The Reliability and Effectiveness of European Organization for Research and Treatment of Cancer Quality of Life Questionnaire, Core Head and Neck Module (EORTC QLQ-H&N35) in Head and Neck Cancer

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Abstract

Background: We aimed to test the validation of the European organization for research and treatment of cancer (EORTC) quality of life questionnaires for head and neck module (QLQ-H&N35) in a tertiary care center.

Methods: Forty patients with head and neck malignancy completed the QLQ-H&N35 while undergoing their treatment. Questionnaires given to them were translated into their regional language Kannada. Evaluation of the responsiveness, reliability, and validity of the questionnaire was undertaken.

Results: The data assessed the reliability of the scales and not validity. The questionnaire was receptive to changes over time; however, the applicability of the European questionnaire in Indian clinical set up was debatable.

Conclusions: Our data suggests that the EORTC QLO-H&N35 is reliable and responsive when applied to patients with head and neck cancer in India. Hence, it may be used as a platform to test validity at a multicentric level.

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Citation: Dsouza C, Rao V. **The Reliability and Effectiveness of European Organization for Research and Treatment of Cancer Quality of Life Questionnaire, Core Head and Neck Module (EORTC QLQ-H&N35) in Head and Neck Cancer.** *Acad J Surg*, 2018; 5(1-2): 12-5.

Keywords: Questionnaire; Head and neck cancer; Validity; Effectiveness

Introduction

Head and neck cancers amounts to 30% of all cancers in men and 13% in women in developing countries like India as compared to the west, where it accounts for only 5% of all cancers (1). As head and neck cancer is widely prevalent in Indian population, therefore it becomes important to measure the outcomes it has in terms of survival after appropriate treatment, and its impact on an individual's quality of life (QOL). To measure this impact, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ) was published after analyzing all the psychometric qualities for the very first time in 1992 (2). The first version of the EORTC QLQ module for patients with head and neck cancer (EORTC QLQ-H&N37) was published in 1994 (3), revised and validated in 1999 (4) as EORTC QLQ-H&N35, which is used as a specific module for head and neck cancer. These questionnaires developed for the European countries, are culturally very different when used in our country. In India, the populations suffering from head and neck cancers are from low socioeconomic group; hence it hinders the usage and

application of these questionnaires in our country. Specific module assesses the problems unique to head and neck cancer, such the approaches used in EORTC questionnaire which are used worldwide. The present study was a pilot study done to check the reliability as well as validity of EORTC QLQ-HN35 (head and neck-specific questionnaire).

Materials and Methods

This prospective longitudinal study was done in Father Muller Medical College, Mangalore, India, after obtaining clearance from the institutional ethics committee. 40 patients suffering from head and neck cancer visiting the outpatient departments of oncology (radiation, medical, and surgical) who were diagnosed with head and neck cancer of any subsite or stage with a definitive treatment plan formulated with a curative intent of any modality, willing to participate in the study were included.

The patients not willing to participate in the study, those in between the treatment course, treatment defaulters, those with disease recurrences or relapses, patients receiving neoadjuvant treatment, and those not

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available for long-term follow up were excluded from the study.

All of the patients were investigated and staged, and appropriate treatment plan was formulated for them. These patients were given EORTC QLQ-HN35 questionnaire, and asked to fill. The questionnaire was translated into Kannada as majority of the patients could read and comprehend it. The same group of patients were followed up posttreatment, and asked to fill the same set of questionnaires. A total of 80 questionnaires were filled and analyzed. The questionnaires were rechecked and values were added wherever they were missing. The relevant clinical details including age, gender, level of education, site and stage of the tumor, and the treatment details were recorded from the hospital case files.

Results

Forty patients completed the questionnaire prior to commencement of treatment, and once after completion of treatment, giving a total of 80 completed questionnaires. All the patients filled this questionnaire in the translated version. Except for few, most of the questions were answered without assistance, brief explanation for the purpose of this study was provided for few.

There were 38 men and 2 women patients. All of them were literate, and could understand the questionnaires well. Sites of primary tumor are described in table 1. Out of theses, 32 were referred for surgery, and 8 for concurrent chemoradiotherapy.

Reliability was measured using Cronbach's alpha coefficient (Table 2). Most of the scales in both the questionnaires demonstrated a coefficient of > 0.70 which was considered high.

In EORTC QLQ-H&N35, global and pain scale showed a lower coefficient in both pretreatment (0.244/-0.059) and posttreatment (0.105/0.098), whereas swallowing scale showed lower coefficient in posttreatment scale (0.549) compared to pretreatment (0.726), and senses problem scale in pretreatment (-0.118) showed a lower coefficient compared to

posttreatment (0.943). Other values in both questionnaires in all other domains demonstrated a high coefficient value (> 0.70). Hence, satisfactory results were achieved.

Table 1. Site distribution of cases

Site	Subsite	Frequency	
Oral cavity	Lip	2	23
	Buccal mucosa	7	
	GB sulcus	3	
	Tongue	6	
	FOM	1	
	RMT	3	
	Alveolus	1	
Oropharynx			1
Larynx			5
Hypopharynx			9
Nose and paranasal sinuses (PNS)			2
Total			40

Considering clinical validity, with the respect to pretreatment and posttreatment values, the questionnaire showed statistically significant difference in all domains as all the p values are less than 0.001 (Table 3).

Discussion

Head and neck cancer is quite prevalent in this part of the continent, and various studies have been published from different tertiary care centers, a lot has been discussed about its pathophysiology and control. In past few years, equal importance has been given to facial aesthetics, organ preservation, and QOL which formed an integral part of disease management. Oral cavity is the commonest subsite as seen in our study as well. Disease specific management of head and neck tumors can lead to structural defects and functional disability which affects the overall well-being, self-esteem, and social integration and self-confidence of the patient. Treatment of head and neck tumors can be mutilating, thereby affecting the QOL. These questionnaires provide an opportunity to have insight about the mental and social impact the disease has on an individual which was noticed by Chaukar et al, (5).

Table 2. Cronbach's alpha coefficient for different aspects of EORTC QLQ-H&N35

Aspect	Item	Pretreatment	Posttreatment
Symptom scale			
Pain	31-34	0.105	0.098
Swallowing problems	35-38	0.726	0.549
Functional scale			
Trouble with social eating	49-52	0.861	0.919
Less sexuality	59-60	1.000	1.000
Speech problems	53-54	0.946	0.976
Trouble with social contact	55-58	0.978	0.993
Senses problems	43-44	-0.118	0.943
Global scale	61-65	0.244	-0.059

EORTC QLQ-H&N35: European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Head and Neck-35

Table 3. Test for validity between pretreatment and posttreatment scores in EORTC QLQ-H&N35

Aspect	Pretreatment		Posttreatment		P-value
	Mean	SD	Mean	SD	
Global	6.65	0.949	8.57	0.594	< 0.001
Social eating	10.43	2.952	13.25	2.753	< 0.001
Less sexuality	4.30	1.786	6.55	1.568	< 0.001
Speech problems	5.05	1.894	6.60	1.464	< 0.001
Social contact	9.57	3.587	12.65	3.438	< 0.001
Pain	7.40	1.985	7.98	2.069	0.006
Swallowing problems	9.63	2.789	10.83	2.194	0.001
Senses problem	2.23	0.660	5.93	2.005	< 0.001

EORTC QLQ-H&N35: European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Head and Neck-35; SD: Standard deviation

We, in our study, found similar usefulness of the questionnaire therefore, QOL is an important end-point in evaluating treatment outcomes, and mental and social well-being of patients with head and neck cancer. Various QLQ scales are available which can be used, but we chose a disease specific scale to enhance the outcome as mentioned by Tamburini (6).

The QLQ-H&N35 has 35 questions, and is a head and neck specific questionnaire. The questions are broadly grouped as global, functional, and symptoms which are well balanced. In the translated questionnaire, all the items showed acceptable reliability, except for cognitive and pain items along with global and senses items. There was no statistically significant difference in interpretation between the scales as similar items were showing poor reliability with no association with other items. Most of the items showed high pretreatment reliability, and prospectively the scores improved in most of the cases; similar findings were reported by Melo Filho et al. (7) and Braam et al. (8) with slight contradiction with Bansal et al. (9) where they demonstrated positive correlation with worsening functions and increasing symptoms.

This study was not done to assess the QOL based on the disease stage; but, when observed closely, the early stage tumors showed better QOL than those with advanced stage. However, there were too many confounding factors to comment upon the stage specific QOL which we thought was a shortcoming in this study, maybe a large volume stage specific QOL study can be done to address this.

With respect to validity of the questionnaire, it can be stated that this questionnaire was not valid, but was reliable; this is because the sample size taken for this study was inadequate according to Kaiser-Meyer-Olkin measures of sample of adequacy (10).

Certain questions were not very appropriate for Indian population, and many of our participants could not comprehend the questions related to sexual activity, as it either made them uncomfortable to answer; or the shear burden of the disease in terms of financial burden and loss of productivity made it impractical for them to associate their QOL with sexual life hence, we did not find it appropriate in our setting. Chaukar et al. in their study found similar responses, too (5).

Vital property of QOL tools in a study is it's responsiveness to changes to health status of the patient. In this study, there was a statistically significant difference in all the different domains as expected. Patients had a significant poor score in most of the scales in posttreatment compared to patients prior to treatment. However, based on the above results, it can be concluded that the new scale does not replace the older one.

This study can be seen as a pilot study, and the positive data can be used to conduct a multicentric study across the state with a bigger sample size for better randomization. Therefore, this study can serve as a template to effectively test the validity of EORTC QLQ-H&N35 questionnaire.

Conclusion

EORTC QLQ-H&N35 questionnaire helps the clinician to gather disease specific QOL data which otherwise is often missed. This QOL questionnaire is highly reliable; however; validity warrants a much bigger study. The items included are all relevant except for few which may vary based on cultural differences. Core questionnaires may be combined with site specific questionnaires for better QOL outcome. This study can act as a template for testing effective validity in future.

Conflict of Interests

Authors have no conflict of interests.

Acknowledgments

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