Observational Study

External validation of the Moroccan Arabic version of the European Organization for Research and Treatment of Cancer colorectal (CR29) module: Monocentric study

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Abstract

BACKGROUND
Quality of life (QoL) outcomes are a focal endpoint of cancer treatment strategies.

AIM
To externally validate the Moroccan Arabic version of the European Organization for Research and Treatment of Cancer (EORTC) QoL Questionnaire (QLQ) for colorectal cancer (CRC) patients (CR29).

METHODS
Both Moroccan Arabic modules of QLQ-CR29 and QLQ-C30 were administered to Moroccan CRC. Psychometric properties were retested by measuring Cronbach's alpha coefficient for reliability and Intraclass correlation coefficient (ICC) to examine test-retest reproducibility. The multitrait-scaling analysis was performed to demonstrate the validity of the instrument and known-groups comparison was used to test the score's ability to discriminate between different groups of patients.

RESULTS
In total, 221 patients were included in our study and 34 patients completed the questionnaire twice. The Urinary Frequency scale and Stool Frequency scale had good internal consistency with alpha Cronbach coefficients of 0.79 and 0.83 respectively, while the same coefficients were moderately lower for the Blood and Mucus in Stool scale (0.61) and the Body Image scale (0.67). The ICCs ranged from

0.88 to 1 indicating good to excellent reproducibility. In multitrait scaling analyses, the criterion for item convergent and divergent validity was satisfactory. The known-group comparison showed statistically significant differences between patients according to age, gender, stoma status, tumor location, and radiotherapy.

CONCLUSION
The Moroccan Arabic version of the EORTC QLQ-CR29 is a valid and reliable tool that can be used safely for research and clinical purposes in Moroccan CRC patients.

Key Words: Rectal neoplasm; Colorectal cancer; Health-related quality of life; Patient reported outcome measures; European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-CR29; European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-C30

Core Tip: Patient related outcomes such as quality of life (QoL) are a focal endpoint of cancer treatments strategies. Many QoL Questionnaire (QLQ) are not trully validated. We aim to externally validate the Moroccan Arabic version of the European Organization for Research and Treatment of Cancer QLQ CR29 on larger and more heterogenous population in order to affirm its validity and reliability in arabic colorectal cancer patients.

INTRODUCTION

Colorectal cancer (CRC) is a global challenge[1]. However, even with an increasing incidence, the implementation of screening programmes and the large array of advanced treatment modalities has significantly reduced mortality[2,3]. Nonetheless, CRC survivors suffer impaired physical and bowel functions, as well as psychological symptoms such as anxiety, sleep disruption, and depression[4]. All together, these symptoms negatively reflect on the quality of life (QoL)[5] and makes looking beyond oncological outcomes of great importance.

Health-related QoL (HRQL) is an abstract and multidimensional concept[6] which can be assessed by the European Organization for Research and Treatment of Cancer (EORTC) questionnaires. Core measurement tools examine issues common to different cancer sites and can be used as a stand-alone questionnaire or in combination with disease specific modules[7]. The EORTC QoL Questionnaire (QLQ) CR29 questionnaire specific to CRC and its psychometric properties have been tested in several languages and contexts[8-16].

Recently, The QLQ-CR29 has just been only translated for Moroccan Arabic dialect[17]. However this adaptation was performed on a very limited sample size of 120 patients under the usual requests of the EORTC organization. The aim of this study is to externally validate this version and assess its psychometric properties on larger Moroccan CRC patients.

MATERIALS AND METHODS

Description of the instruments
We followed the STROBE directive guidelines write the manuscripts[18]. The participants completed a general information section including sociodemographic and clinical data, alongside both the Moroccan Arabic module of EORTC QLQ-CR29[18], and the validated Moroccan Arabic version of the QLQ-C30 (version 3.0)[19].

The EORTC QLQ-C30
The EORTC QLQ-C30 includes five functional subscales (*i.e.*, physical functioning, role functioning, emotional functioning, cognitive functioning, and social functioning), three symptom subscales (*i.e.*, fatigue, nausea and vomiting, and pain), a global QoL subscale, and six single symptom items (*i.e.*, dyspnea, insomnia, appetite loss, constipation, diarrhea, and financial difficulties). The scoring of items is on a 1 to 7 and 1 to 4 Likert scales for the global health status/QoL and the other scales. High scores represent better functioning and worse symptoms[20,21].

The EORTC QLQ-CR29
The morocan arabic module of EORTC QLQ-CR29[17], is a colon and rectum site-specific QoL module with 29 items

consisting of 4 multi-item scales (body image, urinary frequency, blood and mucus in stool, and stool frequency) and 17 functional/symptomatic single-items (sexual interest, urinary incontinence, dysuria, abdominal pain, buttock pain, bloating, dry mouth, hair loss, taste, flatulence, fecal incontinence, sore skin, embarrassment, stoma care problem, impotence or dyspareunia). Among these items, only body image, anxiety, weight, and sexual interest are functional scales.

The eighteenth item (Q18) is an indicator of colostomy/ileostomy construction, while the following items are separately arranged for patients with a stoma (Q19-Q25) and without (Q19-Q25) according to symptoms of stool frequency, flatulence, fecal incontinence, sore skin and embarrassment while item 25 is specific for stoma care. Sexual interest, impotence and dyspareunia items are categorized according to gender with the corresponding questions being Q26-Q27 and Q28-Q29 for male and female respondents respectively. All questionnaire items ask about the past week except the ones on sexuality, which request the patients to evaluate the past four weeks. As regards the scoring, the multi-item scales and single items are scored using a 1 to 4 point Likert scale ("not at all", "a little", "quite a bit", "very much") with the highest score representing the best functional status or the worst symptom[22].

Study population and data collection

Patients were prospectively recruited from the national oncology institute during the period between November 2019 and January 2020[23,24]. Patients aged over 18 years old, with pathologically confirmed colon and/or rectum cancer and who underwent surgery at least 6 mo prior to the enrollment in the study were included. Patients were excluded if they were unable to understand the questionnaire, had cognitive and/or medical complications that hindered the interview completion and those who submitted an incomplete questionnaire. Participants were either approached during follow up visits or contacted *via* telephone. Patient's characteristics were reported according to age, gender, stoma status, cancer location (colon *vs* rectum), neoadjuvant radiochemotherapy and adjuvant chemotherapy.

As the sample size determination for psychometric validation studies lacks clear recommendations[25], we determined the required sample by allocating a number of observations 5 to 10 times greater than the variables[26]. Accordingly, the sample needed size ranged between 150 and 300 participants in order to externally validate this version.

Statistical analysis

The scores for the QLQ-CR29 and the QLQ-C30 questionnaires were linearly converted into 0 to 100 point scores according to the standard EORTC guidelines[20]. Descriptive statistics were generated through mean, median, standard deviation, and floor and ceiling effects, while age was categorized in 3 groups: < 40 years ; 41- 65 years and > 65 years.

In order to proceed to the external validation of the Moroccan Arabic module of de QLQ-CR29 we followed the identical steps of a first validation in a totally different population. There are two different levels of reliability, namely internal consistency and reproducibility. Internal consistency reliability was determined using Cronbach's alpha coefficient with a score greater than 0.7 considered acceptable, above 0.8 was good and higher than 0.9 was considered excellent.

A random subgroup of patients was selected to retake the QLQ CR-29 questionnaire after 7 to 14 d from the first interview in order to examine the test-retest reliability. The results of the two measurements were assessed using the Intraclass correlation coefficient (ICC) and an ICC score of 0.7 or higher was considered acceptable.

We tested the construct validity of the EORTC QLQ-CR29 using multitrait scaling analysis[27]. Convergent validity was examined by correlating each item with its own scale with an item-scale correlation of ≥ 0.40 equivalent to high correlation. Divergent validity on the other hand was tested by demonstrating that the item correlated higher with its own scale than with the others.

Concurrent validity was examined by comparing the scores of the QLQ-CR29 and the QLQ-C30 using Pearson's correlation.

Clinical validity was assessed using known group comparison through the Mann Whitney U test to examine the QLQ-CR29′ ability to differentiate clinically distinct patients. Subgroups were categorized according to: Age (< 65 years *vs* ≥ 65 years), gender (male *vs* female), stoma status (permanent *vs* no stoma), tumor site (colon *vs* rectal) and neoadjuvant radiotherapy (no *vs* yes). All statistical analyses were performed using SPSS 26.0 (SPSS Inc., Chicago,IL, United States). Statistically significant results were defined with a $P < 0.05$.

RESULTS

Patients characteristics

The sociodemographic and clinical characteristics of the patients enrolled in the study are detailed in Table 1. In total, 221 of 250 (88,4%) patients completed the questionnaire among which 123 were males and 98 were females. The mean age of our patients was 55.6 ±12.7years. Seventy-eight (35.9%) participants had colonic cancer and 138 (64.1%) had rectal cancer of wich 89 (64%) received neoadjuvant chemoradiotherapy, while 50 patients had a stoma (22,6%). Missing items were only associated with sexual problems with a miss rate of 9% for males and 23% for females.

Table 2 summarizes the distribution of the EORTC QLQ CR-29 and QLQ-C30 scores. The mean score for the different dimensions of the QLQ CR-29 ranged from 16.44 to 75.56 with the items "Hair loss" and "Weight" scoring the lowest and highest respectively. The percentage of respondents at floor was high (> 50%) in 12 areas while the percentage of respondents at ceiling was high (> 50%) in 1 item. The range of scores was broad in 21 dimensions except for the bag change it ranged from 0 to 83.

Table 1 Patients clinical and demographic characteristics

Variables	Description
Age, mean ± SD	55.65 ± 12.87
Sex	
Female	98 (44.5%)
Male	123 (55.5%)
Tumor location	
Colon	78 (35%)
Rectum	139 (62%)
Neoadjuvant chemoradiotherapy	
No	107 (54,6%)
Yes	89 (45,5%)
Definitive stoma	
No	50 (22.6%)
Yes	171 (77.4%)
Adjuvant chemotherapy[a]	
Yes	91 (70%)
No	39 (30%)

[a]Missing data in this variable.

Reliability

The internal consistency of the EORTC QLQ-CR29 reached the 0.7 criterion showing good consistency for the urinary frequency scale (0.79) and stool frequency scale (0.83), while for the blood and mucus (0.615) and the body image (0.672) scales the alpha Cronbach coefficient was slightly below the criterion (0.7). The Cronbach's alpha coefficient was higher for patients without stoma compared to those with stoma, except for the body image scale (0.64 with *vs* 0.69 without) which indicates higher reliability for patients without a stoma. More details are shown in Table 3.

Thirty four patients took the Arabic version of the QLQ-CR29 and for each item, the ICCs ranged from 0.889 to 0.999 indicating good to excellent reproducibility.

Construct validity

All items exceeded the 0.40 criterion for item-scale convergent validity. Similarly, items correlated better with their own scales than with others which shows good divergent validity. Details of the multitrait scaling analysis are shown in Table 3.

Concurrent validity

Correlations between the scales of the QLQ-CR29 and QLQ-C30 were low ($r < 0.40$). However, some areas with more related content showed higher correlations ($r > 0.40$), namely body image and social functioning. The abdominal pain scale also had a good correlation with the QLQ-C30 pain scale and stoma care problems were correlated to the global QoL scale. In addition, most functional scales of the QLQ-CR29 were positively correlated with functional scales of the QLQ-C30 and negatively correlated with symptom scales of the QLQ-C30, while most symptom scales of the QLQ-CR29 were positively correlated with symptom scales of the QLQ-C30 and negatively correlated with functional scales of the QLQ-C30 as detailed in Table 4.

Clinical validity

The EORTC QLQ-CR29 allowed the distinction between patients based on differences between known groups (Tables 5 and 6).

Differences in the scores of patients with stoma were noted as they presented significantly more anxiety and body image issues. Males with stoma reported higher symptom scores for the "impotence" scale.

The participants with rectal cancer had worse QoL than those with colon cancer and male patients with rectal cancer had significantly higher symptom scores for flatulence, fecal incontinence, sore skin around the anus, stool frequency, defecation problems, and sexual dysfunction.

In addition, patients who received neoadjuvant radiotherapy had significantly higher symptom scores and more problems related to blood and mucus, buttock pain, bloating, stoma care problems, flatulence, fecal incontinence, sore skin, stool frequency, embarrassment and defecation problems.

Table 2 Quality of life scores according to European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-C30 and Quality of Life Questionnaire-CR29 structure and reliability

Scaling/single-item name	*n*	Item No.	Mean	SD	Floor	Ceiling	Range	ICC
EORTC QLQ-CR29								
All patients	221							
Urinary frequency		31.32	39.89	33.46	26.2	10.9	0-100	0.961
Blood & mucus in stool		38.39	24.73	29.02	43.4	4.1	0-100	0.969
(F) Body image		45-47	77.82	24.83	1.8	38	0-100	0.950
Defecation/stoma problems		49–54	-	-	-	-	-	
Urinary incontinence		33	20.96	32.22	64.7	7.2	0-100	0.982
Dysuria		34	20.66	31.30	63.3	6.8	0-100	0.950
Abdominal pain		35	30.61	34.12	48	8.6	0-100	0.922
Buttock pain		36	27.14	34.62	55.7	9	0-100	0.921
Bloated feeling		37	28.80	33.77	50.2	8.6	0-100	0.945
Dry mouth		40	24.58	34.14	60.2	8.6	0-100	0.979
Hair loss		41	16.44	29.57	71.5	5.9	0-100	0.968
Trouble with taste		42	20.51	32.89	67.0	8.1	0-100	0.975
(F) Anxiety		43	64.67	37.60	16.7	43.4	0-100	0.951
(F) Weight		44	75.56	32.66	8.1	56.6	0-100	0.960
Patients with stoma	50							
Flatulence		49s	41.49	33.00	28.6	10.2	0-100	0.908
Leakage		50 s	42.17	36.49	32.7	16.3	0-100	0.889
Sore skin around stoma		51s	42.85	38.49	34.5	20.4	0-100	0.965
Bags change		52.53 s	18.36	22.62	49	2	0-83	0.969
Embarrassed		54s	45.56	43.09	41.8	29.1	0-100	0.956
Stoma care pb		55s	40.08	41.47	46.8	21.5	0-100	0.912
Stoma pb		49-54s	37.41	20.18	4.1	4.1	0-100	0.999
Patients without stoma	172							
Flatulence		49	30.62	37.01	52.9	12.8	0-100	0.980
Faecal incontinence		50	26.16	37.38	61.6	14.0	0-100	0.970
Sore skin around anus		51	20.34	31.72	64.5	7.6	0-100	0.979
Stool frequency		52.53	29.65	32.33	38.4	7.6	0-100	0.977
Embarrassment		54	31.20	38.51	54.7	15.1	0-100	0.975
Defecation pb		49-54	28.79	25.84	16.1	0.7	0-100	0.969
Male	123							
Sexual functioning		56	42.85	37.81	33	20.5	0-100	0.928
Impotence		57	38.18	38.79	40.9	20	0-100	0.966
Female	98							
Sexual functioning		58	67.06	36.76	11.9	48.8	0-100	0.933
Dyspareunia		59	26.58	35.75	58.3	10.7	0-100	0.985
C30	221							
Physical function		1 - 5	73.64	23.85	0.9	23.9	0-100	-
Role function		6.7	62.92	37.00	13.3	39.0	0-100	-

Emotional function	21-24	67.24	30.77	4.1	30.7	0-100	-
Cognitive function	20. 25	83.94	23.45	0.5	58.3	0-100	-
Social function	26 . 27	79.58	28.93	3.7	57.3	0-100	-
Fatigue	10.12.18	30.98	29.17	27.1	2.8	0-100	-
Nausea and vomiting	14.15	7.79	17.16	78.0	0.5	0-83	-
Pain	9.19	24.31	29.72	46.8	3.7	0-100	-
Dyspnoea	8	21.10	30.59	62.4	4.6	0-100	-
Insomnia	11	27.67	35.25	56.4	9.2	0-100	-
Appetite loss	13	20.48	30.99	63.3	6.4	0-100	-
Constipation	16	27.52	33.97	53.8	1.4	0-100	-
Diarrhea	17	27.67	34.67	53.2	10.6	0-100	-
Financial difficulties	28	51.22	40.61	30.7	30.7	0-100	-

EORTC: European Organization for Research and Treatment of Cancer; QLQ: Quality of Life Questionnaire.

Table 3 Convergent and discriminant validity of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-CR29

QLQ-CR29 scales	Total sample (*n* = 221)			Patients without stoma (*n* = 50)			Patients with stoma (*n* = 171)		
	Convergent	Discriminant	α	Convergent	Discriminant	α	Convergent	Discriminant	α
Urinary frequency	0.905-0.907	-0.00-0.25	0.795	0.83-0.84	-0.00-0.21	0.66	0.91-0.92	-0.12-0.25	0.82
Blood or mucus in stool	0.74-0.89	-0.27-0.35	0.615	0.62-0.96	-0.44-0.35	0.581	0.79-0.87	-0.20-0.30	0.65
Body image	-0.66-0.75	-0.00-0.36	0.672	-0.51-0.89	-0.20-0.39	0.690	-0.63-0.72	-0.07-0.19	0.64
Stool frequency	0.83-0.96	-0.30-0.39	0.835[1]	0.83-0.96	-0.31-0.39	0.804	-0.85-0.91	-0.14-0.34	0.87

[1]Mean of cronbach's alpha coefficient for patients without and with stoma.
Multitrait scaling analysis' summary of the results; ranges for convergent and discriminant validity of each multiitem scale and their internal consistency using cronbach's alpha. QLQ: Quality of Life Questionnaire.

Furthermore, the QLQ-CR29 showed differences between age groups with younger patients found to suffer more from defecation problems, stool frequency and embarrassment.

DISCUSSION

HRQL in CRC is an important component in both day to day practice and clinical research, therefore the proper assessment of patients' HRQOL is crucial[28]. This study showed that the Arabic version of the EORTC QLQ-CR29 questionnaire has good internal consistency, test-retest reliability and validity and is therefore valid and reliable to assess the QoL of Moroccan CRC patients.

The internal consistency of the Arabic EORTC QLQ CR-29 demonstrated satisfactory results for the urinary frequency scale and stool frequency scale, with higher reliability scores for patients without a stoma which is similar to the Chinese validation[14]. As regards the blood and mucus and the body image scales, the alpha Cronbach coefficients were acceptable which was the case in other similar studies[12,29]. On the other hand, as suggested by Arraras *et al*[12], some differences may be due to the fact that the EORTC original validation was conducted on an international sample with high variance, while the Spanish validation concerned a more homogenous sample which may impact the alpha Cronbach coefficient.

The ICCs of our study were all greater than 0.8, thus indicating good to excellent reproducibility for both single item and multi-item scales. The Reliability coefficients were higher in our study than those reported by the Dutch validation [10] and mostly similar to those in the original psychometric validation study[8]. As such, the Moroccan Arabic translation of the QLQ CR-29 is a stable instrument.

The multitrait analysis confirmed the structure of all scales, which proves that the Moroccan Arabic translation of the QLQ-CR29 has a valid construct.

Table 4 Correlation between the Quality of Life Questionnaire-CR29 and the Quality of Life Questionnaire-C30

CR-29	EORTC QLQ C30														
	Functional scales						Symptom scales								
Scales/Single items	QoL	PF	RF	EF	CF	SF	FA	NV	PA	DY	SL	AP	CO	DI	FI
Functional scales															
Body image	0.294[2]	0.279[2]	0.370[2]	0.214[2]	0.244[2]	0.403[2]	-0.298[2]	-0.256[2]	-0.161[1]	-0.250[2]	-0.151[1]	-0.278[2]	-0.221[2]	-0.003	-0.079
Anxiety	0.297[2]	0.314[2]	0.264[2]	0.315[2]	0.273[2]	0.285[2]	-0.294[2]	-0.160[1]	-0.210[2]	-0.169[1]	-0.138[1]	-0.117	-0.029	-0.008	-0.167[1]
Sexual function: Male	-0.121	-0.133	-0.058	-0.011	-0.034	-0.111	0.009	-0.010	0.084	0.089	0.124	0.109	0.049	0.049	0.018
Sexual function: Female	-0.299[2]	-0.192	-0.115	-0.079	-0.256[1]	0.040	0.082	-0.033	0.221[1]	-0.001	0.230[1]	0.040	0.017	0.112	0.033
Symptom scales															
Urinary frequency	-0.137[1]	-0.247[2]	-0.201[2]	-0.237[2]	-0.089	0.029	0.244[2]	0.070	0.218[2]	0.230[2]	0.176[2]	0.165[1]	0.042	0.221[2]	0.122
Blood and mucus in stool	-0.241[2]	-0.283[2]	-0.269[2]	-0.190[2]	-0.110	-0.123	0.359[2]	0.215[2]	0.349[2]	0.190[2]	0.277[2]	0.268[2]	0.152[1]	0.302[2]	0.256[2]
Urinary incontinence	-0.009	-0.128	-0.060	-0.237[2]	-0.152[1]	-0.050	0.102	0.014	0.108	0.150[1]	0.195[2]	0.030	0.135[1]	0.032	0.044
Dysuria	-0.017	-0.103	-0.161[1]	-0.069	-0.065	-0.047	0.153[1]	0.012	0.172[1]	0.058	0.133[1]	0.086	0.091	0.100	0.025
Abdominal pain	-0.138[1]	-0.161[1]	-0.099	-0.125	-0.099	-0.055	0.232[2]	0.143[1]	0.443[2]	0.140[1]	0.254[2]	0.122	0.168[1]	0.107	-0.039
Buttock pain	-0.212[2]	-0.265[2]	-0.270[2]	-0.103	-0.098	-0.074	0.363[2]	0.149[1]	0.469[2]	0.194[2]	0.253[2]	0.190[2]	0.025	0.149[1]	0.280[2]
Bloated feeling	-0.206[2]	-0.213[2]	-0.138[1]	-0.213[2]	-0.145[1]	-0.084	0.292[2]	0.171[1]	0.377[2]	0.256[2]	0.380[2]	0.058	0.253[2]	0.040	0.073
Dry mouth	-0.309[2]	-0.341[2]	-0.257[2]	-0.266[2]	-0.283[2]	-0.125	0.340[2]	0.390[2]	0.205[2]	0.202[2]	0.141[1]	0.329[2]	0.211[2]	0.145[1]	0.113
Hair loss	-0.036	-0.195[2]	-0.133[1]	-0.337[2]	-0.242[2]	-0.131	0.183[2]	0.217[2]	0.084	0.080	0.141[1]	0.182[2]	0.200[2]	0.135[1]	0.033
Trouble with taste	-0.099	-0.247[2]	-0.236[2]	-0.134[1]	-0.173[1]	-0.125	0.243[2]	0.343[2]	0.036	0.202[2]	0.010	0.271[2]	0.173[1]	0.101	0.072
Weight	0.176[2]	0.280[2]	0.291[2]	0.157[1]	0.121	0.179[2]	-0.238[2]	-0.128	-0.081	-0.060	-0.143[1]	-0.165[1]	-0.169[1]	-0.083	-0.017
Flatulences	0.124	-0.023	0.139	-0.126	-0.180	-0.260	0.077	0.056	-0.062	0.262	0.042	0.065	0.131	0.147	0.117
Leakage	0.083	0.142	0.046	-0.271	-0.128	-0.146	0.033	0.059	-0.023	0.114	-0.004	0.093	0.029	0.127	0.240
Sore skin around stoma	-0.041	-0.190	0.025	-0.600[2]	-0.402[2]	-0.330[1]	0.295[1]	0.261	0.297[1]	0.247	0.380[2]	0.073	0.172	0.002	0.133
Bags changes	-0.085	-0.169	0.002	-0.404[2]	-0.025	-0.273	0.228	-0.018	0.155	0.218	0.344[1]	0.192	-0.003	0.019	-0.098
Embarrassment	-0.407[2]	-0.312[2]	-0.394[2]	-0.272[1]	-0.150	-0.164	0.476[2]	0.155	0.419[2]	0.325[2]	0.353[2]	0.156	-0.079	0.030	0.361[2]
Stoma care problems	-0.502[2]	-0.391[2]	-0.458[2]	-0.277[1]	-0.182	-0.228[1]	0.529[2]	0.239[1]	0.587[2]	0.328[2]	0.468[2]	0.239[1]	0.093	-0.064	0.343[2]

Stoma problems	-0.077	-0.142	-0.009	-0.580[2]	-0.277	-0.364[1]	0.336[1]	0.108	0.181	0.264	0.301[1]	0.138	0.104	0.179	0.139
Flatulences	-0.160[1]	-0.151[1]	-0.034	-0.149	-0.137	-0.112	0.144	0.032	0.177[1]	0.269[2]	0.173[1]	-0.003	0.008	0.252[2]	0.200[2]
Faecal incontinence	-0.036	-0.081	-0.040	-0.142	-0.122	-0.117	0.153[1]	0.084	0.190[1]	0.141	0.111	-0.017	-0.140	0.403[2]	0.203[2]
Sore skin around anus	-0.081	-0.012	-0.045	-0.057	-0.047	-0.102	0.049	0.113	0.086	0.121	0.027	0.027	-0.006	0.149	0.195[1]
Stool frequency	0.002	-0.019	-0.024	-0.071	0.002	0.024	0.083	-0.044	0.259[2]	0.092	0.123	0.004	-0.035	0.452[2]	0.189[1]
Embarrassment	-0.101	-0.133	-0.135	-0.207[2]	-0.167[1]	-0.208[2]	0.178[1]	0.141	0.149	0.276[2]	0.152[1]	0.062	0.146	0.224[2]	0.203[2]
Defecation	-0.111	-0.116	-0.038	-0.202[1]	-0.159	-0.173[1]	0.190[1]	0.157	0.280[2]	0.316[2]	0.181[1]	0.040	0.106	0.379[2]	0.290[2]
Impotence	0.019	-0.065	-0.149	-0.104	-0.170	-0.218[1]	0.075	0.243[1]	-0.104	0.313[2]	0.065	0.308[2]	0.175	0.008	0.064
Dyspareunia	-0.083	-0.096	-0.118	-0.174	-0.243[1]	-0.345[2]	0.108	0.025	0.260[1]	0.163	0.162	0.156	0.045	0.157	0.236[1]

[1]$P < 0.05$.

[2]$P < 0.01$.

EORTC: European Organization for Research and Treatment of Cancer; QLQ: Quality of Life Questionnaire; QoL: Quality of life; PF: Physical functioning; RF: Role functioning; EF: Emotional functioning CF: Cognitive functioning; SF: Social functioning; FA: Fatigue; NV: Nausea/vomiting; PA: Pain; DY: Dyspnea; SL: Insomnia; AP: Appetite loss; CO: Constipation; DI: Diarrhea; FI: Financial problems.

In the assessment of concurrent validity, correlations between the scales of the QLQ-C30 and the QLQ CR-29 were mostly low (< 0.4) indicating that the two questionnaires measure different concepts. Few areas with related content had higher correlation scores which was expected given the similar concepts of these particular scales. Nonetheless, the results show that the two questionnaires are independent.

In terms of clinical validity, we found less significant differences related to stoma status than the original study[8]. Moreover, patients with colon cancer had a better function and fewer symptoms, including sexual interest in males and stool frequency as opposed to rectal cancer. Interestingly, patients with rectal cancer and a stoma experienced more embarrassment with borderline significance (P = 0.053). When comparing age groups, younger patients reported worse symptoms than older patients[30]. Similar results were reported by the Dutch and Spanish Validation studies[10,12]. In addition, the particularities of the Moroccan population may be contributing to elderly patients' display of better resilience, QoL satisfaction, relatively better acceptance and the aforementioned results. Consequently, the QLQ-CR29 was found to discriminate between age groups.

A higher missing data rate was registered for sexual dimensions compared to others as patients were more reticent about answering sex-related questions which makes their interpretation more difficult. Similar observations were made in the Chinese and Iranian studies, which hindered discussions regarding sexual activity and even ostomy[14,16]. Nonetheless, providing explanations to patients when answering the questionnaire was noted to help. In our context, this issue may be explained by the cultural and religious particularities of the Moroccan population where sexual practices are taboo[31]. More studies addressing this problem should be conducted to determine the reliability and validity of the CR-29 in evaluating the sexual aspects of QoL for patients according to cultural contexts.

This study has some limitations, one of which is the limited sample size of patients. However, the minimum sample size was set at one hundred and fifty patients according to EORTC organization and other EORTC QLQ-CR29 validations were performed on a smaller population such as El Alami's research[18]. Self-administration was not possible due to the high level of illiteracy in our context; consequently, patients received the help of one of the investigators who was in

Table 5 Known-group comparisons

CR-29 scales/single items	Stoma status			Colon *vs* Rectum			Neoadjuvant radiochemotherapy		
	Yes (*n* = 50)	No (*n* = 171)	*P* value	Colon (*n* = 78)	Rectum (*n* = 139)	*P* value	Yes (*n* = 89)	No (*n* = 107)	*P* value
Urinary frequency	35.6 (41.1)	41.1 (34.6)	0.412	35.4 (31.2)	42.2 (34.8)	0.215	45.5 (33.9)	35.0 (32.2)	0.031
Blood and mucus in stool	27.6 (28.8)	23.8 (29.1)	0.247	20.2 (26.8)	27.4 (30.2)	0.086	29.9 (30.3)	19.3 (27.1)	0.004
Body image	66.6 (27.5)	81.1 (23.0)	0.000	77.4 (24.8)	77.7 (25.0)	0.938	77.6 (24.1)	78.9 (24.5)	0.625
Urinary incontinence	24.0 (35.0)	20.0 (31.4)	0.451	18.3 (28.7)	21.5 (33.0)	0.788	20.2 (32.0)	21.4 (32.1)	0.592
Dysuria	21.3 (29.1)	20.4 (31.9)	0.469	18.8 (30.6)	22.3 (31.9)	0.120	23.2 (32.3)	18.3 (29.7)	0.299
Abdominal pain	28.0 (32.5)	31.3 (34.6)	0.590	28.6 (34.2)	32.1 (34.3)	0.440	34.4 (34.6)	26.7 (33.4)	0.095
Buttock pain	28.6 (33.6)	26.7 (34.9)	0.563	17.0 (30.26)	32.3 (36.1)	0.001	38.5 (36.2)	14.3 (27.5)	0.000
Bloated feeling	30.6 (33.5)	28.2 (33.9)	0.545	27.7 (32.4)	29.0 (34.2)	0.892	35.2 (35.6)	23.6 (31.7)	0.017
Dry mouth	30.0 (36.4)	23.0 (33.4)	0.183	20.5 (29.0)	26.6 (36.5)	0.477	30.7 (38.3)	19.0 (28.9)	0.055
Hair loss	17.3 (28.7)	16.1 (29.1)	0.608	10.6 (24.9)	19.4 (31.5)	0.027	18.7 (30.1)	14.6 (28.6)	0.222
Trouble with taste	27.3 (36.0)	18.5 (31.7)	0.069	13.2 (27.5)	24.4 (35.1)	0.016	20.5 (31.1)	17.7 (31.8)	0.375
Anxiety	52.6 (40.4)	67.8 (36.1)	0.016	63.2 (37.8)	65.4 (37.0)	0.658	65.9 (36.5)	63.5 (38.4)	0.725
Weight	69.3 (38.6)	77.3 (30.6)	0.305	79.4 (30.4)	73.8 (33.2)	0.194	75.6 (30.4)	76.3 (33.9)	0.492
Flatulence				45.8 (31.9)	39.3 (32.7)	0.601	35.0 (34.1)	45.6 (33.7)	0.361
Leakage				45.8 (31.9)	40.4 (38.8)	0.558	42.1 (39.8)	45.6 (31.8)	0.705
Sore skin around stoma				39.5 (32.7)	44.4 (41.3)	0.748	50.8 (43.5)	43.8 (33.4)	0.598
Bags changes				21.8 (27.0)	16.6 (20.4)	0.584	17.5 (19.6)	26.3 (27.3)	0.351
Embarrassment				64.5 (28.46)	40.7 (44.9)	0.056	56.3 (46.3)	36.9 (39.8)	0.055
Stoma care problems				37.5 (38.2)	40.7 (42.5)	0.804	54.0 (42.1)	23.4 (36.7)	0.003
Stoma problems				39.9 (17.1)	36.1 (21.6)	0.499	37.1 (23.4)	41.8 (16.4)	0.387
Flatulences				21.5 (33.6)	34.5 (37.3)	0.017	43.8 (39.1)	19.6 (31.8)	0.000
Faecal incontinence				16.12 (30.6)	31.4 (39.5)	0.009	35.7 (41.0)	17.0 (31.5)	0.001
Sore skin around anus				11.8 (24.2)	25.1 (34.6)	0.012	29.5 (36.1)	13.6 (26.0)	0.002
Stool frequency				19.3 (26.8)	35.8 (34.2)	0.002	37.6 (36.1)	21.5 (26.8)	0.008
Embarrassment				23.1 (35.4)	34.9 (39.1)	0.053	40.4 (39.2)	23.4 (35.7)	0.004
Defecation pb				18.8 (21.5)	36.5 (36.5)	0.000	37.8 (27.4)	19.5 (21.0)	0.000
(F) Sexual function: Male	54.1 (39.1)	39.7 (37.1)	0.162	32.4 (32.4)	48.1 (39.4)	0.047	46.3 (39.4)	36.0 (32.8)	0.211
Impotence	47.2 (39.2)	35.6 (38.5)	0.021	31.5 (34.6)	41.6 (40.6)	0.248	43.9 (39.2)	33.3 (36.8)	0.167
Sexual function: Female	56.8 (38.6)	69.6 (36.1)	0.064	65.4 (33.3)	66.6 (39.6)	0.770	69.4 (35.9)	70.0 (35.2)	0.928
Dyspareunia	33.3 (39.1)	24.8 (34.9)	0.156	20.23 (33.1)	29.4 (37.1)	0.240	26.8 (32.6)	23.3 (35.5)	0.459

charge of reading the questions and different options for the answer. Furthermore, although the use of confirmatory factor analysis may be an option, multitrait scaling analysis is the most frequently used method for the EORTC tools' transcultural validations[21]. Notwithstanding the foregoing, this study clearly validate the Moroccan Arabic validation of the EORTC QLQ-CR29 questionnaire which will allow the correct evaluation of HRQOL of CRC patients.

CONCLUSION

To summarize, the psychometric properties of the Moroccan Arabic version of the EORTC QLQ CR-29 show that it's a reliable and valid instrument to measure the QoL of CRC patients and could be used to complement the EORTC QLQ-C30 in assessing HRQOL. Conducting more transcultural validations and standardizing patient-reported outcome questionnaires, especially in the field of oncology, will allow us to broadly assess cancer therapy outcomes and weigh the benefits against the QoL impact.

Table 6 Known-group comparisons, *P* < 0.0001						
	Gender			**Age**		
CR-29 scales/single Items	Male (*n* = 123)	Female (*n* = 98)	*P* value	≤ 40 (*n* = 26)	41-65 (*n* = 144)	≥ 66 (*n* = 45)	*P* value
Urinary frequency	39.7 (33.1)	40.1 (34.1)	0.862	28.2 (30.4)	42.4 (33.3)	38.1 (34.1)	0.115
Blood and mucus in stool	24.6 (27.8)	24.8 (30.5)	0.794	25.6 (29.5)	26.7 (29.4)	19.2 (27.5)	0.183
Body image	77.4 (25.0)	78.3 (24.7)	0.777	74.3 (23.2)	76.6 (26.1)	80.7 (21.8)	0.481
Urinary incontinence	19.5 (31.9)	22.7 (32.6)	0.385	19.2 (28.5)	19.6 (32.3)	26.6 (33.0)	0.273
Dysuria	23.3 (32.2)	17.3 (29.9)	0.101	23.0 (36.2)	20.8 (31.5)	20.7 (29.5)	0.978
Abdominal pain	27.6 (33.5)	34.3 (34.6)	0.172	32.0 (34.6)	31.9 (35.2)	26.6 (29.8)	0.772
Buttock pain	28.1 (34.9)	25.8 (34.3)	0.478	32.0 (34.6)	27.7 (36.1)	22.2 (30.1)	0.500
Bloated feeling	27.3 (32.8)	30.6 (35.0)	0.495	26.9 (32.6)	31.9 (35.0)	22.9 (30.8)	0.293
Dry mouth	17.3 (28.7)	33.6 (38.1)	0.001	23.0 (33.6)	24.7 (33.8)	25.1 (36.3)	0.967
Hair loss	8.6 (21.7)	26.2 (34.9)	0.000	12.8 (28.4)	19.6 (32.3)	10.3 (19.8)	0.228
Trouble with taste	16.8 (31.4)	25.1 (34.2)	0.040	30.7 (38.7)	20.6 (33.4)	14.8 (27.1)	0.282
Anxiety	69.6 (34.9)	57.8 (39.9)	0.032	65.3 (38.2)	60.1 (38.2)	73.3 (34.5)	0.116
Weight	75.3 (33.3)	75.8 (32.0)	0.920	75.6 (30.6)	74.5 (33.6)	77.0 (31.6)	0.933
Flatulence	43.6 (32.2)	38.3 (34.6)	0.566	38.8 (32.7)	44.7 (33.2)	33.3 (36.5)	0.667
Leakage	47.1 (36.2)	35.0 (36.6)	0.241	61.1 (44.3)	41.9 (34.6)	27.7 (38.9)	0.299
Sore skin around stoma	44.8 (39.1)	40.0 (38.3)	0.650	66.6 (42.1)	42.8 (37.5)	33.3 (36.5)	0.287
Bags changes	20.1 (22.4)	15.8 (23.2)	0.427	22.2 (25.0)	20.9 (23.6)	5.5 (8.6)	0.328
Embarrassment	46.3 (42.4)	44.4 (44.6)	0.680	51.8 (50.3)	51.3 (41.8)	31.4 (40.3)	0.230
Stoma care problems	42.7 (43.1)	36.3 (39.4)	0.481	66.6 (50.0)	40.9 (40.2)	29.6 (37.7)	0.093
Stoma problems	39.8 (20.0)	33.8 (20.3)	0.336	48.1 (31.7)	38.8 (16.9)	23.1 (20.9)	0.183
Flatulences	29.0 (38.5)	32.4 (35.2)	0.452	36.6 (41.7)	33.6 (37.8)	20.5 (31.1)	0.142
Faecal incontinence	23.4 (35.8)	29.4 (39.1)	0.391	40.0 (44.0)	28.7 (38.3)	14.5 (28.4)	0.050
Sore skin around anus	17.3 (29.6)	23.9 (33.9)	0.300	26.6 (36.8)	21.7 (32.8)	12.8 (24.9)	0.266
Stool frequency	27.8 (30.2)	31.8 (34.7)	0.836	35.8 (34.7)	33.0 (33.7)	18.3 (25.0)	0.029
Embarrassment	27.3 (36.5)	35.8 (40.4)	0.179	41.6 (38.8)	36.0 (40.8)	14.5 (26.2)	0.005
Defecation pb	26.9 (25.3)	30.9 (26.4)	0.499	37.5 (33.0)	30.3 (25.5)	17.5 (19.0)	0.032
Sexual function: Male				33.3 (36.9)	42.7 (37.8)	45.8 (36.5)	0.575
Impotence				48.7 (44.3)	35.2 (38.5)	42.0 (35.1)	0.465
Sexual function: Female				57.5 (36.7)	63.5 (37.7)	82.3 (31.4)	0.109
Dyspareunia				33.3 (36.5)	27.6 (36.8)	9.8 (22.8)	0.098

ARTICLE HIGHLIGHTS

Research background

Health-related quality of life is an abstract and multidimensional concept which can be assessed by the European Organization for Research and Treatment of Cancer (EORTC) questionnaires. Core measurement tools examine issues common to different cancer sites and can be used as a stand-alone questionnaire or in combination with disease specific modules.

Research motivation

The EORTC Quality of Life Questionnaire (QLQ) CR29 questionnaire specific to colorectal cancer (CRC) and its psychometric properties have been tested in several languages and contexts. Recently, The QLQ-CR29 has just been only translated for Moroccan Arabic dialect. However this adaptation was performed on a very limited sample size of 120 patients under the usual requests of the EORTC organization.

Research objectives

The aim of this study is to externally validate this version and assess its psychometric properties on larger Moroccan CRC patients.

Research methods

In order to externally validate the QLQ CR-29, Both Moroccan Arabic modules of QLQ CR-29 and QLQ C-30 were administered to Moroccan colorectal cancer (CRC). Psychometric properties were retested by measuring Cronbach's alpha coefficient for reliability and Intraclass correlation coefficient (ICC) to examine test-retest reproducibility. The multitrait-scaling analysis was performed to demonstrate the validity of the instrument and known-groups comparison was used to test the score's ability to discriminate between different groups of patients. All statistical analyses were performed using SPSS 26.0 (SPSS Inc., Chicago,IL, USA). Statistically significant results were defined with a $P < 0.05$.

Research results

In total, 221 patients were included in the study and 34 patients completed the questionnaire twice. The urinary Frequency scale and Stool Frequency scale had good internal consistency with alpha Cronbach coefficients of 0.79 and 0.83 respectively, while the same coefficients were moderately lower for the Blood and Mucus in Stool scale (0.61) and the Body Image scale (0.67). The ICCs ranged from 0.88 to 1 indicating good to excellent reproducibility. In multitrait scaling analyses, the criterion for item convergent and divergent validity was satisfactory. The known-group comparison showed statistically significant differences between patients according to age, gender, stoma status, tumor location, and radiotherapy.

Research conclusions

The Moroccan Arabic version of the EORTC QLQ-CR29 is a valid and reliable tool that can be used safely for research and clinical purposes in Moroccan CRC patients.

Research perspectives

This tool can safely be used in research and clinical purpose and can be also used in the validation of other patient-reported outcome measure tools.

FOOTNOTES

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