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Reliability and Validity of Assamese Version of EORTC QLQ-C30 Questionnaire for Studying the Quality of Life of Cancer Patients of Assam

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Abstract: Measuring the quality of life of cancer patients in a community is very much essential for evaluating the status of rehabilitation and palliative care in that community which are important components of cancer control programme. The EORTC QLQ-C30 is a widely used quality of life measuring instrument for cancer patients. Considering the spatial variability, the reliability and validity of the instrument should be tested in context of Assam. Here an attempt has been made to test the reliability and validity of the Assamese version EORTC QLQ-C30 on oesophagus cancer patients of Assam by administrating it to 153 oesophagus cancer patients diagnoised during the study period. For testing the internal consistency and construct validity of the instrument the Cronbach's alpha (α coefficient, multitrait/multi-item correlation matrix and factor analysis were used. The alpha Coefficient showed that almost all the multi item scales were internally consistent. All the multiple items also satisfied the convergent and discriminant validity. The factor analysis resulted in 8 different components for measuring the quality of life. The items of physical and role functioning were loaded in the same factor suggesting that both may be combined into a single factor. However, in the context of Assam, items measuring dyspnoea, diarrhea and financial difficulties may be dropped.

Key words: Quality of life · Construct validity · Cronbach's alpha Coefficient · convergent and discriminant validity · Factor analysis

INTRODUCTION

The perception of health related quality of life is used to measure the impact of diseases and treatments on different aspects such as physical, emotional, social etc. of people's daily lives. Clinicians administrated treatments to patients to increase survival, reduce the impact of morbidity or make patients feel better. Feeling better may include avoiding discomfort (e.g. Pain, nausea, breathlessness), disability (i.e. loss of function) and distress (i.e. emotional problems). For many years clinicians were willing to substitute physiological or laboratory tests for the direct measurement of the third end point, in part because of difficulty in measurement. However, during the last 3 decade, the situation has changed and the concept of health related quality of life evolved which can be used in the direct measurement of how people are feeling and the extent to which they are able to function their daily activities. The concept of quality of life is very crucial for studying the rehabilitation and palliative care for patients with chronic disease such as cancer in which the cure is very unlikely. The World Health Organization also recognized the rehabilitation and palliative care for cancer patients as one of the major component to reduce the impact of the disease [1].

In the recent past a number of instruments for measuring the quality of life for different diseases have been developed which are basically divided into two parts viz., generic measure and disease specific measure. The European Organization for Research and Treatment of Cancer (EORTC) quality of life group has developed a series of instruments such as EORTC QLQ-C30 and other site specific modules for measuring the quality of life of cancer patients [2]. The EORTC QLQ-C30, an instrument consisting of 30 questions, has been developed to study the quality of life of cancer patients irrespective of the site. A number of research works have been conducted to study the quality of life of cancer patients by using EORTC QLQ-C30 questionnaire around the globe [3-8]. But EORTC QLQ-C30 was developed specially for

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Table 1: Structural form of EORTC QLQ-C30

Name of Scales	Scales	Number of items	Item range	Item numbers
Global Health Status	QL2	2	6	29, 30
Functional Status				
Physical Functioning	PF	5	3	1 to 5
Role functioning	RF	2	3	6,7
Emotional Functioning	EF	4	3	21 to 24
Cognitive Functioning	CF	2	3	20, 25
Social Functioning	SF	2	3	26, 27
Symptom Scales/items				
Fatigue	FA	3	3	10, 12, 18
Nausea and vomiting	NV	2	3	14,15
Pain	PA	2	3	9,19
Dyspnoea	DY	1	3	8
Insomnia	SL	1	3	11
Appetite loss	AP	1	3	13
Constipation	CO	1	3	16
Diarrhoea	DI	1	3	17
Financial Difficulties	FI	1	3	28

European cancer patients, thus to implement this instrument to cancer patients of other population; the reliability and validity of the instrument must be tested in context of that study population [9-13]. Keeping this point in view, the paper substantiate the results evolved from the research work aim to test the reliability and validity and suggest modifications of EORTC QLQ-C30 in the context of Assam.

The EORTC QLQ-C30: More than decade long researches culminate to the development of EORTC QLQ-C30 which is an integrated system of measuring the quality of life of cancer patients. It is composed of both multi-item and single-item scales which measures quality of life of cancer patients using seven dimensions - functional scales, role function, general symptoms, congnition, emotional status, social functioning and overall health status. Each question may be answered by "not", "a little", 'quite a bit", or "very much", except for the global health/QoL scale, which is a visual analogue scale from 1("very bad") to 7("excellent"). These include five functional scales, three symptom scales, global health status/QoL scale and six single items. Each of the multi-item scales includes a different set of items - no item occurs in more than one scale. Structure of the EORTC QLQ-C30 questionnaire is given in the Table 1.

MATERIALS AND METHODS

Data Collection: The study was a hospital based and conducted in Assam Medical College and Hospital (AMCH), Assam, India. Oesophagus cancer patients diagnosed during the period of 1st January 2008 to 31st December 2009 and who gave consent to participate were included in the study. Before taking consent, the investigators explained the purpose of the study and the EORTC QLQ-C30 questionnaire to the eligible patients and their accompanying persons. After taking the consent, the EORTC QLQ-C30 questionnaire was administrated to the patients and asked them to fill-up the instrument. However, some patients are unable to do this because of cognitive impairments, communication defects, severe distress caused by their symptoms, or because of the quality of life measure is too burdensome physically or emotionally [14]. Under these circumstances, proxy was used who may be a family member or health professionals to complete the quality of life instruments rather than to loss all information on the patient as advocated by Addington et.al. [15]. Studies conducted by Gill et.al. [14] showed that there was a moderate agreement between individual patients and their proxies. He concluded that proxies were almost as good as patients in detecting changes in some quality of life domains over time. In an another study, Beach [16] observed that there seemed to be sufficient agreement between their assessments of quality of life to make the information that proxies provided useful when the patients could not be asked directly. The same study compared the scores on the quality of life questionnaire of the European Organization of Research and Treatment of Cancer (EORTC, QLQ-C30) from cancer patients and their proxies, characteristics of the patients and proxy accounted for less than 15% of the variance between them. These studies justifies our afford to use patient's companions and family members as their proxies. As the patients and their proxies had to fill up the questionnaire by their own, it was translated to the local language of Assamese by using forward backward procedure following the norms approved by EORTC Quality of life Group.

Scaling of EORTC QLQ-C30 : The scaling technique use in EORTC QLQ-C30 is based on the widely applied Likert method of summated scales [17]. As the responses of EORTC QLQ-C30 are recorded in ordinal scale, a linear transformation is applied to standardized the raw score with range 0 to 100 which converted the responses to an interval scale [2]. A higher level of standardized score represent better (higher) level of functioning for functional scales and higher level of symptom score represents worse (higher) level of symptom for symptom scales.

Statistical Methods: For testing the reliability and validity of EORTC QLQ-C30 in context of Assam, scores are computed using the scaling method describe above. The reliability of the questionnaire is tested by assessing the internal consistency of the each multi-item subscales of EORT QLQ-C30 with the help of Cronbach's alpha (α) coefficient [18]. The construct validity of Assamese version of EORTC QLQ-C30 is tested by using convergent and discriminant validity and factor analysis.

RESULTS AND OBSERVATIONS

During the study period a total of 153 oesophagus cancer patients were enrolled in the study. The mean age of the study subjects was 55.76 years with standard deviation 11.82 years. There was a male preponderance in the sample with about 65% of the study subjects were male. Majority of about 76% of the patients were from the rural area in comparison to urban area (24%). The demographic profile of the study subjects are presented in Table 2.

Internal Consistency Reliability: The widely accepted social cut-off is that Cronbach's alpha (α) coefficient should be 0.70 or higher for a set of items to be considered as a reliable scale. The coefficient was estimated for each multi-item scale of the EORTC QLQ-C30 the results of which are presented in Table 3. Table 3 shows that, almost all the subscales of Assamese version of EORTC QLQ-C30 are internally consistent. The Global and Emotional scale produces a high level of internal consistency reliability with $\alpha > 0.9$. Although, for social scale $\alpha < 0.7$; it is close the cut-off value.

Convergent and Discriminant Validity: The Convergent and discriminant validity of Assamese version of EORTC QLQ-C30 was tested by constructing multitrait/multi-item correlation matrix [19]. Convergent validity is a correspondence or convergence between constructs that are theoretically similar which is estimated by calculating Pearson's correlation between each item of a scale with its hypothesized scale. Convergent validity has been considered satisfactory if the correlation between an item and its hypothesized scale is 0.40 and above [19-22]. Discriminant validity is assessed by calculating Pearson's correlation between an item with all other scales. Discriminant validity of an item is supported if the within scale correlation is significantly higher than between scale correlation. The significance of difference between within scales and between scale correlation was tested by constructing the 95% confidence interval. The multitrait/multi-item correlation matrix showing the convergent and discriminant validity of Assamese version of EORTC QLQ-C30 is presented in Table 4.

It can be observed from the multitrait/multi-item correlation matrix presented in table IV, the correlation of all items belonging to different scales with its own hypothesized scale is > 0.40. Thus all of the items satisfy the convergent validity. On the other hand, the items of physical, role, emotional, cognitive, social, fatigue Nausea and vomiting have significantly higher correlation with their own scale in comparison to the correlation with other scale, thus satisfying discriminant validity. The items of the pain scale do not satisfy discriminant validity with physical and fatigue scale. Thought items of physical functioning scale satisfy the discriminant validity, it also registers a high correlation with role, fatigue and global

Table 2: Demographic of the study subjects

Variable	Frequency	(%)	Variable	Frequency	(%)
Age (years)			Location		
< 50	42	(27.45)	Rural	117	(76.471)
50 to 59	43	(28.11)	Urban	36	(23.529)
60 to 69	48	(31.37)	Caste		
70 and above	20	(13.07)	General	45	(29.412)
Sex			Other Backward Class (OBC)	61	(39.869)
Male	99	(64.706)	Schedule Tribe (ST)	16	(10.458)
Female	54	(35.294)	Schedule Caste (SC)	14	(9.150)
Religion					
Tea Garden Community	14	(9.150)			
Hindu	128	(83.660)	Unknown	3	(1.961)
Muslim	17	(11.111)			
Christian	2	(1.307)			
Buddhist	6	(3.922)			

Table 3: Internal Consistency of Assamese ver. of EORTC QLQ-C30

Scales	Cronbach's Alpha (α) Coefficients
Global	0.934
Physical	0.895
Role	0.861
Emotional	0.901
Cognitive	0.863
Social	0.650
Fatigue	0.837
Nausea and Vomiting	0.894
Pain	0.777

Table 4: Multitrait/multi-item Correlation Matrix

Scales		Mean	SD	PF	RF	EF	CF	SF	Fatigue	N andV	Pain	GF
PF	Q1	2.280	0.935	0.86	0.62*	0.07*	0.30*	0.11*	0.50*	0.24*	0.38*	-0.45*
	Q2	2.240	0.930	0.90	0.67*	0.03*	0.39*	0.13*	0.50*	0.25*	0.30*	-0.42*
	Q3	1.745	0.757	0.87	0.57*	0.02*	0.27*	0.09*	0.41*	0.09*	0.31*	-0.33*
	Q4	1.725	0.821	0.81	0.52*	0.01*	0.22*	0.07*	0.43*	0.07*	0.37*	-0.35*
	Q5	1.333	0.618	0.78	0.54*	0.18*	0.34*	0.20*	0.33*	0.16*	0.27*	-0.36*
RF	Q6	1.778	0.829	0.67*	0.94	0.13*	0.38*	0.13*	0.43*	0.35*	0.47*	-0.40*
	Q7	1.614	0.828	0.64*	0.94	0.06*	0.31*	0.10*	0.33*	0.21*	0.44*	-0.32*
EF	Q21	1.804	0.882	0.03*	0.12*	0.78	0.17*	0.22*	-0.01*	0.23*	0.13*	-0.03*
	Q22	1.895	0.933	0.02*	0.07*	0.82	0.26*	0.24*	0.01*	0.28*	0.02*	-0.02*
	Q23	1.549	0.743	0.11*	0.06*	0.68	0.14*	0.10*	0.09*	0.17*	0.13*	-0.08*
	Q24	1.712	0.886	0.08*	0.12*	0.85	0.32*	0.21*	0.03*	0.23*	0.13*	-0.15*
CF	Q20	1.444	0.769	0.36*	0.32*	0.22*	0.76	0.22*	0.31*	0.46*	0.31*	-0.28*
	Q25	1.510	0.804	0.37*	0.37*	0.27*	0.76	0.19*	0.37*	0.54*	0.33*	-0.29*
SF	Q26	1.333	0.639	0.14*	0.10*	0.10*	0.20*	0.49	0.12*	0.16*	0.17*	-0.20*
	Q27	1.222	0.516	0.10*	0.12*	0.32*	0.18*	0.49	0.12*	0.17*	0.08*	-0.23*
Fatigue	Q10	2.229	0.862	0.48*	0.40*	0.09*	0.42*	0.23*	0.69	0.37*	0.55	-0.27*
	Q12	2.484	0.933	0.44*	0.32*	-0.02*	0.23*	0.04*	0.63	0.29*	0.46*	-0.31*
	Q18	2.438	0.857	0.45*	0.35*	0.01*	0.30*	0.09*	0.78	0.29*	0.53*	-0.38*
N and V	Q14	1.810	1.018	0.29*	0.31*	0.23*	0.49*	0.18*	0.39*	0.81	0.27*	-0.15*
	Q15	1.621	0.932	0.11*	0.29*	0.27*	0.52*	0.18*	0.29*	0.81	0.11*	-0.10*
Pain	Q9	2.248	0.797	0.49	0.45*	0.09*	0.23*	0.16*	0.55	0.26*	0.64	-0.22*
	Q19	1.941	0.905	0.50	0.43*	0.11*	0.34*	0.12*	0.52	0.13*	0.64	-0.29*
GF	Q 29	3.935	1.043	-0.45*	-0.39*	0.07*	0.28*	0.25*	0.37*	0.15*	0.27*	0.88
	Q30	4.059	1.131	-0.46*	-0.36*	0.08*	0.30*	0.23*	0.35*	0.11*	0.28*	0.88

Abbreviations : PF= Physical functioning, RP= Role functioning, EF= Emotional functioning,
CF= cognitive functioning, SF= Social functioning, N andV= Nausea and vomiting, GF= Global functioning
Qi (i=1,2,...,30) indicates the ith question number of EORTC QLQ-C30
*Correlation with own scale is significantly different from other scale.

scale. Same type of relation can be observed in role with pain scale, cognitive functioning with nausea and vomiting, pain scale with fatigue and role scale. Higher correlation among these scales indicates chance of combining these factors into a single scale. However, factor analysis will provide more idea whether these scales can be kept in the same construct or not.

Factors Analysis: The objective of conducting factor analysis was to identify the nature of the factors underlying the set of measures in the questionnaire. Before conducting the factor analysis, Kaiser-Meyer-Olkin (KMO) Measure of Sampling Adequacy and Bartlett's Test of Sphericity were used to study the suitability of the data for factor analysis. High value of KMO statistic (0.836) and high significance level (p-value < 0.001) in Bartlett's Test showed the sample was adequate for factor analysis. Principal component analysis was used to extract the factors of Assamese version of EORTC QLQ-C30. Extraction of factors was based on the criterion of an eigen value greater than one with varimax rotation. The factor analysis extracted eight factors with eigen values ranging from 9.07 to 1.17 from 30 items with total cumulative variance 73.47%. The first factor

Table 5: Results of Factor analysis

	Components							
Items	1	2	3	4	5	6	7	8
Q 1	0.64							
Q 2	0.73							
Q 3	0.82							
Q 4	0.79							
Q 5	0.80							
Q 6	0.66							
Q 7	0.76							
Q 9					0.70			
Q 10				0.65				
Q 11				0.75				
Q 12				0.70				
Q 13			0.75					
Q 14			0.84					
Q 15			0.89					
Q 16							0.80	
Q 18				0.76				
Q 19					0.75			
Q 20							0.58	
Q 21		0.86						
Q 22		0.87						
Q 23		0.83						
Q 24		0.90						
Q 25							0.57	
Q 26								0.85
Q 27								0.77
Q 29						-0.87		
Q 30						-0.91		

Extraction Method: Principal Component Analysis.
Rotation Method: Varimax with Kaiser Normalization.
Rotation converged in 8 iterations.

contributed maximally 30% of variance and rest of the 7 factors contributed totally 43% of the variance on quality of life. The eight components and factors loadings with their related items are presented in Table 5.

The first factor with eigen value of 9.07 loaded significantly all the items of physical (Q1, Q2, Q3, Q4, Q5) and role (Q6, Q7) scales with factor loading ranging from 0.82 to 0.64; the second factor loaded significantly all the items of emotional scale (Q21, Q22, Q23, Q24) with factor loading ranging from 0.90 to 0.83 which has an eigen value of 3.62 and explaining about 12% of the total variance. The third factor that explained 7.54% of the total variance represented the symptom scales of nausea and vomiting (Q14, Q15) and Appetite loss (Q 13) with higher factor loadings ranging from 0.89 to 0.75. The fourth factor loaded significantly the items of symptom scales of fatigue (Q10, Q12, Q18) and Insomnia (Q11) with high factor loadings ranging from 0.75 to 0.65. The fourth factor explained 6.30% of the total variance. The fifth factor explained 5.27% of the total variance which loaded items of symptom scales of pain (Q 9 and Q 19) with factor loadings ranging from 0.70 to 0.75. The sixth factor loaded the two items of the global health status (Q 29 and Q 30) with high factor loadings of 0.91 and 0.87 which explained 4.18% of the total variance. The seventh factor explained 3.97% of the total variance and loaded items of cognitive functioning scale (Q 20 and Q 25) and single item scale of constipation (Q16) with factor loadings ranging from 0.80 to 0.57. The last factor loaded the two items of social scale (Q 26 and Q 27) with factor loading of 0.85 and 0.77 which explained 3.89% of variance. The symptom scale dyspnoea (Q 8), diarrhoea (Q 17) and financial difficulties (Q 28) did not load in any one of the factors.

DISCUSSION

The EORTC QLQ-C30 questionnaire is a well-known instrument for measuring the quality of life of cancer patients and has been translated in to various languages worldwide [23- 28]. The researchers conducted this study to develop the Assamese version of EORTC QLQ-C30 by testing its reliability and validity in context of Assamese patients so that it can be used in future. The translation of EORTC QLQ-C30 was conducted in compliance with the procedures recommended by EORTC Quality of life group. The internal consistency of the questionnaire was tested by using Cronbach's alpha (α) coefficient. Results showed that almost all the multi-item scales of the questionnaire registered high value of α (>0.70) signifying that the scales are internally consistent. In case of social functioning scale the value of α is less but very close to the cutoff value for satisfying internal consistency; there is a scope for modification of this domain in context of Assam. Thus this QLQ instrument with exception of social functioning domain possesses good internal consistency reliability.

Validity determines whether the research truly measures that it would intended to measure or how truthful the research results are. In other words, validity explains whether the research instrument allow one to hit "the bull's eye" of one's research objects. Construct validity is the most widely applied measure for testing the validity of a quality of life measuring instrument. In the present study multitrait/multi-item correlation matrix and factor analysis were used to test the construct validity. The multitrait/multi-item correlation matrix (Table 4) constructed for the multi-items scales of instrument shows that all the domains satisfy both the convergent and discriminant validity. But items of physical functioning scale have a high correlation with role

functioning scale, a moderate level of correlation with fatigue and global health status. Similar type of correlation can be observed between items of cognitive functioning with Nausea and vomiting, symptom scale of pain with role functioning and fatigue. To study whether these different domains with high correlation can be kept with in the same construct factors analysis was employed.

The factors analysis showed that all the items of physical and role functioning scale were loaded on one factor. This result was consistent with studies conducted elsewhere [26-28]. Some researchers had also recommended to combine the items of both the scales and this indicated that both the scales may not be separable [27-28]. This factor describes the functioning of all forms of daily activities from sedentary to strenuous. The items of emotional functioning were loaded in the second factor, thus the second factor addressed the emotional issues of cancer patients. The items of Nausea and vomiting scale were loaded together with the single item symptom scale of appetite loss in the third factor. As nauseas, vomiting and appetite loss is closely associated morbid condition, they may be loaded in a single factor. All the items of symptom scale of fatigue are loaded with single item symptom scale of Insomnia in the fourth factor. The two items of symptom scale of pain is loaded in the fifth factor. The sixth factor loads two items of global health status scale with high factor loading. The items of cognitive functioning scale are loaded in the seventh factor. The eight factor loads the items of social functioning scale with high factor loading.

Thus the study reveal that the Assamese version of EORTC QLQ-C30 questionnaire is reliable and valid with some modifications in some of the domains as discuss above.

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