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Translation and validation study of the Hindi versions of the coronary revascularisation outcome questionnaire (CROQ-H)

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Abstract--Objectives: The Coronary Revascularisation Outcome Questionnaire (CROQ) is a patient reported outcome measure. It is used to measure health related outcomes from the patient's perspective before and after coronary revascularisation procedures (PTCA and CABG). This study involved the translation and validation of the Coronary Revascularisation Outcome Questionnaire into Hindi language (CROQ-H). Methodology: The English version of the CROQ was translated into Hindi version; some terms were revised to, adjust for the sociocultural status of the Indian environment. Ten patients completed the questionnaire in a pilot to check for comprehension and, face validity. In the field study, subjects were recruited from

Geetanjali Cardiac Centre (GCC), Geetanjali Medical College & Hospital, Geetanjali University, Udaipur, India. Questionnaires were self-administered. Analysis included acceptability, reliability (internal consistency and test-retest), validity (factor analysis, known-groups and responsiveness testing). Results: A total of 470 patients gave informed consent to participate and 391(83%) of these participated in field study. All versions were met pre-specified criteria; (1) acceptability of items (low missing data); (2) reliability: internal consistency (Cronbach's $\alpha > 0.70$, item total correlations >0.30) and test-retest reliability (intra-class correlation coefficients > 0.70); (3) construct validity based on within-scale analyses (internal consistency (Cronbach's $\alpha >0.70$); Principal axis factor analysis (factor loading ≥ 0.30) (4) Responsiveness large effect sizes (≥ 0.80). Conclusions: The Hindi translation of CROQ is a valid and reliable scale for assessing the patient's HRQOL in CAD.

Keywords---PTCA, CABG, HRQOL, CROQ-H.

Introduction

Health status and health-related quality of life (HRQOL) assessed by patient-reported outcome measures (PROMs) directly collect data from the patients' perspective (Thompson et. al., 2003). General health status is measured and reported in terms of mortality and morbidity while PROMs, have the potential to add important information beyond that captured by mortality and morbidity (Norekval et. al., 2016). PROMs are used not only to measure health outcomes in research and audit but also to compare the performance of healthcare providers (Devlin et. al., 2010). There are a number of validated disease specific PROMs for coronary heart disease, however, few PROMs have been developed to measure outcomes for those treated surgically and most have not been rigorously validated (Mackintosh et. al., 2010). The most widely used coronary artery disease-specific PROMs include the Seattle Angina Questionnaires (SAQ) (Sperts et. al., 1995; Sperts et. al, 2006) the MacNew heart disease health-related quality of life questionnaires (Valenti et. al., 1996; Fernandez et. al., 2007; Benzer et. al. 2003); and the Angina Pectoris Quality of Life Questionnaire (APQLQ) (Marquis et. al. 1995; Janson et. al. 2004). The Coronary Revascularisation Outcome Questionnaire (CROQ) is a coronary heart disease-specific PROM developed specifically to measure health outcomes before and after coronary artery bypass graft surgery (CABG) and percutaneous transluminal coronary angioplasty (PTCA) but it has not been used widely. It is disease specific tool, developed specifically to measure health outcomes, before and after coronary revascularisation procedure (Schroter et. al., 2017). The CROQ differs from the SAQ, MacNew and APQLQ tools by measuring adverse effects from revascularisation treatment and from validation specifically with patients undergoing revascularisation (Sperts et. al., 1995; Valenti et. al., 1996; Fernandez et. al., 2007). The CROQ was originally developed in 2004, revised in 2017, and has been used in the UK NHS Coronary Revascularisation PROMs pilot as well as in some clinical trials (Ascione et. al., 2004; Rogers et. al., 2014). It has also been translated and validated for use in several languages including Serbian (Aleksic et al., 2022), Norwegian (Lillevik et.

al., 2018), Japanese (Seki et. al., 2011), Persian (Shahali et. al., 2008), Greek (Takousi et. al., 2016) Korean (Takousi et. al., 2016). CROQ has not yet been translated and validated for use in India. In this paper we describe the translation and validation of the CROQ into Hindi (CROQ-H).

Method

The study was approved by the human research ethical committee review board with reference number GU/HREC/EC/2019/1678.

The Coronary Revascularisation Outcome Questionnaire (CROQ)

The Coronary Revascularisation Outcome Questionnaire CROQ has four versions: two pre-revascularisation versions, to be administered before CABG or PTCA procedures, and two post-revascularisation versions to be administered three or six months after these revascularisation procedures. All four versions contain the same 32 core items covering four domains: symptoms (7 items), physical functioning (8 items), psychological functioning (14 items), and cognitive functioning (3 items). The post revascularization versions include - additional items: 6 items on treatment satisfaction and either 6 items adverse effects of PTCA or 11 items on adverse effects of CABG. Items included in the CROQ are rated using 3- to 6-point likert type scales. Scores for each domain are calculated by summing the items in the domain and then converting these to 0–100 scales, with 0 representing worst and 100 representing the best outcome (Schroter et. al., 2004; Seki et. al., 2011). The estimated time required to complete the CROQ is approximately 15 minutes.

CROQ translation into Hindi

Permission for translation into Hindi was obtained from the developer of the original English version of the CROQ. The translated version (CROQ-H) was prepared according to standard processes for translation (Santos et. al., 2015). Firstly; the English version was translated into Hindi by two translators who were native Hindi speakers proficient in English. The translated version was then evaluated for clarity, word choice, and closeness to the original by an expert panel comprising a cardiothoracic surgeon, an interventional cardiologist, two cardiac nurses and two medical interns. The translated version was then piloted with five PTCA and five CABG patients to assess comprehension and face validity. This pilot identified minor changes needed to make the questions valid to this patient group and the expert panel met to agree the following five changes to the questionnaires. (1) In the symptoms domain, the 6th item was changed to include Isodril/Sorbitrate instead of “nitros (nitroglycerin tablets or spray)” (2) In the physical functioning domain, the 1st item was changed from “Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf” to “Medium work like push or pull table, simple cleaning of home” because golf playing is not common in Indian culture. (3) In the physical functioning domain, the 6th item was changed from “Walking half a mile” to “one kilometer” because miles are not commonly used in India. (4) In the physical functioning domain, the 7th item was changed from “Walking one hundred yards” to “walking 100 gaj” as yards are not commonly used in India. (5) In the psychosocial functioning

domain, the 2nd item was changed from “Feeling like you are a burden on others” to “Feel like you are dependent on others” because this item was not completed by any of the patients. After these changes were made, the questionnaires were back-translated again into English by two translators who were native speakers of English and proficient in Hindi. A pilot study for the pre-revascularisation questionnaires was not necessary as these versions contain the same 32 core items as, the post- revascularisation versions. The time taken to complete each of the questionnaires was approximately 15 min, and no confusing or unclear items were reported by the patients.

Inclusion criteria for the sample population

Patients were eligible to participate in this study if they had been diagnosed with coronary artery disease, were at least 20 years old, were able to read and understand Hindi and were cognitively able. Eligible patients were sorted into four groups on the basis of treatment stage and type: pre- PTCA, pre-CABG for those awaiting PTCA and CABG respectively and post-PCI or post-CABG for those who had undergone PTCA or CABG within 3 to 9 months, respectively

Data collection

In-patients treated at Geetanjali Cardiac Centre (GCC), Geetanjali Medical College & Hospital, Geetanjali University, Udaipur between 1 February 2019 and 21 November 2021 were recruited in this study. Eligible patients admitted to GCC for revascularisation procedures were recruited after giving consent. After revascularisation procedures, at the time of discharge, patients were informed they would be sent a prepaid post-revascularisation questionnaire three months later through Indian postal services and that they should complete it and return it to GCC. Relevant medical information such as history of myocardial infarction, PTCA, and CABG, number of affected vessels, left ventricular ejection fraction, comorbidities, and disease duration were obtained from the patients' medical records.

Statistical analyses

Table 1 gives an overview of the psychometric tests and criteria applied for the validation of CROQ-H. Data were analysed using SPSS software.

Table 1: Overview and criteria for psychometric analysis of CROQ-H

Tests property	Definition/test	Criteria
Acceptability	Quality of data; assessed by completeness of data and score distributions.	<ul style="list-style-type: none"> ▶ Proportion of missing data for scales (<10%) (Schroter et. al., 2004) ▶ Low floor/ceiling effects in the pre-revascularisation samples (percentage scoring lowest/highest possible scale scores)
Reliability: internal consistency	Extent to which items in a scale measure the same construct (such as	<ul style="list-style-type: none"> ▶ Cronbach's α for scales >0.70 (Nunnally et. al., 1994) ▶ Item-total correlations >0.30

	homogeneity of the scale); assessed by Cronbach's α and, item-total correlations	(Nunnally et. al., 1994)
Test-retest reliability	Stability of an instrument; assessed by administering it to subgroup of respondents on two occasions separated by a short interval and examining the agreement between test and retest scores	Intra class correlation coefficients >0.70 (Scientific 1995)
Construct validity (within scale analyses)	Evidence that each scale measures a single construct and those items can be combined to form scales; assessed on the basis of evidence of good internal consistency, factor analysis and intercorrelations between scale scores.	<ul style="list-style-type: none"> ▸ Internal consistency (Cronbach's α >0.70) ▸ Principle axis factor analysis (factor loadings \geq0.30 (Schroter et. al., 2004)), Kaiser-Meyer-Olkin test of sampling adequacy should be is at least 0.5, and Bartlett's test of sphericity (BS) should be significant. ▸ low to moderate intercorrelations between scale scores
Responsiveness	Calculated as mean change between the pre- and post-revascularisation scores divided by the standard deviation of scores at pre-revascularisation	Effect sizes (0.20), medium (0.50) or large (\geq 0.80)). (Scientific 1995)

Results

Sample

During the study period, 470 patients were invited to participate of which 400 responded. Of the 400 respondents, nine were excluded due to incomplete data (more than 10 % of the questionnaire was blank) (Seki et. al., 2011). A total of 391 (83%) patients participated in the field study with a mean (SD) age of 60.5 (\pm 10.4) years. A subset of 79 patients consented to participate in the test-retest reliability testing where a second CROQ-H post-revascularisation questionnaire was administered two weeks after the first post-revascularisation questionnaire to assess the stability of the instrument.

Table 2 shows the respondent characteristics for the 391 participants 320 were male and 71 female; 240 underwent PTCA and 151 CABG. Of the 151 patients undergoing CABG, 32 patients completed only the pre-CABG CROQ-H version, 46 completed only the post-CABG CROQ-H version, and a further 73 completed both the pre-CABG& post-CABG CROQ-H versions. Of the 240 patients undergoing PTCA, 62 patients completed only the pre-PTCACROQ-H, 111 patients completed only the post-PTCACROQ-H version, and a further 67 patients completed both the pre-and post PTCA-CROQ-H.

Table 2: Respondent characteristics

Characteristic Type	Frequency	Percentage
[1] Gender	(n=391)	
Male	320	81.8
Female	71	18.2
[2] Age Group (Years)	(n=391)	
30 to 49	58	14.8
50 to 59	100	25.6
60 to 69	152	38.9
70 to 79	70	17.9
80 and above	11	2.8
[3] Revascularisation Procedure	(n=391)	
PTCA	240	61.4
CABG	151	38.6
[4] Blocked Vessels	(n=389)	
Single Vessel Disease (SVD)	136	34.8
Double Vessel Disease (DVD)	101	25.8
Triple Vessel Disease (TVD)	152	38.9
[5] LVEF	(n=391)	
Normal (50% to 70%)	137	35.0
Mild Dysfunction (40% to 49%)	167	42.7
Moderate Dysfunction (30% to 39%)	37	9.5
Severe Dysfunction (Less than 30%)	50	12.8
[6] Diagnosis	(n=391)	
CAD-DVD	161	41.2
ACS-AWMI	46	11.8
CAD-MVR	1	0.3
CAD-AVR	1	0.3
CAD-TVD-LMCA	9	2.3
CAD-DVD-LMCA	4	1.0
CAD-SVD-LMCA	1	0.3
CAD-TVD-MR	1	0.3
ACS-IWMI	21	5.4
CAD-SVD	17	4.3
ACS-STE-AWMI	64	16.4
ACS-STE-IWMI	26	6.6
ACS-NSTEMI	19	4.9
ACS-STEMI	3	0.8
IHD	15	3.8
ACS-PWMI	2	0.5
[7] Co-Morbidity	(n=391)	
NO-COMORBIDITY	178	45.5
HTN	70	17.9
T2-DM	46	11.8
HTN+T2-DM	64	16.4
ARI	1	0.3
RHD	2	0.5

HYPOTHYROIDISM	12	3.1
CHF	4	1.0
COPD	6	1.5
ANEMIA	3	0.8
CKD	5	1.3

Abbreviations

ACS-AWMI: Acute Coronary Syndrome-Anterior Wall Myocardial Infarction; ACS-IWMI: Acute Coronary Syndrome-Inferior Wall Myocardial Infarction; ACS-NSTEMI: Acute Coronary Syndrome-Non-ST-Elevation-Myocardial Infarction; ACS-PWMI: Acute Coronary Syndrome-Posterior Wall Myocardial Infarction; ACS-STE-AWMI: Acute Coronary Syndrome-ST-Elevation-Anterior Wall Myocardial Infarction; ACS-STE-IWMI: Acute Coronary Syndrome-ST-Elevation-Inferior Wall Myocardial Infarction; ACS-STEMI: Acute Coronary Syndrome-ST-Elevation-Myocardial Infarction; ARI: Acute Renal Injury; CABG: Coronary artery bypass graft; CAD-AVR: Coronary Artery Disease- Aortic Valve Replacement; CAD-DVD: Coronary Artery Disease- Double Vessel Disease; CAD-DVD-LMCA: Coronary Artery Disease-Double Vessel Disease-Left Main Coronary Artery; CAD-MVR: Coronary Artery Disease-Mitral Valve Replacement; CAD-SVD: Coronary Artery Disease-Single Vessel Disease; CAD-SVD-LMCA: Coronary Artery Disease-Single Vessel Disease-Left main Coronary Artery; CAD-TVD-LMCA: Coronary Artery Disease-Triple Vessel Disease-Left Main Coronary Artery; CAD-TVD-MR: Coronary Artery Disease- Triple Vessel Disease-Mitral Regurgitation; CHF: Congestive heart Failure; CKD: Chronic Kidney Disease; COPD: Chronic Obstructive Pulmonary Disorder; HTN: Hypertension; HTN+T2-DM: Hypertension+ Type-II Diabetes Mellitus; IHD: Ischemic Heart Disease; PTCA: Percutaneous transluminal coronary angioplasty; RHD: Rheumatic Heart Disease; T2-DM: Type-II Diabetes Mellitus

Acceptability

A low level of missing data (<3%) was found for each of scales in the four CROQ-H versions (Table 3). Floor effects (a high proportion scoring at the bottom of the scales, poorer health outcomes) were seen for the pre-revascularisation versions as you may expect for in-patients awaiting these procedures (Table 3). Ceiling effects were also seen for all post-revascularisation scales in the post-revascularisation versions and no floor effects as you may expect following effective surgical treatment of this type.

Table: 3 Acceptability, reliability CROQ-CABG and CROQ-PTCA

CROQ SCALE	Acceptability		Internal Consistency		
	% missing	% floor/% ceiling effect	n	Cronbach's α	Mean item-total Correlation (Range)
PTCA Pre-revascularisation (n=129)					
Symptoms	0	39/3	129	0.97	0.93(0.89-0.95)

Physical functioning	1	55/12	128	0.95	0.84 (0.79-0.87)
Psychosocial functioning	0	34/25	127	0.99	0.93 (0.87-0.97)
Cognitive functioning	1	46.5/14	129	0.92	0.93 (.90-.94)
CABG Pre-revascularisation (n=105)					
Symptoms	2	27/10	105	0.94	0.86 (0.83-0.90)
Physical functioning	0	67/6	105	0.95	0.85 (0.78-0.90)
Psychosocial functioning	1	25/23	105	0.99	0.95 (0.92-0.99)
Cognitive functioning	1	56/24	105	0.97	0.97 (0.96-0.97)
PTCA Post-revascularisation (n=178)					
Symptoms	1	0/78	176	0.93	0.87 (0.56-0.94)
Physical functioning	1	0/60	176	0.97	0.90 (0.82-0.95)
Psychosocial functioning	0	0/62	178	0.99	0.93 (0.53-0.99)
Cognitive functioning	0	0/50	178	0.91	0.93 (0.89-0.95)
Adverse effects	1	0/78	177	0.81	0.74 (0.69-0.78)
Satisfaction	0	0/70	178	0.81	0.74(0.68-0.89)
CABG Post-revascularisation (n=119)					
Symptoms	0	0/74	119	0.96	0.89 (0.80-0.93)
Physical functioning	0	0/77	119	0.97	0.92 (0.87-0.94)
Psychosocial functioning	1	0/68	118	0.99	0.93 (0.76-0.97)
Cognitive functioning	0	0/61	119	0.88	0.90 (0.88-0.94)
Adverse effects	1	0/75	118	0.95	0.81 (0.72-0.89)
Satisfaction	0	0/61	119	0.77	0.71 (0.63-0.79)

Reliability

Internal consistency

Cronbach's α coefficients for all scales at pre-revascularisation and post-revascularisation far exceeded the criterion of >0.70 indicating excellent internal consistency (Table 3). Scales in all versions demonstrated evidence of homogeneity. All item-total correlations exceeded the criterion of >0.30 (Nunnally et. al., 1994) (Nunnally et. al., 1994).

Test-retest

Table 4 shows the results of the test-retest reliability analysis of the CROQ-H. Three months after revascularisation, a total of 79 (38 CABG and 41PTCA) patients completed the post-revascularisation questionnaires twice separated by a two-week interval. The intra class correlation coefficients exceeded the criterion of 0.7 for all scales in the PTCA and CABG samples.

Table 4: Test-retest reliability of CROQ-H

CROQ-H SCALE	Intraclass correlation coefficients ^a
PTCA Post-revascularisation (Test-retest) n=38	
Symptoms	0.86
Physical Functioning	0.90
Psychosocial Functioning	0.89
Cognitive Functioning	0.73
Post PTCA adverse effects	0.89
Satisfaction items	0.89
CABG Post-revascularisation (Test-retest) n=41	
Symptoms	0.88
Physical Functioning	0.88
Psychosocial Functioning	0.89
Cognitive Functioning	0.84
Post CABG adverse effects	0.88
Satisfaction items	0.72

Abbreviation: ICC: Intra-class correlation coefficients.

Construct validity (within scale analyses)

Construct validity was demonstrated by evidence of high internal consistency (high values of Cronbach's α (>0.7) and moderate to high item-total correlations) for all scales, see Table 3. In terms of internal consistency, the results shown in Table 3, Cronbach's α exceeded 0.7 in all domains of CROQ-H. The mean item-total correlation for each CROQ-H domain ranged from 0.61 to 0.97. Principal axis factor analysis with Promax rotation (see Tables 5-8) confirmed the scaling structure of each version. For all versions, every item loaded on it's own scale at least 0.30 and there was minimal cross loading on the other factors. Where cross loading occurred the highest loading was on the correct factor and the difference was at least 0.2. Kaiser-Meyer-Olkin test of sampling adequacy was at least 0.5 and Bartlett's test of sphericity was significant for all of the versions. The patterns of intercorrelations between the CROQ scales are shown in Table 5 6, 7, and 8 that show pattern of factor analysis of pre-PTCA, post-PTCA, pre-CABG, and post-CABG respectively.

Table 5: Factor Analysis of Pre PTCA (n=129)

Factor Matrix	Factor			
	1	2	3	4
Family or Friends overprotective (Preop)	.92	.12	-.02	-.00
Feeling a Burden (Preop)	.97	.15	.04	.01
Feeling restricted in social activities (Preop)	.96	.16	.03	.02
Worried about going too far from home (Preop)	.96	.17	.04	.00
Worried about Heart Condition (Preop)	.96	.10	.06	-.03
Worried about doing too much (Preop)	.96	.13	.02	.01

Worried might have heart attack or die (Preop)	.96	.17	.05	.02
Frightened by Pain or discomfort (Preop)	.95	.13	.06	-.02
Uncertain about the future (Preop)	.94	.14	-.01	-.02
Depressed (Preop)	.95	.14	.06	.01
Frustrated or impatient (Preop)	.96	.12	.04	.01
Interfered with enjoyment of life (Preop)	.96	.11	.07	.02
Difficult to keep positive outlook (Preop)	.97	.13	.04	.01
Difficult to plan ahead (Preop)	.95	.13	.03	.03
Moderate activities (Preop)	-.27	.84	.34	-.09
Lifting & carrying (Preop)	-.26	.85	.29	-.11
Climbing flights of stairs (Preop)	-.24	.85	.32	-.08
Climbing one flight of stairs (Preop)	-.23	.85	.29	-.14
Bending, Kneeling, stooping (Preop)	-.22	.83	.32	-.12
Walking half a mile (Preop)	-.26	.85	.32	-.13
Walking 100 yards (Preop)	-.25	.86	.29	-.13
Bathing or Dressing (Preop)	-.24	.79	.31	-.10
Chest Pain (Preop)	-.00	-.43	.81	-.06
Chest Discomfort (Preop)	-.00	-.33	.85	-.02
SOB (Preop)	.01	-.40	.85	-.03
Radiating Pain (Preop)	.06	-.36	.84	.00
Palpitations (Preop)	.04	-.39	.85	-.03
Nitro Frequency (Preop)	.05	-.35	.81	.02
Global trouble (Preop)	.05	-.40	.87	-.01
Difficulty reasoning (Preop)	-.13	.24	.14	.93
Forget things (Preop)	-.06	.21	.13	.93
Difficulty with activities involving concentration (Preop)	-.11	.29	.13	.91
Extraction Method: Principal Axis Factoring; Promax rotation				
Kaiser-Meyer-Olkin Measure of Sampling Adequacy .880				
Bartlett's Test of Sphericity Sig. .000				

Table 6: Factor Analysis of Post PTCA (n=178)

Factor Matrix						
	Factor					
	1	2	3	4	5	6
Family or friends overprotective (Postop)	.94	.01	-.03	-.06	.03	-.03
Feeling a Burden (Postop)	.97	-.04	-.09	-.03	.02	-.00
Feeling Restricted in social activities (Postop)	.97	-.05	-.07	-.03	.00	.02
Worried about going too far from home (Postop)	.94	-.01	-.07	-.04	.00	-.06
Worried about heart condition (Postop)	.94	-.03	-.04	-.04	.00	-.04
Worried about doing too much (Postop)	.99	-.02	-.06	-.05	.00	.00
Worried might have heart attack or die (Postop)	.98	.00	-.03	-.06	-.02	.02
Worried that symptoms might return (Postop)	.98	-.03	-.06	-.04	.00	.00
Frightened by pain or discomfort (Postop)	.98	-.02	-.03	-.04	.01	.02
Uncertain about the Future (Postop)	.95	-.02	-.08	-.03	-.00	-.01
Depressed (Postop)	.97	-.03	-.06	-.02	-.01	.03
Frustrated or impatient (Postop)	.97	-.00	-.06	-.05	-.03	.03
Interfered with enjoyment of life (Postop)	.97	-.03	-.05	-.06	-.01	.04

Difficult to keep positive outlook (Postop)	.84	.01	-.11	-.02	.01	.04
Difficult to Plan Ahead (Postop)	.49	.08	-.04	.05	.13	.00
Moderate activities (Postop)	.12	.85	.09	.18	.02	-.04
Lifting & Caring (Postop)	.07	.91	.03	.27	-.03	-.11
Climbing flights of stairs (Postop)	.08	.86	.07	.26	-.00	-.05
Climbing one flight of stairs (Postop)	.07	.83	.07	.26	.06	-.10
Bending, Kneeling, Stooping (Postop)	.03	.85	.08	.21	.04	-.07
Walking Half a mile (Postop)	.05	.83	-.04	.25	.04	-.11
Walking 100 yards (Postop)	.07	.90	-.00	.28	-.04	-.07
Bathing or dressing (Postop)	-.01	.73	-.07	.28	.02	-.02
Chest Pain (Postop)	.14	.12	.86	-.28	.04	.04
Chest Discomfort (Postop)	.08	.11	.90	-.35	.03	.07
SOB (Postop)	.03	.05	.86	-.28	.07	.08
Radiating Pain (Postop)	.10	.10	.85	-.34	-.02	.04
Palpitation (Postop)	.13	.19	.88	-.34	.05	.00
Nitro frequency (Postop)	-.02	-.06	.38	-.12	-.02	-.02
Global trouble (Postop)	.13	.12	.79	-.35	.04	.02
Satisfaction with result of operation	.18	-.41	.27	.75	.06	-.15
Satisfaction with info about operation	.16	-.29	.26	.80	.06	-.16
Satisfaction with info about recovery from operation (Postop)	.18	-.39	.29	.78	.02	-.17
Heart condition Compare to before operation (Postop)	.09	-.29	.29	.60	.19	-.15
Speed of recovery (Postop)	.16	-.38	.32	.77	.04	-.14
Expectation of Result (Postop)	-.09	-.23	.28	.54	.04	-.03
Pain in groin or wound (Postop)	-.02	-.10	-.17	-.05	.72	.00
Tenderness around groin or arm wound (Postop)	-.02	-.03	-.02	.02	.65	-.02
Numbness tingling groin area around your arm wound (Postop)	.04	.06	-.16	-.12	.76	.03
Bruising around groin wound thigh or arm wound (Postop)	-.09	.01	-.07	-.09	.70	.02
Problem in groin or arm from catheter in secretion (Postop)	-.02	-.01	-.01	-.045	.70	-.12
Concern over appearance of bruise (Postop)	-.13	.13	-.03	-.10	.51	.10
Difficulty in reasoning (Postop)	.04	.06	.05	.37	.05	.86
Forget things (Postop)	.06	.08	.09	.34	.06	.89
Difficulty with activities involving concentration (Postop)	-.01	.05	-.02	.29	-.05	.70
Extraction Method: Principal Axis Factoring; Promax rotation						
Kaiser-Meyer-Olkin Measure of Sampling Adequacy .847						
Bartlett's Test of Sphericity Sig. .000						

Table 7: Factor Analysis of Pre CABG (n=105)

Factor Matrix				
	Factor			
	1	2	3	4
Family or Friends overprotective (Preop)	0.97	0.14	0.00	0.10

Feeling a Burden (Preop)	0.93	0.09	-0.05	-0.05
Feeling restricted in social activities (Preop)	0.93	0.12	-0.02	0.10
Worried about going too far from home (Preop)	0.92	0.15	-0.02	0.04
Worried about Heart Condition (Preop)	0.89	0.16	-0.02	0.11
Worried about doing too much (Preop)	0.95	0.14	-0.01	0.11
Worried might have heart attack or die (Preop)	0.90	0.17	-0.07	0.02
Frightened by Pain or discomfort (Preop)	0.95	0.15	-0.02	0.11
Uncertain about the future (Preop)	0.94	0.13	-0.05	0.02
Depressed (Preop)	0.92	0.18	0.05	0.08
Frustrated or impatient (Preop)	0.96	0.15	-0.08	0.02
Interfered with enjoyment of life (Preop)	0.94	0.16	0.03	0.12
Difficult to keep positive outlook (Preop)	0.90	0.17	-0.06	-0.04
Difficult to plan ahead (Preop)	0.90	0.07	0.01	0.04
Moderate activities (Preop)	-0.31	0.70	0.10	-0.16
Lifting & carrying (Preop)	-0.25	0.82	0.28	-0.08
Climbing flights of stairs (Preop)	-0.33	0.66	0.16	-0.06
Climbing one flight of stairs (Preop)	-0.11	0.86	0.10	-0.15
Bending, Kneeling, stooping (Preop)	-0.28	0.74	0.25	-0.05
Walking half a mile (Preop)	-0.25	0.75	0.16	-0.12
Walking 100 yards (Preop)	-0.15	0.79	0.12	-0.07
Bathing or Dressing (Preop)	-0.28	0.80	0.17	-0.15
Chest Pain (Preop)	0.21	-0.29	0.81	0.05
Chest Discomfort (Preop)	0.03	-0.14	0.80	-0.02
SOB (Preop)	0.17	-0.17	0.81	0.12
Radiating Pain (Preop)	0.00	-0.11	0.82	0.01
Palpitations (Preop)	0.09	-0.15	0.77	-0.05
Nitro Frequency (Preop)	0.13	-0.13	0.80	0.06
Global trouble (Preop)	0.08	-0.23	0.85	0.01
Difficulty reasoning (Preop)	-0.40	0.24	-0.02	0.84
Forget things (Preop)	-0.40	0.17	-0.03	0.85
Difficulty with activities involving concentration (Preop)	-0.32	0.25	0.03	0.85
Extraction Method: Principal Axis Factoring; Promax rotation				
Kaiser-Meyer-Olkin Measure of Sampling Adequacy .838				
Bartlett's Test of Sphericity Sig. .000				

Table 8: Factor Analysis of Post- CABG (n=119)

Factor Matrix						
	Factor					
	1	2	3	4	5	6
Family or friends overprotective (Postop)	.94	-.24	-.10	-.00	-.00	-.05
Feeling a Burden (Postop)	.94	-.23	-.11	-.03	-.02	-.03
Feeling Restricted in social activities (Postop)	.95	-.10	-.10	.00	-.02	-.05
Worried about going too far from home (Postop)	.94	-.19	-.07	-.01	.02	-.07
Worried about heart condition (Postop)	.92	-.19	-.06	.06	.02	-.09
Worried about doing too much (Postop)	.82	-.19	-.04	.08	-.05	-.10
Worried might have heart attack or die (Postop)	.91	-.27	-.14	-.02	-.05	-.07

Worried that symptoms might return (Postop)	.93	-.21	-.10	-.02	-.01	-.11
Frightened by pain or discomfort (Postop)	.91	-.21	-.08	-.04	-.03	-.06
Uncertain about the Future (Postop)	.91	-.21	-.10	-.01	-.09	-.05
Depressed (Postop)	.91	-.21	-.11	-.00	-.07	-.06
Frustrated or impatient (Postop)	.84	-.02	-.02	.07	.01	.00
Interfered with enjoyment of life (Postop)	.86	-.24	-.07	-.04	-.06	-.05
Difficult to keep positive outlook (Postop)	.70	-.19	-.08	-.04	.00	-.05
Difficult to Plan Ahead (Postop)	.91	-.10	-.06	-.01	-.01	.06
Pain in chest wound (Postop)	.42	.62	.23	-.27	.05	-.04
Infection in chest wound (Postop)	.32	.59	.23	-.26	.02	-.02
Tenderness around chest wound (Postop)	.23	.70	.18	-.35	.04	.05
Numbness or Tingling around chest wound (Postop)	.24	.65	.27	-.34	.04	.00
Bruising on chest (Postop)	.21	.62	.17	-.29	.12	-.00
Pain In Leg or arm wound (Postop)	.24	.63	.19	-.36	-.04	-.02
Other pain in leg or arm (Postop)	.24	.65	.19	-.24	.07	-.05
Infection in Leg or arm wound (Postop)	.20	.63	.24	-.27	.20	-.06
Numbness or Tingling in leg or arm (Postop)	.17	.62	.21	-.39	.04	.10
Bruising on leg or arm (Postop)	.24	.62	.14	-.46	.13	.10
Swollen fit or ankles (Postop)	.26	.52	.21	-.29	.08	.09
Moderate activities (Postop)	.01	-.27	.87	.06	-.00	.03
Lifting & Caring (Postop)	.08	-.25	.88	.04	.03	-.03
Climbing flights of stairs (Postop)	.05	-.28	.90	.02	.01	-.01
Climbing one flight of stairs (Postop)	.05	-.22	.81	.15	.09	-.01
Bending, Kneeling, Stooping (Postop)	.04	-.32	.86	.00	.04	-.00
Walking Half a mile (Postop)	.04	-.29	.85	-.02	.07	-.12
Walking 100 yards (Postop)	.03	-.39	.82	.05	.02	-.01
Bathing or dressing (Postop)	.02	-.35	.84	.01	.05	-.04
Chest Pain (Postop)	.28	.43	.09	.69	-.03	.02
Chest Discomfort (Postop)	.24	.54	.07	.67	-.02	.01
SOB (Postop)	.23	.54	.08	.70	-.05	.02
Radiating Pain (Postop)	.29	.49	.09	.70	-.07	.04
Palpitation (Postop)	.23	.51	.17	.71	-.05	.01
Nitro frequency (Postop)	.11	.39	.03	.64	-.01	.19
Global trouble (Postop)	.21	.51	.10	.65	-.02	-.01
Satisfaction with results of operation (Postop)	.00	-.10	-.08	.16	.70	-.00
Satisfaction with info about operation (Postop)	-.11	-.01	-.08	.08	.64	-.04
Satisfaction with info about recovering from operation (Postop)	.07	-.12	-.06	.14	.66	-.11
Heart condition Compare to before operation (Postop)	-.03	-.18	-.14	.14	.72	.02
Speed of recovery (Postop)	-.03	-.02	-.15	.02	.69	-.07
Expectation of results (Postop)	.28	.13	-.16	.03	.52	-.07
Difficulty in reasoning (Postop)	.32	-.10	.02	-.02	.06	.68
Forget things (Postop)	.23	-.19	.00	-.07	.06	.92
Difficulty with activities involving concentration (Postop)	.28	-.17	.02	-.01	.09	.73
Extraction Method: Principal Axis Factoring; Promax rotation						
Kaiser-Meyer-Olkin Measure of Sampling Adequacy 0.847						

Bartlett's Test of Sphericity Sig. .000

Responsiveness

Table 9 shows the effect sizes for change between pre-revascularisation and post-revascularisation for the four core scales in the CABG and PTCA responsiveness samples. All scales demonstrated significant change between pre-revascularisation and post-revascularisation ($p < 0.05$). For the CROQ-CABG, and GCROQ-PTCA large effect size sizes were found for all scales (Husted et. al., 2000).

Table 9: Responsiveness of CROQ-H from pre-revascularisation to post-revascularisation

Responsiveness of the CROQ (before to three months after revascularisation)				
CROQ scale	Before	At 3 months	Change	Effect size
CROQ-CABG (n = 73)				
<i>Symptoms</i>	32.89 (26.52)	92.29 (10.95)	59.40	2.23
<i>Physical functioning</i>	18.33 (25.19)	86.18 (21.24)	67.85	2.70
<i>Psychosocial functioning</i>	32.26 (24.36)	91.67 (10.72)	59.41	2.43
<i>Cognitive functioning</i>	14.71 (16.72)	91.59 (10.35)	76.88	4.60
CROQ-PTCA (n = 67)				
<i>Symptoms</i>	25.79(29.02)	94.75(08.12)	68.96	2.73
<i>Physical functioning</i>	31.42 (29.75)	94.13 (14.64)	62.71	2.11
<i>Psychosocial functioning</i>	27.60 (26.75)	88.96 (13.16)	61.36	2.29
<i>Cognitive functioning</i>	37.00 (30.87)	88.88 (12.09)	76.88	1.68

Discussion

Translation and validation of the CROQ-H is much needed in the Indian clinical setting. The CROQ can be used not only to assess disease-specific HRQOL, but also to assess treatment outcomes for each therapeutic modality. Regarding the content validity of the CROQ-H, the changes in the terms used and the elimination of some items are consistent with the socio-cultural and procedural characteristics in India. The CROQ-H was pilot-tested before proceeding to the major field study, and none of the items were reported as confusing or unclear. Consequently, the content and face validity of CROQ-H was confirmed. Considering the response variance in CROQ-H, all items showed floor effects in both pre-PTCA and pre-CABG patients because these were administered to patients who were stabilized and ready for PTCA and CABG procedures.

Like the original English version of the CROQ (Schroter et. al., 2004), and the Japanesed version (CROQ-J) (Seki et. al., 2011), the average number of missing items was 1.5 % in CROQ-H, which is low, and an indication that CROQ-H is acceptable to patients. Exploratory factor analysis of the CROQ-H showed item loadings above the 0.3 as per criteria needed (Schroter et. al., 2004). The Stability (Schroter et. al., 2004) of CROQ-H; was confirmed by administering it to

respondents on two occasions and examining the agreement between test and retest. The intra class correlations coefficients in all domains for of both procedures CABG and PTCA were above the criterion of 0.7.

Study limitations

An important limitation is that this study did not make comparisons with any other quality of life tools to assess its validity against external criteria due to unavailability of such tools in Hindi. The findings of the study cannot be generalized because of the geographical limitations. Further evaluation of the CROQ-H should be performed in multi-center facilities to confirm the generalizability of the findings and to increase the sample size.

Conclusion

CROQ-H is much needed in the Indian clinical setting. The psychometric validation of CROQ-H was carried out in this study. Translation and cultural adaptation were done by following international guidelines. The validity and reliability of this scale were reasonably verified through a patient-based field study, and the CROQ-H was found to be a reliable and valid scale for the assessment of CAD patients.

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