

The City of Hope Quality of Life Stoma Questionnaire: Malayalam Translation and Validation

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Abstract

Background: Malayalam is the language spoken by 38.5 million people worldwide. There is no specific instrument to measure stoma-related quality of life (QOL) in Malayalam language. **Aim:** This study was designed to translate and validate the city of hope QOL (COH-QOL) Ostomy Questionnaire, which is a robust tool developed in English language. **Materials and Methods:** The instrument was translated to Malayalam, abiding by internationally accepted translation methodology. Trained interviewer (first author) administered the questionnaire to patients with stoma, who were visiting the stoma clinic. The reliability of the subscales and the total scores were established by calculating correlation coefficients. Convergent and divergent validity were evaluated by calculating Pearson's correlations of each item with its own scale and other scales. **Results:** Cronbach's alpha coefficients for all subscales were 0.70 or more. Similarly, split-half coefficients also were more than 0.70, which were acceptable. All subscales met the minimum acceptable standards of convergent and discriminant validity. Discriminant validity of all scores was less than convergent validity which suggests that there was no overlap between various constructs in measuring the same traits. The validation study of Malayalam translation of COH stoma questionnaire has shown that the tool is valid and reliable. **Conclusion:** The validation study of Malayalam translation of City of Hope Stoma questionnaire has shown the tool is valid and reliable.

Keywords: Quality of life, stoma, translation, validation

INTRODUCTION

Creation of ostomy is one of the most common procedures done in the treatment of various abdominal cancers. The most common indication for stoma is colorectal cancers, although stoma is done in many other cancers like carcinoma urinary bladder, gynecological malignancies, and other pelvic malignancies. It is assumed that stoma causes significant changes in health-related quality of life (HRQOL) of patients.^[1,2] It is very important to learn and quantify the HRQOL of stoma patients. Knowing and quantifying the changes in HRQOL produced by stoma will help to assess the outcome of treatment and in turn help to modify various aspects of treatment in such a way to reduce the detrimental effects. To measure HRQOL of stoma patients, we need good instruments. Different questionnaires have been developed to measure and study the change in QOL by stoma; these questionnaires include Stoma Care QOL Scale Questionnaire,^[3] Ostomy Adjustment Scale,^[4] Stoma Care QOL Scale Index,^[5]

Ostomy Adjustment Inventory-23, and City of Hope Stoma QOL Questionnaire (COH-QOL).^[6] In the present study, we have translated and validated the COH QOL questionnaire, which is one of the most popular and robust tools.

COH questionnaire has two parts. The first one consists of 46 items that relate to patient's sociodemographic characteristics including work-related items, health insurance, sexual activity, psychological support, clothing, diet, and daily ostomy care. The second component has 43 QOL items using 10-point Likert scales. The QOL model is divided into four domains or subscales: physical well-being (items 1–11), psychological well-being (items 12–24), social well-being (items 25–36),

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and spiritual well-being (items 37–43). Higher scores were indicative of severe problems in each parameter concerned. These QOL items are followed by a statement from patients about living with an ostomy and challenges faced. The questionnaire needed to be translated to local vernacular to use in various geographical regions. The translation should be according to internationally accepted methodology. This is done to ensure proper translation and transcultural adaptation of the tool.^[7]

This questionnaire is being successfully translated in many languages including Chinese and Persian.^[8,9] In the present study, we have translated and validated this instrument to local language Malayalam, which is the language spoken by 38.5 million people living in South Indian state, Kerala. Colorectal cancer is one of the diseases which has increased in incidence and caused maximum disability adjusted life years, in India in general and Kerala in particular.^[10]

MATERIALS AND METHODS

The patients who visited the stoma care unit of our hospital were interviewed by the first author. Two interviews were scheduled twice at 24–72 h apart. The inclusion criteria were patient aged 20–70, who have an ostomy in place and who are willing to join the interview. The questionnaire was administered by the first author, and questions were answered by the patients with the help of her interpretation.

We have interviewed 92 patients, at various stages of disease and various phases of treatment.

Statistical analysis

The questionnaire needs to be evaluated for reliability and validity. Reliability is the ability of a tool to measure the constructs it is supposed to measure. Reliability is assessed by Cronbach's alpha (internal consistency reliability), intraclass correlation coefficient (ICC), and split-half reliability. The validity is measured by face validity, content validity, and construct validity. Face and content validity are decided by experts, while construct validity is identified by items' own domain (convergent validity) and items' other domains' correlation (divergent validity). The test of internal consistency reliability is calculated by Cronbach alpha value. The accepted value of Cronbach alpha is 0.7, above which the questionnaire has sufficient reliability.^[11,12] Construct validity comprised of two parts: convergent and discriminant validity. Convergent validity is the index of correlation between an item and its subscale.^[13] The accepted value is more than 0.4. The items' own domain correlation (discriminant validity) ideally should be as low as possible and should be ideally less than items other domain validation (divergent validity). Convergent and discriminant validity were evaluated by calculating Pearson correlation coefficient. Interscale correlation is done to know that each subscale only measures a single trait. Interscale correlation coefficients should be lesser than the internal consistency estimate of individual subscales.

Various demographic- and patient-related factors were correlated with QOL scores using linear regression and multinomial regression. All tests were done using SPSS V13 Software (Chicago, IL, USA).

RESULTS

After successful translation process under the supervision of the author of the original questionnaire (Marcia Grant), a pilot testing was done in 10 patients, where all patients stated that they understood all questions and some suggested modification of few sentences which were then reframed, according to their suggestion. The face and content validity were evaluated by ten experts: two stoma nurses and eight oncologists. Few questions were again reframed according to their suggestions as well. After correction, they found that the tool has adequate content and face validity.

A total of 92 patients were interviewed for validation study. The mean age (standard deviation [SD]) was 54.9 (9.9) (range 34–77 years). 54 patients (58.7%) were males. Majority of them were from southern Kerala (65.3%) and belonged to Hindu religion (58.7%). 49 (53.3%) were educated up to secondary schools. 72 (78.3%) had carcinoma rectum, 14 (15.2%) had carcinoma urinary bladder, 3 (3.3%) had carcinoma colon, 2 (2.2%) had carcinoma cervix, and 1 (1.1%) had carcinoma ovary. 62 (67.4%) had a colostomy, 16 (17.4%) had urostomy, and 14 (15.2%) had ileostomy. All 16 patients with urostomy used bags always. The mean duration of bag usage for the entire study group was 55.1 (SD 32.2, range 4–108) days. Demographic and disease details are given in Table 1.

59 patients were either doing full-time or part-time jobs. 24 people changed jobs after cancer and its treatment and 10 of them changed jobs because of ostomy.

Majority (92%) people had insurance under welfare schemes, and in 57, the insurance covered the cost of the stoma bags entirely, and in another nine, it covered partially [Table 2].

Stoma affected sexual life significantly. 69 patients were sexually active before stoma. However, only 28 (40.58%) have resumed sexual activity after stoma. This shows that stoma significantly affected the sexual relations. 10 (18.52%) males had erectile problems after treatment and stoma surgery.

46 (50%) patients were depressed after stoma and 14 (15.21%) patients even thought of suicide due to depression. 76 (82.61%) had availed preoperative counseling for stoma. 31 (33.7%) patients thought the location of stoma caused problems and 29 (31.52%) changed their clothing style because of stoma. 46 (50%) patients adjusted their diet because of ostomy and 39 (42.39%) did it to prevent passage of gas in public. 56 (60.87%) patients started avoiding carbonated drinks, 17 (18.48%) avoided dairy products, 7 (7.6%) avoided fruits, 15 (16.3%) avoided snacks, and 6 (6.5%) avoided vegetables.

Mean time to develop comfort in stoma care was 32.8 (112.8) days and in diet was 24.7 (82.1) days, after the creation of stoma.

Table 1: Demographic information (n=92)

	Number of patients (%)
Age	
Mean (SD)	54.9 (9.9)
Minimum - Maximum	34-77
Gender	
Male	54 (58.7)
Female	38 (41.3)
Residential area	
South Kerala	60 (65.3)
Middle Kerala	12 (13.0)
North Kerala	20 (21.7)
Religion	
Christian	11 (12.0)
Hindu	54 (58.7)
Muslim	21 (22.8)
Unknown	6 (6.5)
Education	
Primary	4 (4.3)
Middle	10 (10.9)
Secondary	49 (53.3)
College	16 (17.4)
Unknown	13 (14.1)
Disease	
Ca Rectum	72 (78.3)
Ca Urinary Bladder	14 (15.2)
Ca Colon	3 (3.3)
Ca Cervix	2 (2.2)
Ca Ovary	1 (1.1)
Type of stoma	
Colostomy	62 (67.4)
Ileostomy	14 (15.2)
Urinary stoma	16 (17.4)
Colostomy status	
Permanent	78 (84.8)
Temporary	14 (15.2)
Bag usage (Urine stoma)	
Yes	16
Duration of usage (months)	
Mean	55.1 (32.2)
Minimum - Maximum	4-108
Marital status (before)	
Unmarried	2 (2.2)
Married	84 (91.3)
Widowed	2 (2.2)
Divorced	2 (2.2)
Unknown	2 (2.2)
Marital status (now)	
Unmarried	2 (2.2)
Married	81 (88.8)
Widowed	5 (5.4)
Divorced	2 (2.2)
Unknown	2 (2.2)

Normal appetite took 36.7 (107.6) days to return. Patients spent 39.3 (31) min every day to care for stoma [Table 3].

The Cronbach's alpha values are given in Table 4. The Cronbach alpha scores were 0.85 for physical well-being, 0.91

for psychological well-being, 0.88 for social well-being and 0.90 for spiritual well-being and 0.96 for whole instrument. The high values of Cronbach's alpha show that the internal consistency reliability of the tool is adequate.

ICC for the tool was 0.34 (0.26–0.43). Among subscales, the highest score was for spiritual well-being (0.55 [0.46–0.65]) and the lowest score was for physical well-being (0.34 [0.26–0.43]). Split-half correlation coefficient was 0.83 for the tool, and 0.79, 0.76, 0.73, and 0.73, respectively, for physical, psychologic, social, and spiritual well-beings [Table 4].

The item own domain correlations for tools were 0.43–0.75 for physical well-being, 0.38–0.84 for psychological well-being, 0.51–0.75 for social well-being, and 0.71–0.83 for spiritual well-being. The item other domain correlations were 0.15–0.74 for physical well-being, 0.16–0.70 for psychological well-being, 0.17–0.67 for social well-being, and 0.08–0.69 for spiritual well-being. All interscale correlations were as expected. The internal consistency of each subscale was higher than the correlation estimates between subscales suggesting that each subscale has the capacity to measure single concept specifically.

Interscale correlation coefficients are given in Table 5. Interscale correlation coefficients were less than internal consistency reliability of each items, showing the accuracy of scale in measuring its own construct.

Regarding maximum values on floor, question 25 and question 9 were the highest (62%) followed by question 35 (59.8%) and question 18 (58.7%). Question 25 asked about the difficulty in meeting new people and question nine asked about diarrhea. The questions with least values on the floor were question 27 (8.7%) followed by question 26 (9.8%). Question 27 asked about the distress of the family and question 26 asked about financial burden. These questions were having least floor values because of the familial and financial implications created by stoma. The question 34 (23.9%) followed by question 27 (20.7%) had maximum values on the floor. Question 27 asked about the distress to family by stoma and question 34 asked about the ability to intimate. Maximum values in the ceiling showed that intimacy or distress were not of much concern in Indian families and stoma did not affect those significantly. Question 40, 24, 3, and 5 (1.1%) had the least values in the ceiling. These questions dealt with hope, fear of disease recurrence, skin issues, and pain. It is shown that people were unhappy about these things significantly, resulting in low scores [Table 6].

DISCUSSION

Validation of any QOL tool is important after its translation. Translation and validation by the structured pathway assure the credibility and utility of tools across various languages and cultures.^[13] The results of the validation study of Malayalam

Table 2: Questions regarding work, health and other issues

Question no.	Question	Yes	Total
13	Are you working full-time?	31	92
14	Are you working part-time?	28	61
15	Are you retired?	7	33
16	Are you working in the same occupation that you had before your ostomy?	35	59
17	If you are not working in the same occupation as before your ostomy, was the change related to having an ostomy?	10	24
18	Do you currently have health insurance?	68	92
19	Have you had difficulty getting health insurance?	8	68
20	Have you had difficulty maintaining your health insurance?	13	68
21	Does your insurance pay all costs for your ostomy supplies?	57	68
22	Does your insurance pay part of the costs for your ostomy supplies?	9	11
23	Were you sexually active before getting your ostomy?	69	92
24	Have you resumed sexual activity since having your ostomy?	28	69
25	Is your sexual activity satisfying?	26	28
26	If you are male, do you have a problem getting an erection or keeping an erection?	10	54
27	Were you depressed after having your ostomy?	46	92
28	Since having your ostomy, have you ever considered or attempted suicide?	14	46
29	Do you belong to an ostomy support group?	33	92
30	Do you belong to another kind of support group?	4	59
31	Have you had the opportunity to talk with someone else who was going to have or had a new ostomy?	76	92
32	Does the location of your ostomy cause you problems?	31	92
33	Have you changed the style of clothing you wear because of your ostomy?	29	92
34	Do you adjust your diet because of your ostomy?	46	92
35	Do you change your diet to prevent passing gas in public?	39	46
39	I avoid drinking carbonated beverages.	56	92
40	I avoid eating dairy products.	17	92
41	I avoid eating fruits.	7	92
42	I avoid eating snacks.	15	92
43	I avoid eating vegetables.	6	92

Table 3: Questions regarding time to adjust with stoma

Question	Mean [Days]*(SD)	Range [Days]
36 How long was it before you felt comfortable with your daily ostomy care?	32.8 (122.8)	0-730
37 How long was it before you felt comfortable with your diet?	24.7 (82.1)	0-365
38 How long was it before your appetite returned?	36.7 (107.6)	0-365
45 On the average, how long does it take to do your daily ostomy care?	39.3 min (31.0)	3-240 min

translation of COH-QOL-Ostomy questionnaire showed that this is a valid and reliable questionnaire for assessing QOL of patients with ostomy, qualifying it to be used as a search tool in studies about QOL. Apart from original tool, various translations are shown to be valid and reliable (Persian, Chinese).^[8,9] Now with this translation and validation in Malayalam language, it is once again proved to be a good tool with transcultural adaptability and validity.

When scores of individual items are scored in Likert score of 0–10, mean scores of various domains were compared; it was

lowest for physical well-being (2.2 ± 1.5) and highest for social well-being (2.9 ± 2). Higher scores indicated better QOL scores.

Cronbach’s alpha is an index of internal consistency reliability, which shows internal relation of set of items as a group, reflecting how reliable the tool in measuring the parameters it is required to measure. In the present study, the Cronbach’s alpha was lowest (0.85) for physical well-being and highest (0.91) for psychological well-being. The value for the whole tool was even higher (0.96). These values were above the accepted lower limit of 0.7; hence, this questionnaire is having enough internal consistency reliability.

ICCs were found to be lowest for physical well-being (0.34 [0.26–0.43]) and highest for spiritual well-being (0.55 [0.46–0.65]). ICC describes how strongly items in each group resemble each other. This is a measure of relatedness and used for measuring reliability.

Similarly, split-half coefficient correlation values were calculated by splitting the test in half and comparing one half of the test with the other half. This is a measure of internal consistency. All domains showed value more than 0.7, suggesting good internal consistency.

Similarly when the item own domain correlation showed psychological domain has the lowest (0.38–0.84) and

Table 4: Descriptive statistics and measures of reliability of the QOL

Domain	No. of items	Range of score	Mean±SD	a ^	Split half correlation	ICC (95% CI)	Item-own domain correlation	Item-other domain correlation
Physical	11	0-10	2.2±1.5	0.85	0.79	0.34 (0.26-0.43)	0.43-0.75	0.15-0.74
Psychological	13	0-10	2.7±1.9	0.91	0.76	0.44 (0.36-0.53)	0.38-0.84	0.16-0.70
Social	12	0-10	2.9±2.0	0.88	0.73	0.37 (0.28-0.47)	0.51-0.75	0.17-0.67
Spiritual	7	0-10	2.2±2.1	0.90	0.73	0.55 (0.46-0.65)	0.71-0.83	0.08-0.69
Overall QOL	43	0-10	2.6±1.7	0.96	0.83	0.34 (0.26-0.44)		

a^ -Cronbach's alpha value

Table 5: Inter scale correlation

Domain	Physical	Psychological	Social	Spiritual
Physical	-	0.76	0.64	0.71
Psychological	-	-	0.77	0.79
Social	-	-	-	0.75
Spiritual	-	-	-	-

spiritual domain has the highest (0.71–0.83). Values >0.4 were suggestive of good convergent validity. In our study, all domains have convergent validity of 0.4 or more. Similarly, discriminant validity of all scores was less than convergent validity, which suggests that there is no overlap between various constructs in measuring a same trait.

From this validation study, we also got some information about how the QOL is affected by stoma. 24 (26.08%) patients changed their jobs after cancer and stoma. 10 patients said that it was stoma which made them change jobs. One study done among occupational physicians have shown that they believed that hard work, food handling, and driving were thought unsuitable for ostomates.^[14] The physician thought that the risk of spread of infection was greater for ostomates. Apart from changes of jobs and loss of income, another problem which is faced by ostomates is cost of stoma bags; only in 66 (79%) patients, the welfare schemes of state covered the expenses of stoma bag as well.

It is also noted that stoma also affected sexual life significantly; 40% patients stopped sexual activity after stoma surgery. 18.52% males had erectile problems after surgery and stoma. According to a meta-analysis, 5%–88% of men and 50% of women experienced sexual dysfunction after creation of stoma.^[15] The changes of body image by stoma, fear of revealing stoma, and fear of stoma coming off during sexual intercourse are the reasons for changes in sexual behavior after stoma.^[16]

Depression was a significant problem after the creation of stoma; 50% patients were seriously depressed after stoma and 14 people even thought of doing suicide after stoma. Ostomy support was good, and the majority of patients got good counseling. Another concern was diet, which augmented the gas production from stoma. People tried various things to reduce the gas production such as avoiding carbonated beverages (60.1%), dairy products (18.5%), fruits (7.6%), snacks (16.3%), and vegetables (9.8%) with varying degrees of success.

Table 6: Mean, SD, unknown data, floor and ceiling scores of each item (n=92)

Item	Mean	SD	Unknown (%)	Floor (%)	Ceiling (%)
QLQ1	3.0	2.5	3.3	23.9	2.2
QLQ2	3.4	2.5	3.3	17.4	4.3
QLQ3	1.8	2.2	4.3	50.0	1.1
QLQ4	2.8	3.1	2.2	41.3	4.3
QLQ5	1.6	1.8	3.3	42.4	1.1
QLQ6	3.8	3.0	3.3	18.5	8.7
QLQ7	1.7	2.3	2.2	41.3	2.2
QLQ8	1.5	2.4	2.2	57.6	2.2
QLQ9	1.1	1.7	2.2	62.0	2.2
QLQ10	1.8	2.5	2.2	53.3	3.3
QLQ11	2.7	2.5	3.3	27.2	2.2
QLQ12	4.0	3.0	4.3	13.0	9.8
QLQ13	3.6	3.0	5.4	21.7	7.6
QLQ14	3.8	3.1	2.2	18.5	8.7
QLQ15	3.5	3.1	3.4	22.8	8.7
QLQ16	3.6	2.7	2.2	18.5	3.3
QLQ17	2.7	2.7	2.2	34.8	2.2
QLQ18	1.5	2.4	2.2	58.7	3.3
QLQ19	2.4	2.6	4.3	34.8	3.3
QLQ20	2.3	2.5	4.3	33.7	3.3
QLQ21	2.5	2.6	4.3	28.3	4.3
QLQ22	2.6	2.5	3.3	27.2	5.4
QLQ23	2.6	2.7	2.2	32.6	4.3
QLQ24	1.5	2.0	5.4	47.8	1.1
QLQ25	1.3	2.3	2.2	62.0	3.3
QLQ26	5.3	3.2	3.3	9.8	18.5
QLQ27	5.5	3.3	8.7	8.7	20.7
QLQ28	4.0	3.0	3.3	16.3	8.7
QLQ29	2.2	2.7	4.3	42.4	4.3
QLQ30	2.4	3.0	2.2	43.5	6.5
QLQ31	2.2	2.7	3.3	47.8	2.2
QLQ32	3.4	3.4	4.3	30.4	10.9
QLQ33	2.6	3.3	3.3	44.6	7.6
QLQ34	4.2	4.1	15.2	26.1	23.9
QLQ35	1.3	2.3	2.2	59.8	3.3
QLQ36	3.1	3.3	3.3	32.6	10.9
QLQ37	2.8	3.0	5.4	33.7	7.6
QLQ38	2.1	2.5	5.4	38.0	3.3
QLQ39	2.3	2.7	6.5	38.0	3.3
QLQ40	1.9	2.2	4.3	41.3	1.1
QLQ41	2.0	2.8	5.4	51.1	4.3
QLQ42	2.4	3.2	6.5	44.6	8.7
QLQ43	2.5	2.8	2.2	32.6	5.4

The validation study of Malayalam translation of COH stoma questionnaire has shown that the tool is valid and reliable. This tool will be very much useful for assessing and quantifying the QOL of stoma patients speaking Malayalam language in South Indian state, Kerala.

CONCLUSION

The validation study of Malayalam translation of City of Hope Stoma questionnaire has shown the tool is valid and reliable. This tool will be very much useful for assessing and quantifying the quality of life of stoma patients speaking Malayalam language in South Indian state, Kerala.

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Conflicts of interest

There are no conflicts of interest.

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