

## ORIGINAL ARTICLE

# PSYCHOMETRIC VALIDATION OF THE BAHASA MALAYSIA VERSION OF THE EORTC QLQ-C30 IN MALAYSIAN COLORECTAL CANCER PATIENTS

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## ABSTRACT

*This study aimed to assess the validity and reliability of the Bahasa Malaysia (BM) version of European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire core (QLQ-C30) (version 3.0) in Malaysian patients with colorectal cancer. A cross sectional study design was used to obtain data from patients receiving treatment at two teaching hospitals in Kuala Lumpur, Malaysia. Self-administered method was used. Statistical analysis included reliability, convergent and discriminant validity and known-groups comparisons. Statistical significance was based on  $p$  value  $\leq 0.05$ . The internal consistency Cronbach's alpha coefficient ( $\alpha$ ) was acceptable ( $> 0.70$ ) in all scales but cognitive ( $\alpha = 0.56$ ) and pain in patients with stoma bag ( $\alpha = 0.35$ ). Test-retest coefficients were high ( $r = 0.93$  to  $1.00$ ). All items showed adequate convergent validity ( $r > 0.40$ ) except for questionnaire item 5 "needs help in eating/dressing/washing". Similarly, criteria for discriminant validity were achieved in all but item 10 "need rest". Patients with high Karnofsky Performance Scores (KPS) scores reported significantly less dyspnoea ( $p = 0.021$ ) and appetite loss ( $p = 0.047$ ) compared to patients with low KPS scores. There was no significant difference between patients with and without stomas. The psychometric properties of the BM version of the QLQ-C30 were comparable to previous studies in other settings. Therefore, the questionnaire could be used to measure quality of life in Malaysian patients with colorectal cancer.*

**Key words:** EORTC QLQ-C30-colorectal carcinoma-Malaysia

## INTRODUCTION

The European Organization for Research Treatment of Cancer (EORTC) Quality of Life core (QLQ-C30) questionnaire is designed to be applicable in all cancer patients<sup>1</sup>. Thus, since its development and release in 1993, EORTC QLQ-C30 has been translated, and its' psychometric properties studied, across several settings and cancer types<sup>2-10</sup>. In Malaysia however, the psychometric properties of the QLQ-C30 has not been tested among colorectal cancer (CRC) patients despite the fact that colorectal cancer is the second leading cancer among the general population in Malaysia<sup>11</sup>. In addition, colorectal cancer accounts for 12.7% of all cancers diagnosed in Malaysia, comprising 15.7% and 10.4% of male and female cancers respectively. Nearly equal numbers of colon

and rectal cancers were diagnosed (4,547; 15.7 per 100,000 versus 4,689; 16.2 per 100,000) with similar mortality rates (241; 0.83 per 100,000 versus 229; 0.79 per 100,000)<sup>11</sup>. Therefore, evaluating the psychometric properties in Malaysian patients with colorectal cancer is both necessary and timely.

This study aimed to assess the psychometric properties (validity and reliability) of the Bahasa Malaysia (BM) version of EORTC-QLQ-C30 (version 3.0) in patients with colorectal cancer. This is part of a large project on epidemiology, survival, prognostic factors and health-related quality of life (HRQoL) of Malaysian colorectal cancer patients. The protocol as well as earlier findings from the study was published earlier<sup>12-14</sup>.

## METHODS

Colorectal cancer patients receiving treatment at University Malaya Medical Centre (UMMC) and University Kebangsaan Malaysia Medical Centre (UKMMC) were included. This study received ethics approval from the Medical Research Ethics Committees of UMMC (PPUM/UPP/300/02/02, MEC 770.2) and UKMMC (Project code: FF-274-2011). Recruitment took place between February 2012 and June 2012. Demographic and clinical data was retrieved from patients' medical records using a pre-designed form. Quality of life data was obtained using the Bahasa Malaysia translated version of the EORTC QLQ-C30. The original questionnaire was obtained from the Quality of Life department of EORTC. All participants provide written informed consent. Participants were requested to complete the questionnaire by themselves while waiting to see the doctor at the outpatient surgical clinic or immediately after the consultation. In addition, surgeons rated the patient's overall wellbeing using the Karnofsky Performance Scale (KPS). For the test-retest analysis, thirty patients were requested to complete and return another set of the questionnaire one to two weeks after the first assessment.

Descriptive analysis was performed; continuous data was summarized using mean and standard deviations, while categorical data was summarized using proportions. The internal consistency of the multi-item scales was examined by the use of Cronbach's alpha coefficient. A coefficient of  $\geq 0.70$  is considered acceptable. Inter-item correlation coefficient was used to examine test-retest reliability. Multi-trait scaling analyses were used to examine the scale structures (convergent and discriminant validity). A criterion considered is that each item's own scale correlation should exceed 0.4 for convergent validity to be achieved. The discriminant validity measures item correlation with other scales. It is hypothesized that self-correlation of an item should be higher than with the other scales. Validity between clinically distinct groups was examined by comparing the scores of patients with and without stomas. In addition, patients were grouped into two; KPS score of  $<80\%$ , and  $>80\%$ . ) were also compared using Mann Whitney U-

tests. All analyses were done via SPSS version 21.0 for Windows, (SPSS Inc., and Chicago, Illinois, USA). A two-tailed probability value of 0.05 was used to determine the level of significance. Further details can be obtained in the published protocol<sup>12</sup>.

## RESULTS

### Patient characteristics

A total of 93 patients (UMMC 47, UKMMC 46) completed the questionnaire. The mean age and standard deviation (SD) was 57 years (SD 11) (range 25 to 74). There were more males (59%); 28% were not formally educated. Full time workers accounted for 45% of the respondents. Stage information was missing for 10 patients. Dukes' stages C and D taken together accounted for 61% of total patients. The mean KPS was 80% (SD 10) and 32% of patients had a stoma (Table 1).

### Internal consistency and test-retest coefficients

With regards to the internal consistencies of the GHS/QOL, most of the functioning and multi-symptom scales were acceptable with Cronbach's  $\alpha \geq 0.70$ . The exception was the cognitive functioning scale, which was persistently low across all levels (highest Cronbach's  $\alpha$  ranges from 0.51 to 0.56); the pain scale was moderate overall (Cronbach's  $\alpha = 0.63$ ), but low in patients with stoma bag (Cronbach's  $\alpha = 0.35$ ).

The test-retest reliability in the GHS/QOL, functioning scales and in most of the symptoms scales was high ( $r = 0.93$  to  $1.00$ ). The lowest test-retest reliability coefficients were found for appetite loss scale ( $r = 0.14$ ) and dyspnoea ( $r = 0.53$ ).

### Multi-trait scaling analyses for convergent and discriminant validity

The convergent ( $r \geq 0.40$ ) and discriminant validities were achieved in all but question number 5. The correlation of question number 5 with its proposed domain (the physical functioning scale) was  $r = 0.38$ , which was less than the minimum required coefficient of  $r \geq 0.40$ . On the other hand, this item's correlation with its domain was less than its correlation with other scales such as cognitive ( $r = 0.43$ ) and social/family functioning ( $r = 0.41$ ).

Table 1: Socio-demographic characteristics of the patients

Characteristics	Number (%)	Employment status	
<b>Hospital</b>		Full time	42(45)
UMMC	46(49)	Retired	36(39)
UKMMC	47(51)	Unemployed	7(8)
<b>Age (years)</b>		Unknown	8(9)
Mean (SD)	57[11]	<b>Site</b>	
Range	25-74	Colon	48(52)
<b>Gender</b>		Rectum	35(38)
Male	55(59)	Unknown	10(10)
Female	38(41)	<b>Dukes' stage</b>	
<b>Ethnicity</b>		A	4(4)
Malay	71(76)	B	26(28)
Indians	18(20)	C	17(18)
Others	4(4)	D	40(43)
<b>Educational status</b>		Unknown	6(7)
Primary	17(18)	<b>Stoma</b>	
Secondary	24(26)	Yes	32(34)
Tertiary	12(13)	No	61(66)
Not formally educated	26(28)	<b>Karnofsky performance status</b>	
Unknown	14(15)	Mean (SD)	80(10)
		≤ 80	50(54)
		≥ 81	43(46)

Table 2: Internal consistency coefficient (Bahasa Malaysia)

Scale	Cronbach's alpha		
	Overall	With stoma	Without stoma
<i>Global health status/quality of life</i>			
Global health status/quality of life	0.9	0.93	0.87
<i>Functioning scales</i>			
Physical	0.75	0.75	0.76
Role	0.91	0.93	0.89
Emotional	0.86	0.87	0.85
Cognitive	0.53*	0.56*	0.51*
Social and family	0.84	0.74	0.92
<i>Multi-item symptoms scales</i>			
Fatigue	0.7	0.7	0.7
Nausea/Vomiting	0.77	0.83	0.71
Pain	0.64*	0.35*	0.73

Table 3: Multi-trait scaling analysis (Bahasa Malaysia)

Questionnaire item		GHS/QOL	Functioning scales					Multi-item symptom scales		
			Physical	Role	Cognitive	Emotional	Social Family	Fatigue	Nausea/Vomiting	Pain
<i>GHS/QOL</i>										
29	Global Health Status	<b>0.95</b>	0.33	0.30	0.36	0.41	0.29	-0.42	-0.31	-0.44
30	Quality of Life	<b>0.96</b>	0.37	0.41	0.40	0.49	0.34	-0.51	-0.29	-0.48
<i>Functioning scales</i>										
Physical										
1	Strenuous activity	-0.39	<b>-0.79</b>	-0.60	-0.33	-0.36	-0.38	0.46	0.29	0.57
2	Long walk	-0.32	<b>-0.82</b>	-0.49	-0.34	-0.36	-0.33	0.33	0.24	0.63
3	Short walk	-0.27	<b>-0.79</b>	-0.33	-0.26	-0.19	-0.25	0.23	0.16	0.38
4	Stay in bed/chair	-0.12	<b>-0.68</b>	-0.26	-0.27	-0.25	-0.25	0.29	0.15	0.28
5	Need help in eating/dressing/washing	-0.16	<b>-0.38*</b>	-0.18	<b>-0.43*</b>	-0.23	<b>-0.41*</b>	0.08	0.33	0.19

GHS/QOL, global health status/quality of life

\*Question number 5 correlations with physical, cognitive and social/family functioning scales

Table 3, continued

Questionnaire item		GHS/QOL	Functioning scales				Multi-item symptom scales			
			Physical	Role	Cognitive	Emotional	Social Family	Fatigue	Nausea/Vomiting	Pain
Role										
6	Limited work	-0.34	-0.54	<b>-0.95</b>	-0.34	-0.37	-0.45	0.48	0.28	0.65
7	Limited hobbies	-0.38	-0.52	<b>-0.96</b>	-0.39	-0.35	-0.51	0.51	0.34	0.62
Cognitive										
20	Concentration	-0.31	-0.35	-0.44	<b>-0.81</b>	-0.35	-0.38	0.39	0.49	0.47
25	Memory	-0.35	-0.36	-0.20	<b>-0.84</b>	-0.47	-0.36	0.39	0.35	0.35
Emotional										
21	Tense	-0.50	-0.39	-0.32	-0.41	<b>-0.83</b>	-0.52	0.36	0.30	0.53
22	Worried	-0.39	-0.32	-0.31	-0.41	<b>-0.86</b>	-0.45	0.49	0.19	0.48
23	Irritable	-0.25	-0.15	-0.14	-0.32	<b>-0.75</b>	-0.29	0.24	0.10	0.27
24	Depressed	-0.42	-0.43	-0.35	-0.52	<b>-0.89</b>	-0.45	0.56	0.33	0.48
Social/Family										
26	Family life	-.035	-0.23	-0.40	-0.38	-0.42	<b>-0.92</b>	0.31	0.21	0.47
27	Social life	0.01	-0.47	-0.52	-0.45	-0.53	<b>-0.94</b>	0.48	0.43	0.49

GHS/QOL: global Health Status/Quality of Life

**Clinically distinct group comparisons**

We observed a trend where patients with a stoma bag reported lower mean scores for GHS/QOL, and functioning scores, as well as more symptoms compared to patients without a stoma. However, the differences were not

statistically significant. With reference to KPS scores, patients with high KPS scores reported significantly less dyspnoea ( $p = 0.021$ ) and appetite loss ( $p = 0.047$ ) compared to patients with low KPS scores.

**Table 4: Group comparison according to Karnofsky Performance Scores (KPS) for EORTC QLQ-C30 versions**

Domains	Bahasa Malaysia		p-value
	≤80	≥81	
	(n=50) Mean (SD)	(n=43) Mean (SD)	
<i>GHS/QOL</i>			
GHS/QOL	70.33(23.52)	74.81(14.14)	0.063
<i>Functioning scales</i>			
Physical	72.27(23.30)	82.48(15.67)	0.055
Role	67.67(38.59)	76.36(25.26)	0.755
Emotional	75.83(23.59)	81.20(20.66)	0.291
Cognitive	84.67(17.44)	82.94(17.63)	0.535
Social/Family	82.00(22.55)	83.72(21.35)	0.759
<i>Multi-items symptom scales</i>			
Fatigue	40.22(25.18)	30.23(17.87)	0.063
Nausea/Vomiting	11.00(17.69)	6.59(17.49)	0.054
Pain	29.67(26.99)	20.54(20.19)	0.121
<i>Single item/symptoms</i>			
Dyspnoea	18.67(25.34)	7.75(17.57)	0.021*
Sleep loss	28.67(31.59)	24.03(25.53)	0.646
Appetite loss	25.33(33.37)	11.63(21.68)	0.047*
Constipation	20.00(34.99)	17.83(24.50)	0.628
Diarrhoea	12.00(24.05)	17.05(25.58)	0.207
Financial difficulty	26.00(35.82)	20.15(27.35)	0.695

\*Significant difference ( $p < 0.05$ ), GHS/QOL: Global Health Status/Quality of Life

## DISCUSSION

Evaluation of the reliability and validity of the Bahasa Malaysia version of the EORTC QLQ-C30 was both necessary and timely. The psychometric properties obtained in this study were comparable to the previous studies<sup>15</sup>. The persistent poor internal consistency coefficients for cognitive function scale were observed in previous validation studies of the QLQ-C30 in Indonesia<sup>9</sup>, Singapore<sup>10</sup>, Korea<sup>6</sup>, simplified Chinese<sup>3</sup>, and Malay patients with breast cancer<sup>7</sup>. In these studies, the alpha ranges from 0.19 to 0.67. However, the poor internal consistency pain scale obtained in patients with stomas contradicts previous studies<sup>3,9,10</sup>. Appetite loss low test-retest correlation is likely due to transient nature of the appetite loss symptom, especially if it was not as a result of any organic cause.

With reference to the convergent-discriminant validity, all the items in the questionnaire met the criteria for the convergent and discriminant validity with exception of item 5 “need help in eating/dressing/washing”. We found the questionnaire item correlation with the social and family function scale was higher than its correlation with the proposed physical functioning scale. The study findings were similar to the Indonesian and several other studies where questionnaire item number 5 correlate higher with emotional function than its own proposed physical function scale<sup>3,9,16</sup>.

Our findings on clinical utility of the questionnaire showed that appetite loss was the only domain that differentiated between patients with and without stoma bag and that dyspnoea and appetite loss demonstrated significant difference between patients in two spectra of the Karnofsky performance scale. A recent Cochrane review found that variations in HRQOL domains between patients with and without stoma were not consistent<sup>17</sup>. Several previous studies failed to identify differences between patients with different cancers stages<sup>9</sup>, and co-morbid conditions<sup>10</sup>. However, patients with the worse ECOG performance scores reported poor functioning, global health status/Quality of life, and higher symptoms compared to those with good/higher ECOG<sup>18</sup>. Our study is the first to attempt to examine the psychometric properties of the Malaysian versions of the EORTC QLQ- QLQ-C30 among Malaysian colorectal cancer patients. The limitation of this study is the use of patients

from urban setting only. Further studies might be needed to compare our findings with that of patients from rural setting.

## CONCLUSION

Our study findings indicated that the Bahasa Malaysia version of the QLQ-C30 is a valid and reliable measure of HRQOL in patients with colorectal cancer. This demonstrated the global applicability of the QLQ-C30 in the assessment of cancer patients' HRQOL. Clinicians should make appropriate use of these tools and examine the possibility of collecting HRQOL as part of the routine clinical follow up of care. This could be done before and after commencement of major treatment modalities such as surgery, chemotherapy or radiotherapy.

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## COMPETING INTEREST

None declared.

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