Validation of Malayalam Translation of the European Organization for the Research and Treatment of Cancer Quality of Life Instrument OG25 for Esophagogastric Junction Cancers

Mira Sudam Wagh, Arun Peter Mathew, Bharat Veerabhadran, Madhu Muralee, Sajeed Abdul Rahuman[1], Preethi Sarah George[2], K. Chandramohan

Departments of Surgical Oncology, [1]Radiation Oncology and [2]Bio-Statistics, Regional Cancer Centre, Thiruvananthapuram, Kerala, India

Abstract

Background: Quality of life questionnaire (QLQ) OG25 is the questionnaire used for measuring quality of life (QOL) of patients with esophago-gastric junction (OG) cancers. QLQ-OG 25 is a disease-specific tool to capture the QOL parameters of patients with OG junction cancers. OG 25 was developed by the European Organization for the Research and Treatment of Cancer (EORTC) using inspiration from their questionnaires for carcinoma stomach (STO22) and carcinoma esophagus (OES18). It is usually used along with QLQ-C30, which is a general tool applicable for all cancers. This questionnaire is in the English language. In order to use this questionnaire in a non-English speaking population, the English questionnaire has to be initially translated to the local languages. Malayalam is the language spoken by 38.5 million people residing in the South Indian state, Kerala, India. We have translated and validated the QLQ-OG 25 to Malayalam language in an attempt of enabling it to be used for future studies at this geographic region. **Methods:** The translation was done by the standard protocol adopted by EORTC. QLQ-C30 and QLQ-OG25 questionnaires were then filled in by patients with OG junction cancers. These patients had cancers of various subsites of the OG junction and were at different stages of treatment, at the time of interview. The interview was done twice, at an interval ranging from 48 h to 1 week between the two interviews. **Results:** A total of 46 patients with OG junction tumors at varying stages of treatment completed the questionnaire. There were no missing data. The average time to finish the interview was 12.12 min. The Cronbach's alpha, which signifies the internal consistency of the questionnaire, was found to be >0.7 in all the domains studied, except in cognitive function. The intraclass correlation coefficients varied from 0.63 to 0.93. **Conclusion:** The Malayalam translation of the QOL tool QLQ-OG25 has been found to be an acceptable and valid tool in assessing the QOL parameters of patients with OG junction cancers.

Keywords: Esophagus, esophago-gastric junction, quality of life, translation, validation

INTRODUCTION

Esophago-gastric (OG) junction cancers are cancers occurring in the junctional zone between the stomach and esophagus. The incidence of these cancers is not mentioned separately in most national and international databases. Stomach cancer as such, is also one of the most common cancers and is the second-leading cause of cancer deaths in the world, with an estimated rate of 723,000 deaths in 2012 (8.8% of all cancer deaths in that year).[1] According to Globocan 2012, stomach (9.1% of the total incidence of cancers) and esophageal (7.1% of the total incidence) cancers were the third and sixth most common cancers diagnosed among men in India. In comparison, among women in India, stomach (5.6% of total incidence) and esophageal (4.1% of total incidence) cancers were the fifth and eighth most common cancers.[1]

OG junction cancers usually present with dysphagia and other symptoms, most of which significantly affect quality of

Access this article online

Quick Response Code:

Website:
www.jpalliativecare.com

DOI:
10.4103/IJPC.IJPC_135_19

How to cite this article: Wagh MS, Mathew AP, Veerabhadran B, Muralee M, Rahuman SA, George PS, *et al*. Validation of Malayalam translation of the European organization for the research and treatment of cancer quality of life instrument OG25 for esophagogastric junction cancers. Indian J Palliat Care 2020;26:295-301.

life (QOL). Moreover, the treatment itself often results in a significant drop in the QOL. For example, surgery although being one of the more important treatment modalities, still results in marked change in anatomy and physiology of upper digestive tract, which therein leads to myriads of functional sequelae. Two troublesome sequelae of surgery are early satiety due to the loss of stomach volume and biliary reflux caused by the loss of OG sphincter and denervation of stomach tube. Since the disease and its subsequent treatment results in changes in QOL, the assessment of QOL is very important to characterize and follow-up the outcomes of treatment.[2] The QOL group of the European Organization for the Research and Treatment of Cancer (EORTC) has developed a specific instrument to evaluate the QOL of OG junction cancers; quality of life questionnaire (QLQ)-OG 25 questionnaire. This module is created by combining elements from both esophageal (OES 18) and stomach (STO22) modules from EORTC.[3] EORTC QLQ-C30, which is the general tool for cancers, has the following components; global-health status, five multi-item functional scales, and several single- or multi-item symptom scales.[4] The QLQ-OG 25, which is specific for esophageal cancer, is a 25-item scale. This has six multi-item functional scales (dysphagia, eating restrictions, reflux, odynophagia, pain, and anxiety) and 10 single-item symptom scales. In QLQ-OG 25, higher symptom scales or lower functional scales indicate worse outcomes. The aim of the study is to develop a Malayalam translation of the EORTC QLQ-OG25 questionnaire and further, to validate it in the population which speaks Malayalam.

METHODS

Under the supervision of the EORTC QLQ team, the translation procedure of EORTC QOL-OG 25 was initiated. This was approved by the institutional review board and the human ethics committee of our institution. The following universally accepted methodology was adopted.[5,6] The methodology included translation and back translation of the English questionnaire. The tool was translated to the Malayalam language by two-independent language experts, following which, both these forward translations were back translated to English by two other language experts. Following this, the inadvertent discrepancies were corrected and finally, a consensus among the translations was arrived at. The work, in its entirety, was led by the principal investigator and a trained interviewer, under the guidance of the EORTC team. Back translation ensured conceptual and cultural correlation of the two versions. Later, this final questionnaire was pilot tested in 10 patients. Then, this version was finalized after incorporating suggestions from the interviewed patients as well as from the EORTC QOL group. Pilot testing ensured cultural adaptation and content validity of the translated questionnaire.

After the said translation was done, the validation of the questionnaire was undertaken. Patients with OG junction cancers being treated at our hospital were recruited for the study. Clinical stage was done in accordance with the seventh edition of the staging system of the American Joint

Committee on Cancer (AJCC 7).[7] Reliability analysis (internal consistency reliability, split-half reliability, and test-test reliability) was planned.

We had excluded patients who were <18 years old, who were unable to read and understand the questionnaire, and patients who could not give a valid written consent. All the eligible patients were asked to read and confer with the consent form after detailed counseling by the investigator. The filled questionnaires included a sociodemographic sheet, the EORTC QLQ-C30, and the QLQ-OG25 questionnaires. The sociodemographic details collected included age, gender, marital status, monthly income, details regarding their children, current employment status, and details of their disease and its treatment. The study group included a heterogeneous group of patients in terms of treatment status (ranging from those who were totally untreated to those in various stages of treatment), age, location, and stage of tumor. OG junction cancers were classified into three types based on the location of lesions.[8] All the questions were read out to the patient and if they were unable to comprehend, the meanings of the questions were further explained in detail, by the interviewer. This questionnaire was repeated after an interval (between 48 h to 1 week) for calculating the test-retest validity.

The questionnaires used were the QLQ-C30 for general evaluation and the QLQ-OG25 for disease-specific evaluation. The QLQ-C30 had 30 questions and QLQ-OG25 had 25 questions. The QLQ-C30 was already translated to Malayalam and QLQ-OG 25 needed to be translated and validated which was attempted during the present study.

Statistical analysis

The individual responses were entered in Likert scale with values ranging from 1–4. The scores were added together to get functional or symptom scales. The scores of multi-item functional or symptom scales were calculated by linear transformation of scores varying from 0 to 100. Score 100 represented the best global health and best functional score. However in case of symptom scales, a score of 100 meant the worst symptom scale. Statistical tests were used for description of the parameters, assessment of item quality, and the analysis of reliability. The analysis was performed by the software, Windows SPSS 17 (SPSS Inc., Chicago, IL, USA). For each parameter, mean, standard deviation, lowest and highest scores were calculated. The various domains which were studied included physical functioning (5 items), role functioning (2 items), emotional functioning (4 items), cognitive functioning (2 items), social functioning (2 items), and global health status (2 items). For each parameter and domain, range of score, mean, standard deviation, Cronbach's alpha, split-half coefficient, test-retest reliability, and intraclass correlation coefficient were calculated. Thus, the internal consistency reliability of the scores was assessed.

RESULTS

Forty-six patients with biopsy-proven carcinoma of the OG junction were recruited for the study. The descriptive statistics

are given in Table 1. Mean age was 57.2 (35–76). Among studied patients, 37 (80.4%) were male and nine (19.6%) were female. 39 (84.8%) presented with dysphagia as the most predominant symptom, while 7 (15.2%) had pain as the main symptom. When staged according to the AJCC 7th Edition, 1 (2.2%) patient belonged to Stage I, 15 (32.6%) to Stage II, 24 (52.2%) to Stage III and 6 (13%) to Stage IV. According to Siewert classification, 14 (30.4%) patients were Type 1 OG junction cancers, whereas four (8.7%) were Type 2, 21 (45.7%) were Type 3, and seven (15.2%) remained unclassified. Thirty-three (71.7%) patients had undergone curative treatment, whereas 13 (28.3%) patients were treated with palliative intent. Nine patients (19.6%) had undergone radiotherapy, whereas 37 (80.4%) had received no radiation. Thirty-eight (82.6%) patients had undergone chemotherapy while eight (17.4%) had not undergone chemotherapy. Thirty-five (76.09%) patients had undergone surgery, while 11 (23.9%) had not undergone surgery. The various surgical procedures done are shown in Table 1. Five patients initially planned for a curative procedure later became inoperable and underwent only a palliative feeding jejunostomy. The interview was done before commencing any treatment in 5 (10.9%) patients while undergoing neoadjuvant chemotherapy in 19 (41.3%) and after completing treatment in 22 (47.8%) patients.

When the area of inhabitation was looked into, 13 (28.3%) patients were from the southern districts of Kerala, while 11 (23.9%) were from the central districts and 21 (45.7%) were from the northern districts of Kerala. Regarding marital status, 2 (4.3%) patients were unmarried, 42 (91.3%) were married, and 2 (4.3%) were widows. Details of patient demographics are given in Table 1.

All 46 patients answered all the questions in the questionnaires. The results of Multitrait scaling are shown in Table 2. The multi-item scales showed a good correlation. The scores ranged from 0 to 10. Few items had missing entrees (QLQ20, QLQ25, OG6, OG8, OG9, OG15, OG16, OG18, OG19, and OG 25).

Floor and ceiling effects were observed among a few questions. QLQ17 scored the highest (89.4%) values on the floor. QLQ 28 and OG4 showed 36.2% and 27.7% values, respectively, on the ceiling.

Among the mean score for various domains, anxiety (2.6 ± 0.9) was the highest and trouble with talking was the lowest (1.2 ± 0.6) (1.1) while among the single items, QLQ29 scored the highest (3.2).

To check internal consistency reliability, Cronbach's alpha values were calculated. The Cronbach's alpha values were >0.7 except for cognitive functioning (0.49). The Cronbach's alpha value is >0.7 in most of the parameters, suggest that the questionnaire had good internal consistency reliability [Table 3].

The split-half coefficients of all domains ranged from 0.35 (cognitive functioning) to 0.87 (anxiety). The split-half

Table 1: Characteristics of the patients (*n*=46)	
	Number of patients (%)
Age	
Mean±SD	57.2±10.6
Minimum-Maximum	35-76
Gender	
Male	37 (80.4)
Female	9 (19.6)
Main symptoms	
Dysphagia	39 (84.8)
Pain	7 (15.2)
Composite stage	
I	1 (2.2)
II	15 (32.6)
III	24 (52.2)
IV	6 (13.0)
Site	
1	14 (30.4)
2	4 (8.7)
3	21 (45.7)
9	7 (15.2)
Intention of treatment	
Curative	33 (71.7)
Palliative	13 (28.3)
RT	
No	37 (80.4)
Yes	9 (19.6)
Chemo	
No	8 (17.4)
Yes	38 (82.6)
Surgery	
Yes	35 (76.09)
No	11 (23.9)
Inoperable	5 (10.9)
Surgery	
Transabdominal esophagogastrecomy	8 (17.4)
THE	7 (15.2)
Lap THE	3 (6.5)
Iver-Lewis esophagectomy	6 (13.0)
Superior polar gastrectomy	6 (13.0)
Palliative FJ	5 (10.9)
No surgery	11 (23.9)
Timing of interview	
Before treatment	5 (10.9)
During treatment before the surgery	19 (41.3)
After treatment	22 (47.8)
Interview status	
I	44 (95.7)
II	2 (4.3)
Area	
South Kerala	13 (28.3)
Middle Kerala	11 (23.9)
North Kerala	21 (45.7)
Religion	
Christian	9 (19.6)
Hindu	25 (54.3)

Contd...

Table 1: Contd...

	Number of patients (%)
Muslim	12 (26.1)
Marital status	
Unmarried	2 (4.3)
Married	42 (91.3)
Widow	2 (4.3)
Number of children	
1	1 (2.2)
2	20 (43.5)
3	15 (32.6)
4	3 (6.5)
5	1 (2.2)
Unknown	6 (13.0)
Employed children	
1	8 (17.4)
2	1 (2.2)
Unknown	37 (80.4)

SD: Standard deviation, RT: Radiotherapy, FJ: Feeding jejunostomy, THE: Trans-hiatal esophagectomy

Table 2: Mean, standard deviation, missing data, floor, and ceiling scores of each item (*n*=46)

Item	Mean±SD	Missing (%)	Floor (%)	Ceiling (%)
QLQ1	2.5±1.0	0.0	19.1	19.1
QLQ2	2.0±1.2	0.0	48.9	17.0
QLQ3	1.4±0.7	0.0	74.5	2.1
QLQ4	1.9±0.8	0.0	34.0	2.1
QLQ5	1.3±0.7	0.0	72.3	2.1
QLQ6	1.9±1.0	0.0	44.7	10.6
QLQ7	2.0±1.0	0.0	44.7	10.6
QLQ8	1.4±0.6	0.0	63.8	4.3
QLQ9	1.8±0.8	0.0	40.4	4.3
QLQ10	2.3±1.1	0.0	27.7	17.0
QLQ11	1.9±0.9	0.0	34.0	6.4
QLQ12	2.3±1.1	0.0	27.7	19.1
QLQ13	1.5±0.8	0.0	61.7	2.1
QLQ14	1.8±0.7	0.0	34.0	2.1
QLQ15	1.8±0.9	0.0	42.6	8.5
QLQ16	1.6±0.9	0.0	57.4	8.5
QLQ17	1.1±0.4	0.0	89.4	2.1
QLQ18	2.8±1.0	0.0	12.8	25.5
QLQ19	2.0±1.0	0.0	36.2	12.8
QLQ20	1.6±0.9	2.2	55.3	8.5
QLQ21	2.0±1.0	0.0	38.3	8.5
QLQ22	2.3±1.0	0.0	25.5	10.6
QLQ23	1.9±0.9	0.0	38.3	2.1
QLQ24	1.8±0.9	0.0	46.8	6.4
QLQ25	1.2±0.6	2.2	83.0	2.1
QLQ26	1.7±0.9	0.0	55.3	6.4
QLQ27	2.7±1.0	0.0	14.9	25.5
QLQ28	2.8±1.1	0.0	19.1	36.2
QLQ29	3.2±1.2	0.0	6.4	6.4
QLQ30	3.0±1.3	0.0	8.5	6.4
OG1	2.7±1.0	0.0	19.1	23.4
OG2	1.7±1.0	0.0	57.4	8.5
OG3	1.5±0.8	0.0	68.1	4.3
OG4	2.6±1.1	0.0	23.4	27.7
OG5	2.1±1.0	0.0	29.8	10.6
OG6	2.7±0.9	2.2	8.5	19.1
OG7	2.4±1.1	0.0	25.5	17.0
OG8	2.1±0.8	2.2	19.1	8.5
OG9	2.0±0.8	2.2	29.8	4.3
OG10	2.1±0.9	0.0	25.5	10.6
OG11	1.7±0.9	0.0	51.1	8.5
OG12	1.7±0.9	0.0	51.1	6.4
OG13	1.8±0.9	0.0	40.4	10.6
OG14	2.6±0.9	0.0	10.6	14.9
OG15	2.7±0.9	2.2	12.8	19.1
OG16	2.2±1.0	2.2	31.9	8.5
OG17	1.9±0.9	0.0	29.8	8.5
OG18	1.8±0.8	2.2	38.3	6.4
OG19	2.2±1.0	2.2	27.7	14.9
OG20	1.5±0.8	0.0	61.7	4.3
OG21	1.5±0.7	0.0	61.7	2.1
OG22	1.7±0.6	0.0	38.3	2.1
OG23	1.2±0.6	0.0	85.1	2.1
OG24	1.8±0.9	0.0	42.6	8.5
OG25	1.6±0.8	2.2	57.4	4.3

OG: Esophago-gastric, SD: Standard deviation, QLQ: quality of life questionnaire

coefficient was often used instead of test-retest. Here, most of the parameters had a score more than 0.7 except emotional functioning, cognitive functioning, social functioning, dysphagia, and eating. Most domains having split-half coefficient >0.7 fulfills the acceptable internal consistency of the test. The test-retest validities of all domains were >0.7 except for the domain "eating with others" which was 0.63 (0.33–0.80). The item's own domains ranged from 0.02 to 0.91 and the item's other domains correlation varied from 0.01 to 0.93.

DISCUSSION

There is a need to complement conventional clinical outcomes with information representing the patients' perception of outcome and this may be undertaken by measuring health-related QOL (HRQOL).[9] These results are from the validation process of the Malayalam version of EORTC QLQ-OG25 which is designed to assess the QOL of patients with OG junction cancers as a supplement to the EORTC QLQ-C30, which is a general tool for all cancers.

Important correlation between scales in the QLQ-C30 and the QLQ-OG25 demonstrates clinical overlapping. Therefore, data support the EORTC recommendation that the use of both questionnaires is critical to detect both benefits and disadvantages of medical or surgical treatments The Malayalam translation of QLQ-OG25 demonstrated acceptable validity and its clinical validity supports its use to supplement the core questionnaire to assess QOL in patients with different stages of OG junction cancers undergoing multimodal treatment either palliative or potentially curative treatments.[10,11]

The descriptive statistics reveal that the patients were heterogeneous as per the various epidemiologic and treatment variables [Table 1]. Male-to-female ratio was 80:20, reflecting

Table 3: Descriptive statistics and reliability of the quality of life-radiation therapy instrument/head and neck (*n*=46)

Domain	Number of items	Range of score	Mean±SD	a^	Split-half coefficient	ICC (95% CI)	Item-own domain correlation	Item-other domain correlation
Physical functioning	5	1-4	1.8±0.7	0.867	0.734	0.80 (0.64-0.89)	0.36-0.81	0.82-0.93
Role functioning	2	1-4	1.6±0.7	0.911	0.837	0.70 (0.46-0.84)	0.52-0.82	0.49-0.93
Emotional functioning	4	1-4	2.1±0.9	0.770	0.583	0.84 (0.71-0.91)	0.42-0.64	0.53-0.88
Cognitive functioning	2	1-4	1.7±0.5	0.487	0.353	0.72 (0.49-0.84)	0.50-0.73	0.42-0.78
Social functioning	2	1-4	1.8±0.7	0.680	0.520	0.82 (0.68-0.90)	0.89-0.91	0.19-0.56
Global health status/QOL	2	1-4	2.2±0.8	0.918	0.849	0.73 (0.51-0.85)	0.50-0.71	0.25-0.59
Dysphagia	3	1-4	1.9±0.8	0.735	0.618	0.85 (0.72-0.92)	0.79-0.84	0.19-0.66
Eating	4	1-4	2.4±0.8	0.825	0.623	0.76 (0.57-0.87)	0.42-0.65	0.23-0.68
Reflux	2	1-4	2±0.8	0.814	0.686	0.65 (0.36-0.81)	0.02-0.44	0.11-0.50
Odynophagia	2	1-4	1.9±0.9	0.809	0.679	0.92 (0.86-0.96)	0.11-0.55	0.29-0.79
Pain and discomfort	2	1-4	1.8±0.8	0.793	0.658	0.93 (0.87-0.96)	0.08-0.41	0.23-0.77
Anxiety	2	1-4	2.6±0.9	0.931	0.873	0.72 (0.49-0.84)	0.06-0.15	0.24-0.61
Eating with others	1	1-4	2.1±1.0	NA	NA	0.63 (0.33-0.80)	1.00	0.04-0.61
Dry mouth	1	1-4	1.9±0.9	NA	NA	0.85 (0.73-0.92)	1.00	0.23-0.63
Trouble with taste	1	1-4	1.7±0.9	NA	NA	0.72 (0.50-0.85)	1.00	0.03-0.63
Trouble swallowing saliva	1	1-4	1.5±0.8	NA	NA	0.83 (0.69-0.90)	1.00	0.03-0.59
Choked when swallowing	1	1-4	1.5±0.8	NA	NA	0.80 (0.63-0.89)	1.00	0.13-0.63
Trouble with coughing	1	1-4	1.7±0.6	NA	NA	0.91 (0.85-0.95)	1.00	0.01-0.66
Trouble talking	1	1-4	1.2±0.6	NA	NA	0.95 (0.91-0.97)	1.00	0.04-0.71
Weight loss	1	1-4	1.8±0.9	NA	NA	0.67 (0.40-0.82)	1.00	0.22-0.64
Hair loss	1	1-4	1.5±0.9	NA	NA	0.72 (0.49-0.84)	1.00	0.01-0.44

a^Cronbach's alpha value. NA meant no value, due to one single item. ICC: Intra-class correlation coefficient, CI: Confidence interval, NA: Not available, QOL: Quality of life

the distribution of OG junction cancer patients registered for treatment in our hospital. Interviewed patients had cancers of various subsites of OG Junction. The age of patients in the study varied from 35 to 76. Among the patients studied, 33 (71.1%) had undergone curative treatment, while 13 (28.3%) has undergone palliative treatment. Thirty-seven (80.4%) patients had undergone radiation, while nine (19.6%) had not. Thirty-eight (82.6%) patients had undergone chemotherapy, while 8 (17.4%) had not. Thirty-six (78.3%) had undergone surgery, while 10 (21.7%) had not undergone any surgery [Table 1]. The various surgical procedures performed included transabdominal esophagectomy, transhiatal esophagectomy, Ivor-Lewis esophagectomy and superior polar gastrectomy [Table 1]. The interviews were conducted at various phases of treatment on the heterogeneous group of patients undergoing treatment with both curative and palliative intentions.

Recent researches have shown important advances in neoadjuvant and adjuvant therapy in treating patients with OG junction cancers. Hence, it was suggested, HRQOL measurement as the most important outcome in oncology patients undergoing different treatment procedures.[12,13]

In any QOL instrument, the two most desirable requirements are good validity and reliability.[14] Validity means the ability of the tool to measure the parameter it is supposed to measure. Reliability depicts the ability of the tool to show consistency in repeated measurements. Reliability and validity are interdependent.

Cronbach's alpha was developed by Lee Cronbach, and it provides a measure of the internal consistency of the test or scale. It is usually valued from 0 to 1.[15,16] In our study, Cronbach's alpha values of more than 0.7 in most domains suggested good internal consistency validity. Similarly, split-half coefficient, which is related to the inter-relatedness of the item, is >0.7 except in a few domains.

Similarly, test-retest validity was >0.7 except for one domain (domain of eating with others). Test-retest reliability means the reproducibility of the scale, which is the ability of the tool to provide consistent scores over time in a stable population.[17] All of this suggests that the translated questionnaire was a valid one. A similar study has also proved good validity for a Persian translation of the EORTC OG25 questionnaire.[18] Clinical trials, including HRQOL outcomes, provide invaluable information concerning the effects of medical management. However, there is controversy on whether HRQOL data contribute significantly to the clinical decision-making process.[19,20]

The scores of individual items in QOL tools may or may not shift during longitudinal studies. If a score is shifting in time, it is a factor which is being modified by the treatment. If a score does not shift, it is not being modified by treatment. If maximum values are on the floor or ceiling, these actors are unlikely to shift during treatment. Whenever questions show high responses on ceiling or on the floor, they usually are not directed to disease and are unlikely to improve by treatment and hence the parameter measured cannot be used as an indicator

of the success of therapy. On the contrary, more values on midrange are usually acceptable and may vary according to disease response to treatment.

QLQ17 scored the highest (89.4%) values on the floor. It was a question asking about the incidence of diarrhea in patients. Since diarrhea is not a symptom of upper GI cancer maximum responses were on the floor. Similarly, QLQ 28 and OG 4 have shown maximum (36.2% and 27.7%, respectively) values on the ceiling. QLQ 28 asked about the financial difficulty caused by cancer. Since cancer has its economic impact on patients and families, responses touched ceiling in 36.6% of patients. Similarly, OG4 was "Have you had trouble enjoying your meals?"; 27.7% of answers touched the ceiling, indicating that enjoying a meal was significantly affected by dysphagia. Similarly, 25.5% of responses touched the ceiling for questions QLQ 18 (tiredness) and QLQ 27 (affection of disease on social activities).

Among the mean score for various domains, anxiety (score 2.6 ± 0.9) was the highest, and trouble in talking was lowest (score 1.2 ± 0.6). This is perhaps because esophageal cancer causes severe anxiety. The patients in our study were more of middle and lower thirds of the esophagus, and hence, their disease did not affect speech and speech much and this explains the lowest scores.

The most common symptom of esophageal cancer is dysphagia. Dysphagia is assessed by the first three questions of the OG25 questionnaire. The first question deals with difficulty to eat solid food and the remaining two deals with the difficulty in taking liquid food. As commonly seen, esophageal cancers mostly affect dysphagia for solid food rather than liquid food.

Those values which have none of their responses on the floor included QLQ 23–24 and OG 10–14, OG17, and OG 20–24. These questions dealt with issues which are more concerned with OG junction tumors such as eating problems, dysphagia, and pain in the stomach.

One study done in Iran showed worse QOL scores in patients who are managed with palliative intent compared to those who were managed with curative intent.[18]

When the individual scores were looked at, 89.4% of responses in QLQ 17 and 85.1% values in OG23 touched the floor. QLQ 17 enquired about diarrhea and OG23 asked about the difficulty in talking. In general, for those questions which objective were, more responses touched the floor or the ceiling. Regarding higher most indices that touched the ceiling, 36.2% of responses touched the ceiling for QLQ 28, while 25.5% touched for QLQ18 and QLQ27. The first question was about the financial difficulty and most patients responded strongly to choosing the extreme value. So were questions QLQ18 and QLQ 27 which dealt with tiredness and implications of ill health on social activities.

Those values which had none of the responses on the floor included QLQ 23–24 and OG 10–14, OG17, and OG 20–24.

These questions were more specific to QOL issues which were of relevance to OG junction cancers, i.e., enquiring about eating problems, dysphagia, pain in the stomach, etc.

The Cronbach's alpha values were >0.7 except for cognitive functioning (0.49) The Cronbach's alpha value >0.7 in most of the parameters suggests that the questionnaire has good internal consistency validity.

The patient's acceptance was well and we did not notice any problem when it was administered to the Malayalam language patients who indicated the translation was satisfactory and understandable.

An interesting point of research is the association of some HRQOL domains with prognosis in patients with cancer, as shown by Quinten *et al.*[21]

CONCLUSION

The Malayalam version of QLQ-OG25 has acceptable validity and is recommended to be administered, together with the core questionnaire, in patients with OG Junction cancers. The QLQ-OG25 tool can distinguish between various patient and disease factors, which support its benefit in routine administration to OG junction cancers.

Conflicts of interest
There are no conflicts of interest.

REFERENCES

1. Ferlay J, Soerjomataram I, Dikshit R, Eser S, Mathers C, Rebelo M, *et al*. Cancer incidence and mortality worldwide: Sources, methods and major patterns in GLOBOCAN 2012. Int J Cancer 2015;136:E359-86.
2. Asadi-Lari M, Tamburini M, Gray D. Patients' needs, satisfaction, and health related quality of life: Towards a comprehensive model. Health Qual Life Outcomes 2004;2:32.
3. Lagergren P, Fayers P, Conroy T, Stein HJ, Sezer O, Hardwick R, *et al*. Clinical and psychometric validation of a questionnaire module, the EORTC QLQ-OG25, to assess health-related quality of life in patients with cancer of the oesophagus, the oesophago-gastric junction and the stomach. Eur J Cancer 2007;43:2066-73.
4. Fayers P, Bottomley A, EORTC Quality of Life Group, Quality of Life Unit. Quality of life research within the EORTC-the EORTC QLQ-C30. European Organisation for research and treatment of cancer. Eur J Cancer 2002;38 Suppl 4:S125-33.
5. Koller M, Aaronson NK, Blazeby J, Bottomley A, Dewolf L, Fayers P, *et al*. Translation procedures for standardised quality of life questionnaires: The European Organisation for Research and Treatment of Cancer (EORTC) approach. Eur J Cancer 2007;43:1810-20.
6. Beaton DE, Bombardier C, Guillemin F, Ferraz MB. Guidelines for the process of cross-cultural adaptation of self-report measures. Spine (Phila Pa 1976) 2000;25:3186-91.
7. Edge SB, Compton CC. The American Joint Committee on Cancer: The 7th edition of the AJCC cancer staging manual and the future of TNM. Ann Surg Oncol 2010;17:1471-4.
8. Siewert JR, Stein HJ. Classification of adenocarcinoma of the oesophagogastric junction. Br J Surg 1998;85:1457-9.
9. Oñate-Ocaña LF, Velázquez-Monroy N, Vázquez L, Espinosa-Mireles-de-Villafranca P, Núñez-Rosas E, Ovando-Lezama M, *et al*. Clinical validation of the EORTC QLQ-OG25 questionnaire for

the evaluation of health-related quality of life in Mexican patients with esophagogastric cancers. Psychooncology 2012;21:745-53.

10. Blazeby JM, Avery K, Sprangers M, Pikhart H, Fayers P, Donovan J. Health-related quality of life measurement in randomized clinical trials in surgical oncology. J Clin Oncol 2006;24:3178-86.

11. Tomaszewski KA, Püsküllüoğlu M, Biesiada K, Bochenek J, Nieckula J, Krzemieniecki K. Validation of the polish version of the eortc QLQ-C30 and the QLQ-OG25 for the assessment of health-related quality of life in patients with esophagi-gastric cancer. J Psychosoc Oncol 2013;31:191-203.

12. Matuschek C, Bölke E, Peiper M, Knoefel WT, Budach W, Erhardt A, *et al*. The role of neoadjuvant and adjuvant treatment for adenocarcinoma of the upper gastrointestinal tract. Eur J Med Res 2011;16:265-74.

13. Ku GY, Ilson DH. Adjuvant therapy in esophagogastric adenocarcinoma: Controversies and consensus. Gastrointest Cancer Res 2012;5:85-92.

14. Aaronson N, Alonso J, Burnam A, Lohr KN, Patrick DL, Perrin E, *et al*. Assessing health status and quality-of-life instruments: Attributes and review criteria. Qual Life Res 2002;11:193-205.

15. Cronbach L. Coefficient alpha and the internal structure of tests. Psychomerika 1951;16:297-334.

16. Tavakol M, Dennick R. Making sense of cronbach's alpha. Int J Med Educ 2011;2:53-5.

17. Hyland ME. A brief guide to the selection of quality of life instrument. Health Qual Life Outcomes 2003;1:24.

18. Hesari AE, Lari MA, Shandiz FH. Psychometric analysis of a Persian version of the European Organization for Research and Treatment of Cancer OG25 quality of life questionnaire in oesophagogastric cancer patients. Asian Pac J Cancer Prev 2014;15:2739-45.

19. Scott NW, Fayers PM, Aaronson NK, Bottomley A, de Graeff A, Groenvold M, *et al*. The relationship between overall quality of life and its subdimensions was influenced by culture: Analysis of an international database. J Clin Epidemiol 2008;61:788-95.

20. Pagano IS, Gotay CC. Ethnic differential item functioning in the assessment of quality of life in cancer patients. Health Qual Life Outcomes 2005;3:60.

21. Quinten C, Coens C, Mauer M, Comte S, Sprangers MA, Cleeland C, *et al*. Baseline quality of life as a prognostic indicator of survival: A meta-analysis of individual patient data from EORTC clinical trials. Lancet Oncol 2009;10:865-71.