The City of Hope-Quality of Life-Ostomy Questionnaire: Persian Translation and Validation

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Abstract

Background: Since there is no disease-specific instrument for measuring quality-of-life (QOL) in Ostomy patients in Persian language. **Aim:** This study was designed to translate and evaluate the validity and reliability of City of Hope-quality of life-Ostomy questionnaire (COH-QOL-Ostomy questionnaire). **Subjects and Methods:** This study was designed as cross-sectional study. Reliability of the subscales and the summary scores were demonstrated by intra-class correlation coefficients. Pearson's correlations of an item with its own scale and other scales were calculated to evaluated convergent and discriminant validity. Clinical validity was also evaluated by known-group comparisons. **Results:** Cronbach's alpha coefficient for all subscales was about 0.70 or higher. Results of interscale correlation were satisfactory and each subscale only measured a single and specified trait. All subscales met the standards of convergent and discriminant validity. Known group comparison analysis showed significant differences in social and spiritual well-being. **Conclusion:** The findings confirmed the reliability and validity of Persian version of COH-QOL-Ostomy questionnaire. The instrument was also well received by the Iranian patients. It can be considered as a valuable instrument to assess the different aspects of health related quality-of-life in Ostomy patients and used in clinical research in the future.

Keywords: City of Hope-quality of life questionnaire-Ostomy questionnaire, Ostomy, Quality-of-life, Reliability, Validity

Introduction

Ostomy is a surgical procedure to treat several gastrointestinal diseases, including trauma, colon and rectum cancer, Crohn's disease, bowel obstruction, congenital malformations, and complications of diverticulitis.[1,2] The ostomas may be temporary and can be removed at a later date.[1]

Ostomy is known to impact negatively on a patient's physical activity, psychological performance and social function.

Patients with Ostomy suffer from rectal discharge, inability to control gas, difficulties and adjustments of returning to work, decreased sexual activity, and difficulties in travel and leisure activities.[3] They are involved with consequences of this therapeutic method for a long time.[3,4] These problems will reduce quality-of-life (QOL) in Ostomy patients. Thus, assessment of QOL of stoma patients is necessary and can be useful for decisions made in order to control disease, complications, treatment and improve QOL.[1,4,5]

Different reasons for assessing QOL have led to the development and use of different generic and disease-specific instruments.[6] Several instruments have been developed to measure health related quality-of-life (HRQOL) among Ostomy patients. They include quality from the patient's perspective, stoma care QOL index, City of Hope-quality of life-Ostomy questionnaire (COH-QOL-Ostomy questionnaire), Ostomy adjustment scale, Ostomy adjustment inventory-23, coping strategies inventory, QOL index, survey of pre-operative

factors of Ostomy adjustment and stoma-QOL.[7] However, the instruments used in most studies have not been validated specifically for stoma patients.[8-12]

One of disease-specific tools is COH-QOL-Ostomy questionnaire. This questionnaire has been derived from a research on QOL conducted in 1983 by the investigators in Nursing Research at the COH National Medical Center, Duarte, CA and revised and validated by Grant *et al.*, in 2004.[4]

Until now, there has not been a suitable tool for measuring QOL in Ostomy patients in Iran. Due to the increased prevalence of colorectal cancer and other conditions leading to ostoma construction in Iran,[13-15] standardization of the instrument for evaluating the QOL in these patients seems necessary. The aim of the present study is to translate and evaluate the reliability and validity of the COH-QOL-Ostomy questionnaire when applied to an Iranian sample of patients with Ostomy.

Subjects and Methods

Patients

This survey was a cross-sectional study conducted from March to October 2011 on a random sample of 103 stoma patients who were referred to the Iranian Ostomy Society. Any patient, with adequate physical and mental ability, who had an Ostomy in place for at least 3 months, was eligible to enter the study.

The exclusion criteria were the presence of a psychologic disorder and chronic diseases affecting the QOL such as diabetes mellitus, heart and respiratory diseases, cirrhosis and physical disability. The individuals were informed that participation in the study was not compulsory. Informed consent for enrolment was obtained and patient's anonymity was preserved. The research protocol was approved by the Ethics Committee of Shahid Beheshti University of Medical Sciences.

Questionnaire

The COH-QOL-Ostomy questionnaire is multidimensional and made up of 43 items, which are categorized into four subscales including physical (Item: 1-11), psychological (Item: 12-24), social (Item: 25-36) and spiritual (Item: 37-43) well-being. Each question is answered with a Likert graded response in the range of 0-10, in which zero reflects the worst outcome and 10 the best. Subscale scores are calculated by adding all the scores of each subscale and dividing their sum by the number of items in that subscale. A total QOL score is calculated by adding the scores on all 10-point items and dividing by the total number of items.[3,4,16,17]

The standard "forward-backward" procedure was applied to translate the questionnaire from English into Persian. First, questionnaire was translated by one Coloproctologist. Then, an official bilingual translator did the back translation into English.

Then the back-translation was compared with the original questionnaire with a reasonable match. The final version was approved by the COH National Medical Center. In the next step, a pilot testing was performed for determining of conceptual and perceptual problems of Persian version of the questionnaire. We asked 10 patients about difficulty, confusing, difficult word and upsetting of each item of questionnaire.

Standardization procedures

To test the reliability, the internal consistency of the questionnaire was measured using Cronbach's alpha coefficient. Cronbach's alpha coefficient above 0.7 is considered as a desirable reliability estimate.[6]

The face validity indicates the ability of an instrument to cover all relevant aspects of the phenomena of interest based on medical experts' opinions.[18] In this study, the face validity was examined by four physicians (two Gastroenterologists and two Psychologists).

Construct validity is composed of two components, convergent validity and discriminant validity. Convergent validity refers to a moderately high correlation between an item and its own subscale. Correlation coefficient of 0.4 or higher is considered as evidence of satisfactory convergent validity.[6,19] Discriminant validity indicates a low correlation between an item and any of the other subscales. Each items should be correlated with own subscales significantly equal or higher than two standard errors than correlations with other subscales. Since the standard error value is heavily influenced by sample size and given the relatively small sample size in the present study, one standard error was used as a criterion for assessment of discriminant validity.[20] Pearson's correlation coefficient was estimated in order to evaluate the convergent and discriminant validity.

Interscale correlations indicate that each subscale only measures a single trait. Correlation coefficients between different subscales should be lower than the internal consistency estimates of each subscale separately.

Clinical validity has been estimated by known-groups comparison. In order to evaluate the extent to which the COH-QOL-Ostomy questionnaire had been able to discriminate between sub-groups of patients with different clinical status, the underlying cause of the disease leading to Ostomy was taken into consideration as a variable. For analyzing the comparison made between known groups, *t*-test was used. All tests were two-sided and $P < 0.05$ were considered as statistically significant. Calculations were performed using SPSS v. 13 software (Chicago, IL, USA).

Results

In total, 103 patients were included in the study. The mean (SD) age was 53.5 (12.28) (range: 21-75 years). 56.3% (58/103) of patients were male.

Most patients (67%, 69/200) had a colostomy, 22 patients (21%) had an ileostomy, 9% had a urostomy (9/102), 2% had both colostomy (2/102) and urostomy and 1 patient (1%) had both colostomy and ileostomy. Cancer had been the most common condition leading to Ostomy surgery ($n = 79$, 77%). Other diseases were inflammatory bowel disease ($n = 11$, 10.5%) and other conditions including polyp, trauma, peritonitis, obstruction and fistula ($n = 13$, 12.5%).

In pilot testing, all patients stated that they have not had any difficulty in understanding the questions. Rate of missing data was less than 5%. Cronbach's alpha coefficient for all subscales was about 0.70 or higher, indicating satisfactory internal consistency. The physical well-being subscale had the lowest reliability (0.74). Reliability outcomes are shown in Table 1.

All interscale correlations were in the expected direction. The correlation estimate between the subscales was lower than the internal consistency of each of them. It means that each subscale of COH-QOL-Ostomy questionnaire had an ability to measure only a single concept [Table 2].

The face validity of the Persian version of COH-QOL-Ostomy questionnaire was approved by the experts. According to Multitrait scaling analysis of the COH-QOL-Ostomy Questionnaire, all item-scale correlations were above 0.40 indicating satisfactory convergent validity of the items. However, Item 9 showed a lower correlation with physical well-being subscale. The results of the assessment of convergent validity are shown in Table 3.

Given the sample size in the current study and standard error of 0.1, correlation coefficient of each subscale with its own items had to be at least one SD larger than its correlation with items of other subscales. In this study, all items, except Item 8 and Item 39, represented adequate discriminant validity [Table 3] (Item 8 on physical-being an Item 39 on spiritual well-being had high correlation with other subscales and did not have adequate discriminant validity).

Known group comparison analysis showed significant differences in social and spiritual well-being, and the cancer patients with Ostomy had the worst well-being in the mentioned subscales [Table 4].

Discussion

The results of this study suggest that the Persian version of COH-QOL-Ostomy questionnaire is a valid and reliable tool for assessing QOL in patients with Ostomy in Iran, and it can be used in clinical researches. Minimum rate of incomplete questions and missing items indicate that this instrument is acceptable and intelligible for patients.

Although, the original COH-QOL-Ostomy questionnaire has been shown to be valid and reliable in the English language;[4] no

Table 1: Cronbach's alpha for COH-QOL-Ostomy questionnaire subscales

Subscales	Items	Mean (SD)	Cronbach's alpha
Physical	1-11	7.33 (0.99)	0.75
Psychological	12-24	7.83 (1.01)	0.85
Social	25-36	6.88 (0.9)	0.75
Spiritual	37-43	7.82 (1.15)	0.74

COH-QOL: City of Hope-quality of life-Ostomy questionnaire, SD: Standard deviation

Table 2: Interscale correlation coefficients

Subscales	Physical	Psychological	Social	Spiritual
Physical	-	0.65	0.46	0.07
Psychological	-	-	0.66	0.47
Social	-	-	-	0.40
Spiritual	-	-	-	-

Table 3: Convergent and discriminant validity for subscales of COH-QOL-Ostomy questionnaire

Subscales	Convergent validity*	Discriminant validity**
Physical	0.38-0.72	0.03-0.46
Psychological	0.43-0.75	0.043-0.56
Social	0.59-0.71	0.3-0.501u8
Spiritual	0.57-0.72	0.06-0.49

*Pearson correlation coefficient between each item and own subscale, **Pearson correlation coefficient between each item and other subscales, ***Significant correlation $P<0.0001$ for all the values, COH-QOL: City of Hope-quality of life-Ostomy questionnaire

Table 4: Comparison group analysis based on underlying disease

Subscales	Underlying disease		*P* value
	Non-cancer mean (SD)	Cancer mean (SD)	
Physical	7.32 (1.04)	7.39 (.08)	0.73
Psychological	7.87 (1.07)	7.69 (0.77)	0.36
Social	6.98 (0.91)	6.52 (0.78)	0.03
Spiritual	7.99 (1.13)	7.21 (1.05)	0.004

SD: Standard deviation

article has been published about validation of this questionnaire in other languages. Our findings showed that this questionnaire has the potential to be used as a cross-culturally valid instrument to measure the health-related QOL in multicultural research settings.

The present study proved that the Persian version of COH-QOL-Ostomy questionnaire has good convergent validity, marginal discriminatory power, internal consistency and reliability. The results of the reliability analysis were satisfactory. The internal consistency reliability coefficient was high for all subscales. Internal consistency coefficient greater than 0.7 is considered as optimal;[6] therefore, these results suggest that the COH-QOL-Ostomy questionnaire has a good internal consistency.

Interscale correlation analysis showed that all subscales of COH-QOL-Ostomy questionnaire had a low to moderate

correlation with the other subscales, indicating that these areas are related but represent various aspects of QOL.

Findings showed that all item-scale correlation coefficients met the standards of convergent and discriminant validity. The convergent validity was acceptable and correlation between items within each subscale was high. The correlation of each item with its constitutive dimension was higher than with the others that indicates to good discriminative ability of COH-QOL-Ostomy questionnaire.

To test the discriminatory power of COH-QOL Ostomy in separating different subgroups of people with different clinical status, the subscale scores of patients were compared according to their underlying diseases. According to the analysis, social and spiritual subscales were able to differentiate between patients with different underlying diseases, but physical and psychological subscales did not have such a significant discriminatory power. However, this could be due to use of inappropriate variable for known group comparison analysis. In other words, it is possible that the underlying disease leading to Ostomy surgery has had no impact on current physical and psychological well-being of patients.

The current study is the first study of its type in Iran focusing on standardizing a specific instrument to measure QOL in patients with Ostomy. However, the interpretation of results is limited due to using exclusively Ostomy patients of Iranian Ostomy Association. Multicentric studies are needed to confirm these results and their generalizability.

Conclusion

The findings supported the reliability and validity of Persian version of COH-QOL-Ostomy Questionnaire. This questionnaire is the only disease-specific QOL questionnaire available for patients with Ostomy in Iran. The instrument was also found to be acceptable to Iranian patients. It will be considered as a valuable instrument to assess the different aspects of HRQOL in Ostomy patients and recommended for use in clinical research.

Acknowledgments

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