometric Validation of the Electronic Hidradenitis Suppurativa (HS) Symptom Daily Diary (eHSSDD) and Electronic HS Symptom Questionnaire (eHSSQ) Using Data from the Phase 3 BE HEARD Trials of Bimekizumab in HS

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Objective

To assess the psychometric properties of the electronic hidradenitis suppurativa (HS) Symptom Daily Diary (eHSSDD) and HS Symptom Questionnaire (eHSSQ) using data from two phase 3 trials evaluating bimekizumab in moderate to severe HS.

Background

- HS is a chronic inflammatory disease characterized by painful skin lesions. Symptoms such as pain, itch and smell/odor can have a substantial negative impact on the physical and mental wellbeing of affected patients.[1]
- The eHSSDD and eHSSQ are patient-reported outcome (PRO) tools that have been specifically developed to capture patient-perceived severity of core HS symptoms over the last 24 hours (eHSSDD) or 7 days (eHSSQ).
- For both instruments, patients score items on an 11-point numeric rating scale (0–10), with higher scores indicating a higher level of symptomology.

Methods

- Pooled, blinded data from patients enrolled in the BE HEARD I and II (NCT04242446; NCT04242498) phase 3 trials were analyzed at baseline and Week 16 (eHSSDD: N=934; eHSSQ: N=1,007) (**Table 1**).
- Psychometric analyses were conducted on observed scores for all randomized patients who had at least one non-missing item symptom score of the eHSSDD/eHSSQ at any scheduled assessment visit.
- Simulation analyses to assess the appropriateness of the weekly scoring rule (i.e. ≥4/7 daily scores required) were conducted for the 5 eHSSDD items.
- Test-retest reliability was assessed by calculating intraclass correlation coefficients (ICCs) between baseline and Week 4 (eHSSDD) as well as Week 32 and Week 36 (eHSSQ).
- Convergent/divergent validity was assessed between the eHSSDD and eHSSQ symptom item scores and the following PROs: Dermatology Life Quality Index (DLQI) total score, HS Quality of Life Questionnaire (HiSQOL) total score and clinician-reported outcome (ClinRO; International HS Severity Score System (IHS4), [derived programmatically] post-collection) at baseline and Week 16.
- Known-groups validity was evaluated by comparing eHSSDD and eHSSQ symptom item scores between patient subgroups pre-defined using PRO/ClinRO measures (Patient Global Impression of HS severity [PGI-S-HS], Hurley Stage, and IHS4 [derived programmatically]) at baseline and Week 16.
- Responsiveness was assessed using Spearman's correlation to compare changes over time in eHSSDD and eHSSQ symptom item scores with changes in PGI scales between baseline and Week 16.

Results

- eHSSDD and eHSSQ completion rates were 90.7% and 99.0%, respectively, at baseline and 70.1% and 90.2% respectively, at Week 16.
- Simulation analyses confirmed the appropriateness of the eHSSDD weekly scoring rule.
- Convergent/divergent validity was good for both eHSSDD and eHSSQ, with all correlations in the pre-specified direction and strength (**Table 2**).
- Week 16 changes from baseline in eHSSDD and eHSSQ item scores and PGI scale anchors were moderately-to-strongly correlated (>0.30), establishing responsiveness (**Table 3**).
- Test-retest reliability analyses demonstrated good item score reproducibility for eHSSDD between baseline and Week 4 (ICC 0.80–0.85) and eHSSQ between Week 32 and Week 36 (ICC 0.73–0.82) exceeding the pre-specified threshold of acceptability (0.70) (**Table 4**).
- eHSSDD and eHSSQ item scores discriminated between subgroups as defined by Hurley Stage measures at baseline and Week 16, demonstrating good known-groups validity (**Figure 1**). Similar results were seen comparing eHSSDD and eHSSQ item scores in subgroups defined using PGI-S-HS and IHS4.

Conclusions

eHSSDD and eHSSQ item scores demonstrated good reliability, validity, and responsiveness in patients with moderate to severe HS.

These study results demonstrate that the eHSSDD and eHSSQ item scores are fit-for-purpose to confidently assess treatment effects in the phase 3 BE HEARD trials.

Summary

eHSSDD and eHSSQ showed **good convergent/divergent validity**

eHSSDD and eHSSQ demonstrated **good responsiveness**

eHSSDD and eHSSQ demonstrated **good test-retest reliability**

eHSSDD and eHSSQ could both differentiate between pre-defined severity groups, showing **good known-groups validity**

Table 1 Demographics and baseline disease characteristics of patients

	eHSSDD Pooled Analysis Set (N=934)	eHSSQ Pooled Analysis Set (N=1,007)
Age, years, mean (SD)	37.1 (12.2)	36.7 (12.2)
Sex, female, n (%)	525 (56.2%)	569 (56.5%)
Race, n (%)		
White	722 (77.3%)	771 (76.6%)
Black or African American	88 (9.4%)	103 (10.2%)
Asian	37 (4.0%)	41 (4.1%)
Other or Mixed	44 (4.7%)	46 (4.6%)
Region, n (%)		
North America	350 (37.5%)	382 (37.9%)
Western Europe	271 (29.0%)	290 (28.8%)
Central and Eastern Europe	243 (26.0%)	260 (25.8%)
Asia and Australia	70 (7.5%)	75 (7.4%)
BMI, n (%)		
<25 kg/m^2	140 (15.0%)	155 (15.4%)
25 to <30 kg/m^2	236 (25.3%)	253 (25.1%)
≥30 kg/m^2	555 (59.4%)	596 (59.2%)
Duration of disease, years, mean (SD)	8.0 (7.8)	7.9 (7.8)
Hurley Stage, n (%)		
1	0	0
2	524 (56.1%)	561 (55.7%)
3	409 (43.8%)	446 (44.3%)

Table 2 Convergent/divergent validity for eHSSDD and eHSSQ at baseline and Week 16

Spearman's correlation, r		DLQI Total		HiSQOL Total		IHS4	
		Baseline	Week 16	Baseline	Week 16	Baseline	Week 16
eHSSDD	n	833	652	834	652	846	654
	Worst Skin Pain	0.52	0.56	0.55	0.62	0.25	0.38
	Average Skin Pain	0.51	0.54	0.54	0.60	0.26	0.35
	Smell or Odor	0.45	0.44	0.52	0.53	0.30	0.41
	Itch	0.45	0.45	0.52	0.51	0.20	0.30
	Drainage or Oozing	0.46	0.47	0.54	0.56	0.34	0.48
eHSSQ	n	994	908	996	908	997	904
	Skin Pain	0.59	0.64	0.64	0.70	0.25	0.37
	Smell or Odor	0.48	0.54	0.57	0.62	0.30	0.42
	Itch	0.49	0.55	0.57	0.59	0.18	0.31
	Drainage or Oozing	0.49	0.58	0.58	0.67	0.35	0.49

Gray text indicates a weak correlation (r<0.30), orange text indicates a moderate correlation (0.30≤r<0.70), and green text indicates a strong correlation (0.70≤r<0.90); p<0.001 for all.

Table 3 Correlation between changes in eHSSDD and eHSSQ and external anchors at Week 16 (responsiveness)

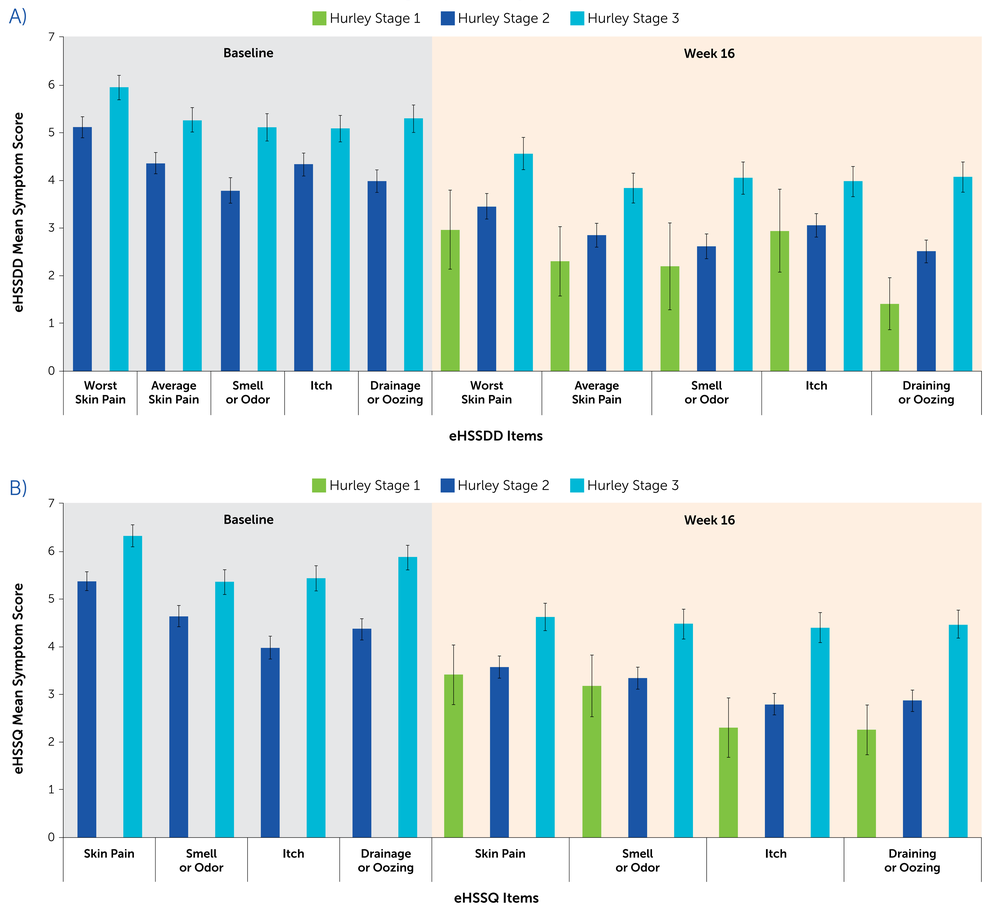
Spearman's correlation, r		External Anchors			
		PGI-S-SP	PGI-C-SP	PGI-S-HS	PGI-C-HS
eHSSDD	n	603	613	602	613
	Worst Skin Pain	0.63	0.51	0.57	0.50
	Average Skin Pain	0.62	0.48	0.58	0.46
	Smell or Odor	0.44	0.37	0.40	0.37
	Itch	0.36	0.34	0.36	0.36
	Drainage or Oozing	0.50	0.40	0.47	0.41
eHSSQ	n	896	898	894	898
	Skin Pain	0.73	0.53	0.68	0.52
	Smell or Odor	0.46	0.39	0.43	0.39
	Itch	0.43	0.40	0.43	0.40
	Drainage or Oozing	0.52	0.42	0.51	0.43

Orange text indicates a moderate correlation (0.30≤r<0.70), and green text indicates a strong correlation (0.70≤r<0.90); p<0.001 for all.

Table 4 Test-retest reliability for eHSSDD between baseline and Week 4, and eHSSQ between Week 32 and Week 36

		ICC
eHSSDD (Baseline vs Week 4)	n	934
	Worst Skin Pain	0.83
	Average Skin Pain	0.84
	Smell or Odor	0.85
	Itch	0.80
	Drainage or Oozing	0.84
eHSSQ (Week 32 vs Week 36)	n	482
	Skin Pain	0.73
	Smell or Odor	0.82
	Itch	0.80
	Drainage or Oozing	0.76

Figure 1 eHSSDD (A) and eHSSQ (B) symptom scores in HS subgroups as defined by Hurley Stage at baseline and Week 16 (known-groups validity)



Error bars show 95% confidence intervals

BMI: body mass index; **ClinRO:** clinician-reported outcome; **DLQI:** Dermatology Life Quality Index; **eHSSDD:** electronic Hidradenitis Suppurativa Symptom Daily Diary; **eHSSQ:** electronic Hidradenitis Suppurativa Symptom Questionnaire; **HiSQOL:** Hidradenitis Suppurativa Quality of Life Questionnaire; **HS:** hidradenitis suppurativa; **ICC:** intraclass correlation coefficient; **IHS4:** International Hidradenitis Suppurativa Severity Score System; **PRO:** patient-reported outcome; **PGI:** Patient Global Impression; **PGI-C-HS:** Patient Global Impression of Change in Severity of Hidradenitis Suppurativa; **PGI-C-SP:** Patient Global Impression of Change in Severity of Skin Pain; **PGI-S-HS:** Patient Global Impression of Severity of Hidradenitis Suppurativa; **PGI-S-SP:** Patient Global Impression of Severity of Skin Pain.

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References: [1]Ingram JR et al. J Eur Acad Dermatol Venereol 2022;36(9):1597–605. **Author Disclosures: JRI:** Receives a stipend as Editor-in-Chief of the British Journal of Dermatology and an authorship honorarium from UpToDate; consultant for Boehringer Ingelheim, ChemoCentryx, Citryll, Novartis and UCB Pharma and has served on advisory boards for Insmed, Kymera Therapeutics and Viela Bio; co-copyright holder of HiSQOL®, Investigator Global Assessment and Patient Global Assessment instruments for HS; his department receives income from copyright of the Dermatology Life Quality Instrument (DLQI) and related instruments. **JSK:** Speaker for AbbVie, Janssen, and UCB Pharma; received grants from Incyte and served as a consultant for AbbVie, ChemoCentryx, InflaRx, Incyte, MoonLake, Novartis, Janssen, and UCB Pharma. **JL, VC, RR, IP, EM:** Employees and shareholders of UCB Pharma. **CGP:** Employee of Evidera, a part of Thermo Fisher Scientific that receives funding for research from UCB Pharma. **Acknowledgments:** This study was funded by UCB Pharma. The authors acknowledge Susanne Wiegratz, MSc, UCB Pharma, Monheim, Germany, for publication coordination, Aditi Mehta, MSc, Costello Medical Consulting, London, UK, for medical writing and editorial assistance and the Costello Medical Creative team for design support. All costs associated with development of this poster were funded by UCB Pharma.

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