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Title: Hidradenitis Suppurativa Patient-Reported Outcome Measures: A Systematic Review and Meta-Analysis

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Key Points

Question

What are the measurement properties of hidradenitis suppurativa (HS)-specific patient-reported outcome measures (PROMs)?

Findings

In this systematic review and meta-analysis of 26 studies, 15 HS-specific PROMs were identified. Seven (HiSQOL-17, PBI-HS, HODs, HIDRAdisk, PtGA-HS, HSBOD, HSSID) met COSMIN standards, demonstrating sufficient content validity and internal consistency. These PROMs involved patients in concept elicitation and presented evidence for unidimensionality. HiSQOL-17 showed the strongest psychometric support and established interpretation thresholds.

Meaning

Seven PROMs met COSMIN criteria for recommendation. Remaining PROMs show promise, but further psychometric validation is needed to inform recommendations for their clinical and research use.

Abstract

Importance: Hidradenitis suppurativa (HS) is a chronic inflammatory skin disorder with high psychosocial burden. Despite growing use of patient-reported outcome measures (PROMs) in HS trials, existing instruments vary in quality and validation.

Objective: To systematically review HS-specific PROMs using the COSMIN framework, evaluating development quality and psychometric evidence, and to perform a meta-analysis of key properties to summarize the evidence base and provide recommendations for clinical and research use.

Data Sources: MEDLINE, EMBASE, and PubMed were searched from inception to October 23, 2025, for English-language studies.

Study Selection: Articles describing the development or validation of HS-specific PROMs that evaluated at least one psychometric property were included. Generic instruments (e.g., Dermatology Life Quality Index, pain NRS) were excluded. Screening was conducted by two independent reviewers.

Data Extraction and Synthesis: Two reviewers independently extracted data, appraised risk of bias with the COSMIN checklist, and graded quality of evidence (QoE) using COSMIN-modified GRADE. Random-effects meta-analysis pooled Cronbach α and correlation coefficients; heterogeneity was quantified using I^2.

Main Outcome(s) and Measure(s): COSMIN-guided appraisal and graded QoE of PROM measurement properties, including content validity, structural validity, internal consistency, reliability, responsiveness, and measurement error.

Results: Of 504 records screened, 26 studies (14 developmental, 12 validation) met criteria, identifying 15 unique HS-specific PROMs (10 health-related quality of life, four symptom, one treatment benefit). Fourteen achieved sufficient content validity and eight (HiSQOL-17, HiSQOL-23, HSIA, HS-QoL, HSSA, QoL-HS, HSSID, HIDE) demonstrated 'very good' development design. Meta-analysis demonstrated strong internal consistency and construct validity for HiSQOL-17 (pooled Cronbach $\alpha = 0.96$; $I^2 = 81.3\%$; pooled $r = 0.84–0.88$; $I^2 = 74–92\%$). Of seven evaluated PROMs, two displayed sufficient internal consistency. The remainder were indeterminate due to absent or low-quality evidence for unidimensionality. Test-retest reliability was sufficient in nine PROMs, and responsiveness was rated sufficient in five. No studies evaluated measurement error. Seven PROMs (HiSQOL-17, PBI-HS, HODs, HIDRAdisk, PtGA-HS, HSBOD, HSSID) met COSMIN criteria for recommendation.

Conclusions and Relevance: Seven (HiSQOL-17, PBI-HS, HODs, HIDRAdisk, PtGA-HS, HSBOD, and HSSID) demonstrated sufficiency of both content validity and either internal consistency, or another relevant measurement property (formative instruments). Further research is needed to strengthen the validation of HS-specific instruments.

Introduction

Hidradenitis suppurativa (HS) is a chronic, inflammatory skin disorder with substantial psychosocial burden.[1] Patient-reported outcome measures (PROMs) capture functional impact and quality of life (QoL), supporting shared decision-making and treatment evaluation.[2] In HS, use of dermatology-specific measures such as the Dermatology Life Quality Index (DLQI) remains common in trials. However, these tools may underestimate disease burden and have poorer responsiveness to change than HS-specific measures that better capture the diverse effects of HS.[3] The Hidradenitis Suppurativa Core Outcomes Set International Collaboration (HiSTORIC) has recommended core patient-reported domains and encouraged outcome standardization.[6] As HS-specific measures vary in quality and measurement properties, identifying those with the strongest validation is important for clinical practice and ~~researcht~~trials.[3] This systematic review identifies and appraises HS-specific PROMs using the COSMIN framework.

Methods

This review followed COSMIN guidance (Version 2.0).[7] The protocol was registered on PROSPERO [CRD420251018744]. MEDLINE, EMBASE, and PubMed were searched to October 23, 2025 (Table S1-S3) to identify English-language studies reporting psychometric validation or development of HS-specific PROMs. Generic PROMs were excluded.

Two reviewers independently screened, extracted, and appraised studies. Appraised measurement properties (Table S4) were judged using COSMIN criteria and COSMIN-modified GRADE.[7] The risk of bias (RoB) was assessed using the COSMIN RoB Checklist (Version 3.1).

For reflective instruments, structural validity and internal consistency were evaluated; these were not applied to formative or single-item PROMs. Random-effects models were used to pool Cronbach α and correlation coefficients (language versions and subscales analyzed separately). **Heterogeneity** was summarized with **I^2**.

Results

Study Selection and Characteristics

From 504 records, 26 studies were included[5,8-32] (14 development and 12 validation, Figure S1), encompassing 15 unique HS-specific PROMs (Table 1). Ten assessed HRQoL, four symptoms, and one treatment-benefit. Total sample sizes were 599 (development) and 5212 (validation) (Table S5).

PROM Development and Content Validity

Eight PROMs – HS Quality of Life (HiSQOL-17) and precursor HiSQOL-23, HS Symptom Assessment (HSSA), HS Impact Assessment (HSIA), HS Quality of Life measure (HS-QoL), Quality of Life in HS (QoL-HS), HS Symptoms and Impacts Daily Diary (HSSID), and the HS Drainage Instrument (HIDE) – achieved 'very good' development based on qualitative concept elicitation and cognitive debriefing (Table S6). Hidradenitis Odour and Drainage Scale (HODs), Patient Global Assessment for HS-specific HRQoL (PtGA-HS), and Patient Benefit Index for HS (PBI-HS) used informal data collection methods and were rated adequate. Four relied on clinician guidance or lacked pilot testing, receiving doubtful/inadequate ratings (Table 2). Only HODs applied a formal Content Validity Index (CVI = 0.77 and 0.74 for Odour and Drainage domains).

All PROMs had sufficient content validity except for PtGA-HS (rated 'inconsistent') (Figure 1). Evidence quality for content validity was low-to-moderate, with moderate QoE the highest grade observed (HiSQOL-17 and 23, HSSA, HSIA, HS-QoL, QoL-HS, HSSID, HIDE).

Quality of Other Measurement Properties

HiSQOL-17 showed the strongest psychometric support, with high-quality evidence for structural validity, internal consistency, reliability, and responsiveness. HODs, PBI-HS, and HIDRAdisk also showed sufficient results for multiple domains, while evidence for the remaining PROMs was mixed. Structural validity was sufficient in three reflective PROMs, with QoE ranging from high (HiSQOL-17) to low/very low (QoL-HS, HODs) due to small samples. Although the HIDE development study and French HiSQOL-17 validation followed COSMIN translation procedures, neither assessed cross-language equivalence. Of seven reflective PROMs assessed for internal consistency, two were sufficient and the rest were indeterminate due to absent or low-quality evidence of unidimensionality (Table S7-S8, Figure 1). Meta-analysis for total HiSQOL-17 (English version) yielded pooled Cronbach's α of 0.94 (I^2 = 94%) (Table S9).

Reliability was sufficient in nine PROMs, and construct validity in nine (≥75% hypotheses confirmed), with meta-analytic results supporting validity for HiSQOL-17 (Pearson r = 0.84; Spearman r = 0.90) and HSQoL-24 (Pearson r = 0.81) (Table S9). Responsiveness was sufficient in five of six evaluated PROMs; PtGA-HS was downgraded due to weak anchors (Figure 1). HiSQOL-17 provided the strongest anchor-based evidence for interpretability, with meaningful change thresholds established for total and subscale scores using multiple convergent anchors. In contrast, the HSSID study found low item–anchor correlations, allowing threshold estimation only for the "worst pain" item.

Recommendations (COSMIN)

Based on COSMIN criteria, HiSQOL-17 demonstrated the most comprehensive validation among HRQoL instruments, with high-quality evidence for reliability, responsiveness, construct validity, and interpretability in both clinical trial and real-world settings. Six additional instruments (HODs, HIDRAdisk, PBI-HS, PtGA-HS, HS Burden of Disease tool [HSBOD], and HSSID) also met Category A criteria, supported by sufficient content validity and internal consistency or another key measurement property. Other PROMs remain promising but limited by incomplete validation (Category B). No PROMs met Category C (high-quality evidence for insufficient measurement properties).

Discussion

This review provides an updated COSMIN-based evaluation of 15 HS-specific PROMs. Among these, HiSQOL-17 demonstrated the strongest psychometric evidence, meeting high-quality criteria across core domains. HODs, HIDRAdisk, PtGA-HS, HSBOD, and HSSID also met COSMIN standards for recommendation, spanning HRQoL, symptoms, and treatment-benefit. However, data on measurement error and feasibility remain limited.

Most instruments, including HiSQOL-17, PBI-HS, and HODs, incorporated semi-structured qualitative interviews and cognitive debriefing, aligning with COSMIN standards for content validity. Although the French HiSQOL-17 validation followed COSMIN-recommended cross-cultural procedures, it lacked any formal invariance testing.

HiSQOL-17 and HODs were the only instruments with strong evidence for unidimensional structure and internal consistency across domains. In contrast, several multidomain tools such as

HSQoL-24, HS-QoL, and QoL-HS limited evidence for unidimensionality undermined justification for score aggregation. Importantly, HiSQOL-17 provided clinically meaningful change thresholds aiding interpretation of within-patient and group-level changes. Although such thresholds reflect group averages and may not capture individual trajectories due to measurement error, they remain essential for contextualizing clinically important differences between treatments. Emerging instrument HSSID presented preliminary interpretability data, with valid thresholds estimated for the "worst lesion-related pain" item. This mirrors findings in other dermatologic conditions, such as psoriasis, where interpretation evidence is inconsistent.[33]

The HiSTORIC consensus identified patient-reported core domains for HS trials, including HS-specific QoL, pain, patient global assessment, and symptoms of drainage and fatigue.[6, 34] Recently developed instruments such as HSSID and HIDE address these under-measured symptoms, targeting broader symptom burden (pain, fatigue, odour, and drainage) and drainage severity, respectively. However, both remain in early validation, with HIDE evaluated only for content validity. Although pain is often assessed using generic NRS or VAS scales, none of the reviewed PROMs captured detailed pain characteristics (e.g. neuropathic vs inflammatory pain).[3, 35]

This review has several limitations. Statistical heterogeneity was high in several pooled analyses ($I^2 > 90\%$), limiting confidence in pooled estimates. Subgroup analyses were not feasible due to few eligible studies per category. Generic dermatology instruments such as the DLQI and NRS/VAS pain scales were not evaluated in this review. Although the French HiSQOL-17 and the HIDE study followed recommended translation steps, none of the studies assessed measurement invariance. Measurement error and feasibility remain unaddressed. A broader

limitation of the COSMIN framework is its reliance on classical test theory, with limited integration of modern approaches such as Rasch and item response theory.[36] None of the included instruments were developed or validated using these models.

Despite these gaps, this review provides a foundation for standardizing PROM use in HS trials, with recommendations grounded in the gold standard COSMIN criteria. Further high-quality psychometric validation is needed to strengthen patient-centered outcome measurement in HS.

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Author contributions:

N.T. had full access to all the data and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Concept and design: NT

Acquisition, analysis, or interpretation of data: All authors.

Drafting of the manuscript: NT.

Critical revision of the manuscript for important intellectual content: All authors.

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Data sharing:

The review protocol was registered in PROSPERO [CRD420251018744] and can be accessed. Additional materials such as data collection template, raw data included in analysis, and R software code used for meta-analysis can be provided by the corresponding author (NT) upon reasonable request.

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Figure 1. COSMIN Ratings and GRADE Certainty of Evidence of Other Measurement Properties for HS-Specific PROMs

COSMIN quality ratings were assigned according to the criteria for good measurement properties and are represented by a green/red/yellow/grey scale: Sufficient (green), Insufficient (red), Indeterminate (yellow), and Not Evaluated (grey). Certainty of evidence for each measurement property was graded using the COSMIN-modified GRADE approach and is displayed in shades of blue (High**,** Moderate**,** Low**,** Very Low), with greater color intensity indicating higher certainty of evidence. Abbreviations: NA=not applicable; NE=not evaluated; ?=indeterminate. For single-item or formative instruments where structural validity and internal consistency are not conceptually applicable (e.g., PtGA-HS, HIDRAdisk, PBI-HS), these were denoted as 'NA' in tables, whereas 'NE' indicates properties that were applicable but not evaluated.

Table 1. Characteristics of Hidradenitis Suppurativa-Specific Patient-Reported Outcome Measures

PROM [a]	Construct	Recall Period	No. of Items	(Sub)scale(s)	Response Options	Range of (Sub)Scale and Scoring [b]
HiSQOL-17 [7] (English)	HRQoL	7 days	17	3 domains: Symptom, psychosocial, activities/adaptation	**5-point Likert/adjectival scale**	0–68
HiSQOL-17 [29] (French version)	HRQoL	7 days	17	3 domains: Symptom, psychosocial, activities/adaptation	**5-point Likert/adjectival scale**	0-68
PBI-HS [15]	Patient-reported treatment benefit	NR	26	2 domains: Physical impairments, Psychosocial impairments	**5-point Likert/adjectival scale**	0 to 4, Mean benefit score (higher = more benefit)
HSQoL-24 [16]	HRQoL	4 weeks	24	6 domains: Psychosocial; Daily activities; Symptoms; Sexual activity; Employment; Relationships	4-point Likert/adjectival scale	0 to 96
HS-QoL [20]	HRQoL	NR	44	7 domains/subscales: Physical consequences; HS symptoms; sexual activity; emotional; social; work; social support	5-point Likert/adjectival scale	Each subscale scored as a mean (1–5)
PtGA-HS [12]	HRQoL	7 days	1	1 (single-item global measure)	5-point Likert/adjectival scale	0-4
HSSA [22]	HS-symptom severity	7 days	9	1 domain: Signs and symptoms	11-point NRS (0-10)	0-100 (rescaled)
HSIA [22]	HRQoL	7 days	18	1 domain: Impacts	11-point NRS (0-10)	0-100 (mean of items 1-16)
HiSQOL-23 [23]	HRQoL	7 days	23	3 domains: Physical, psychological, and social QoL domains	5-point Likert/adjectival scale	NR
HIDRAdisk [c, 24]	HRQoL	7 days	10	10 domains: skin; symptom control; uneasiness; sexuality; social life; work; daily activities; odour; general health; pain	5-point Likert/adjectival scale	Scores connected in a polygon. Larger polygon area = greater burden

Senthilnathan et al's HSSA [26]	HS-symptom Severity	NR	1	1 severity selection task using photo grid	One score (from 10 photographs representing Hurley stages 0–3)	0–3 (clear skin to Hurley Stage 3)
QoL-HS [27]	HRQoL	7 days	22	2 domains/subscales: social and psychological impairment; physical impairments	5-point Likert/adjectival scale	For each subscale: Average of all item scores (0-4)
HODS [13]	Odour and drainage-specific symptom severity	NR	8	2 domains/subscales: odour; drainage	5-point Likert/adjectival scale	1-5 for each subscale
HSBOD [28]	HRQoL	NR	19	5 domains: symptoms and feelings, daily activities, leisure, work/school, personal relationships	Visual analog scale	0-10, Average of all item scores
HSSID[30]	Symptoms and associated burden	24-hour	11	Two domains: symptoms of HS (pain, itching, drainage, odour, and physical fatigue) and impacts (walking, moving, sleep, socializing, emotions, work)	NRS and verbal rating scales	For NRS-formatted questions, range was 0-10; daily responses incorporated into weekly score calculated as average of 7 daily scores
HIDE[31]	Drainage symptom severity and burden	7 days	2	One domain: drainage	NRS for both items/questions	0-10, one score for overall drainage and one score for worst level of drainage experienced in last 7 days

Abbreviations: HiSQOL (17 items) = Hidradenitis Suppurativa Quality of Life (an instrument developed by Kirby et al. in 2020); HSQoL-24 = HS-specific Quality of Life (24 items); HiSQOL (23 items)=Hidradenitis suppurativa-specific quality of life instrument (developed by Thorlacius et al. in 2019); HSBOD = Hidradenitis Suppurativa Burden of Disease tool; HRQoL=health-related quality of life; HS= Hidradenitis Suppurativa; PROM = patient-reported outcome measure; Pt-GA-HS = Patient global assessment for HS-specific health-related quality of life; PBI-HS = Patient benefit index for HS; HSSID = HS symptoms and impacts daily diary; HIDE =HS drainage instrument; NR = not reported; NRS = numeric rating scale

[a]Citation for development study of PROM

[b]Higher scores generally indicate worse disease burden or poorer QoL unless otherwise specified (e.g. PBI-HS, higher score = greater benefit)

[c]For HIDRAdisk, scores are visually represented as a polygon; larger polygon area denotes greater burden

Table 2. HS-Specific Patient-Reported Outcome Measure (PROM) Development and Content Validity Quality Rating

Source[c]	PROM	PROM Development [a]		Content Validity [b]			Overall	
		Design	Pilot Study	Relevance	Comprehensiveness	Comprehensibility	Quality [c]	GRADE [d]
Kirby 2020[7]	HiSQOL-17	VG	VG	+	+	+	+	M
Thorlacius 2025[29]	HiSQOL-17 (French)	NA	D	NA	NA	?	?	?
Kirby 2021 [12]	PtGA-HS	A	VG	+	-	+	±	VL
Machado 2021 [13]	HODs (odour and drainage scales)	A	VG	+	+	+	+	L
Marron 2019 [16]	HSQoL-24	D	D	+	+	+	+	VL
Kirsten 2025 [15]	PBI-HS	A	VG	+	+	+	+	L
Kimball 2018 [22]	HSSA	VG	VG	+	+	+	+	M
Kimball 2018 [22]	HSIA	VG	VG	+	+	+	+	M
Thorlacius 2019 [23]	HiSQOL-23	VG	VG	+	+	+	+	M
Sisic 2017 [20]	HS-QoL	VG	VG	+	+	+	+	M
Chiricozzi 2019 [24]	HIDRA Disk	A	D	+	+	+	+	L
Senthilnathan 2019 [26]	HSSA	I	D	+	+	+	+	VL
Otten 2023 [27]	QoL-HS	VG	VG	+	+	+	+	M

Pinard 2018 [28]	HSBOD	D	D	+	+	+	+	VL
Ingram 2025[30]	HSSID	VG	A	+	+	+	+	M
Thorlacius 2025[31]	HIDE	A	A	+	+	+	+	L

Abbreviations: HiSQOL (17 items) = Hidradenitis Suppurativa Quality of Life (an instrument developed by Kirby et al. in 2020); HSQoL-24 = HS-specific Quality of Life (24 items); HiSQOL (23 items)=Hidradenitis suppurativa-specific quality of life instrument (developed by Thorlacius et al. in 2019); HSBOD = Hidradenitis Suppurativa Burden of Disease tool; HS= Hidradenitis Suppurativa; PROM = patient-reported outcome measure; Pt-GA-HS = Patient global assessment for HS-specific health-related quality of life; PBI-HS = Patient benefit index for HS

[a]Methodological quality and risk of bias (RoB) scored according to COSMIN RoB guidelines, denoted as: VG = very good; A=adequate; D=doubtful; I=inadequate

[b]Summarized quality score based on COSMIN definitions and 10 criteria for good measurement properties, taking into account 1) PROM development quality; 2) pilot study quality and 3) reviewers' own ratings. No additional content validity studies outside of original development study were identified for HS-specific PROMs. Denoted as: (+)=Sufficient; (±) = Inconsistent, (–) = Insufficient

[c]Summarized rating for content validity per PROM evaluated as follows: (+) if all elements (relevance, comprehensiveness, and comprehensibility) are (+); (-) assigned if all elements are (-). (±) assigned if at least one of the ratings is (+) or (±) and at least one of the ratings is (–) or (±)

[d]Quality of evidence scored using COSMIN Grade Scoring, denoted as: H=high; M=moderate; L=low; VL= very low

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