A Systematic Review and Quality Assessment of Cardiovascular Disease-Specific Health-Related Quality of Life Instruments Part I: Instrument Development and Content Validity

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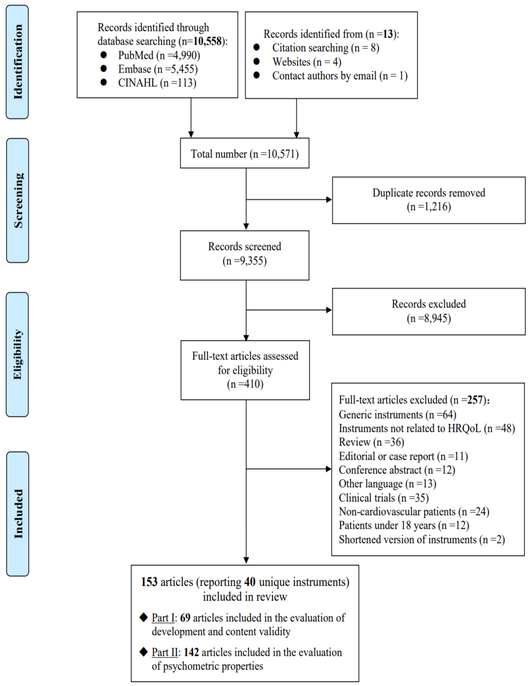
Background

- Health-related Quality of Life (HRQoL) instruments for cardiovascular diseases (CVD) have been commonly used to measure important patient-reported outcomes (PROs) in clinical trials and practices.
- This study aimed at systematically identifying and assessing the content validity of CVD-specific HRQoL instruments in clinical research.

Methods

- We searched CINAHL, Embase, and PubMed from inception to January 20, 2022. We included studies that reported the development and content validity for CVD-specific instruments.
- Two reviewers independently assessed the methodological quality using the Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN) methods on evaluating content validity of PROs. Content analysis was used to categorize the items included in the instruments.

Figure 1. Study selection process



Results

- We found 69 studies reporting the content validity of 40 instruments specifically developed for CVD. Fourteen (35.0%) were rated “sufficient” with very low to moderate quality of evidence.
- For PRO development, all instruments were rated “doubtful” or “inadequate”. 28 (70.0%) instruments cover the core concepts of HRQoL.

Table 5. Quality of the evidence for content validity of the instruments

Instrument	Relevance		Comprehensiveness		Comprehensibility		Content validity	
	OVERALL RATING	QUALITY OF EVIDENCE	OVERALL RATING	QUALITY OF EVIDENCE	OVERALL RATING	QUALITY OF EVIDENCE	OVERALL RATING	QUALITY OF EVIDENCE
			+ / - / ±	high, , low, very low	+ / - / ±	high, moderate, low, very low	+ / - / ±	high, moderate, low, very low
HFQOL	+	⊕⊕⊕◯	+	⊕⊕⊕◯	+	⊕⊕⊕◯	+	⊕⊕⊕◯
KAPQ-HF	+	⊕⊕⊕◯	+	⊕⊕⊕◯	+	⊕⊕⊕◯	+	⊕⊕⊕◯
PPAQ	+	⊕⊕⊕◯	+	⊕⊕⊕◯	+	⊕⊕⊕◯	+	⊕⊕⊕◯
CHD-TAAQOL	+	⊕⊕⊕◯	+	⊕⊕⊕◯	+	⊕⊕⊕◯	+	⊕⊕⊕◯
QOLVAD	+	⊕⊕⊕◯	+	⊕⊕⊕◯	+	⊕⊕⊕◯	+	⊕⊕⊕◯
QLICD-CHD	+	⊕⊕◯◯	+	⊕⊕⊕◯	+	⊕⊕⊕◯	+	⊕⊕◯◯
QLAF	+	⊕⊕◯◯	+	⊕⊕◯◯	+	⊕⊕◯◯	+	⊕⊕◯◯
CHF-PROM	+	⊕⊕◯◯	+	⊕⊕◯◯	+	⊕⊕◯◯	+	⊕⊕◯◯
MILQ	+	⊕⊕◯◯	+	⊕⊕◯◯	+	⊕⊕◯◯	+	⊕⊕◯◯
AF-6	+	⊕◯◯◯	+	⊕◯◯◯	+	⊕◯◯◯	+	⊕◯◯◯
CHP	+	⊕◯◯◯	+	⊕◯◯◯	+	⊕◯◯◯	+	⊕◯◯◯
CHAT	+	⊕◯◯◯	+	⊕◯◯◯	+	⊕◯◯◯	+	⊕◯◯◯
70-item questionnaire	+	⊕◯◯◯	+	⊕◯◯◯	+	⊕◯◯◯	+	⊕◯◯◯
ICD-QOL	+	⊕◯◯◯	+	⊕◯◯◯	+	⊕◯◯◯	+	⊕◯◯◯
PROMIS-Plus-HF	±	⊕⊕◯◯	+	⊕⊕⊕◯	+	⊕⊕⊕◯	±	⊕⊕◯◯
CHPchf	±	⊕⊕◯◯	+	⊕⊕⊕◯	+	⊕⊕⊕◯	±	⊕⊕◯◯
KCCQ	±	⊕⊕◯◯	+	⊕⊕⊕◯	+	⊕⊕⊕◯	±	⊕⊕◯◯
MLHFQ	±	⊕⊕◯◯	+	⊕⊕⊕◯	+	⊕⊕⊕◯	±	⊕⊕◯◯
HeartQoL	±	⊕⊕◯◯	+	⊕⊕⊕◯	+	⊕⊕⊕◯	±	⊕⊕◯◯
MIDAS	±	⊕⊕◯◯	+	⊕⊕⊕◯	+	⊕⊕⊕◯	±	⊕⊕◯◯
Macnew	±	⊕⊕◯◯	+	⊕⊕⊕◯	+	⊕⊕⊕◯	±	⊕⊕◯◯
SAQ	±	⊕⊕◯◯	+	⊕⊕⊕◯	+	⊕⊕⊕◯	±	⊕⊕◯◯
AFEQT	±	⊕⊕◯◯	+	⊕⊕⊕◯	+	⊕⊕⊕◯	±	⊕⊕◯◯
AFImpact	±	⊕⊕◯◯	+	⊕⊕⊕◯	+	⊕⊕⊕◯	±	⊕⊕◯◯
U22	±	⊕⊕◯◯	+	⊕⊕⊕◯	+	⊕⊕⊕◯	±	⊕⊕◯◯
ASTA	±	⊕⊕◯◯	+	⊕⊕⊕◯	+	⊕⊕⊕◯	±	⊕⊕◯◯
ACHD PRO	±	⊕⊕◯◯	+	⊕⊕⊕◯	+	⊕⊕⊕◯	±	⊕⊕◯◯
HSSI	±	⊕⊕◯◯	+	⊕⊕⊕◯	+	⊕⊕⊕◯	±	⊕⊕◯◯
CROQ	±	⊕⊕◯◯	+	⊕⊕⊕◯	+	⊕⊕⊕◯	±	⊕⊕◯◯
QLQ-SHF	±	⊕⊕◯◯	+	⊕⊕⊕◯	+	⊕⊕⊕◯	±	⊕⊕◯◯
LVD-36	±	⊕◯◯◯	+	⊕⊕◯◯	+	⊕⊕◯◯	±	⊕◯◯◯
UBQ-H	±	⊕◯◯◯	+	⊕◯◯◯	+	⊕◯◯◯	±	⊕◯◯◯
CHQ	±	⊕◯◯◯	+	⊕◯◯◯	+	⊕◯◯◯	±	⊕◯◯◯
QLMI	±	⊕◯◯◯	+	⊕◯◯◯	+	⊕◯◯◯	±	⊕◯◯◯
ITG-CAD	±	⊕◯◯◯	+	⊕◯◯◯	+	⊕◯◯◯	±	⊕◯◯◯
AF-QoL-18	±	⊕◯◯◯	+	⊕◯◯◯	+	⊕◯◯◯	±	⊕◯◯◯
Questionnaire for quality of life Syndrome X	±	⊕◯◯◯	+	⊕◯◯◯	+	⊕◯◯◯	±	⊕◯◯◯
The Aquarel questionnaire	±	⊕◯◯◯	+	⊕◯◯◯	+	⊕◯◯◯	±	⊕◯◯◯
TASQ	±	⊕◯◯◯	+	⊕◯◯◯	+	⊕◯◯◯	±	⊕◯◯◯
QLCS	±	⊕◯◯◯	+	⊕◯◯◯	+	⊕◯◯◯	±	⊕◯◯◯

+: Sufficient; - : Insufficient; ± : Inconsistent.

⊕⊕⊕⊕: high; ⊕⊕⊕◯: moderate; ⊕⊕◯◯: low; ⊕◯◯◯: very low

Conclusions

- The quality of development and content validity vary among existing CVD-specific instruments.
- The evidence on the content validity should be considered when choosing a HRQoL instrument in CVD clinical research.