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Systematic Review

A Systematic Review of the Development and Psychometric Properties of Constipation-related Patient-reported Outcome Measures: Opportunities for Digital Health

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Background/Aims
Constipation can be a chronic condition that impacts daily functioning and quality of life (QoL). To aid healthcare providers in accurately assessing patient symptoms and treatment outcomes, patient-related outcome measures (PROMs) have been increasingly adopted in clinical settings. This review aims to (1) evaluate the methodological quality and measurement properties of constipation-related PROMs, using the COnsensus-based Standards for the selection of health Measurement INtruments (COSMIN) criteria; and (2) assess the modes of digital dissemination of constipation-related PROMs.

Methods
PubMed, Embase, and PsycINFO databases were searched and 11 011 records ranging from 1989 to 2020 were screened by 2 independent reviewers. A total of 26 studies (23 PROMs; 18 measuring symptom-related items and 5 measuring constipation-related QoL items) were identified for the review and assessed.

Results
There were multiple variations between PROMs, including subtypes of constipation, methods of administration, length of PROM and recall period. While no PROM met all the COSMIN quality standards for development and measurement properties, 5 constipation-related PROMs received at least 4 (out of 7) sufficient ratings. Only 2 PROMs were developed in Asia. Five PROMs were administered through digital methods during the validation process but methods of adapting the PROMs into digital formats were not reported.

Conclusions
The constipation-related PROMs identified in this review present varying quality of development and validation, with an overall need for improvement. Further considerations should be given towards more consistent methodology and reporting of PROM development, increase in culturally-specific PROMs, and better reporting of protocol for the digitization of PROMs.
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Key Words
Constipation; Digital health; Patient-reported outcome measures; Quality of life

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Introduction

Chronic constipation is a prevalent worldwide problem that affects up to 10-15% of the adult population.[1] Symptoms of primary and secondary constipation include hard stools, excessive straining, infrequent bowel movements, bloating, and abdominal pain.[2] While constipation can often be managed by medication and lifestyle modification, prolonged constipation can significantly decreases quality of life (QoL).[2,3] To better assess patients' health status and QoL, it is important to have an accessible tool that can accurately assess patients' symptoms and treatment outcomes, which may enable personalized intervention strategies. The usage of reliable and validated patient-related outcome measure (PROM) can help provide a consistent method of measuring clinical symptoms and QoL outcomes in patients.[4] PROMs are standardized, validated questionnaires that measure patients' perception of their own health status and well-being.[5] While PROMs were initially developed for research use, they have been increasingly adopted in clinical practice to aid clinicians provide better and more patient-centered care.[6]

To date, 2 reviews have examined existing assessment scales measuring constipation symptoms.[7,8] A combination of 9 self-reported measures, developed between 1989 to 2010, were assessed by both reviews. While the reviews provided an insight on the reliability and validity of existing constipation PROMs, the reviews were not conducted systematically and constipation-related QoL PROMs were not included. Given the impact of constipation on QoL, including mental, social, and physical functioning,[9,10] it is important to consider QoL in treatment outcomes.

As the capabilities and adoption of digital technology expand in healthcare, it is also important for us to explore the potential of digitizing PROMs. This could sustain longitudinal patient assessment, which can further support the individualization of patient care. In patients with inflammatory bowel disease, collecting consistent electronic patient reported outcomes (ePRO) on a cloud-based digital therapeutics and monitoring application has been shown to significantly reduce yearly hospitalizations and emergency room visit rates most likely due to immediate interventions prompted by concerning questionnaire scores. Patients also reported having a better understanding of the nature and causes of their health condition after a year.[11] Given the importance of incorporating QoL into treatment outcomes and the potential of incorporating digital health technologies that are patient-centric into constipation management, the current review aims to (1) systematically review constipation-related PROMs, including QoL reporting, using the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN)[12] guideline to evaluate the methodological quality of included studies and the quality of the measurement properties themselves, and (2) assess the current modes of digitization of constipation-related PROMs.

Methods

A systematic review protocol was developed in accordance with the Preferred Reporting for Items for Systematic Reviews and Meta-analyses (PRISMA) and the COSMIN guidelines. The study protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) database (No. CRD42021236257).

Search Strategy

The PRISMA guidelines were used to identify studies for this

Table 1. Inclusion/Exclusion Criteria for Preliminary Screening and Full-text Screening

Screening criteria
Inclusion criteria for preliminary (abstract and title) screening
1) Gastrointestinal-related
2) Developed or validated PROM or questionnaire or survey or scale
Exclusion criteria for full-text screening
1) PROM did not measure constipation symptoms or constipation-related QoL
2) Revalidated an existing questionnaire for a different language or patient population
3) Review papers or conference abstracts
4) PROM examined constipation as subset or question
5) Paediatric-related PROM
6) Not in English

PROM, patient-reported outcome measures; QoL, quality of life.

review. A comprehensive literature search was performed using PubMed, Embase, and PsycINFO to identify all articles on the development or validation of constipation-related PROMs. The search was conducted up to February 2021. Searches in all 3 databases were performed using the following keywords: (*constipation* OR *gastrointestinal*) AND (*question** OR [*patient* AND *outcome* AND *measure*]) AND (*validation* OR *development*).

Study Selection

The initial search yielded 11 011 articles after duplicates were removed. Four articles were identified via hand-checking of reference lists of published reviews and were included retrospectively. Two authors (V.V.L. and N.Y.L.) independently reviewed titles and abstracts of the identified records for preliminary inclusion. Articles were included for further screening based on inclusion criteria listed in Table 1. Five hundred and seventy-nine articles satisfied the preliminary inclusion criteria and were accepted for a full review. Interrater agreement was assessed with Cohen's κ indicator, where κ of 0.60-0.79 was classified as "moderate," 0.80-0.90 as "strong," and above 0.90 as "almost perfect" interrater agreement.[13] There was a moderate interrater agreement for study selection (Cohen's $\kappa = 0.72$; 95% CI, 0.68-0.75) and discrepancies were resolved by discussion.

Full texts of the eligible articles were retrieved and reviewed. Articles were excluded based the exclusion criteria listed in Table 1. Five hundred and fifty-three articles did not meet the eligibility criteria and were excluded. There was strong interrater agreement for the second screening (Cohen's $\kappa = 0.80$; 95% CI, 0.67-0.93) and discrepancies were resolved by discussion. An independent third reviewer (A.T.) was brought in when discrepancies were not resolved. Figure depicts the flow diagram of the study selection.

Quality Assessment

The methodological quality of the studies and the quality of the PROM itself was assessed using the COSMIN guidelines. Firstly, the COSMIN Risk of Bias checklist[14] consisting of 117 questions was used to assess the methodological quality of the studies. The following measurement properties were assessed: PROM development, content validity, structural validity, internal consistency, reliability, measurement error, criterion validity, hypothesis testing for constructive validity, and responsiveness. A 4-point rating system of "very good," "adequate," "doubtful," and "inadequate" was used to rate each property. The final rating was determined by taking the lowest score of an assessment area (ie, "worst score counts" principle). No rating was given if measurement property was not assessed or described.

Following that, the quality of the PROM itself was assessed using the COSMIN updated criteria for good measurement properties.[12] The following psychometric properties were assessed: internal consistency, reliability, measurement error, content validity, structural validity, hypotheses testing, criterion validity, and responsiveness. Using the criteria provided, a rating of "+" for sufficient, "–" for insufficient, or "?" for indeterminate was given to each measurement property.

Two authors (V.V.L. and D.J.Y.X.) independently reviewed the included studies using the COSMIN risk of bias checklist and updated criteria for good measurement properties. There was moderate interrater agreement for risk of bias (Cohen's $\kappa = 0.71$; 95% CI, 0.69-0.74) and almost perfect interrater agreement for criteria for good measurement properties (Cohen's $\kappa = 0.93$; 95% CI, 0.88-0.98). Any discrepancies were resolved by discussion.

Results

Summary of Included Studies

A total of 23 PROMs measuring constipation symptoms[15-35] or constipation-related QoL[36-40] were identified. The PROMs were reported in 26 different studies with publication years ranging from 1989 to 2020. The Bowel Function Index and Patient Assessment of Constipation–Symptom (PAC-SYM) had more than 1 validation study with additional information on measurement properties. A summary of included studies is presented in Table 2.

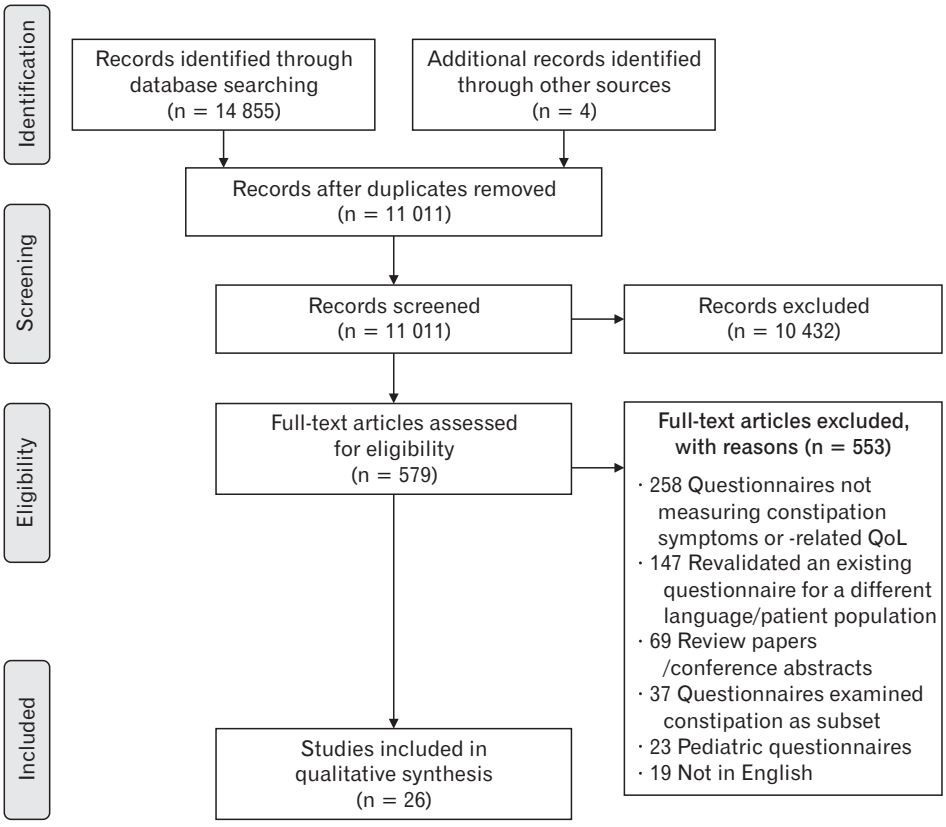

Figure. Flow diagram of study selection.

Patient-related Outcome Measures Measuring Constipation Symptoms

Eighteen out of the 23 identified PROMs evaluated constipation symptoms. The majority of the PROMs (n = 10) were developed with intentions to assess severity of constipation in patients.[16,19,21,23,24,26,27,30-32] Seven PROMs were developed as a potential diagnosis tool to detect clinically significant constipation, with some having dual functionality for diagnosis and measurement of severity.[19,21,27,29,30,34,35] A subset of PROMs (n = 4) were created and/or validated for research purposes, specifically to assess treatment benefits in patients during varying stages of clinical trials.[15,20,25,28]

The items included in the PROMs can be categorised into 5 categories: abdominal symptoms, bowel movement-related symptoms, stool-related symptoms, anal or rectal symptoms, and others. The most common questionnaire items were incomplete evacuation during bowel movement[15,16,19,22-24,26,27,29-32,34,35] and stool consistency,[15,19-22,25-29,31,32,34,35] with both items included in 77.8% of PROMs assessed. To measure incomplete bowel movement, PROMs have included a combination of frequency and/or severity related questions. To measure stool consistency, questions include rating of consistency based on the 7-point Bristol stool form scale[15,20,28] or a self-constructed scale,[27,29,31,35] frequency or severity of hard or lumpy stools,[19,32,34] and presence of hard and loose/water stools.[21,22,26]

More than half of the studies included a measure of abdominal pain,[15,20,24-28,30,32,34] abdominal bloating,[15,19-21,25-29,32] frequency of bowel movements,[19-29,34,35] and straining during bowel movement.[15,20,22,23,25-28,30-32,34,35] Abdominal pain, abdominal bloating, and straining during bowel movement have been measured through both severity and/or frequency while questions on frequency of bowel movements have generally been measured using a self-constructed time scale. Two PROMs differentiated complete spontaneous bowel movement from spontaneous bowel movement.[20,28] A summary of questionnaire items in PROMs measuring constipation symptoms is presented in Table 3.

Patient-related Outcome Measures Measuring Constipation-related Quality of Life

Five out of the 23 PROMs assessed constipation-related QoL. Three PROMs were developed to measure the impact of constipation on multiple aspects of QoL, including social relationships, treatment satisfaction, physical symptoms, diet, daily activities, and

Table 2. Characteristics of Included Studies

PROM	Authors	Type of constipation	Participants (validation study)	Method of administration	Recall period	Items and subsets	Location of study	Original language
Constipation symptoms								
BF-Diary	Camilleri et al,[15] 2011	OIC	238 patients with chronic pain	Handheld electronic PDA device	Past 24 hours and immediately after each defecation event for some items	10 items (3 modules per bowel movement, daily assessment, and treatments used)	USA	English
BFI	Rentz et al,[16] 2009	OIC	985 patients with chronic pain (202 Phase II; 460 Phase III; 323 Phase III)	Clinician administered	Last 7 days	3 items	Germany	English
	Ducrotté and Caussé,[17] 2012	OIC	987 patients with chronic pain (202 Phase II, 463 Phase III, 322 Phase III)	Clinician administered	Last 7 days	3 items	France	English
	Abramowitz et al,[18] 2013	OIC	520 patients with pain induced by cancer	Clinician administered	Last 7 days	3 items	France	English
Chinese Constipation Questionnaire	Chan et al,[19] 2005	Functional constipation	221 (111 patients with chronic constipation, 110 healthy controls)	Pen and paper	Past 2 weeks	6 items	Hong Kong	Chinese
CC Symptom Severity Measures	Nelson et al,[20] 2014	Chronic constipation	1579 with chronic constipation (307 Phase IIb; 1272 Phase III)	Telephone-based IVRS	Administered daily during trial	7 items (2 subscales: bowel and abdominal symptoms)	USA	English
CAS	McMillan and Williams,[21] 1989	Iatrogenic constipation	64 (32 at risk for constipation, 32 healthy controls)	Pen and paper	Past week	8 items	USA	English
Constipation during pregnancy questionnaire	Ponce et al,[22] 2008	Constipation during pregnancy	207 pregnant women	Pen and paper, telephone interview (follow ups)	None reported	42 items (5 subscales: demographic, obstetric history, bowel habits and laxative consumption, lifestyle and eating habits, and urinary or fecal incontinence)	Spain	Not reported
CSI	Varma et al,[23] 2008	Multiple subtypes	294 (191 patients with constipation, 103 healthy controls)	Pen and paper	Last month (2 items), no recall period (14 items)	16 items (3 subscales: obstructive defecation, colonic inertia, and pain)	USA	English
CSS	Agachan et al,[24] 1996	Idiopathic constipation	232 patients with constipation	Pen and paper	None reported	8 items	USA	English
DIBSS-C	Coon et al,[25] 2020	IBS-C	532 IBS-C patients from multicentre phase IIb study	Handheld electronic diary	Every BM event (3 items), past 24 hours (3 items)	7 items (2 subcales: bowel movement-related symptoms and abdominal symptoms severity)	USA	English

Table 2. Continued 1

PROM	Authors	Type of constipation	Participants (validation study)	Method of administration	Recall period	Items and subsets	Location of study	Original language
FICA	Bharucha et al,[26] 2004	Functional constipation & faecal incontinence	83 women	Pen and paper	Last 12 months (symptoms-related items)	98 items (8 subscales: general bowel habits, abdominal pain, treatment of constipation, faecal incontinence, urinary symptoms, anorectal disease, surgical history and other, health care utilization, and quality of life)	USA	English
Fecal Incontinence and Constipation Questionnaire	Österberg et al,[27] 1996	Constipation & faecal incontinence	90 (36 with faecal incontinence, 38 with constipation, 16 healthy controls)	Pen and paper	None reported	38 items	Sweden	Not reported
IBS-C Symptom Severity Measures	Williams et al,[28] 2014	IBS-C	1608 patients with IBS-C	Telephone-based IVRS	Administered daily during trial	9 items (2 subscales: bowel and abdominal symptoms subsets)	USA	English
KESS	Knowles et al,[29] 2000	Chronic constipation	91 (71 patients with chronic constipation, 20 healthy controls)	Researcher administered	None reported	11 items	UK	English
ODS-S	Renzi et al,[30] 2013	ODS	200 (100 patients with ODS, 100 healthy controls)	Pen and paper	None reported	5 items	Italy	Not reported
ODS Score	Altomare et al,[31] 2008	ODS	106 (76 patients with ODS, 30 healthy controls)	Researcher administered	None reported	8 items	Italy	Not reported
PAC-SYM	Frank et al,[32] 1999	Chronic constipation	216 patients with chronic constipation	Pen and paper	Past 2 weeks	12 items (3 subscales: stool, rectal, and abdominal symptoms)	USA	English
Modified PAC-SYM	Neri et al,[33] 2015	Chronic constipation	2203 patients with chronic constipation	Pen and paper	Past 2 weeks	11 items (2 subscales: stool and abdominal symptoms)	Italy	English
Rome III Criteria Questionnaire	Digesu et al,[34] 2010	Functional constipation (Rome III)	201 women	Pen and paper	Last 3 months (9 items), last 6 months (2 items), no recall period (6 items)	17 items	UK	English
VSAQ	Pamuk et al,[35] 2003	Constipation (unspecified)	369 hospital personnel	Pen and paper	Last 12 months (symptoms-related items)	5 items	Turkey	Not reported

Table 2. Continued 2

PROM	Authors	Type of constipation	Participants (validation study)	Method of administration	Recall period	Items and subsets	Location of study	Original language
Constipation-related quality of life								
CTSAT-Q	Szeinbach et al,[36] 2009	Chronic constipation and IBS-C	311 patients with chronic constipation and IBS-C	Online questionnaire	None reported	12 items (5 subscales: expectations, value, treatment satisfaction, activities, and effectiveness)	USA	English
Constipation-related Disability Scale	Hart et al,[37] 2012	Chronic constipation	343 (240 patients with constipation, 103 healthy controls)	Pen and paper	Past week	13 items (2 subscales: leisure/work activities and activities of daily living)	USA	English
CRQOL	Wang et al,[38] 2009	Chronic constipation	343 (240 patients with constipation, 103 healthy controls)	Pen and paper	Past 12 months	18 items (4 subscales: social impairment, distress, eating habits, and bathroom attitudes)	USA	English
E-CIS	Abdul Wahab et al,[39] 2020	Chronic constipation	470 elderly people with chronic constipation	Researcher administered	None reported	22 items (7 subscales: daily activities, treatment satisfaction, lack of control of bodily function, diet restriction, symptom intensity, anxiety, and preventive actions)	Malaysia	Malay
PAC-QOL	Marquis et al,[40] 2005	Chronic constipation	223 patients with chronic constipation	Pen and paper	Past 2 weeks	28 items (4 subscales: worries/concerns, physical discomfort, psychosocial discomfort, and satisfaction)	USA, UK, France, Sweden	English

PROM, patient-reported outcome measure; BF-Diary, Bowel Function Diary; BFI, Bowel Function Index; CC, chronic constipation; CAS, Constipation Assessment Scale; CSI, Constipation Severity Instrument; CSS, Constipation Scoring System; DIBSS-C, Diary for Irritable Bowel Syndrome Symptoms–Constipation; FICA, Fecal Incontinence and Constipation Assessment; IBS-C, constipation-predominant irritable bowel syndrome; KESS, Knowles-Eccersley-Scott Symptom Questionnaire; ODS-S, Obstructive Defecation Syndrome Score; PAC-SYM, Patient Assessment of Constipation–Symptom; VSAQ, Visual Scale Analog Questionnaire; CTSAT-Q, Chronic Constipation Treatment Satisfaction Questionnaire; CRQOL, Constipation-related Quality of Life; E-CIS, Elderly-constipation Impact Scale; PAC-QOL, Patient Assessment of Constipation–Quality of Life; OIC, opioid-induced constipation; PDA, personal digital assistant; IVRS, interactive voice response system; USA, United States of America; UK, United Kingdom.
Method of administration was assumed to be pen and paper unless reported otherwise.

Table 3. Summary of Questionnaire Items in Patient-reported Outcome Measures Measuring Constipation Symptoms

Questionnaire items	n (out of 18)	%
Overall rating for constipation	4	22.2
Abdominal symptoms		
Pain	10	55.6
Bloating	10	55.6
Discomfort	6	33.3
Gas	3	16.7
Cramping	2	11.1
Distention	1	5.6
Fullness	1	5.6
Pressure during defecation	1	5.6
Bowel movement-related symptoms		
Incomplete evacuation	14	77.8
Frequency	13	72.2
Straining	13	72.2
Inability to pass	7	38.9
Ease/pain during bowel movement	5	27.8
Urgency	2	11.1
Attempts a day	1	5.6
Lack of urge	1	5.6
Stool-related symptoms		
Consistency	14	77.8
Amount	3	16.7
Anal/rectal symptoms		
Pain	4	22.1
Bleeding	2	11.1
Anus blockage	2	11.1
Burning	1	5.6
Fullness/pressure	1	5.6
Pruritus ani	1	5.6
Others		
Use of laxatives/enemas	9	50.0
Use of digital manoeuvres	8	44.4
Time spent in toilet	5	27.8
History (duration of constipation)	4	22.2
Lack of appetite	1	5.6
Changes to diet	1	5.6

psychological state.[38-40] While all 3 PROMs are suitable for patients with chronic constipation, the Elderly-constipation Impact Scale (E-CIS) was developed for elderly Malay speaking individuals aged 60 years and above.[39]

Two PROMs evaluated specific aspects of QoL in patients with constipation. The Chronic Constipation Treatment Satisfaction Questionnaire (CTSAT-Q) specifically focused on treatment satisfaction in patients with chronic constipation and constipation-predominant irritable bowel syndrome (IBS-C).[36] Items include patient's expectations on and attitude towards medication, value of medication, interference due to treatment, and effectiveness of treatment. On the other hand, the Constipation-related Disability Scale[37] focused on the impact of constipation symptoms on day-to-day activities. The PROM includes a rating of difficulty in performing various leisure, work, and daily activities.

COnsensus-based Standards for the Selection of Health Measurement INstruments Risk of Bias

The COSMIN risk of bias assessment demonstrated very few studies with consistent "very good" and/or "adequate" ratings across all domains. A summary of risk of bias scores for each study are presented in Table 4. Cross-cultural validity was not assessed as the current review only included studies that assessed the original version of the PROM.

Twenty-three studies were rated on PROM development and the majority of the studies (n = 14) scored "inadequate" due to the lack of a PROM development study involving the target population or a cognitive interview study to assess the comprehensibility or comprehensiveness of the PROM. The remaining 9 studies scored "doubtful" due to poor reporting of study methods including the use of skilled group moderators or interviewers, interview guides, recording and transcription process of interviews and independent coding of data. Poor reporting of methods similarly resulted in "doubtful" ratings for content validity. Only 2 studies[19,38] comprehensively examined content validity (ie, asking patients and professionals about relevance, comprehensibility, and comprehensiveness).

Construct validity was the most common measurement properties analysed (n = 23), nevertheless, not all studies examined both convergent and discriminative validity. Four studies[15,21,24,31] only examined discriminative validity while 2 studies[26,35] only examined convergent validity. Half of the studies that examined construct validity scored "doubtful" due to the lack of detailed description of comparator instruments and/or important characteristics of subgroups.

Following construct validity, reliability (n = 17), and internal consistency (n = 16) were the second and third most analyzed measurement properties. The majority of studies that scored "doubtful" and "inadequate" for reliability did not fulfill appropriate design requirements (eg, patients' stability in the interim period, similarity of test conditions, and appropriate time interval). Most of the studies that analyzed internal consistency fulfilled the COSMIN criteria for "very good." "Doubtful" ratings for internal consistency were given due to lack of clarity if scale or subscale was unidimensional.

Less than half of the studies analyzed structural validity,

Table 4. Individual PAC-SYM Category Scores for Each Study as Assessed by the COnsensus-based Standards for the Selection of Health Measurement INstruments Risk of Bias Checklist[14]

PROM	Authors	PROM development	Content validity	Structural validity	Internal consistency	Reliability	Measurement error	Criterion validity	Construct validity	Responsive-ness
Constipation symptoms										
BF-Diary	Camilleri et al,[15] 2011	Doubtful	Doubtful			Adequate	Adequate		Doubtful	Doubtful
BFI	Rentz et al,[16] 2009	Inadequate			Very good	Doubtful	Inadequate		Doubtful	Doubtful
	Ducrotté and Caussé,[17] 2012				Very good	Doubtful			Doubtful	Doubtful
	Abramowitz et al,[18] 2013							Very good	Doubtful	
Chinese Constipation Questionnaire	Chan et al,[19] 2005	Doubtful	Doubtful	Doubtful	Very good	Doubtful		Very good	Inadequate	
CC Symptom Severity Measures	Nelson et al,[20] 2014	Inadequate		Very good		Doubtful			Doubtful	Doubtful
CAS	McMillan & Williams,[21] 1989	Inadequate			Very good	Inadequate			Adequate	
Constipation during pregnancy questionnaire	Ponce et al,[22] 2008	Inadequate						Very good		
CSI	Varma et al,[23] 2008	Doubtful	Doubtful	Very good	Very good	Adequate			Very good	
CSS	Agachan et al,[24] 1996	Inadequate							Doubtful	
DIBSS-C	Coon et al,[25] 2020	Doubtful	Doubtful	Adequate	Very good	Adequate	Doubtful		Doubtful	Doubtful
FICA	Bharucha et al,[26] 2004	Inadequate				Doubtful			Doubtful	
Fecal Incontinence and Constipation Questionnaire	Österberg et al,[27] 1996	Inadequate				Inadequate			Inadequate	
IBS-C Symptoms Severity Measures	Williams et al,[28] 2014	Inadequate		Very good		Adequate			Doubtful	Doubtful
KESS	Knowles et al,[29] 2000	Inadequate							Doubtful	
ODS-S	Renzi et al,[30] 2013	Doubtful	Doubtful		Doubtful	Doubtful		Very good	Doubtful	
ODS Score	Altomare et al,[31] 2008	Inadequate			Doubtful				Doubtful	
PAC-SYM	Frank et al,[32] 1999	Doubtful	Doubtful	Adequate	Very good	Adequate			Adequate	Inadequate
Modified PAC-SYM	Neri et al,[33] 2015			Very good	Very good				Doubtful	Doubtful
Rome III Criteria Questionnaire	Digesu et al,[34] 2010	Inadequate	Doubtful		Very good	Adequate			Inadequate	
VSAQ	Pamuk et al,[35] 2003	Inadequate							Inadequate	
Constipation-related quality of life										
CTSAT-Q	Szeinbach et al,[36] 2009	Doubtful	Doubtful	Very good	Very good					
Constipation-related Disability Scale	Hart et al,[37] 2012	Inadequate		Very good	Very good	Doubtful			Very good	
CRQOL	Wang et al,[38] 2009	Doubtful	Doubtful	Very good	Very good	Doubtful			Very good	
E-CIS	Abdul Wahab et al,[39] 2020	Doubtful	Doubtful	Very good	Very good					
PAC-QOL	Marquis et al,[40] 2005	Inadequate		Adequate	Very good	Doubtful			Inadequate	Doubtful

PROM, patient-reported outcome measure; BF-Diary, Bowel Function Diary; BFI, Bowel Function Index; CC, chronic constipation; CAS, Constipation Assessment Scale; CRQOL, Constipation-Related Quality of Life; CSI, Constipation Severity Instrument; CSS, Constipation Scoring System; CTSAT-Q, Chronic Constipation Treatment Satisfaction Questionnaire; DIBSS-C, Diary for Irritable Bowel Syndrome Symptoms–Constipation; E-CIS, Elderly-Constipation Impact Scale; FICA, Fecal Incontinence and Constipation Assessment; IBS-C, constipation-predominant irritable bowel syndrome; KESS, Knowles-Eccersley-Scott Symptom Questionnaire; PAC-SYM, Patient Assessment of Constipation–Symptom; ODS-S, Obstructive Defecation Syndrome Score; PAC-QOL, Patient Assessment of Constipation–Quality of Life; VSAQ, Visual Scale Analog Questionnaire.

Table 5. Individual Rating for Each Measurement Properties Based on the Updated COnsensus-based Standards for the Selection of Health Measurement INstruments Criteria[12]

PROM	Authors	Structural validity	Internal consistency	Reliability	Measurement error	Criterion validity	Construct validity	Responsiveness
Constipation symptoms								
BF-Diary	Camilleri et al,[15] 2011			−	?		+	+
BFI	Rentz et al,[16] 2009		+	−	?		+	?
	Ducrotté and Caussé,[17] 2012		+	?			?	?
	Abramowitz et al,[18] 2013					−	+	
Chinese Constipation Questionnaire	Chan et al,[19] 2005	?	+	+		+	+	
CC Symptom Severity Measures	Nelson et al,[20] 2014	+		−			+	?
CAS	McMillan and Williams,[21] 1989		+	?			+	
Constipation during pregnancy questionnaire	Ponce et al,[22] 2008					?		
CSI	Varma et al,[23] 2008	+	+	+			+	
CSS	Agachan et al,[24] 1996						?	
DIBSS-C	Coon et al,[25] 2020	?	−	+	?		+	?
FICA	Bharucha et al,[26] 2004			−			?	
Fecal Incontinence and Constipation Questionnaire	Österberg et al,[27] 1996			?			+	
IBS-C Symptom Severity Measures	Williams et al,[28] 2014	?		+			+	?
KESS	Knowles et al,[29] 2000						+	
ODS-S	Renzi et al,[30] 2013		+	?		+	+	
ODS Score	Altomare et al,[31] 2008		−				+	
PAC-SYM	Frank et al,[32] 1999	?	+	+			+	+
Modified PAC-SYM	Neri et al,[33] 2015	+	+				−	+
Rome III Criteria Questionnaire	Digesu et al,[34] 2010		+	+			−	
VSAQ	Pamuk et al,[35] 2003						?	
Constipation-related quality of life								
CTSAT-Q	Szeinbach et al,[36] 2009	+	+					
Constipation-related Disability Scale	Hart et al,[37] 2012	+	+	+			+	
PAC-QOL	Wang et al,[38] 2009	+	+	+			+	
E-CIS	Abdul Wahab et al,[39] 2020	+	−					
CRQOL	Marquis et al,[40] 2005	?	+	−			?	?

PROM, patient-reported outcome measure; BF-Diary, Bowel Function Diary; BFI, Bowel Function Index; CC, chronic constipation; CAS, Constipation Assessment Scale; CRQOL, Constipation-Related Quality of Life; CSI, Constipation Severity Instrument; CSS, Constipation Scoring System; CTSAT-Q, Chronic Constipation Treatment Satisfaction Questionnaire; DIBSS-C, Diary for Irritable Bowel Syndrome Symptoms–Constipation; E-CIS, Elderly-Constipation Impact Scale; FICA, Fecal Incontinence and Constipation Assessment; IBS-C, constipation-predominant irritable bowel syndrome; KESS, Knowles-Eccersley-Scott Symptom Questionnaire; PAC-SYM, Patient Assessment of Constipation–Symptom; ODS-S, Obstructive Defecation Syndrome Score; PAC-QOL, Patient Assessment of Constipation–Quality of Life; VSAQ, Visual Scale Analog Questionnaire.
Ratings for measurement properties: +, sufficient; ?, indeterminate; −, insufficient.

measurement error, criterion validity, and responsiveness. Studies that examined structural validity mostly scored "very good" and "adequate." Only 1 study scored "doubtful" for structural validity due to the lack of description of rotation method. Two studies scored "doubtful" and "inadequate" for measurement error due to unclear description on stability of patients in the interim period

and inadequate calculations of standard error of measurement. All studies that examined responsiveness only examined comparison between subgroups accordingly, ratings were based on that aspect. Scores of "doubtful" and "inadequate" for responsiveness were due to poor description of important characteristics of subgroups and inadequate statistical methods applied.

COnsensus-based Standards for the Selection of Health Measurement INstruments Rating of Measurement Properties

Due to the limited amount of validation studies per PROM, the studies were assessed individually and the total ratings were not provided. The individual ratings for each measurement property of all the studies are presented in Table 5.

Twenty-one studies had at least 1 insufficient (−) or indeterminate (?) rating, and no PROM was fully assessed in all measurement properties, with measurement error and criterion validity most commonly missing. The PROMs with the most sufficient (+) ratings include the Chinese Constipation Questionnaire, Constipation Severity Instrument (CSI), PAC-SYM, Constipation-related Disability Questionnaire, and Patient Assessment of Constipation–Quality of Life (PAC-QOL). To improve ratings of measurements properties, focus should be given to obtaining sufficient rating for measurement error (smallest detectable change/limits of agreement < minimal important change), criterion validity (correlation with gold standard or area under the curve ≥ 0.70), and responsiveness (results in accordance with hypothesis or area under the curve ≥ 0.70).

Digitization of Patient-related Outcome Measures

Five studies reported using digital formats to administer PROMs during the validation process.[15,20,25,28,36] Both the Bowel Function Diary and Diary for Irritable Bowel Syndrome Symptoms-Constipation (DIBSS-C) were completed as part of an electronic diary and were administered using a handheld device. For the Bowel Function Diary, participants were given a handheld electronic personal digital assistant (PDA) device while the type of device was not specified for the DIBSS-C. The CTSAT-Q was described to be disseminated online however, no further information was provided.

The Chronic Constipation Symptom Severity Measures and IBS-C Symptom Severity Measures were administered using interactive voice response system technology, a computer-automated telephone system that collects data through spoken answers or keypad responses.[41] For all 5 studies, methods of digitizing and validating the digital formats of the PROMs were not reported.

Discussion

Digitizing constipation-related PROMs represents a promising step towards individualizing patient intervention in a longitudinal and scalable manner. Therefore, the current systematic review provides an overview of constipation-related PROMs that have been developed and validated over the past 32 years. The review identified 23 different constipation-related PROMs, with 18 measuring symptom-related measures and 5 measuring constipation-related QoL measures.

The review revealed a large amount of variation between PROMs used to measure symptom-related constipation outcomes. Variations include outcome measures targeting different subtypes of constipation (eg, opioid-induced constipation, obstructive defecation syndrome, and IBS-C), functions of PROM (eg, clinical use and research purposes), methods of administration (eg, pen and paper, clinician administered, and electronic diary), length of PROM (range = 3-98 items), and recall period (eg, last 2 weeks and past 24 hours). Given the multiple possible etiologies of constipation, subtype-specific PROMs can be a useful tool to further facilitate customization of outcome measures monitoring, and to provide more accurate feedback to clinicians about treatment progress. Nevertheless, the heterogeneity of variables between PROMs can indicate the lack of standardization during the PROM development process. For instance, multiple studies scored "inadequate" for PROM development based on the COSMIN checklist due to the lack of patients' involvement and input when developing PROM items. While physical symptoms and functioning are vital aspects of disease monitoring, patients may be more focused on regaining or preserving QoL, including emotional wellbeing and social functioning.[42]

Considering the known impact of constipation on QoL,[9] the review also examined constipation-specific QoL-related PROMs. Similar to studies that developed symptom-related outcomes measures, none of the QoL-related PROMs reviewed met all the COSMIN quality standards for development and measurement properties. While all 5 of QoL PROMs involved patients in the development process through individual interviews or focus groups, issues include incomplete reporting of interview methods and lack of a follow-up cognitive testing session. Based on the ratings of measurement properties, out of the reviewed PROMs, the current review recommends the Chinese Constipation Questionnaire, CSI, PAC-SYM, Constipation-related Disability Questionnaire, and PAC-QOL to measure constipation symptoms or constipation-

related quality of life. Nevertheless, none of the reviewed PROMs report all measurement properties indicated in the COSMIN checklist thus, there is a need for better standardization of PROM creation, from the development stages to the final reporting of validation studies. In their efforts to better regulate PROM creation and usage, the Food and Drug Administration (FDA) released a guidance for the industry on recommendations for PROM development and validation,[43] and more recently, a draft on selecting, developing or adapting PROMs for medical device evaluation.[44] To ensure more consistent methodological quality and reporting, it would be ideal for future PROM development studies to familiarize themselves with the FDA recommendations and COSMIN guidelines.

Despite the variety of PROMs identified in this review, only 2 PROMs were developed and validated within the Asian context. Chan et al[19] developed and validated the Chinese Constipation Questionnaire in the Chinese language with an ethnic Chinese population. Similarly, Abdul Wahab et al[39] developed and validated the E-CIS using the Malay language spoken in the local dialects of Terengganu and Kelantan in Malaysia. While there are translated versions of questionnaires including the PAC-SYM[32] and PAC-QOL,[40] culture and language are intertwined, and language should be examined in conjunction with culturally specific health beliefs and understanding.[45] Regardless of English fluency, patients of different ethnic groups may differ in terms of pronunciation, speech delivery, grammar/vocabulary and culturally specific presentation styles when describing their issues to medical practitioners.[45] Hence, a relatable and culturally-specific PROM can be beneficial in increasing the efficacy of patient-clinician communication, and further facilitate a more personalised, patient-centric symptoms monitoring and treatment.

The current review also assessed the modes of digital dissemination of currently available PROMs and identified 5 PROMs that used digital formats to administer the questionnaire during the validation process. Methods of dissemination were varied, ranging from electronic diary formats on PDA devices to computer-automated telephone systems. Given the widespread adoption of smart devices, such as smartphones and tablets, the use of ePROs presents as a viable option for remote monitoring led by patients themselves. Consistent symptom reporting through digital means can improve patient-clinician communication, detection of unrecognised problems, and patients' health behaviors, including patient self-management and patient empowerment.[46] Nevertheless, to ensure reliable reporting of ePROs, evidence is needed to support measurement equivalence between the electronic and paper-based PROMs.[47] The 5 studies in the current review that utilized digital PROMs did not report methods undertaken to digitize the PROMs. Accordingly, there is a need for better standardization for digitization of PROMs to maximize the potential of ePRO tools. Recommendations from the International Society of Pharmacoeconomics and Outcomes Research (ISPOR) ePRO Task Force include cognitive debriefing, usability testing or full psychometric testing of the electronic versions, depending on the level of modification. Future ePRO development studies can benefit by reporting level of modification and relevant methods undertaken to ensure measurement equivalence.

With growing interests to integrate technology into healthcare, PROM development and implementation should keep pace with the fast and evolving field of digital health. Digital health has the potential to offer new modalities of probing patient state in real time through minimally invasive methods (eg, experience sampling method, day reconstruction method). Furthermore, increasing accessibility to ePROs can open doors to personalization of PROMs. A recent real-world longitudinal study of patients with rheumatic and musculoskeletal diseases allowed patients to customize their tracking on the Arthritis Power mobile application between 3 and 10 PRO symptom measures over a period of 3 months.[48] While some PROM items were prioritized more, there were variations between patients in the items chosen for tracking and in ranking of importance. It should also be noted that minimal changes to items tracked were observed, suggesting that patients continue to only track symptoms that are important to them. The ePROs can further benefit from concepts commonly employed in digital health, such as gamification and behavioral nudges, to sustain users' engagement.[49] As the concept of personalized medicine continues to grow, digital technologies can aid in the continual evolution and optimization of PROMs.

A limitation of the current systematic review is the subjective nature of the COSMIN evaluation methods. Multiple items of the COSMIN checklist require subjective judgement of the reviewer based on experience and knowledge, hence, there is possibility of subjectivity within the review.[50] Furthermore, we acknowledge that there may be other methods to assess psychometric measures beyond the COSMIN guidelines. Nevertheless, the current review endeavored to reduce subjectivity by utilizing 2 independent reviewers with good interrater reliability and a third for any discrepancies. Secondly, the current review did not include PROMs assessing the pediatrics population. Constipation-related pediatric PROMs rely on patient-reported measures, parent/caregiver-reported measures or a combination of both, and assessing the differences between the method of reporting is beyond the scope of the current review.

Poor concordance between parent- and child-reporting have been observed when assessing gastrointestinal symptoms. For instance, children tended to rate their pain/discomfort intensity more severely than parents did, and up to 60% of parents of 10- to 19-year-olds could not answer items relating to defecation habits.[51] Therefore, it would be beneficial for future studies to focus on the differences in reporting methods and the involvement of both parent and child in the PROM development process.

In conclusion, this review assessed constipation symptoms and constipation-related QoL PROMs using the COSMIN guidelines and identified a lack of consistent methodology and reporting of development and validation studies. Furthermore, more culturally-specific PROMs, especially in the Asian context, will be beneficial. There are varying modes of digital dissemination of constipation-related PROMs however, greater standardization of the process is required to ensure transparency and consistency. As PROM is a useful tool that can provide clinicians and researchers insights into patients' health status and health-related QoL, further developments of constipation-related PROMs can be made by more consistent methodology and reporting of PROM development, increase in culturally-specific PROMs, and better reporting of protocol for digitization of PROMs.

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Conflicts of interest: Agata Blasiak and Dean Ho are co-inventors or previously filed pending patents on artificial intelligence-based therapy development. Dean Ho is a shareholder of KYAN Therapeutics, which has licensed intellectual property pertaining to artificial intelligence -based drug development. Others have nothing to disclose.

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