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[1]Julius Centre University of Malaya, Department of Social & Preventive Medicine, Faculty of Medicine, University of Malaya, 50603, Kuala Lumpur, Malaysia
[2]Department of Community Health, College of Health Sciences, Usmanu Danfodiyo University, PMB 2346, Sokoto, Nigeria
[3]Department of Surgery, Faculty of Medicine, University of Malaya, 50603, Kuala Lumpur, Malaysia
[4]University of Malaya Cancer Research Institute (UMCRI), Kuala Lumpur, Malaysia
[5]Department of Surgery, Universiti Kebangsaan Malaysia Medical Centre, Jalan Ya'acob Latif, Bandar Tun Razak, Cheras 56000 Kuala Lumpur Received on 29/07/2022

***Corresponding author's email:**

bello.magaji@udusok.edu.ng

mbarkilla@gmail.com

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Validation of the Malaysian Chinese-version of the EORTC QLQ-CR29 among Colorectal cancer patients in Malaysia

Bello A. Magaji[1,2*], Foong M. Moy[1], April C. Roslani[3], Chee W. Law[4] and Ismail Sagap[5]

Patient reported outcome research are becoming a very important way of understanding patient's satisfaction and tolerance with the treatment they receive. This study examined the validity and reliability of the Malaysian Chinese version of the European Organization for Research and Treatment of Cancer (EORTC) colorectal cancer-specific quality of life questionnaire (QLQ-CR29). Patients were recruited at the outpatient clinics of the University of Malaya and Universiti Kebangsaan Medical Centre, Malaysia. The QLQ-CR29 and Karnofsky Performance Scales (KPS) were used. Multi-traits scaling analysis such as Cronbach's alpha, inter-class correlation (ICC) and known-groups comparisons (Wilcoxon-rank sum test) were performed. Significant level was pre-set at ≤ 0.05. Patients mean age (standard deviation, SD) was 64 (10) years, and 60% were male. Colon cancer was 50%. While 60% had advanced stage (Dukes' C/D) cancers and about 30% of patients had a stoma. The mean KPS was 80% (SD 10). The internal consistency coefficient (ICC) was 0.89, 0.84, 0.46, and 0.73 for body image, urinary frequency, blood & mucus in stool and stool frequency scales respectively. The correlation coefficients for convergent validity were moderate to large (r ranged from 0.72 to 0.93) across all scales. For the discriminant validity measurements, small to moderate correlations were observed across the scales. The psychometric properties of the Malaysian Chinese version of the QLQ-CR29 were comparable to the original English version. This work provides a translated, culturally adapted, reliable and valid measure of HRQOL for use among Malaysian Chinese patients with colorectal cancer.

Keywords: EORTC QLQ-CR29; Malaysian-Chinese; Colorectal cancer; Validation.

1. Introduction

Presently, Health related quality of life (HRQOL) is important in guiding investigators, clinicians and policy makers in assessing the role of treatment or interventions in cancer care, HRQOL assessment is now an integral part of cancer research including cancer of the colorectum [1- 4]. As at the time of this study, there is no locally developed or culturally adapted Malaysian-Chinese colorectal cancer specific instrument used to assess HRQOL among patients with colorectal cancer. Therefore, we adopted the European Organization for Research and Treatment of Cancer (EORTC) colorectal cancer-specific questionnaire (QLQ-CR29) [5]. The QLQ-CR29 is the updated version of the QLQ-CR38 and it consists of 29 questions assessing symptoms, treatment side effects, body image, sexual dysfunction and concern about the future [6].

The EORTC QLQ-CR29 is a colorectal cancer specific module comprising 29-items. The questionnaire is intended to be administered together with EORTC QLQ-C-30. It consists of one multi-item scale function scale (body image), four single items assessing functioning (anxiety, weight, sexual function in men, and women), three symptoms scales (urinary frequency, blood and mucus in stool and stool frequency), single item symptoms (abdominal pain, 105 buttock pain, dry mouth, bloated feeling, flatulence, dysuria, faecal incontinence, urinary incontinence, trouble with taste, stoma care related problem, sore skin, embarrassed due to frequent change in stoma bag or bowel movement), and sexual pleasure (Impotence, Dyspareunia). All questions use a

four-point Likert like scales of 1 ‘not at all’, 2 ‘a little’, 3 ‘quite a bit’ and 4 ‘very much’ except question on the presence of stoma, which used two categories of ‘Yes’ or ‘No’. Questions number Q31 to Q48 are to be answered by all patients, patients answering ‘Yes’ to the question on presence of stoma complete the subsequent questions Q50 to Q55 (stoma), those answering ‘No’ go for the next set of questions Q50 to Q54. Question Q55 is about stoma care related problem, thus unique for those with stoma. Question Q56 and Q57 are for male patients, while later two (Q58 and Q59) are for female patients respectively [6].

Since its release in 2009, the QLQ-CR29 questionnaire has been validated and adapted for use in Spain [7], Columbia [8], Portugal [9], China [10], Egypt [11] and Poland [12], Malay [13]. The aim of this study was to examine the reliability and validity of the Malaysian-Chinese version of the QLQ-CR29 questionnaire among patients with colorectal cancer.

2. Materials and Methods

Patients for this study were recruited using convenient sampling from the surgical clinics of University Malaya Medical Centre (UMMC) and Universiti Kebangsaan Malaysia Medical Centre (UKMMC). A cross sectional descriptive study was used to collect data from 96 patients. Details can be found in the published protocol [14] and earlier publications of the sub-componets of the validation studies (13, 15, 16). Research tools used included patient data sheet, translated versions of the QLQ-CR29 questionnaires and the Karnofsky Performance Scale (KPS). The Malaysian-Chinese version of the EORTC QLQ-CR29 was translated from the English original version obtained from the EORTC Quality of Life department with permission. Forward and backward translations of the QLQ-CR29 was conducted by professional translators according to the guidelines for translation by the EORTC [17].

Data collection was conducted between February and June 2012. Patients were recruited using consecutive sampling. Patients are requested to self-administer the translated questionnaires. Patients’ demographic and clinical data was retrieved from the medical records using a pre-designed form. The attending surgeon completed the KPS. For the test-re-test reliability test, thirty patients were requested to administer the questionnaire again after one to two weeks after the first administration.

The internal consistency of the multi-item scales was examined using Cronbach’s alpha coefficient. Intra-class Correlation Coefficient (ICC) was used to examine test-retest reliability. Multi-trait scaling analyses were used to examine the scale structures (convergent and discriminant validity). Convergent validity is achieved when each item’s own scale correlation exceeds 0.4. The discriminant validity measures item correlation with other scales. It is expected that the item’s own correlation should be higher than with the other scales. Known group validity was examined by comparing the scores of patients according to presence of stoma (yes/no) and the Karnofsky performance status (KPS score of ≤80% versus ≥81%). The level of significance was pre-set at 0.05. All data was entered and analysed using SPSS version 21 for Windows.

Ethics approval was obtained from the UMMC (MEC Ref. No: 770.2) and UKMMC (Project code: FF-274-2011). Written informed consent was obtained from all participants.

3. Results and Discussion

3.1 Results

3.1.1 Participants characteristics

Table 1 presents the patients characteristics. The mean age of the patients (standard deviation, SD) was 64 (10) years. Sixty percent were male, fifty eight percent retired civil servants and 36% were educated to a minimum of primary school level. Fifty percent had colon cancer, advanced stage (Dukes’ C/D) cancers accounted for 60% of cases. A total of 30% of patients had a stoma. The mean KPS was 80% (SD 10).

3.1.2 Internal consistency analyses

The internal consistency reliability (ICR) for the four scales was examined. The results were compared with those obtained from the original English versions [6]. Overall, the ICR for the scales in our Malaysian-Chinese version was 0.89 for body image, 0.84 in urinary frequency, 0.46 for blood and mucus and 0.73 in stool frequency as compared to 0.84, 0.75, 0.69 and 0.70 for the same scales in the original English version. Among patients with stoma, the ICR was 0.88, 0.89, 0.63 and 0.80 for body image, urinary frequency, blood and mucus and stool frequency as compared to 0.82, 0.80, 0.54 and 0.78 for the respective scales in the original version. While in patients without stoma, the ICR was 0.90, 0.81, 0.38 and 0.70 for body image, urinary frequency, blood and mucus and stool frequency as compared to 0.83, 0.71, 0.72 and 0.66 for the respective scales in the original version. Except for the scale on blood and mucus, the Cronbach’s alpha coefficients in our study were higher compared to the original validation study [6] (Table 2).

Table 1. Demographic and clinical features of the patients (n=96)

Characteristics	Number (%)
Age (years)	
Mean (SD)	64 (10)
Range	43-83
Gender	
Male	58 (60)
Female	38 (40)
Educational status	
Primary	28 (29)
Secondary	19[20]
Tertiary	3 (3)
Not formally educated	20 (21)
Unknown	26 (27)
Employment status	
Full time	26 (27)
Retired	56 (59)
Unemployed	7 (7)
Unknown	7 (7)
Site	
Colon	48 (50)
Rectal	34 (36)
Unknown	14 (14)
Dukes' stage	
A	4 (4)
B	26 (27)
C	16 (17)
D	41 (43)
Unknown	9 (9)
Stoma	
Yes	29 (30)
No	67 (70)
Karnofsky performance status	
Mean (SD)	80 (10)
Range	50-90
≤ 80	57 (59)
≥ 81	39 (41)

Table 2. Internal consistency (Cronbach's alpha) for the Malaysian-Chinese version and original validation study (EORTC QLQ-CR29)

Scale	Total		With Stoma		Without Stoma	
	Malaysian Chinese	Original validation[b]	Malaysian Chinese	Original validation[b]	Malaysian Chinese	Original validation[b]
Body image	0.89	0.84	0.88	0.82	0.90	0.83
Urinary frequency	0.84	0.75	0.89	0.80	0.81	0.71
Blood and mucus	0.46[a]	0.69	0.63[a]	0.54	0.38[a]	0.72
Stool frequency	0.73	0.70	0.80	0.78	0.70	0.66

[a] Low Cronbach's alpha

[b] Whistance, R. N., Conroy, T., Chie, W., Costantini, A., Sezer, O., Koller, M., et al. (2009). Clinical and psychometric validation of the EORTC QLQ-CR29 questionnaire module to assess health-related quality of life in patients with colorectal cancer *European Journal of Cancer, 45*(17), 3017-3026

Table 3. Convergent validity in the Malaysian-Chinese version and original validation study (EORTC QLQ-CR29)

	Total		Stoma		No stoma	
	Malaysian Chinese	Original validation[a]	Malaysian Chinese	Original validation[a]	Malaysian Chinese	Original validation[a]
Body image	0.88-0.92	0.65-0.77	0.85-0.94	0.61-0.79	0.89-0.93	0.64-0.73
Urinary frequency	0.73-0.93	0.60-0.60	0.95-0.96	0.56-0.56	0.91-0.92	0.67-0.67
Blood and mucus	0.72-0.89	0.53-0.53	0.80-0.92	0.57-0.57	0.68-0.88	0.37-0.37
Stool frequency	0.88-0.89	0.57-0.57	0.89-0.95	0.54-0.54	0.85-0.89	0.65-0.65

[a]Whistance, R. N., Conroy, T., Chie, W., Costantini, A., Sezer, O., Koller, M., et al. (2009). Clinical and psychometric validation of the EORTC QLQ-CR29 questionnaire module to assess health-related quality of life in patients with colorectal cancer. *European Journal of Cancer, 45*(17), 3017-3026.

Table 4. Discriminant validity in the Malaysian-Chinese version and original validation study (EORTC QLQ-CR29)

	Total		Stoma		No stoma	
	Malaysian Chinese	Original validation[a]	Malaysian Chinese	Original validation[a]	Malaysian Chinese	Original validation[a]
Body image	0.04-0.42	0.00-0.43	0.02-0.52	0.01-0.39	0.00-0.42	0.00-0.48
Urinary frequency	0.22-0.43	0.00-0.21	0.13-0.49	0.01-0.25	0.18-0.39	0.00-0.22
Blood and mucus	0.01-0.24	0.00-0.25	0.15-0.37	0.01-0.38	0.02-0.24	0.00-0.34
Stool frequency	0.10-0.26	0.03-0.46	0.09-0.40	0.00-0.49	0.03-0.27	0.02-0.41

[a] Whistance, R. N., Conroy, T., Chie, W., Costantini, A., Sezer, O., Koller, M., et al. (2009). Clinical and psychometric validation of the EORTC QLQ-CR29 questionnaire module to assess health-related quality of life in patients with colorectal cancer. *European Journal of Cancer, 45*(17), 3017-3026.

3.1.3 Test-retest analyses

In this study, the test-retest reliability correlation coefficients were moderate to high for most of the scales (r = 0.55 to 1.00) except for anxiety scale (r = 0.49), weight (r = 0.47), stool frequency (r = 0.25), bloated feeling in the abdomen (r = 0.41) and stoma care related problems (r = 0.25).

3.1.4 Convergent and discriminant validity

Overall inter-item correlations as well as item-domain correlations were used to assess item convergent and discriminant validity in all multi-item scales. All items met the criteria for convergent and discriminant validities. Overall the correlation coefficients were large across all scales in our Malaysian–Chinese version (r ranged from 0.72 in blood and mucus scales to 0.93 in urinary frequency scale) as compared to moderate size (r ranged from 0.53 – 0.77) in the original version (Table 3).

In patients with stoma, the correlation coefficients were large across all scales in our Malaysian–

Chinese version (r ranged from 0.80 in blood and mucus scales to 0.96 in urinary frequency scale) as compared to moderate size (r ranged from 0.54 – 0.79) in the original version. Similarly, among patients without stoma, the correlation coefficients were moderate to large across all scales in the Malaysian-Chinese- version (r ranged from 0.68-0.93), but moderate in the original version (r ranged from 0.37- 0.67).

Similar to the original validation study, small to moderate coefficients were observed in the discriminant validity across the scales (Table 4). However, all the scales in our Malaysian-Chinese-version fulfilled the criteria for discriminant validity.

3.1.5 Known group comparison

Patients with stoma reported significantly higher symptoms of dysuria ($p = 0.008$), sore skin around the stoma bag ($p = 0.006$), faecal incontinence ($p = 0.025$) and being embarrassed due to frequent bowel movement or frequent change in stoma bag ($p < 0.001$) compared to patients without stoma.

With reference to the KPS groups, patients with low KPS scores reported more dysuria compared to those with higher scores ($p = 0.047$). No statistically significant difference was observed between the two groups in other scales (Table 5).

3.2 Discussion

To our best knowledge, this study is the first to evaluate the reliability and validity of the Malaysian-Chinese version of the QLQ-CR29. The internal consistency in our study was higher than the original validation and Spanish studies [6,7] in body image, urinary and stool frequency scales. There was persistently lower internal consistency in blood and mucus scales across all levels. The internal consistency in the stool frequency scale was higher among patients without stoma. The low internal consistency observed in the gastrointestinal symptom (blood and mucus in stool) scale was similar with the previous validation studies [7,12,13].

The multi-trait scaling analysis established the structure of all the four multi-item scales for the tool. All scales in the Malaysian-Chinese version of the QLQ-CR29 met the criteria for convergent validity with moderate to large correlation coefficients. These findings are consistence with the original validation and many other studies [6, 7,13].

Patients with stoma were found to experience more symptoms of dysuria, faecal incontinence, sore skin around the stoma bag area, and embarrassment due to frequent need to change stoma bag compared to non-stoma patients. Dysuria symptom was reported mostly by patients with lower performance scores. Previous studies indicated that only some scales/items were useful in differentiating between distinct patient groups. For example, recent study found blood and mucus, abdominal and buttock pains items to differentiate between patients in KPS groups (≤ 90 and ≥91) [7]. Whereas in the original validation study, stool frequency scale, abdominal pain, bloating, dry mouth, and flatulence items were all found to differ significantly between patients with low and high performance scores [6].

4. Conclusion and Recommendations

In conclusion, the psychometric properties of the Malaysian-Chinese version of the QLQ-CR29 were comparable to the original English version. This work provides a translated, culturally adapted, reliable and valid measure of HRQOL for use among Malaysian Chinese patients with colorectal cancer. The translated version is now available in the EORTC Quality of Life Department [17]. It is recommended that clinical research should use this tool for further research and possible clinical assessment of colorectal cancer patients.

Conflict of Interest

The author declares that there is no conflict of interest.

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References

1. Farkkila, N., Sintonen, H., Saarto, T., Jarvinen, H., Hanninen, J., Taari, K., et al. (2013). Health-related quality of life in colorectal cancer. *Colorectal Dis, 15*(5), e215-222. DOI: 10.1111/codi.12143

2. Doga, G., Papadopoulos, R., Kelly, D., Aslanidis, O., & Anagnostopoulos, F. (2011). Health-related Quality of Life Predictors in Colorectal Cancer Survivors. *European Journal of*

Cancer, 47, S308-S309. DOI: 10.1046/j.1365-2265.2002.01597.x

3. Alacacioglu, A., Binicier, O., Gungor, O., Oztop, I., Dirioz, M., & Yilmaz, U. (2010). Quality of life, anxiety, and depression in Turkish colorectal cancer patients. *Support Care Cancer, 18*(4), 417-421. DOI: 10.1007/s00520-009-0679-2

4. Velikova, G., Coens, C., Efficace, F., Greimel, E., Groenvold, M., Johnson, C., et al. (2012). Health-Related Quality of Life in EORTC clinical trials — 30 years of progress from methodological developments to making a real impact on oncology practice. *European Journal of Cancer Supplements, 10*(1), 141-149.https://doi.org/10.1016/S1359-6349(12)70023-X

5. Sprangers, M. A. G., te Velde, A., Aaronson, N. K., & Quali, E. O. R. T. C. S. G. (1999). The construction and testing of the EORTC colorectal cancer-specific quality of life questionnaire module (QLQ-CR38). *European Journal of Cancer, 35*(2), 238-247. DOI: 10.1016/s0959-8049(98)00357-8.

6. Whistance, R. N., Conroy, T., Chie, W., Costantini, A., Sezer, O., Koller, M., et al. (2009). Clinical and psychometric validation of the EORTC QLQ-CR29 questionnaire module to assess health-related quality of life in patients with colorectal cancer. *European Journal of Cancer, 45*(17), 3017-3026. DOI: 10.1016/j.ejca.2009.08.014

7. Arraras, J. I., Suarez, J., Arias de la Vega, F., Vera, R., Asin, G., Arrazubi, V., et al. (2011). The EORTC Quality of Life questionnaire for patients with colorectal cancer: EORTC QLQ-CR29 validation study for Spanish patients. *Clin Transl Oncol, 13*(1), 50-56. DOI: 10.1007/s12094-011-0616-y

8. Calvo, Ó., Oliveros, R., & Sánchez, R. (2010). Adaptación cultural del formulario EORTC QLQ CR-29 para su aplicación en pacientes con cáncer de recto en el Instituto Nacional de Cancerología de Colombia. *Revista Colombiana de Cancerología, 14*(4), 189-198.https://doi.org/10.1016/S0123-9015(10)70082-2

9. Silva;, J. P. C. M. d. EORTC QLQ CR-29 evaluation in 500 patients with colorectal cancer. In *2012 Gastrointestinal Cancers Symposium, 2012 Journal of Clinical Oncology* 30, no. 4_suppl (February 01, 2012) 429-429. DOI: 10.1200/jco.2012.30.4_suppl.429

10. Peng, J., Shi, D., Goodman, K. A., Goldstein, D., Xiao, C., Guan, Z., et al. (2011). Early results of quality of life for curatively treated rectal cancers in Chinese patients with EORTC QLQ-CR29. *Radiat Oncol, 6*, 93, doi:10.1186/1748-717X-6-93.

11. Emad Hokkam MD, Sherif Farrag MD, and, S. E. K. M., & Msc, M. F. (2013). Assessment of quality of life of colorectal carcinoma patients after surgery.*World Journal of Colorectal Surgery, 3*(1).

12. Nowak, W., Tobiasz-Adamczyk, B., Brzyski, P., Salowka, J., Kulis, D., & Richter, P. (2011). Adaptation of quality of life module EORTC QLQ-CR29 for Polish patients with rectal cancer: initial assessment of validity and reliability. [Validation Studies]. *Pol Przegl Chir, 83*(9), 502-510. DOI:10.2478/v10035-011-0078-5

13. Magaji BA, Moy FM, Roslani AC, Law CW, Raduan F, Sagap I. Psychometric Validation of the Bahasa Malaysia Version of the EORTC QLQ-CR29. Asian Pac J Cancer Prev. 2015;16(18):8101-5. doi: 10.7314/apjcp.2015.16.18.8101.

14. Magaji, B. A., Law, C. W., Roslani, A. C., Moy, F. M., Blazeby, J. M., Sagap, I., et al. (2012). Health-related quality of life among colorectal cancer patients in Malaysia: A study protocol. *BMC Cancer*, 384.DOI: 10.1186/1471-2407-12-384

15. Magaji, Bello & Moy, Foong-Ming & Roslani, April & Law, Chee & Sagap, Ismail. (2016). Psychometric Validation of the Malaysian Chinese Version of the EORTC QLQ-C30 in Colorectal Cancer Patients. Asian Pacific journal of cancer prevention : APJCP. 16. 8107-8112. DOI: 10.7314/apjcp.2015.16.18.8107

16. Bello Arkilla Magaji, Foong Ming Moy, Chee Wei Law, Ismail Sagap, & April Camilla Roslani. (2020). Psychometric Validation of the Bahasa Malaysia version of the EORTC QLQ-C30 In Malaysian Colorectal Cancer Patients. *Malaysian Journal of Public Health Medicine*, *20*(3), 109-116. https://doi.org/10.37268/mjphm/vol.20/no.3/art.945

17. EORTC Quality of Life Department http://www.groups.eortc.be/qol.

