



Evaluating Measurement Properties of HRQOL/PRO Instruments in Ulcerative Colitis: A COSMIN-Based Systematic Review



Thirugnanam A¹, Pass J¹, Kangeyan V¹, Patel R¹, Watson LM^{1,2}
Massachusetts College of Pharmacy and Health Sciences¹, Novo Nordisk²

INTRODUCTION

- Ulcerative colitis (UC) substantially impacts patients' health-related quality of life (HRQOL) and symptom burden.
- Numerous patient-reported outcome (PRO) instruments are used in UC, but measurement quality varies across instruments and populations (adult vs pediatric; post-surgery vs active disease).
- Selecting a PRO without strong psychometric evidence can reduce the interpretability of trial and real-world findings.

OBJECTIVES

Primary: Identify HRQOL/PRO instruments used in UC and evaluate their psychometric properties using COSMIN methodology.

Secondary: Summarize which measurement properties are well-supported vs under-studied, to guide selection of instruments in clinical research and practice.

METHODS

- Systematic search in PubMed and Embase
- Search terms combined ulcerative colitis, HRQOL/PRO instruments, and psychometric/measurement property keywords (e.g., validity, reliability, responsiveness).
- Included UC studies reporting psychometric/measurement properties of HRQOL/PRO instruments.
- Data extraction and quality appraisal are ongoing; this poster reports preliminary findings from the UC psychometric studies currently included.
- Methodological quality assessed using COSMIN Risk of Bias

RESULTS

- Twelve UC PRO/HRQOL instruments were identified: 9 adult-specific and 3 pediatric
- Construct validity was the most frequently assessed COSMIN property across instruments (11/12 studies)
- Content validity was rated Very good in 5 instruments (UC-SQ, UC-PRO/SS, Urgency NRS, TUMMY-UC, DUCS)
- Responsiveness was the most under-studied property — assessed in only 6/12 instruments
- UC-SQ demonstrated the broadest psychometric evidence (6 of 7 COSMIN properties assessed)
- Cross-cultural validity was only evaluated in adaptation studies (IBDQ Japanese, IBDQ Persian, CGQL Italian)
- No instrument achieved very good quality across all COSMIN measurement properties
- Pediatric instruments (PROMIS Pediatric, TUMMY-UC, DUCS) had limited psychometric evidence overall

RESULTS

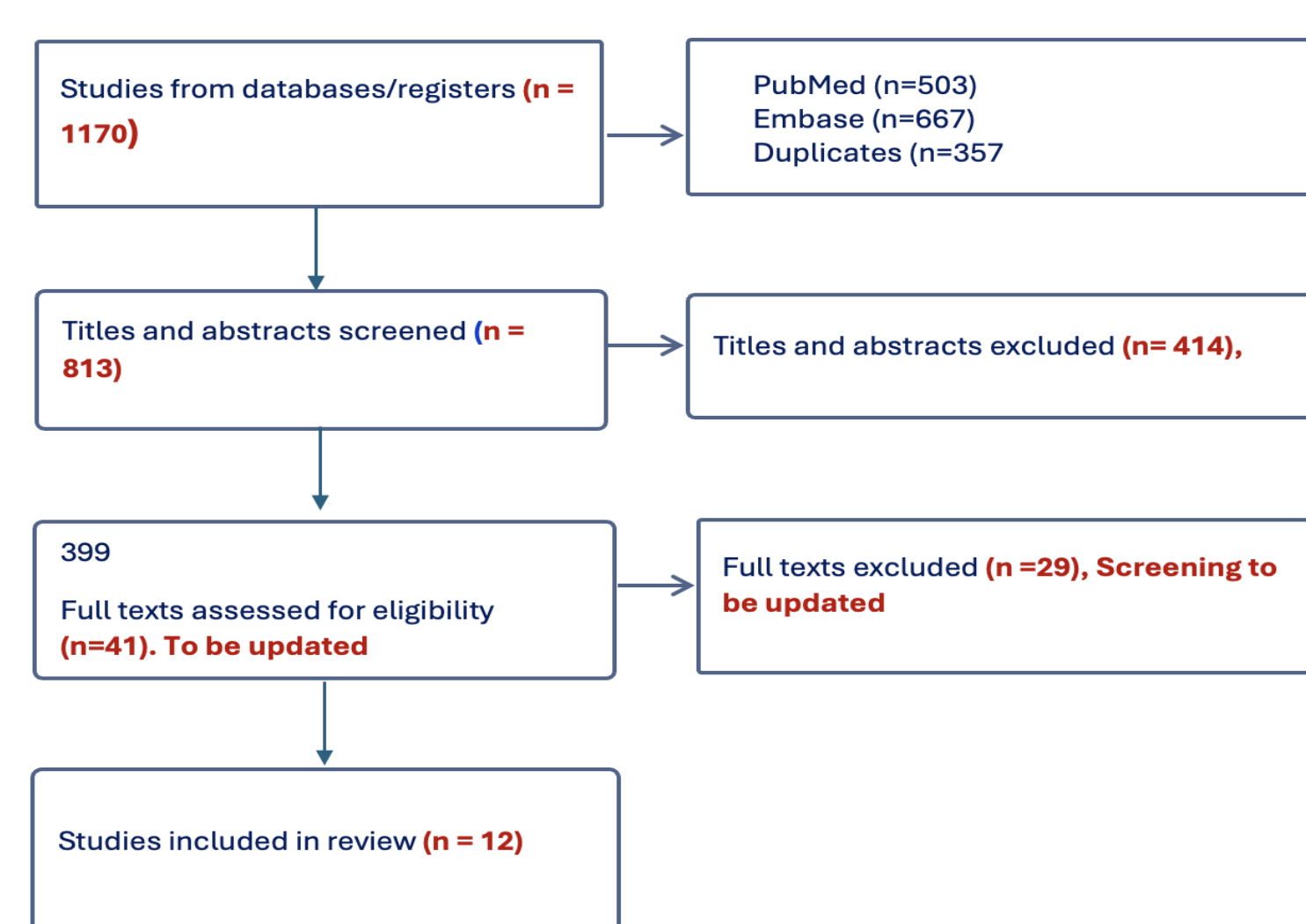


Fig 1: PRISMA flowchart of included studies

Table 1: Study Characteristics

Characteristic	Category	No. of studies (%) N=12
Population	Adult	9 (75%)
	Pediatric	3 (25%)
Instrument focus	HRQOL / QoL	7 (58%)
	Symptom PRO	5 (42%)
Study type	Instrument development (incl. development validation)	6 (50%)
	Validation (existing instrument in UC context)	3 (25%)
	Translation + validation	1 (8%)
	Other psychometric evaluation	2 (17%)
Data source / setting	Trial dataset (psychometrics embedded in trial data)	4 (33%)
	Observational / clinic / registry cohort	8 (67%)
Language version	English	8 (67%)
	Non-English version (Korean/Japanese/Italian/Persian)	4 (33%)
Clinical context	Non-surgical UC	10 (83%)
	Post-surgery UC (IPAA/RPC)	2 (17%)

RESULTS

	Content validity	Structural validity	Internal consistency	Test-retest reliability	Construct validity	Responsiveness	Total Instruments
K-UCSQ	✓	✓	✓	✓	✓	✓	12
CUCQ	✓	✓	✓	✓	✓	✓	9
IBDQ (Japanese)	✓	✓	✓	✓	✓	✓	3
IBDQ (Persian)	✓	✓	✓	✓	✓	✓	3
CGQL (Italian)	✓	✓	✓	✓	✓	✓	3
SICC-IBD	✓	✓	✓	✓	✓	✓	3
UC-SQ	✓	✓	✓	✓	✓	✓	3
Urgency NRS	✓	✓	✓	✓	✓	✓	3
UC-PRO/SS	✓	✓	✓	✓	✓	✓	3
TUMMY-UC	✓	✓	✓	✓	✓	✓	3
PROMIS Pediatric	✓	✓	✓	✓	✓	✓	3
DUCS	✓	✓	✓	✓	✓	✓	3

K-UCSQ: Korean Ulcerative Colitis Symptom Questionnaire; UC-SQ: Ulcerative Colitis Symptom Questionnaire; Urgency NRS: Urgency Numerical Rating Scale; CUCQ: Cambridge Ulcerative Colitis Questionnaire; UC-PRO/SS: Ulcerative Colitis Patient-Reported Outcome Signs and Symptoms; PROMIS Pediatric: Patient-Reported Outcomes Measurement Information System Pediatric; TUMMY-UC: Tool for Understanding and Measuring My Ulcerative Colitis; DUCS: Daily Ulcerative Colitis Score; SICC-IBD: Symptoms Index for Children with Colitis and Crohn's IBD; IBDQ: Inflammatory Bowel Disease Questionnaire; CGQL: Colitis and Crohn's Quality of Life; PRO: Patient-Reported Outcome; HRQOL: Health-Related Quality of Life; COSMIN: Consensus-based Standards for the selection of health Measurement Instruments

Fig 2: Cosmin Evidence map for included instruments (n=12)

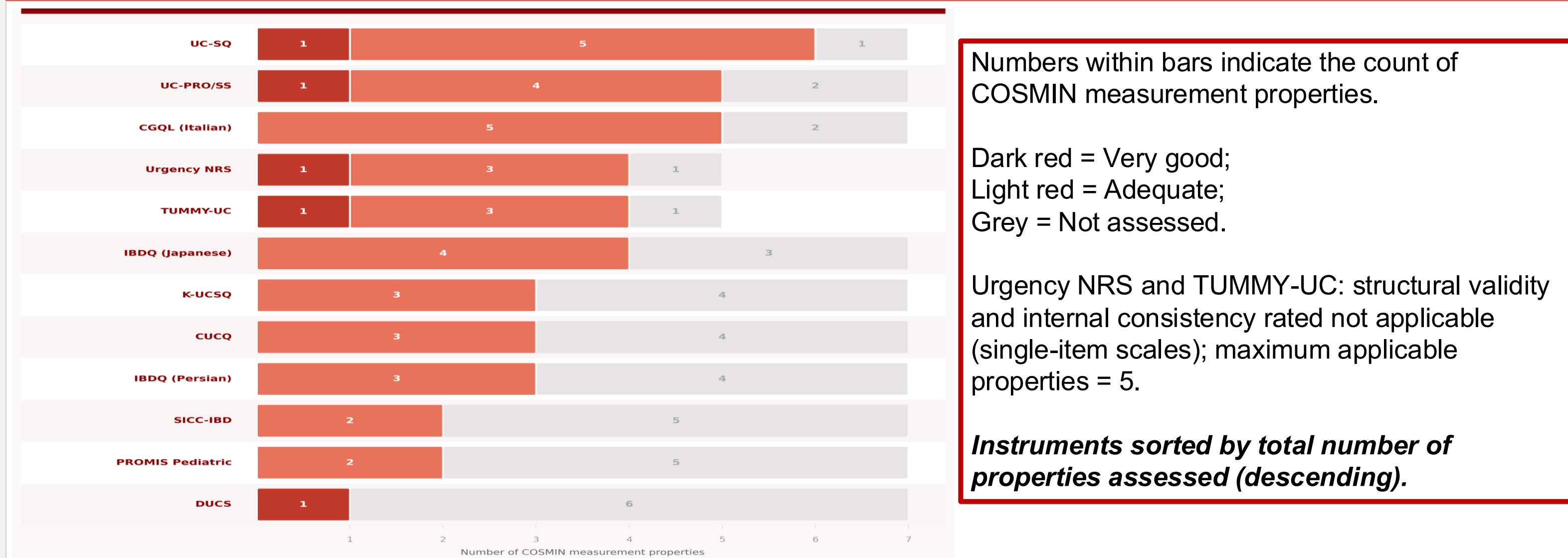


Figure 3. COSMIN methodological quality of measurement properties across UC instruments (n=12)

CONCLUSION

- Psychometric evidence for UC PRO instruments is incomplete and inconsistent across measurement properties. UC-SQ shows the strongest overall measurement quality and may be preferred for adult UC research
- A critical gap in responsiveness data limits the instrument's utility in clinical trials
- Pediatric UC instruments remain substantially understudied
- Findings highlight the need for standardized PRO selection in UC clinical research and trials.
- Full COSMIN systematic review ongoing, with findings expected to support evidence-based PRO instrument selection in UC clinical research and trials

REFERENCES

- Mokkink LB, de Vet HCW, Prinsen CAC, et al. COSMIN Risk of Bias checklist for systematic reviews of Patient-Reported Outcome Measures. *Qual Life Res.* 2018;27(5):1171-1179. doi:10.1007/s11136-017-1765-4
- Prinsen CAC, Mokkink LB, Bouter LM, et al. COSMIN guideline for systematic reviews of patient-reported outcome measures. *Qual Life Res.* 2018;27(5):1147-1157. doi:10.1007/s11136-018-1798-3