



Research Article

TRANSLATION AND VALIDATION OF THE GUJARATI VERSION OF CORONARY REVASCULARIZATION OUTCOME QUESTIONNAIRE IN PERCUTANEOUS CORONARY INTERVENTION SUBJECTS

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ABSTRACT

Introduction: CROQ is a widely used PROM meant for coronary revascularization patients. It had been developed originally in English but has been translated into several languages including Norwegian, Farsi, Japanese etc. It is an acceptable, reliable, valid and responsive instrument. This paper describes the translation of CROQ for Percutaneous Coronary Intervention (PCI) into Gujarati and evaluating its psychometric properties.

Aim: To translate and validate the Gujarati version of CROQ-PCI

Methods: Forward and Backward Translation of CROQ for PCI was done. The Gujarati version of CROQ was then administered to 139 pre and post-operative subjects of PCI. The post-operative subjects were 4 weeks post-op.

Results: The mean of the age pre-op group was 56.6 years whereas that of post-op group was 57.85 years. All the items had <10% missing items. The CROQ-Gujarati version showed good acceptability, reliability and construct validity for within scale analysis. Face and Content validity were established by the expert group.

Conclusion: The Gujarati version of CROQ-PCI is an acceptable, reliable and valid outcome measure for pre and post PCI subjects.

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INTRODUCTION

The prevalence of cardio vascular diseases (CVD) is increasing by the day all over the world. CVD leads to 30% of deaths occurring worldwide.¹As compared to other countries, the burden of CVD in India is going to be the highest by the year 2020.^{2,3}As the burden of CVD rises, there is development of newer techniques of treatment – both medical and surgical. The most common surgical treatments being Percutaneous Coronary Intervention (PCI) and Coronary Artery Bypass Grafting (CABG). In addition to other outcome measures like the survival rate, morbidity rate and mortality rate, there has been an increase in evaluating the Health Related Quality of Life (HRQOL) using Patient-Reported Outcome Measures (PROMs). PROMs can provide detailed information about the patient's perspective of well-being, health, treatment effectiveness and clinical outcome. This information is valuable in reducing the burden of the disease and improving the health of the patient.⁴HRQOL in CHD can be measured using disease specific or general PROM questionnaires. General questionnaires focus more on the overall general well-being of the individual rather than asking questions related to the disease of concern. Disease specific questionnaires provide with more accurate data since they are more sensitive to changes in the disease.

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One questionnaire that is specific to coronary revascularization is Coronary Revascularisation Outcome Questionnaire (CROQ). CROQ is a widely used PROM meant for coronary revascularization patients. It had been developed originally in English but has been translated into several languages including Norwegian, Farsi, Japanese etc.^(4,5,6,7) It is an acceptable, reliable, valid and responsive instrument. This study describes the translation of CROQ into Gujarati and evaluating its psychometric properties.

METHODOLOGY

CROQ structure and scoring

The CROQ was developed as 2 separate questionnaires for Percutaneous Coronary Intervention (PCI) and Coronary Artery Bypass Grafting (CABG). Each questionnaire has 2 different versions for pre and post-surgery. There are 4 main domains: symptoms, physical functioning, psychological functioning and cognitive functioning. The pre-questionnaire has 7 items in symptoms domain, 8 items in physical functioning, 14 items in psychological functioning and 3 items in cognitive functioning domain. The post questionnaire has these items and additional items – 6 items related to treatment satisfaction and 5 items related to adverse effect of treatment procedures. A 3-6 point Likert scale is used to score each item. The scores for each domain are added up and then converted into a 0-100 scale where 0 is the minimum and 100 is the maximum score.⁶

CROQ translation into Gujarati

The process for translation was followed as per previous studies that had translated CROQ into other languages.^{4,5,6,7} The CROQ was first forward translated into Gujarati from English by two independent translators. Both the versions were then reviewed and a combined version (Version 1) was developed by the translators. This Version 1 was then provided to an expert group that constituted of Cardiologists, Cardiothoracic Surgeons, Intensive Care Unit nurses and cardiothoracic physiotherapists. The expert group suggested a few changes in the questionnaire according to the culture and understanding of the concerned population. Hence, the following changes were made. Since playing golf and bowling are not routine recreational activities for the studied population, these activities were then changed to gardening. For better understanding 1 mile and 100 yards were changed to approximately 1 kilometer and approximately 100 meters respectively. Since the preferred route is inguinal through the femoral artery for PCI, arm wound was dropped from item 8 and only groin wounds were mentioned in the post PCI Questionnaire. This changed Version 2 was then back translated in to English by two independent translators. The translated versions were again checked and matched to the original questionnaire. As the context of the questions remained the same, Version 2 was accepted as the final version.

Data Collection

The subjects were selected by convenience sampling. Subjects who were admitted to the hospital for a planned PCI, were 18 years and older, had CAD as their diagnosis, no other severe illnesses (cancer, etc.) and could read and write in Gujarati were included. Those who had an emergency procedure, were not co-operative or unconscious, could not read nor write Gujarati were excluded. All the subjects received a written, informed consent form which they signed prior to filling the questionnaire. The post questionnaire was filled 4 weeks after the surgery.

Statistical Analysis

The collected data was then analyzed using SPSS 16.0. Patient characteristics and the scores for each scale were evaluated by descriptive analysis and floor and ceiling effects were calculated. To assess the construct validity, exploratory factor analysis was done using Principal method and Oblimin rotation. Cronbach's alpha was used to analyze internal consistency and construct validity for within scale analysis. Correlations were analyzed using Pearson's correlation test.

RESULTS

Data Collection

85 pre-operative subjects were screened and were found eligible to participate in the study. They were informed about the nature and purpose of the study and consent was obtained from them. For the post-operative questionnaire, informed consent was obtained from 54 subjects. The subjects were then asked to fill out the questionnaires.

Patient Characteristics

The demographic characteristics of the population are shown in Table 1. The mean age of the pre-operative subjects was

56.6± 11.45 years, whereas the mean age of the post-operative subjects was 57.85 ± 10.79 years. In the pre-operative group, 69 subjects were males and 16 were females, 23 subjects had a history of Hypertension, 4 had Diabetes Mellitus, 1 had Dyslipidemia, 1 had Hyperthyroidism and 1 had a history of Epilepsy. 18 subjects had both Hypertension and Diabetes Mellitus, whereas 4 others had a varying combination of Diabetes Mellitus, Hypertension, Dyslipidemia, Hypothyroidism and Hyperthyroidism. In the post-operative group, 40 subjects were males and 14 were females, 14 subjects had a history of Hypertension, 1 had Diabetes Mellitus and no subject had a positive history of Dyslipidemia. 12 subjects had a history of both Diabetes Mellitus and Hypertension. There were 9 smokers in the pre-operative group, 13 consumed tobacco in some other form, 2 subjects were smokers and tobacco consumers, 1 consumed tobacco and alcohol along with smoking whereas 1 was a past smoker. 6 subjects were smokers in the post-operative group, 4 subjects had history of consuming tobacco in some other form whereas 3 had a positive alcohol consumption history and 7 subjects smoked as well as consumed tobacco.

Table 1 Details of the patient characteristics

	Pre-PCI	Post-PCI
Mean Age (years)	56.6 ± 11.45	57.85 ± 10.79
Males (%)	69 (81.2)	40 (74.1)
Females (%)	16 (18.8)	14 (25.9)
Hypertension	23	14
Diabetes Mellitus	4	1
Dyslipidemia	1	0
Diabetes Mellitus and Hypertension	18	12
Diabetes Mellitus, Hypertension and Dyslipidemia	1	0
Diabetes Mellitus, Hypertension and Hypothyroidism	1	0
Diabetes Mellitus, Hypertension and Hyperthyroidism	1	0
Hypertension and Dyslipidemia	1	0
Epilepsy	1	0
Hyperthyroidism	1	0
Smoking	9	6
Tobacco	13	4
Alcohol	0	3
Smoking and Tobacco	2	7
Smoking, Tobacco and Alcohol	1	0
Past smokers	1	0

Score and acceptability of CROQ-Gujarati version

All the items of the CROQ Gujarati version had less than 10% missing data which indicates good acceptability. The mean scores of each of the domains are as shown in Table 2. There were low floor effects for all the items. However, there were high ceiling effects seen for Adverse effects and Satisfaction items in the post-revascularization sample.

Table 2 Acceptability and Mean scores of CROQ-PCI

Domain	Mean Score ± SD	Acceptability (%) (Proportion of missing data)	Floor effects (%)	Ceiling effects (%)
Symptoms	58.29 ± 26.5	5.75	2.37	4.8
Physical Functioning	58.23 ± 30.65	5.75	2.88	4.8
Cognitive Functioning	56.22 ± 29.58	6.47	4.32	4.6
Psychosocial Functioning	50.26 ± 26.84	2.16	1.37	4.5
Adverse effects	92.05 ± 23.57	2.16	5.5	90.74
Satisfaction	93.68 ± 24.28	2.16	5.5	77.78

Tests of scaling assumptions

There was equal variance among items of the same scale. The item convergent and discriminant correlations supported the scaling structure of the CROQ. All the items were scaling successes except one variable (“Has your recovery from your heart operation so far been”) was a probable failure. The results are shown in Table 3.

Exploratory factor analysis was done by the Principal method using Oblimin rotation. It also supported the construct validity of both the scales. Kaiser Meyer Olkin test concluded values > 0.5 and Barlett’s test of sphericity was also found to be significant (<0.05).

Table 3 Results for convergent and discriminant validity

	Symptom	Physical Functioning	Psychosocial Functioning	Cognitive Functioning	Adverse Effects	Satisfaction
Symptom	0.649-0.817	0.284-0.480	0.469-0.674	0.437-0.625	(-0.018)-0.534	0.016-0.399
Physical Functioning	0.338-0.572	0.615-0.844	0.306-0.547	0.275-0.518	0.038-0.495	0.181-0.302
Psychosocial Functioning	0.405-0.800	0.359-0.535	0.458-0.864	0.289-0.784	0.040-0.667	(-0.163)-0.338
Cognitive Functioning	0.653-0.749	0.461-0.552	0.731-0.814	0.902-0.936	0.302-0.476	(-0.017)-0.329
Adverse Effects	0.268-0.461	0.058-0.366	0.207-0.348	0.250-0.435	0.815-0.969	0.119-0.254
Satisfaction	0.09-0.320	(-0.123)-0.373	(-0.151)-0.160	(-0.071)-0.314	(-0.027)-0.551	0.410-0.867

Reliability

Reliability was measured by calculating the Cronbach’s alpha for internal consistency and the correlation between item and total score. Cronbach’s alpha for all the scales fulfilled the criteria of >0.70. The results are shown in table 4.

Table 4 Internal consistency of pre and post-PCI CROQ

Scale	Cronbach’s alpha
Symptom	0.867
Physical Functioning	0.895
Psychosocial Functioning	0.905
Cognitive Functioning	0.902
Adverse Effects	0.949
Satisfaction	0.751

Correlations between the items and total score for all the scales fulfilled the >0.30 criteria except Satisfaction scale (Table 5).

Table 5 Item-total correlations for pre and post-PCI CROQ

Symptom	0.544-0.735
Physical Functioning	0.476-0.654
Psychosocial Functioning	0.308-0.848
Cognitive Functioning	0.769-0.832
Adverse Effects	0.392-0.629
Satisfaction	0.084-0.511

Face and content validity

During the translation process, both content and face validity were assessed and considered to be good by the expert group comprising of physiotherapists, nurses and Cardiologists as well as cardiothoracic surgeons. A small group of subjects who had undergone PCI also assessed the CROQ-G and found it to be good and easy to understand.

Construct validity (within scale analysis)

Cronbach’s alpha between scale score and total score fulfilled the criteria of >0.70 except Satisfaction scale. (Table 6)

Table 6 Cronbach’s alpha between scale score and total score

Symptom	0.930
Physical Functioning	0.843
Psychosocial Functioning	0.951
Cognitive Functioning	0.919
Adverse Effects	0.816
Satisfaction	0.692

Correlation between the different scales showed moderate to good correlation for Symptom scale whereas it was low to moderate correlations for Physical Functioning, Satisfaction and Adverse effects scales and low to good for Cognitive Functioning and Psychosocial Functioning scales. (Table 7)

Table 7 Correlations between different scales

Symptom	0.321-0.790
Physical Functioning	0.265-0.560
Psychosocial Functioning	0.076-0.841
Cognitive Functioning	0.128-0.841
Adverse Effects	0.307-0.551
Satisfaction	0.076-0.551

DISCUSSION

CROQ is the only disease-specific patient reported outcome measuring questionnaire that can be used to evaluate outcomes before and after a coronary revascularization procedure. It has shown high acceptability, reliability and validity. It measures all the outcomes of importance to patients before and after a coronary revascularization procedure. The development of a Gujarati version of CROQ was essential as it enables self-evaluation of the patient and helps in identifying areas of improvement in patient care and treatment.

The international guidelines for translation, cultural adaptation and validation were followed and a questionnaire that was acceptable to the subjects was developed. The low proportion of missing data suggests that the Gujarati version of CROQ is highly acceptable to the patients. There were low floor effects seen. There were high ceiling effects for Adverse effects and Satisfaction scales in the post-revascularization CROQ which can be attributed to the effective interventions given. This is consistent with the other translated versions of CROQ like Norwegian, Farsi and Japanese.^{4,5,6}The original version of CROQ too had a low missing proportion of <3% and high ceiling effects in the post-revascularization questionnaire.⁸

While evaluating the scaling assumptions, only one item was found to be a probable scaling failure in the Satisfaction scale. This indicates that all the items are correctly grouped in the CROQ-G questionnaire. CROQ-G possesses good divergent and convergent validity.

The Gujarati version was found to be highly reliable as seen with the internal consistency scores of >0.70. All item-total

correlations exceeded the score of >0.30 except Satisfaction. Similar findings were concluded by other studies.

All the scales showed good internal consistency while evaluating the construct validity (within scale analysis) except Satisfaction. However, the Cronbach's alpha value for Satisfaction was 0.692 which is really close to 0.70. Even for the correlations between scales, only Satisfaction scale did not have a good correlation with other scales. But since the exploratory factor analysis and internal consistency criteria were fulfilled, it is acceptable to use the Satisfaction scale.

The current study is limited in a few aspects. The findings and conclusions of the current study cannot be generalized to all geographical areas. The current study was concerned regarding the translation and evaluation of psychometric properties of the CROQ-PCI only. Further studies evaluating the same for CROQ-CABG need to be done.

CONCLUSION

CROQ-PCI Gujarati version was developed after translation and cultural adaptation of the CROQ-PCI English version. The psychometric properties of the same were evaluated and it was concluded that CROQ-G is an acceptable, reliable and valid patient reported Outcome measure for PCI undergoing subjects.

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Conflicts of Interest

There were no conflicts of interests.

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