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ORIGINAL ARTICLE

Reliability Of The Persian Version Of Coronary Revascularization Outcome Questionnaire (CROQ) In Cardiac Patients Undergoing CABG And PTCA Procedures

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ABSTRACT

Background and Aim: The quality of life is a major goal in the context of preventive and therapeutic cardiology. Up to now, there wasn't any validated instrument for patient based outcome measurement, before and after CABG and PTCA procedures, in Iran. In this study, we have translated and evaluated the reliability of the Persian version of coronary revascularization outcome questionnaire (CROQ). The reliability of the Persian version of coronary revascularization outcome questionnaire was not known. We therefore aimed to assess the test-retest reliability and scale internal consistency of the instrument in two groups of patients undergoing CABG and PTCA procedures.

Method: This is a methodological study, and was conducted for the aim of: the Psychometric study of the Persian version of coronary revascularization outcome questionnaire (CROQ). The study's population was 60 patients (30 CABG and 30 PTCA). This instrument has 4 versions (2 versions for CABG and 2 versions for PTCA). It has pre and post operation versions for each group of patients. The patients were assessed 3 months after operation, by the post operation version. For testing the instrument's reliability, the assessment was repeated 1-2 weeks later.

Results: Psychometric tests confirmed the reliability, internal consistency, construct validity and responsiveness of the Persian version of CROQ.

Conclusion: For clinical trials evaluation, we need to compare quality of life before and after interventions, by an instrument. Disease specific measures are more responsive in detecting treatment effects than general measurements, so for this group of patients, disease specific measurement is necessary. With concern for the Psychometric test results, we encourage the use of CROQ in patients undergoing CABG and PTCA procedures.

Key words: Quality of life, Angioplasty, Coronary artery bypass grafting, Reliability, questionnaire.

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Introduction

In the field of cardiology, there has been a long time tradition of assessing the effectiveness of new and emerging health technologies. These evaluations have invariably focused on measures of outcome such as mortality, morbidity and clinical function [18,1]. However, in recent years, there has been an increasing use of more patient focused outcome, in particular, quality of life [6]. Health related quality of

life (HRQOL) questionnaires are increasingly being used as primary outcome measures to assess treatment effectiveness in ischaemic heart disease. They have been used to evaluate the effectiveness of rehabilitation after acute myocardial infarction, to compare the results of percutaneous transluminal coronary angioplasty (PTCA) with and without stents, and PTCA with stents versus coronary bypass graft surgery (CABG) in multivessel disease [11],[7] . Quality of life measures may be disease specific or generic; the former focuses on the complaints that are attributable to a specific diagnosis or patient population. In contrast, the later is intended to be broadly applicable across different interventions, and across patients with different characteristics [17] Disease specific instruments tend to be more sensitive to detecting change in the health status than generic instruments [3],[20],[8] **.** Until recently, there have been no validated instruments to measure patient-based outcome before and after CABG and PTCA [12] Schroter and Lamping have developed a new patient-based instrument, the coronary revascularization outcome questionnaire, to measure health outcome and HRQOL before and after CABG and PTCA [14].

The CROQ includes items in the following domains: symptoms, physical functioning, psychosocial functioning, cognitive functioning, satisfaction and adverse effects. There are several validated and widely used disease specific questionnaires in various linguistic versions (English and Italian) for patients with heart diseases [12],[14] . There wasn't any instrument for assessment of quality of life in cardiac patients undergoing CABG and PTCA procedures, in Iran. In this sequence, we have begun to translate and test the reliability of CROQ in Persian.

Methods

Questionnaire development

The translation procedure adopted by the International Quality Of Life Assessment (IQOLA) project, called for a series forward (into the target language) and backward (into English) translations of the questionnaire [2],[4],[5] . At the first step, CROQ was translated into Persian by two translators. Translators were required to place emphasis on the conceptual rather than the literal equivalence (forward translation). The common forward translation was given to another translator who translated the questionnaire back into English. The backward and forward translations were reviewed by researchers, and the Persian translation was revised in a few items. The Persian version of CROQ which we have developed has four different types: CROQ-CABG-pre and CROQ- PTCA-pre; to be administered before the patient undergoes coronary revascularization, and the CROQ-CABG-post and CROQ- PTCA-post; to be administered three months after CABG and PTCA, respectively. The former two questionnaires are identical in item content and differ only by name, but the later two differ from each other only in the content of adverse effects scale, as these problems differ for the two procedures. [Table /Fig 1]

(Table/Fig 1) CROQ scales and number of each scale's items.

Scale	Number of items
Items common to pre and post-revascularisation versions	7 items
Symptoms	8 items
Physical functioning	14 items
Psychosocial functioning	3 items
Cognitive functioning	1 item
Not classified	
Additional post-revascularisation items	6 items
Satisfaction	
Adverse effects	
CROQ-CABG	11 items
CROQ-PTCA	6 items
Not classified	2 items

Patients

A total of 60 patients (30 CABG and 30 PTCA) drawn from a convenience random sample, were used in this study. The sample involves those patients who were scheduled for elective surgery**.** Patients were supposed to complete the questionnaire by themselves. The exclusion criteria were; patients who couldn't read, understand or reply, patients

who didn't graduate from guidance school, patients who didn't answer the questions completely (before or after surgery), and those who undergoing CABG and PTCA more than one time or undergoing this procedures collectively. All patients completed the consent form. After 3 months, all patients were invited to one cardiac center, where they completed post versions of questionnaires. One to two weeks later, they returned to the center and completed the post versions again, for re-test.

Statistical Analysis

SPSS version 15.0 was used for statistical analysis.Psychometric methods [19],[21][,9] were used to produce item reduced versions of the questionnaires in this study: item-total correlation (item internal consistency), reliability (test-retest and scale internal consistency) and responsiveness of CROQ. Pearson correlation test was used for evaluating item-total correlation**.** The standard for item-total correlations in this questionnaire is more than 0.20 [14]. For testing the reliability of the Persian version of the CROQ questionnaire, all patients were required to complete the post versions after 1 or 2 weeks again. Reliability of the Persian version of CROQ was studied by two ways: test-retest reliability [16] and scale internal consistency. Inter Class Coefficient (ICC), was used for test-retest reliability, and Cronbach's alpha for scale internal consistency. Standard for ICC and Cronbach's alpha is more than 0.70 in this questionnaire [14]. Responsiveness is the ability of the scales to detect clinically important changes over time [4]. Kolmogorov-Smirnov's test showed that the scale's data were not normally distributed, so Wilcoxon-Rank's non parametric test was used for the comparison between the results before and after three months after revascularization.

Results

Out of 30 CABG patients, 10 females (33.30%) and 20 males (66.70%) with 57(±9.61) years as mean age and 75.70(±9.23) kg weight, completed the questionnaire, respectively. Out of 30 PTCA patients, 11 females (36.70%) and 19 males (63.30%) with 52.30(±6.07) years as mean age and 73.86(±11.34) kg weight, completed the questionnaire, respectively [Table/Fig 2].

(Table/Fig 2) Respondent characteristics

Characteristic	CABG	PTCA
N	30	30
Female	10(33.30%)	11(36.70%)
Male	20(66.70%)	19(63.30%)
Mean of height (cm)	164.63(±10.46)	166.40(±7.81)
Mean of weight (kg)	75.70(±9.23)	73.86(±11.34)
Mean of age (years)	57(±9.61)	52.30(±6.07)
Diabetic	17(56.70%)	10(33.30%)

Item total correlations within scales were similar, and exceeded the criterion of 0.20 for two groups of patients. Correlations between items and their hypothesized scale were more than correlations between items and other scales [Table/Fig 3], [Table/Fig 4]. Interclass correlation coefficients and Cronbach's alpha exceeded the criterion of 0.70 for all scales [Table/Fig 5],[Table/Fig 6] showed the results of Wilcoxon-rank non parametric test. Except of cognitive functioning in the CABG sample, there were significant changes in all scales in CABG and PTCA samples that were assessed before and after revascularization ($p < 0.05$).

(Table/Fig 3) Correlations between items and hypothesized scale and with other scales in CABG sample. Sym: Symptoms, Ph: Physical functioning, Psy: Psychosocial functioning, Cog: Cognitive functioning, Sat: Satisfaction, Adv: Not classified.

Scale	Sym	Ph	Psy	Cog	Sat	Adv	n
Sym	0.47-0.87	0.02-0.18	0.02-0.35	0.03-0.29	0.02-0.23	0.00-0.36	0.09-0.48
Ph	0.02-0.17	0.22-0.75	0.02-0.52	0.04-0.29	0.03-0.52	0.03-0.24	0.08-0.28
Psy	0.06-0.45	0.05-0.57	0.26-0.80	0.02-0.34	0.01-0.31	0.02-0.47	0.05-0.53
Cog	0.04-0.36	0.06-0.33	0.01-0.16	0.75-0.86	0.12-0.52	0.05-0.18	0.08-0.24
Sat	0.01-0.42	0.01-0.33	0.01-0.21	0.08-0.52	0.56-0.75	0.16-0.40	0.01-0.34
Adv	0.00-0.20	0.00-0.30	0.12-0.36	0.04-0.21	0.05-0.38	0.21-0.65	0.06-0.46
N	0.05-0.38	0.13-0.25	0.06-0.36	0.13-0.18	0.05-0.30	0.12-0.28	0.30-0.90

(Table/Fig 4) Correlations between items and hypothesized scale and with other scales in PTCA sample. Sym: Symptoms, Ph: Physical functioning, Psy: Psychosocial functioning, Cog: Cognitive functioning, Sat: Satisfaction, Adv: adverse effects, n: Not classified.

Scale	Sym	Ph	Psy	Cog	Sat	Adv	n
Sym	0.31-0.83	0.12-0.53	0.05-0.35	0.00-0.25	0.02-0.23	0.00-0.21	0.01-0.17
Ph	0.07-0.44	0.42-0.85	0.00-0.40	0.00-0.16	0.00-0.33	0.04-0.30	0.09-0.35
Psy	0.04-0.44	0.00-0.41	0.27-0.74	0.06-0.21	0.05-0.31	0.03-0.37	0.04-0.33
Cog	0.03-0.07	0.03-0.08	0.31-0.40	0.90-0.90	0.02-0.09	0.00-0.02	0.03-0.30
Sat	0.05-0.40	0.15-0.50	0.00-0.42	0.07-0.48	0.27-0.65	0.00-0.20	0.04-0.44
Adv	0.11-.29	0.12-0.18	0.05-0.36	0.03-0.12	0.12-0.26	0.61-0.89	0.13-0.23
N	0.03-0.11	0.10-0.30	0.17-0.32	0.01-0.21	0.03-0.05	0.06-0.26	0.29-0.96

(Table/Fig 5) Reliability of CROQ (post-revascularisation). (Confidence Interval in all cases was 95%)

CROQ scale	Reliability Scale Internal consistency (Cronbach's alpha)	Test-retest (ICC)
CROQ-CABG-post		
Symptom	0.85	0.73
Physical functioning	0.96	0.92
Psychosocial functioning	0.97	0.95
Cognitive functioning	0.88	0.79
Satisfaction	0.95	0.91
Adverse effects	0.98	0.98
Not classified	0.93	0.88
Total score	0.76	0.72
CROQ-PTCA-post		
Symptoms	0.96	0.92
Physical functioning	0.95	0.91
Psychosocial functioning	0.98	0.97
Cognitive functioning	0.86	0.76
Satisfaction	0.96	0.92
Adverse effects	0.94	0.89
Not classified	0.88	0.80
Total score	0.98	0.98

(Table/Fig 6) Responsiveness of CROQ (Wilcoxon-Rank's non parametric test) Sym: Symptoms, Ph: Physical functioning, Psy: Psychosocial functioning, Cog: Cognitive, n: Not classified
*** Indicates p-value that was significant (P< 0.05)**

Patients group	Sym	Ph	Psy	Cog	n
CABG P-value	0.00-0.00*	0.00-0.01*	0.00-0.04*	0.20-0.70	0.00-0.03*
PTCA P-value	0.00-0.01*	0.00-0.02*	0.00-0.04*	0.01-0.01*	0.00-0.00*

Discussion

The CROQ is a practical and scientifically validated patient based measure of outcome for coronary revascularization that is acceptable to patients, and satisfies rigorous psychometric criteria for reliability, validity, and responsiveness. As the only validated instrument developed specifically for use before and after CABG and PTCA, and which is quick and easy to administer, the CROQ provides a rigorous method for improving the evaluation of outcomes in clinical trials and clinical audit. Our data show that each item of CROQ questionnaire contributed equally to the scale, because all item-total correlations exceeded the criterion of 0.20 [Table/Fig 3] and [Table/Fig 4]. The scores for each question are significantly more closely correlated with their scales than with others. These results indicate that the questions in the CROQ possess good discrimination validity. The correlation range for each scale in the CABG group varies from 0.21 for adverse effects to 0.86 for cognitive functioning, and that in the PTCA group varies from 0.27 for the psychosocial satisfaction scale to 0.96 for the not classified group. These results consist of the number of questions per scale and their heterogeneity [10]. For instance, the scales for adverse effects, psychosocial and satisfaction include 11, 14 and 6 items, which span a wide spectrum of adverse effects, psychosocial and satisfaction, whereas cognitive functioning and the not classified group (both include 3 items) which are shorter and, have more homogenous scales.

Inter Class Correlation Coefficient (ICC) exceeded the criterion of 0.70 for all scales indicating good test-retest reliability. This finding is like the finding that the developers of CROQ reported [14]. Their reported Inter Class Coefficient (ICC) range is similar to that found in this study. The Cronbach's Alpha Coefficient always exceeded the criterion of 0.70 for all scales. This indicates good reliability. The most common method for demonstrating responsiveness is through a comparison of scores before and after treatment [15],[13]. All scales in CABG samples have shown significant change before and after operation ($p< 0.05$), except to that of cognitive functioning. Pintor and colleagues (2002), after assessing the reliability of the Italian version of CROQ, reported similar findings for cognitive functioning [12]. CROQ developers reported

moderate responsiveness for the cognitive functioning scale in the CABG sample. These findings are more or less similar to this study's findings [14]. There were significant changes in all scales in the PTCA sample and total scores, before and after revascularization. This means that the Persian version of CROQ has good responsiveness. This finding is similar to findings reported by the CROQ developers and the Italian version of this questionnaire [12],[14]. Given its demonstrated high responsiveness, the CROQ is a promising new tool for use in clinical trials. It may detect important differences between procedures that have previously not been detected by less sensitive generic measures [14]. The CROQ provides appropriate content, as it contains items directly addressing the impact of these procedures based on problems that patients reported to be important. As the CROQ is the only evaluated patient-based questionnaire that includes items specific to CABG and PTCA such as adverse effects and satisfaction, use of it in patients undergoing CABG and PTCA is encouraged.

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