



Review Paper

Systematic Review of Health-related Quality of Life Measures for Inflammatory Bowel Disease

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Abstract

Background and aim: Several measures have been developed to assess the health-related quality of life [HRQoL] of patients with inflammatory bowel disease [IBD]. Our aim is to systematically review the HRQoL measures specific for patients with IBD and to appraise their measurement properties and methodological quality.

Methods: We searched the PubMed, Embase, and PsycINFO databases for original articles describing the development and/or evaluation of one or more of the measurement properties [e.g. internal consistency, reliability, validity, responsiveness] of HRQoL measures specific for IBD. We assessed the measurement properties and examined the methodological quality of the measurement properties of each instrument using a standardized checklist.

Results: We examined the full text of 75 articles that we deemed potentially eligible and identified 10 disease-specific HRQoL measures in IBD that covered different aspects of patients' lives. Internal consistency, construct validity, and content validity were the commonly evaluated measurement properties. Seven HRQoL measures scored positive for at least four of eight measurement properties. The majority of studies were rated as 'fair' to 'poor' when assessing their methodology quality. The most established HRQoL measure in the literature was the Inflammatory Bowel Disease Questionnaire [IBDQ].

Conclusions: Most of the included HRQoL measures did not include all the required measurement properties or had a problem with their methodological quality. The most widely used and validated measure was the IBDQ. Further validation studies are required to support the use of other HRQoL measures.

Keywords: Patient-reported outcome measures, quality of life, Crohn's disease, ulcerative colitis, inflammatory bowel disease

1. Introduction

Inflammatory bowel disease [IBD] is known to impair quality of life^{1–4} and cause a substantial burden to patients, their families, and society.^{4–7} It affects patients' lives mentally, emotionally, socially, and physically.^{7,8}

Health-related quality of life [HRQoL] is a multidimensional concept that measures physical, emotional, mental, and social impact of the disease on patients' lives.⁹ Measuring HRQoL provides an

important insight into patients' perception of their health and the effect of treatments. Instruments used to measure HRQoL may be generic or disease-specific. Disease-specific instruments assess domains specific to a given disease and are therefore considered more sensitive to changes in the patient's health state.¹⁰ Generic instruments, by contrast, are aimed at measuring the overall HRQoL of patients and, therefore, are useful to compare HRQoL across different disease states as well as for the evaluation of health economics outcomes.^{11,12}

In the past two decades, measurement of HRQoL has been increasingly used in IBD to support both research and clinical care.^{1,13–19} This has led to a better evaluation of patients' health and subsequently to improvements in their quality of care.^{15,16} In scientific research, these measures are important to evaluate the effectiveness of new therapies in clinical trials. An up-to-date systematic review will provide a useful resource for research professionals and IBD specialists to ensure they can select an appropriate HRQoL measure for patients in their practice.

The aim of this article is to systematically review the current HRQoL measures specific for patients with IBD and to appraise their measurement properties using a robust evaluation methodology checklist.

2. Methods

2.1. Search strategy

This systematic review was undertaken in line with the search strategies checklist of the Cochrane review group²⁰ and followed the PRISMA [Preferred Reporting Items for Systematic Reviews and Meta Analysis] statement²¹ [Appendix 1, available as Supplementary data at JCC online].

We searched the following electronic databases via Ovid SP up to 1 October 2013: MEDLINE, EMBASE, and PsychoINFO. Key search terms and add synonyms were searched separately in three main filters that were merged together. Targeted hand searches using the names of measures identified in the initial searches were carried out. The detailed search strategy can be found in Appendix 2 [available as Supplementary data at JCC online]. It involved:

1. Target population: Inflammatory bowel disease, Crohn's disease, ulcerative colitis, terminal ileitis, regional ileitis, granulomatous enteritis, proctitis, proctocolitis, and colitis.
2. Construct: quality of life, health related outcome measure, patient-reported outcome measure, disability, health status, health-related quality of life, health status measures, patient outcome assessment, and questionnaire.
3. Psychometric properties of HRQoL measures: psychometrics, reproducibility, reliability, validation studies, validation, face validity, content validity, construct validity, concurrent validity, convergent validity, and discriminant validity.

2.2. Selection criteria

We included all original articles in English describing the development and/or evaluation of one or more of the measurement properties [e.g. internal consistency, reliability, validity, responsiveness] of the HRQoL measures specific for patients with IBD. Articles were included if they sought to assess at least one domain of quality of life in IBD.

Two reviewers [LA and IR] independently screened titles, abstracts and the references of these articles to obtain any additional articles of relevance. Full texts of eligible articles were obtained. If any disagreement existed regarding the inclusion or exclusion of articles, a third independent reviewer was consulted.

2.3 Data extraction

Data from eligible articles were extracted independently using a pre-prepared data extraction proforma. The following data were extracted:

1. Different disease-specific HRQoL measures. For each questionnaire we identified the dimensions of HRQoL that were assessed [e.g. social, work, disease burden, etc.].
2. Measurement properties: we assessed the measurement properties of each HRQoL measure using the quality properties checklist proposed by Terwee et al.²² [Table 1] which were: [1] reliability [including internal consistency, reliability, and measurement error]; [2] validity (including content validity, structural validity and hypothesis testing [construct validity]); and [3] responsiveness.
3. Methodology quality assessment: we reported on the methodological quality of the original development studies for the included HRQoL measures using the COSMIN [Consensus-based Standards for the selection of health Measurement Instruments] checklist.^{23,24} The COSMIN checklist assesses the methodology quality of the internal consistency, reliability, measurement error, responsiveness, content validity, construct validity, and factor analysis [structural validity]. Each measurement property methodology was assessed against certain quality standards and rated on a 4-point scale [1 = poor, 2 = fair, 3 = good, or 4 = excellent]. The overall score for the methodological quality of a certain property is determined by taking the lowest rating. Depending on the number of measurement properties assessed in a study, some studies received one quality evaluation whereas other studies received several. The measurement property of a study was rated as having 'excellent' quality if all relevant COSMIN items were scored adequate.
4. Levels of the HRQoL measure establishment or use in literature: we used Cohen's criteria²⁵ [Table 2] to determine the level of establishment of each specific HRQoL measure. The Cohen criteria classify the measures into three levels of establishment depending on the number of publications, the extent to which the measures are described in literature, and their psychometric properties.

3. Results

3.1. Results of the database search and included studies:

The database search resulted in 437 articles [Figure 1]. References were uploaded into EndNote and duplicates were removed, leaving 389 articles. After screening the titles and abstracts, 196 articles were excluded because they did not include validation of the HRQoL, and 10 articles were excluded because they were published as abstracts in conferences and not as full papers. The full texts of 183 articles were obtained and reviewed. We excluded 108 articles that did not include the validation or evaluation of the psychometric properties of the HRQoL measures; 75 articles were deemed eligible. After linking multiple reports of the same HRQoL measure, we identified 10 disease-specific HRQoL measures in IBD [Table 3]:

1. Inflammatory Bowel Disease Questionnaire [IBDQ]^{26,27}
2. Shortened Inflammatory Bowel Disease Questionnaire [SIBDQ]²⁸
3. IBDQ was further shortened to 9 items, the IBDQ-9²⁹
4. Rating form of IBD patient concerns [RFIPC]³⁰
5. Edinburgh IBD Quality of Life Questionnaire [EIBDQ]³¹
6. The IBD disability score³²
7. The IBD disability index³³
8. Social Impact of Chronic Conditions–Inflammatory Bowel Disease [SICC-IBD] questionnaire³⁴
9. Crohn's Disease Perceived Work Disability Questionnaire [CPWDQ]³⁵
10. Crohn's disease burden questionnaire.³⁶

Table 1. Quality criteria for rating the results of measurement properties.²²

Properties	Ratings	Quality criteria
Reliability		
Internal consistency	+	Cronbach's alpha[s] between 0.70 and 0.90
	?	No information available
	–	Cronbach's alpha[s] < 0.70 or > 0.90 or not done
Reproducibility [test-retest reliability]	+	Intra-class correlation coefficient (ICC) ICC or weighted kappa \geq 0.70 OR Pearson's $r \geq$ 0.80
	?	No information available
	–	ICC/weighted kappa < 0.70 OR Pearson's $r <$ 0.80
Measurement error	+	Measurement error, smallest detectable change [SDC] are measured. SDC is less than MIC
	?	No information available
	–	The study did not report convincing evidence that the measurement error was assessed or/ and it was more than the Minimal important change (MIC) MIC
Validity		
Content validity	+	Appropriate assessment of content validity was performed
	?	No information available
	–	Content validity was not assessed properly
Factor analysis	+	Important factors/domains should explain at least 50% of the variance
	?	No information available
	–	Important factors/domains explain < 50% of the variance
Construct validity hypothesis testing	+	Correlation coefficient for the validity should be in the middle, i.e. 0.40.8
	?	No information available
	–	Correlation coefficient for the validity is not between 0.4 and 0.8
Responsiveness	+	Responsiveness was assessed using an appropriate method
	?	No information available
	–	Responsiveness was not assessed using an appropriate method
Ceiling and floor effects	+	\leq 15% of the respondents achieved the highest or lowest possible scores
	?	No information available
	–	>15% of the respondents achieved the highest or lowest possible scores, despite adequate design and methods
Interpretability	+	Mean and SD scores presented of at least four relevant subgroups of patients and MIC defined
	?	No information available
	–	Mean and SD scores were not presented of at least four relevant subgroups of patients or MIC was not defined

+, positive rating; ?, no information available or indeterminate rating; –, negative rating. ICC: Intra-class correlation coefficient, MIC: Minimal important change, SDC: smallest detectable change

Table 2. Cohen criteria for the level of credibility of the outcome measures.²⁵

Category	Criteria
Well-established assessment	I. The measure must have been presented [validated] in at least two peer-reviewed articles by different investigators or investigatory teams II. Sufficient detail about the measure to allow critical evaluation and replication [e.g. measure and manual provided or available upon request] III. Detailed [e.g. statistics presented] information indicating good validity and reliability in at least one peer-reviewed article
Approaching well-established assessment	I. The measure must have been presented in at least two peer-reviewed articles, which might be by the same investigator or investigatory team II. Sufficient detail about the measure to allow critical evaluation and replication [e.g. measure and manual provided or available upon request] III. Validity and reliability information either presented in vague terms [e.g. no statistics presented] or only moderate values presented
Promising assessment	I. The measure must have been presented in at least one peer-reviewed article II. Sufficient detail about the measure to allow critical evaluation and replication [e.g. measure and manual provided or available upon request] III. Validity and reliability information either presented in vague terms [e.g. no statistics presented] or moderate values presented

3.2 Assessing the psychometric properties of the HRQoL measures

A narrative summary of the included measures and their properties assessment is presented in Table 4. The IBDQ was the most

widely used HRQoL in IBD. Although the original papers^{26,27} did not report all the psychometric properties, subsequent studies validated the IBDQ into different languages and have further proved its validity, internal consistency, and reliability.^{37–51} The 32-item IBDQ

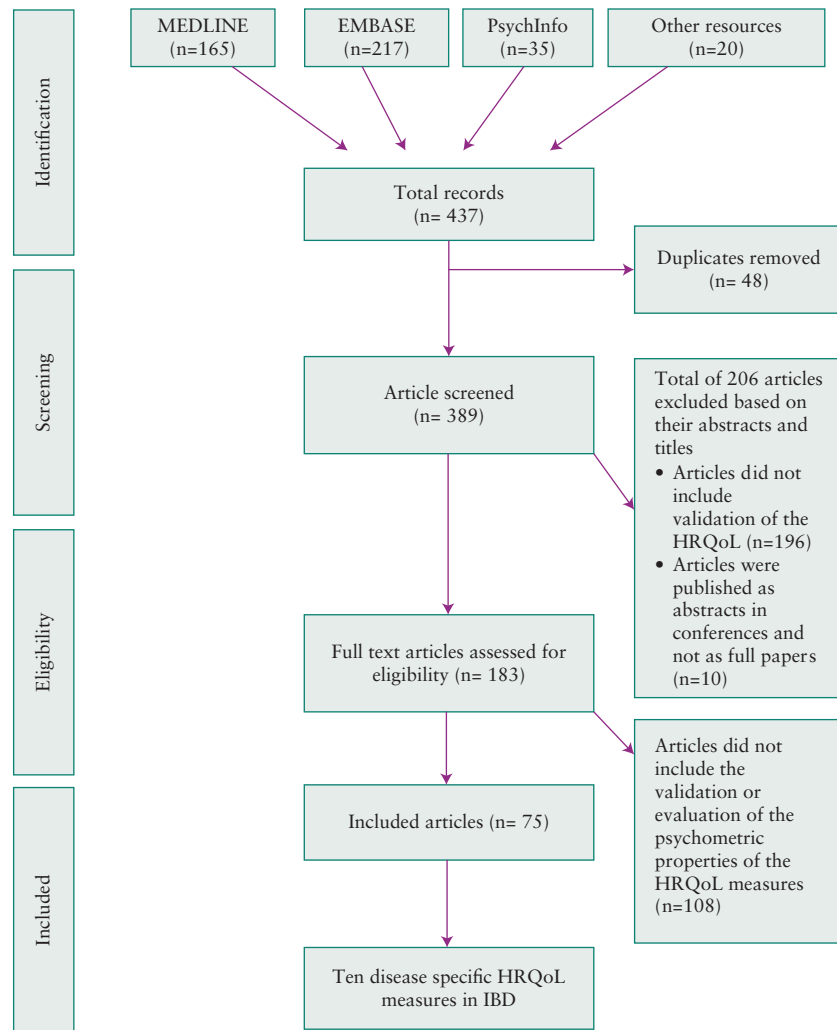


Figure 1. Flow chart of the systematic search results.

questionnaire was shortened to 10 items [short IBDQ]²⁸ and 9 items [IBDQ-9].²⁹ When evaluating the measurement properties for the rest of the HRQoL measures using the Terwee's criteria, none has met all the criteria. Flooring and ceiling effects were not clearly reported when validating most of the HRQoL measures. When appraising the internal consistency of each measure, eight measures achieved the recommended Cronbach α value of 0.70.⁹²² [Table 1]. Two measures did not have their internal consistency assessment reported in the literature. Ratings of the content validity were good for most of the measures, as they used appropriate methods in generating items that covered various quality of life aspects of IBD [e.g. focus group, patient involvement, item generation and selection, measure reduction, etc.]. CD burden measure did not use an appropriate method to generate the items. Construct validity was appropriately assessed in almost all measures except the IBD disability index, which was not fully validated. The HRQoL measures were compared with other measures of disease severity or quality of life. Six HRQoL measures correctly assessed the test-retest reliability and achieved the required values of the intraclass correlation coefficient, Kappa coefficients, or confidence intervals. Most of the measures did not assess the inter-rater reliability as part of the reliability testing. Three HRQoL measures had their responsiveness assessed in the original study report using the required statistics such as responsiveness ratio or paired

t-tests. Seven measures did not have their responsiveness reported in literature. Measurement error evaluation and factor analysis were not assessed for most of the HRQoL measures.

3.3 Assessing the methodology qualities of the HRQoL measures

None of the HRQoL measures development studies showed adequate methodological quality in all COSMIN sections. Most of the publications scored excellent for content validity, having captured the domains that are relevant to IBD patients through consultation with patients and/or literature review or other methods as described by Steiner and Norman.⁵² Although all HRQoL measures assessed the construct validity using other measures of HRQoL or disease activity, more than half of the measures scored 'fair' either because they did not provide information on the missing items, a hypothesis regarding the direction and magnitude of correlations, or sample size, or did not achieve the required statistics. Most HRQoL measures were assessed for reliability, internal consistency, and responsiveness. However, for most of them, this was not described in enough detail to meet the COSMIN criteria. Most of the publications did not report how missing items were handled nor how repeated measurements were conducted [mode of administration, sample size, statistical analyses, and time interval for test-retest].

Table 3. Summary of the specific HRQoL measures in IBD.

HRQoL measures	References	Year	Domains covered	Items (number)
1. IBDQ	26,27	1989	Disease-specific HRQoL measure. It includes gastrointestinal symptoms, systemic symptoms, emotional dysfunction and social dysfunction domains	32
2. SIBDQ	28	1996	A short version of IBDQ. It includes feeling tired, social aspects, sport activities, pain, depression, wind, weight, feeling relaxed, going to toilet even if bowel empty, and feeling angry	10
3. IBDQ-9	29	2004	A shorter version of IBDQ-36. Includes nausea, delay social engagement, passing wind, bowel movements, abdominal cramps, unwellness, fatigue, feeling happy, energy level	9
4. RFIPC	30	1991	Four components are: a) impact of disease [e.g. being a burden, loss of energy, loss of bowel control]; b) sexual intimacy; c) complications of disease [e.g. developing cancer, having surgery, dying early]; and d) body stigma [e.g. feeling dirty or smelly]	25
5. EIBDQ	31	2002	Three underlying dimensions: a disease-specific factor, a bowel-specific factor, and an information factor	15
6. IBD disability score	32	2013	Assesses the disability of patients with IBD. The questionnaire comprises the following domains: demographics, mobility, gastrointestinal-related problems, self-care, major life activities, mental health, and interaction with the environment	49
7. IBD disability index	33	2012	Based on the ICF coding system for IBD. General health, body functions, body structures, activities and participation, environmental factors	28
8. SICC-IBD	34	2012	Assesses social dysfunction of IBD patients. It covers education, work, earnings, and relationships	8
9. CPWDQ	35	2011	Assesses the impact of Crohn's disease on the patients at work. Asks about the impact of weight loss, fistula, surgery, symptoms, stoma, pain, using toilet facilities, medications, feelings, work relationship, work capacity, work stability, incontinence	16
10. CD burden	36	2010	It measures the burden of Crohn's disease [CD] and its treatment on HRQoL	2

HRQoL, health-related quality of life; SIBDQ, Shortened Inflammatory Bowel Disease Questionnaire; RFIPC, rating form of IBD patient concerns; EIBDQ, Edinburgh Quality of Life Questionnaire; SICC-IBD, social impact of chronic conditions – inflammatory bowel disease; CPWDQ, Crohn's Disease Perceived Work Disability Questionnaire. ICF, international classification of functioning, disability and health

Table 4. The measurement properties of the specific HRQoL measures used in IBD.

HRQoL measures	Internal consistency	Test-retest reliability	Measurement error	Content validity	Factor analysis	Construct validity	Responsiveness	Ceiling and floor effects
1. IBDQ	+	+	+	+	+	+	+	+
2. SIBDQ	+	+	-	+	-	+	+	-
3. IBDQ-9	+	+	-	+	-	+	+	-
4. RFIPC	+	+	-	+	+	-	-	-
5. EIBDQ	+	-	-	+	+	+	-	-
6. IBD disability score	+	+	+	+	-	+	-	-
7. IBD disability index	-	-	-	+	-	-	-	-
8. SICC-IBD	+	-	-	+	-	+	-	-
9. CPWDQ	+	+	-	+	+	+	-	-
10. CD burden	-	-	-	-	-	+	-	-

HRQoL, health-related quality of life; SIBDQ, Shortened Inflammatory Bowel Disease Questionnaire; RFIPC, rating form of IBD patient concerns; EIBDQ, Edinburgh Quality of Life Questionnaire; SICC-IBD, social impact of chronic conditions – inflammatory bowel disease; CPWDQ, Crohn's Disease Perceived Work Disability Questionnaire.

Most of the studies did not include the assessment of measurement error or factor analysis in the measure development and were rated 'poor' for these criteria. [Table 5](#) shows the COMSIN ratings for the IBD-specific HRQoL measures.

3.4 Assessing the level of credibility of the HRQoL measures:

We used Cohen's criteria²⁵ to appraise the degree establishment of the different HRQoL measures in IBD. According to Cohen's criteria, only the IBDQ and SIBDQ were considered to be well-established

measures, and the RFIC was approaching the level of well-established assessments. The rest were rated as promising assessments [[Table 6](#)].

4. Discussion

Assessing the HRQoL in patients with IBD is an important outcome measure in assessing the efficacy of new treatments or interventions. Typically, HRQoL measures have been developed and used to describe mean scores [or mean response] for a group of patients

Table 5. The methodological quality of HRQoL measurement properties as described in the original development articles.

	HRQoL measures	References	Internal consistency	Reliability	Measurement error	Content validity	Factor analysis	Construct validity	Responsiveness
1.	IBDQ	^{26,27}	Poor/fair	Fair	Poor	Excellent	Poor	Fair	Fair
2.	SIBDQ	²⁸	Poor/fair	Fair	Poor	Excellent	Poor	Fair	Poor
3.	IBDQ-9	²⁹	Fair	Fair	Poor	Excellent	Poor	Fair	Poor
4.	RFIPC	³⁰	Excellent	Good	Poor	Excellent	Excellent	Excellent	Poor
5.	EIBDQ	³¹	Fair	Poor	Poor	Excellent	Fair	Fair	Poor
6.	Allen et al	³²	Poor	Poor	Fair	Excellent	Poor	Good	Poor
7.	IBD disability index	³³	?	?	?	Excellent	?	?	?
8.	SICC-IBD	³⁴	Poor	Poor	Poor	Excellent	Poor	Good	Poor
9.	CPWDQ	³⁵	Fair	Fair	Poor	Excellent	Fair	Fair	Poor
10.	CD burden	³⁶	Poor	Poor	Poor	Poor	Poor	Fair	Poor

HRQoL, health-related quality of life; SIBDQ, Shortened Inflammatory Bowel Disease Questionnaire; RFIPC, rating form of IBD patient concerns; EIBDQ, Edinburgh Quality of Life Questionnaire; SICC-IBD, social impact of chronic conditions – inflammatory bowel disease; CPWDQ, Crohn's Disease Perceived Work Disability Questionnaire.

Table 6. Assessing the level of establishment of the HRQoL measures.

Category	Outcome measures
Well-established assessment	IBDQ ^{26,27,38,41,69,70,71} and SIBDQ ^{28,72,75}
Approaching well-established assessment	RFIC ^{30,76,78}
Promising assessment	UK-IBDQ, ⁵¹ IBDQ-9, ²⁹ SICC-IBD, ³⁴ CPWDQ, ³⁵ Allen <i>et al.</i> , ³² EIBDQ, ³¹ CD burden, ³⁶ IBD disability index ³³

HRQoL, health-related quality of life; SIBDQ, Shortened Inflammatory Bowel Disease Questionnaire; RFIPC, rating form of IBD patient concerns; EIBDQ, Edinburgh Quality of Life Questionnaire; SICC-IBD, social impact of chronic conditions – inflammatory bowel disease; CPWDQ, Crohn's Disease Perceived Work Disability Questionnaire.

[e.g. those in each arm of a trial]. The past decade has seen a rapid increase in the number of measures to assess HRQoL in patients with IBD.^{32–36,53–57}

In this systematic review we identified 10 different HRQoL-specific measures used for patients with IBD. We assessed the internal consistency, reliability, measurement error, content validity, factor analysis, construct validity, responsiveness, and ceiling and flooring effects, depending on the information obtained from the literature. Some of the HRQoL measures had some aspects of psychometric strength, especially construct validity. However, they varied greatly in terms of their characteristics and most of them did not demonstrate all the properties proposed by Terwee *et al.*²² Notably the IBDQ,^{26,27} which is the most commonly used HRQoL measure in the literature, was not fully validated in the original study. However, it was further validated in subsequent studies that used it or translated it into other languages. The IBDQ has the advantage of having shorter versions [SIBDQ²⁸ and IBDQ-9²⁹] and has been translated into different languages, which facilitates its use worldwide.

We used the COSMIN checklist^{23,24} to appraise the methodological quality of the original HRQoL measures development studies. This included evaluation of the methodological quality of different properties such as the reliability, internal consistency, content validity, structural validity [factor analysis], responsiveness, measurement error, and construct validity. Using the COSMIN criteria of the methodology quality, the majority of studies were rated as 'fair' to 'poor' either because they did not reach the required standards or

because of insufficient information. These studies are not necessarily of poor quality, but our results suggest that high quality studies are required to properly evaluate their measurement properties.

We also assessed the level of establishment of the HRQoL measures using the Crohn's criteria.²⁵ We found that the IBDQ and SIBDQ were considered to be well-established measures, and the RFIC is approaching the level of being well-established. The rest were rated as promising assessments.

We used a robust quality criterion²² to systematically evaluate the psychometric properties of the identified HRQoL measures. We also used the COSMIN checklist²³ to assess the methodological quality of the properties of the HRQoL measures in IBD. These criteria are increasingly used in systematic reviews of outcome measures.^{58–63} The content validity, reliability, and validity of the COSMIN standards checklist were showed to be valid and reliable.⁶⁴ However, a limitation of the COSMIN checklist and the quality properties of outcome measures^{22–24} is that they were recently developed and might not be applicable to measures developed before its introduction. The inconsistency in the measurement properties may be explained by the fact that there was no agreement on a definition of the required measurement properties until recently. However, questionnaires still need to meet validity and reliability criteria and be described in a comprehensive manner. Studies included in the systematic review were judged to be of poor methodological quality when evaluated by the COSMIN checklist if they were not descriptive enough to reach the COSMIN pre-defined standards. Especially when it comes to missing items, if not clearly described, then most properties will be rated fair even if they were undertaken properly in the study. Most of the HRQoL have been recently developed and their validation is still ongoing. Hence, future studies are likely to provide additional evidence to support their validity and reliability.

Although the COSMIN checklist and the quality criteria for the measurement properties were designed to be as objective as possible, reviewers' judgments can be different. Therefore, two reviewers evaluated the included studies and a third reviewer was consulted in case of disagreement.

We limited our search to English language studies because of the limited translation facilities available to us. Therefore, we might have missed HRQoL measures that were developed in other languages. However, our extensive and systematic search included studies that were carried out in non-English speaking countries but written in English. We did not find any mention of a non-English HRQoL measure specifically developed for IBD.

Previous reviews of HRQoL measures in patients with IBD have limited their search to only a single concept of multi-dimensional HRQoL and included a limited number of measures.^{1,65–68} There is no review in the literature that has evaluated the methodological quality of the measurement properties of the included HRQoL measures. One of the strengths of this systematic review is that it did not only focus on the single concept of multi-dimensional HRQoL, but also took into account related concepts such as disease burden, work productivity, fatigue, and social impact. We performed the literature search in a systematic way to identify all HRQoL measures used in IBD.

To our knowledge, this is the first systematic review of HRQoL measures in IBD that systematically appraised the measurement properties and the methodological quality of the HRQoL measures using a robust and standardized approach. This facilitates good comparison between the HRQoL measures on the quality of their measurement properties. This review will better guide the use of HRQoL in various clinical and research settings. It will also help clinicians, researchers, and the general public to better assess the scientific literature on HRQoL in IBD. Several new HRQoL measures are emerging, and our study showed that most of the HRQoL are supported by evidence of at least one type of reliability or validity and further validation studies might support their use. The choice of HRQoL measure in future will depend on the context for which it will be used [for example, social, disease burden, disability, etc.]. Until then, the IBDQ^{26,27} has the strongest published evidence of reliability and validity and it is well established in the literature.

Supplementary Data

Supplementary data are available at JCC online.

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Authors' contributions

LA was responsible for developing initial drafts of the manuscript, designing the study, obtaining funding, data collection and analysis, and final approval of the study. IR contributed to the collection and assembly of data and final approval of the article. PD contributed to data collection and all drafts of the manuscript. HAH and JGW contributed to designing the study, critical revision of all drafts of the manuscript, and data analysis.

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