

RESEARCH ARTICLE

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Cultural Adaptation and Validation of the Moroccan Version of the EORTC QLQ-CR29 in Patients with Colorectal Cancer

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Abstract

The increasing incidence of colorectal cancer in Morocco has generated a need for a disease-specific quality-of-life measuring instrument. The present study aims to translate and evaluate the reliability and validity of the Moroccan Arabic version of the EORTC QLQ-C29 measure in Moroccan subjects with colorectal cancer (CRC). **Methods:** Following translation to Moroccan Arabic, The QLQ-C30 and QLQ-C29 were administered to 135 patients treated for colorectal cancer (CRC) at the national oncology institute of Rabat, in the period from February 2016 to June 2018. Statistical analysis included reliability, convergent, and discriminant validity as well as known-groups comparisons. **Results:** (89 %) patients completed the questionnaires of the EORTC QLQ C-29 and EORTC QLQ C-30. The test-retest, administered to 25 patients and the ICCs for each item ranged from 0.61 to 0.93 indicating good to excellent reproducibility. The internal consistency coefficients for body image, urinary frequency, stool frequency scales were acceptable (Cronbach's alpha ≥ 0.70), while the blood and mucus in the stool dimensions had lower reliability (0.65). Multi-trait scaling analysis showed that multi-item scales met standards of convergent and discriminate validity. All Correlations between the EORTC QLQ C-29 and EORTC QLQ C-30 scores were low ($r < 40$). The known- group comparisons showed differences between group of patients based on tumor location and with/ without a stoma. **Conclusion:** The Moroccan Arabic Dialectal version of the QLQ-C 29 is a valid and reliable measure of health related quality of life (HRQOL) in patients with colorectal cancer.

Keywords: EORTC QLQ-C29- colorectal carcinoma- validation- Morocco

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Introduction

Colorectal cancer (CRC) is a major public health problem in Morocco, according to the Moroccan Cancer Registry, it represents the first gastrointestinal cancer and the third most common cancer 6.7 % of all cancers in Morocco and both the disease and its treatment strongly affect the quality of life (QOL) (CRC, 2016; El Alami et al., 2021; Mrabti et al., 2016).

Health-related quality of life has become an indispensable component of outcomes research, particularly for colorectal cancer (CRC) therapy. However, the wide application of quality-of-life of (CRC) investigations remains an obstruction for most clinicians in Morocco due to the limited validation studies performed up to now and the lack of translated specific measuring instruments.

The European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire core (QLQ-C30 and QLQ-C29) are frequently used in CRC (Aaronson et al., 1993; Whistance et al., 2009). The questionnaire has been translated and validated across many cultures and disease conditions and was found

to have adequate acceptable psychometric properties (El Alami et al., 2021).

The first Moroccan experience with the translation and cross-cultural adaptation of QLQ was with the EORTC C30 in 2014 (Nejjari et al., 2014). This QOL instrument does not address the specific morbidity related to CRC, which are symptoms (gastrointestinal, urinary, pain and others) and functional areas (sexuality, body image and others). Therefore, the need of a valid Moroccan Arabic version of a specific questionnaire is essential to assess CRC patients QOL, which could provide additional information on the functional health and well-being of those patients to provide them with optimal healthcare services.

The aim of our study is to translate The EORTC C-29 specific module to the Moroccan Arabic language, to examine the psychometric properties and assess the reliability and validity of this questionnaire in CRC patients in the National Oncology Institute of Rabat. This is the first psychometric validation of the EORTC QLQ-C29 in CRC patients in Morocco.

Materials and Methods

Patients` recruitment

Between February 2016 and June 2019, patients diagnosed with CRC were recruited from the National Institute of Oncology in Rabat, the capital city of Morocco. Patients receiving treatment in this center are from different region of country. All patients that participated in the questionnaire were adults of 18 years or older. They were newly diagnosed with a histologically proven CRC. The diagnosis had to be made in less than three months before inclusion. Patients who underwent a surgery for their cancer within 3 months before inclusion were also eligible to enter the study. Patients who received a specific treatment, chemotherapy or radiotherapy and those with major neuropsychological problems were excluded.

Instruments

EORTC QLQ-C30

The Moroccan Arabic version of the translated and validated EORTC QLQ-C30 was used to obtain relevant data (El Alami et al., 2021; Nejari et al., 2014). This questionnaire has five functional dimensions: physical functioning (PF), role functioning (RF), cognitive functioning (CF), emotional functioning (EF) and social functioning (SF). It also has three symptom scales: fatigue (FA), pain (PA), and nausea/vomiting (NV) and six single items addressing various symptoms, perceived financial impact and a global health-related quality of life (HRQOL) subscale.

EORTC QLQ-C29

The CR 29questionnaire was designed by EORTC to supplement the C-30 in assessing CRC patients. The QLQ-CR29 is a 29-items modules that evaluates symptoms (gastrointestinal, urinary, pain and others) and functional areas (sexual, body image and others) that are associated with CRC and its treatments. There are separate items for patients with and without a stoma (items 49 to 54, with item 55 only for patients with a stoma) and separate items to evaluate the sexual function of men and women. The questionnaires ask to evaluate all symptoms as experienced in the past week before filling the questionnaire except those pertaining to sexuality, which are requested to be evaluated in the four weeks' time frame.

The QLQ-CR29 has a Likert scale of four response categories (item 48 requires a yes or no answer) (Nowak et al., 2011; Arraras et al., 2011; Magaji et al., 2015). The scores for all questions are linearly converted to scale with a range from 0 to 100 for both the QLQ-C30 and QLQ-CR29 (Magaji et al., 2015; Lin et al., 2017).

Translation and cultural adaptation of the QLQ-CR29

The published guidelines were followed for the process of cross-cultural adaptation (Guillemin et al., 1993; Beaton et al., 2000). Two different translators independently translated the questionnaire from English into Moroccan Arabic, and a consensus version was obtained by discussion of translators under supervision of the main author. This Arabic version was back-translated into

English by two other translators totally blind to the original English version. (dialectal Darija). An expert committee of professionals composed of surgeons, oncologists, epidemiologists and four translators (forward and back translators) reviewed all translations and developed the prefinal version. A final Arabic version was generated after pre-testing the prefinal version on a group of 20 patients .

Participants were requested to complete the QLQ-C30 and QLQ-CR29 by themselves or with the help of an interviewer while waiting to see the doctor at the outpatient surgical clinic or immediately after the consultation. in case a patient required assistance in completing the questionnaire, instrumental help was provided by the interviewer. For the test-retest analysis, 25 patients were requested to complete and return another set of the questionnaire 1 to 2 weeks after the first assessment. According to the feedback, we finally developed the Moroccan Arabic version of the EORTC QLQ-CR29

Ethics

Approval for this study was obtained from the Ethics Committees of the Faculty of Medicine and Pharmacy, Mohamed V University and the National Institute of Oncology in Rabat, Morocco. Before the investigation, we asked patients to provide a signed informed consent, which confirmed their consent to participate in the study to protect their voluntary participation, right to know and right of privacy.

Statistical analysis

Descriptive analysis was performed; continuous data was summarized using mean or median 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 ≥ 0.70 is considered acceptable. Test-retest correlation coefficients were examined to test the reproducibility of the questionnaire. Multi-trait scaling analyses were used to examine the scale structures in terms of convergent and discriminant validity. A criterion considered is that each item 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 the item own correlation should be higher than compared to the other scales. Clinically distinct group validity was examined by comparing the scores of patients with and without stoma as well as the localization cancer colon and rectum using Mann Whitney u-test. All analyses were performed using SPSS version 20. A two-tailed probability value of 0.05 was used to determine the level of significance.

Results

Results of Patients' characteristics and compliance

In general 135 patients with colorectal cancer were included in the study. The mean age at diagnosis was 52 years (SD 11.5) (range: 25 – 86). The male – female sex ratio was 1.31. There were colon cancers 62 (46 %), 73 rectal cancers (54 %) and 38 of patients with a stoma

Table 1. Quality of Life Scores According to the EORTC QLQ-CR29, Structure, Internal Consistency and Test-Retest Reliability

Scaling/single- item name	Item no.	Total(n)	Mean	SD	Range	Cronbach's α	Test-retest (n)	ICCs
CR29 scales								
Urinary frequency	31-32	120	43.1	33.9	0-100	0.71	25	0.63
Blood and mucus in stool	38-39	120	17	15.9	0-100	0.59	25	0.87
Body image	45-47	120	73.7	27.1	0-100	0.72	25	0.93
Stool frequency	52-53	120	31.8	33.2	0-100	0.76	25	0.89
CR29 single items								
Urinary incontinence	33	120	20.8	30.8	0-100		25	0.61
Dysuria	34	120	25.5	34.4	0-100		25	0.77
Abdominal pain	35	120	36.1	34.9	0-100		25	0.85
Buttock pain	36	120	39.1	37.8	0-100		25	0.83
Bloating	37	120	36.6	34.9	0-100		25	0.81
Dry mouth	40	120	29.7	36.8	0-100		25	0.78
Hair loss	41	120	12.5	25.9	0-100		25	0.74
Taste	42	120	20.5	33.8	0-100		25	0.79
Anxiety	43	120	67.7	33.1	0-100		25	0.71
Weight	44	120	73.0	31.5	0-100		25	0.84
Flatulence	49	120	34.4	35.3	0-100		25	0.68
Fecal incontinence	50	120	30.0	38	0-100		25	0.89
Sore skin	51	120	25.0	34.9	0-100		25	0.86
Embarrassment	54	120	43.3	39.7	0-100		25	0.82
Sexual interest (men)	56	69	42.9	39.2	0-100		25	0.65
Impotence	57	68	35.2	36.8	0-100		25	0.67
Sexual interest (women)	58	50	67.3	37.1	0-100		15	0.61
Dyspareunia	59	36	24.0	37	0-100		9	.

Results were considered unchanged with an ICC >0.6. Cronbach α coefficient of ≥ 0.7 being considered acceptable for group comparisons. SD, standard deviation; ICC, intraclass correlation coefficient.

(28 %).

The majority of patients (57%) were married and came from urban areas (69 %). About (47%) had a low socio-economic status and (40%) of patients had no formal education. Only (15 %) of patients had a high level of education and (39 %) had medical insurance.

Acceptability of questionnaires and preferences

A total of 120 patients (89 %) which completed the questionnaires and 15 patients (11 %) refused or were not interested in participating in studies.

The total time for completion of both the EORTC QLQ- C30 and QLQ- CR29 was less than 30 minutes. (58.5%) of patients could not respond the questionnaires without an interview and required assistance. Patients consider the time of administration (immediately after

the consultation with the doctors) to be inappropriate. The lowest response rates were associated with sexual items in the EORTC QLQ-CR29 (items 56, 57, 58 and 59). The questionnaire completion rate was higher than 91%, which shows that over 89 % of the items were answered.

Reproducibility

In 25 patients, the QLQ- CR29 was administered twice to assess test-retest study. Seventy patients returned the repeat -test questionnaire within a period of two weeks. The ICCs for each item ranged from 0.61 to 0.93 indicating good to excellent reproducibility (Table 1).

Reliability

Cronbach's alpha coefficients for each scale are shown in (Table 2). The internal consistencies were computed for

Table 2. EORTC QLQ-C29 Scores (Functional Scales)

QLQ-CR29 Scales	Without a stoma n= 82			With a stoma n=38		
	Convergent	Divergent	α	Convergent	Divergent	α
Urinary frequency	0.93-0.94	0.03-0.31	0,70	0.88-0.90	0.10-0.53	0,65
Blood and mucus in stools	0.80-0.84	0.14-0.58	0,61	0.83-0.89	0.26-0.54	0,63
Stool frequency	0.92-0.93	0.11-0.50	0,69	0.90-0.97	0.03-0.51	0,62
Body image	0.76-0.84	0.01-0.21	0,77	0.70-0.84	0.01-0.46	0,80

Table 3. Tem Convergent and Divergent Validity for the EORTC QLQ-CR29 Scales, and for Patients with and without a Stoma

QLQ-CR29 Scales	Total sample n=120			Without a stoma n= 82			With a stoma n=38		
	Convergent	Divergent	α	Convergent	Divergent	α	Convergent	Divergent	α
Urinary frequency	0.92-0.93	0.02-0.37	0.71	0.93-0.94	0.03-0.31	0,73	0.88-0.90	0.10-0.53	0,64
Blood and mucus in stools	0.81-0.85	0.20-0.58	0.59	0.80-0.84	0.14-0.58	0,61	0.83-0.89	0.26-0.54	0,63
Stool frequency	0.92-0.94	0.01-0.48	0.66	0.92-0.93	0.11-0.50	0,69	0.90-0.97	0.03-0.51	0,62
Body image	0.79-0.82	0.06-0.25	0.72	0.76-0.84	0.01-0.21	0,69	0.70-0.84	0.01-0.46	0,80

all the patients, and separately for patients with and without stoma. Overall, the internal consistency coefficients for body image, urinary frequency, stool frequency scales were acceptable (Cronbach's alpha ≥ 0.70), while the blood and mucus in the stool dimensions had lower, but still moderate reliability (0.65).

Except for the Body image dimension (0.71 without a stoma vs 0.80 with a stoma), the reliability of other dimensions in patients without stoma was higher than that in patients with a stoma.

Validity Multi-trait scaling analyses

The scale structure of the functioning scale (body image) and three multi-item symptoms scales (urinary

frequency, blood and mucus and stool frequency) were confirmed. Analysis was performed in all patients, patients with and without stoma. The results indicated that both the convergent validity (correlation between items and its own scale ($r \geq 0.40$)) and discriminant validities (item's own scale correlation higher than items correlation with other scales) were achieved in all level of analysis and for both patients with and without stoma (Table 3).

Correlations between the EORTC QLQ-CR29 and the QLQ-C30

Correlations between the scales of the QLQ-CR29 and QLQ- C30 were low ($r < 0.40$) in all cases. Most functional scales of the QLQ-CR29 were positively correlated

Table 4. Scales Correlations between the EORTC QLQ-CR29 and the QLQ-C30

QLQ- CR 29	QLQ-C30 Scales								
	Functional scales					Symptom scales			
	QL	PF	RF	EF	CF	SF	FA	NV	PA
Functional scales									
Body image	0.199*	0.209*	0.365**	0.163	0.193*	0.438**	-0.199*	-0.261**	-0.103
Anxiety	0.184*	0.168	0.141	0.053	0.163	0.161	-0.205*	-0.093	-0.184*
Sexual function men	0.202	0.130	0.015	0.056	0.083	-0.001	-0.070	-0.141	0.035
Sexual function women	0.316*	0.382**	0.163	0.003	0.389**	-0.081	0.050	-0.081	0.078
Symptom scales									
Urinary frequency	-0.040	-0.308**	-0.142	-0.312**	-0.245**	0.104	0.374**	0.123	0.265**
Blood and mucus in stool	-0.096	-0.201*	-0.110	-0.354**	-0.054	-0.076	0.354**	0.163	0.380**
Stool frequency	-0.004	-0.060	-0.098	0.261**	0.004	0.054	-0.099	0.032	-0.288**
Urinary incontinence	-0.021	-0.190*	-0.031	-0.281**	-0.205*	-0.008	0.190*	0.088	0.264**
Dysuria	-0.023	-0.134	-0.146	-0.231*	-0.193*	-0.077	0.253**	0.005	0.267**
Abdominal pain	-0.100	-0.122	0.011	-0.244**	-0.127	-0.084	0.228*	0.013	0.488**
Buttock pain	-0.015	-0.197*	-0.069	-0.297**	-0.153	-0.025	0.359**	0.027	0.474**
Bloated feeling	-0.052	-0.141	0.036	-0.212*	-0.079	-0.034	0.204*	0.122	0.295**
Dry mouth	-0.129	-0.257**	-0.199*	-0.396**	-0.254**	-0.097	0.346**	0.344**	0.169
Hair loss	0.043	-0.158	-0.142	-0.389**	-0.183*	-0.134	0.325**	0.396**	0.185*
Buttock pain	0.038	-0.188*	-0.244**	-0.112	-0.118	-0.168	0.214*	0.318**	0.015
Weight	0.171	0.397**	0.334**	0.086	0.128	0.106	-0.306**	-0.170	-0.196*
Flatulence	0.299	0.246	0.146	-0.245	-0.177	-0.064	0.122	0.241	0.005
Fecal incontinence	-0.051	-0.128	-0.063	-0.238**	-0.310**	-0.286**	0.175	0.173	0.231*
Sore skin	0.011	-0.219*	-0.160	-0.274**	-0.264**	-0.323**	0.304**	0.251**	0.227*
Embarrassment	0.065	-0.112	0.083	-0.200*	-0.268**	-0.226*	0.181*	-0.030	0.202*
Stoma care problems	-0.174	-0.316	-0.350	-0.359	-0.344	-0.333	0.304	0.299	0.276
Impotence	0.112	-0.035	-0.255*	-0.016	-0.010	-0.064	0.052	0.265*	-0.008
Dyspareunia	0.177	0.066	0.093	-0.044	-0.066	-0.037	0.072	-0.022	0.295

Table 5. Known-Group Comparisons Using the EORTC QLQ-CR29

	With a stoma		Without a stoma		P- value	Colon		Rectum		P- value
	Mean	(SD)	Mean	(SD)		Mean	(SD)	Mean	(SD)	
Functional scales										
Body image	61.3	27.6	77.7	25.8	0.004	71.9	27.1	74.6	27.2	0.610
Anxiety	63.2	34.8	69.2	32.6	0.398	68.4	30.9	67.4	34.3	0.886
Weight	67.8	35.0	74.7	30.3	0.306	75.4	30.6	71.9	32.0	0.575
Sexual function (men)	53.3	39.4	40.1	39.0	0.252	37.8	33.0	45.3	41.9	0.463
Sexual function (women)	52.3	38.5	73.1	35.4	0.076	72.9	32.7	64.7	39.3	0.472
Symptom scales										
Urinary frequency	32.1	28.4	46.7	34.9	0.045	33.3	33.7	47.7	33.3	0.030
Blood and mucus in stool	28.1	31.5	35.5	30.4	0.263	30.7	29.3	35.1	31.4	0.462
Stool frequency	21.8	31.2	20.5	30.9	0.841	36.8	36.9	35.7	34.2	0.877
Urinary incontinence	22.9	32.2	26.3	35.3	0.647	23.6	36.2	46.3	36.5	0.002
Dysuria	34.4	33.9	36.6	35.5	0.775	38.5	35.1	35.7	35.0	0.682
Abdominal pain	35.6	35.5	40.2	38.6	0.566	20.1	30.5	34.1	38.8	0.053
Buttock pain	33.3	34.5	37.7	35.2	0.558	5.2	16.4	15.8	28.7	0.037
Bloated feeling	29.8	37.1	29.6	37.0	0.978	12.2	28.3	24.3	35.5	0.068
Dry mouth	11.4	22.3	12.8	27.1	0.812	33.3	37.1	47.9	40.2	0.060
Hair loss	32.1	37.2	16.8	31.9	0.033	17.5	31.7	28.4	35.9	0.112
Trouble with taste	65.5	36.1	36.2	38.3	0.001	21.0	29.4	40.6	36.2	0.004
Flatulence	31.0	35.5	23.0	34.6	0.287	16.6	29.7	36.1	39.9	0.008
Fecal incontinence	36.7	28.6	33.6	37.3	0.684	61.1	32.7	76.1	26.1	0.249
Sore skin	36.7	37.1	27.8	38.2	0.272	25.7	30.7	39.8	38.8	0.141
Embarrassment	71.7	27.7	100.	0	0.329	15.3	32.2	28.9	39.3	0.297
Stoma care problems	46.6	37.3	32.0	36.3	0.177	72.9	32.7	64.7	39.3	0.472
Impotence	30.3	21.3	40.7	35.8	0.511	36.8	36.9	35.7	34.2	0.877
Dyspareunia	30.5	19.2	27.2	25.8	0.566	33.5	30.5	26.2	23.7	0.654

with functional scales of the QLQ-C30 and negatively correlated with symptom scales of the QLQ-C30. In addition, most symptom scales of the QLQ-CR29 were positively correlated with symptom scales of the QLQ-C30 and negatively correlated with function scales of the QLQ-C30 (Table 4).

Known-group validity

Patients with rectal cancer had a worse QOL as compared with patients with colon cancer in symptom areas and reported significantly higher symptoms of urinary frequency ($p = 0.030$), urinary incontinence ($p = 0.002$), troubles with taste ($p < 0.004$) buttock pain ($p < 0.037$) and flatulence ($p = 0.008$).

On the other hand, Patients with stoma had lower functioning scores related to body image ($p = 0.004$) and sexual functionality in women ($p = 0.036$) and higher symptom scores related to hair lost ($p = 0.033$), troubles with taste ($p = 0.001$), embarrassment due to the frequent need to change the stoma bag ($p = 0.004$) and Sore skin ($p = 0.010$) compared to patients without a stoma (Table 5).

Discussion

In this paper, we report the result of a cross-cultural adaptation and evaluation of the psychometric properties

of the Moroccan Arabic version of the EORTC QLQ-C29. The EORTC C-29 specific module was one of the first developed to be used in conjunction with the core questionnaire C30. To date, the EORTC QLQ-CR29 has been translated into many languages and is used worldwide as one of the standard instruments in measuring the quality of life in patients with colorectal cancer (Kulis et al., 2016). Translations into Danish, Dutch, French, German, Greek, Hungarian, Italian, Japanese, Korean, Norwegian, Portuguese, Brazilian, Russian, Spanish, Malaysian and Turkish are now available (Magaji et al., 2019; Calderon et al., 2021).

The process of translation and cross-cultural adaptation was carefully conducted following the published criteria (Beaton et al., 2000; Kulis et al., 2016) and resulted in a back-translated version that was very similar to the original validation study (Whistance et al., 2009).

The average time required to complete the questionnaire was similar to that reported in earlier studies regarding similar questionnaires (Wickramasinghe et al., 2020).

Of the 135 participants interviewed, only 48 % were able to answer the questionnaires without an interviewer. Patients consider the time of administration (immediately after the consultation with the doctors) to be inappropriate. The lowest response rates were associated with sexual function, only 25% were able to answer question number

“56,57,58,59” of the EORTC QLQ C-29, these low score might be due to the fact that Moroccan are more reticent and talking about sexuality is a taboo thing in conservative and traditional societies like Morocco, which is different from Western culture.

In similar studies, we observed that our score for sexual function were higher than Corian patients (Ihn et al., 2015) and lower than those obtained in the original validation study and that of the Spanish version (Whistance et al., 2009; Nejari et al., 2014). This may possibly be explained by the difference in socioeconomic as well as psychosocial and cultural composition of the Moroccan population

The reproducibility of the questionnaires was studied among 25 patients in 1 to 2 weeks after the first assessment, good test-retest correlation was observed in all scale. The ICCs for each item ranged from 0.61 to 0.93 indicating good to excellent reproducibility (Calderon et al., 2021) the reliabilities of the items in the original study (ICCs > 0.55) were lower than ours. The other studies did not report test-retest reliability (Stiggelbout et al., 2016).

In the evaluation of constructive validity, this study shows that the internal consistency coefficients of the Moroccan version were greater than the acceptable level in most of the scales examined ($\alpha > 0.70$). However, the symptom blood and mucus in stool scale ($\alpha=0.65$). failed to meet the minimum requirement for adequate internal consistency ($\alpha \leq 0.70$).

Our findings largely replicate the finding of the original study and other publications involving the EORTC QLQ-C29 in many countries and language (Magaji et al., 2015; Stiggelbout et al., 2016).

The poor internal consistency coefficient in the gastrointestinal symptom scales was similar to several other validation studies involving the EORTC QLQ-C29 (Whistance et al., 2009; 8. Arraras et al., 2011; Peng et al., 2011). Our finding and those of the previous studies might be an indicator of the need to develop the scale examining the presence of blood and mucus in the stool, and the utility of the stool frequency scale in patients with a stoma bag.

The multi-trait scaling analyses of the Moroccan Arabic version of the QLQ-C29 was conducted to examine item convergent and discriminant validity and showed that all item-scale correlations were above 0.40. In terms of concurrent validity, most correlations between the QLQ-CR29 and QLQ-C30 were <0.4 demonstrating that the scales in the new module did not overlap unduly with HRQL constructs in the QLQ-C30 as shown original study (Whistance et al., 2009). These results indicate the independence of the QLQ-CR29 and QLQ-C30 questionnaires.

The ability of the scales/items in the Moroccan Arabic language version of the QLQ-C29 to differentiate between two clinically distinct patients groups was examined based on localization of cancer and by the presence or absence of stoma.

The stoma patients group showed lower functioning scores related to body image, sexual functionality in women and higher symptom scores related to hair lost, troubles with taste, embarrassment due to the frequent

need to change the stoma bag and Sore skin, which has a bad impact on their quality of life. Our findings are consistent with previous studies indicating that creation of a stoma negatively affects specific aspects of colorectal cancer patients' health related quality of life (Magaji et al., 2015; Pachler et al., 2012; El Alami et al., 2021).

Distinct group comparison shows a significant difference for the sexual function scale, with female patients with stoma reporting lower sexual function scores. This is due to female patients experiencing rejection or fear of rejection by their sexual partners. This is consistent with the study in which 80% of patients reported that the reason for their inactive sexual life was their spouse's abdominal colostomy, which they found repulsive (Calderon et al., 2021; Souadka et al., 2015; Cakmak et al., 2010). However, it must be noted that measurement of the sexual function scale was imperfect, as many patients refused to respond to this part of the questionnaire due to the cultural stigma and shame attached to sexuality in Moroccan society. Furthermore, this difference should be nuanced in light of the fact that most Moroccan men and women become sexually active only after marriage.

In the comparison between the localization of cancer, we found that patients with rectal cancer had a worse QOL as compared with patients with colon cancer in symptom areas and reported significantly higher symptoms of urinary frequency and incontinence, troubles with taste, buttock pain and flatulence. This finding might be due to multi-factorial causes related to differences in the treatment modalities between colon and rectal cancer (Pachler et al., 2012).

There are some limitations to our study. Due to the high level of illiteracy, (48 %) of patients could not respond the questionnaires without interviewer. Despite the fact that illiteracy rates are declining in Morocco, the questionnaire could not be used as an auto-administered questionnaire except for a minority of Moroccan population. The Moroccan Arabic language is commonly spoken across all the country but there are other national language such as «Tamazight, Tarifit and Tachilhit. Nevertheless, the majority of people speak the Moroccan Arabic besides their local languages (Hoopman et al., 2006; Nejari et al., 2014). Sexual functions and symptoms are the most difficult scales from which to draw conclusions, as many patients are reluctant to complete the questions or give the truth to doctors. We would recommend also that additional studies be carried out to determine if the EORTC QLQ C-29 is valid tool for evaluating sexual dysfunction in CRC patients (Sanna et al., 2017).

In general, the findings of this study was the first of its kind and we have developed a semantically equivalent translation with cultural adaptation of EORTC QLQ-C29 questionnaire. The Moroccan version of the EORTC QLQ C-29 is a reliable and valid outcome measure that can be used in Moroccan subjects with CRC and can be used in clinical trials and studies of outcome research in oncology.

Author Contribution Statement

Yacir el alami: Designed the study, reviewed the paper, collected data, analyzed data, and edited the final

version. Said benamr: Designed the study, reviewed the paper, collected data, analyzed data, and edited the final version. Hadj Omar Malki: Designed the study, reviewed the paper, collected data, analyzed data, and edited the final version. Hafid Hachi : Designed the study, reviewed the paper, collected data, analyzed data, and edited the final version. All authors read and approved the final version.

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References

- Aaronson NK, Ahmedzai S, Bergman B (1993). The European Organisation for Research and treatment of Cancer QLQ-C30: a quality of life instrument for use in international clinical trials in oncology. *J Nat Cancer inst*, **85**, 364–76.
- Arraras JI, Suárez J, Arias de la Vega F, et al (2011). The EORTC Quality of Life questionnaire for patients with colorectal cancer: EORTC QLQCR29 validation study for Spanish patients. *Clin Transl Oncol*, **13**, 50-6.
- Beaton D, Bombardier C, Guillemin F, et al (2000). Guidelines for the process of cross-cultural adaptation of self-report measures. *SPINE*, **25**, 3186–91.
- Cakmak A, Aylaz G, Kuzu MA (2010). Permanent stoma not only affects patients' quality of life but also that of their spouses. *World J Surg*, **34**, 2872–6.
- Calderon C, Ferrando PJ, Lorenzo-Seva U, et al (2021). Psychometric properties of the Spanish version of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ- C30). *Qual Life Res*. Dec 20.
- Cancer Registry of Grand Casablanca region Morocco. (2016) Edition.
- El Alami Y, Essangri H, Majbar MA, et al (2021). Psychometric validation of the Moroccan version of the EORTC QLQ-C30 in colorectal Cancer patients: cross-sectional study and systematic literature review. *BMC Cancer*, **21**, 99.
- El Alami Y, Malki H, Benamr S (2021). Quality of life assessment in patients with a stoma due to rectal cancer in Morocco. *J Clin Images Med Case Rep*, **2**, 1483.
- Guillemin F, Bombardier C, Beaton D (1993). Cross-cultural adaptation of health-related quality of life measures: literature review and proposed guidelines. *J Clin Epidemiol*, **46**, 1417–32.
- Hoopman R, Muller MJ, Terwee CB, Aaronson NK (2006). Translation and validation of the EORTC QLQ-C30 for use among Turkish and Moroccan ethnic minority cancer patients in the Netherlands. *Eur J Cancer*, **42**, 1839-47.
- Ihn MH, Lee SM, Son IT, et al (2015). Cultural adaptation and validation of the Korean version of the EORTC QLQ-CR29 in patients with colorectal cancer. *Support Care Cancer*, **23**, 3493-501.
- Kulis D, Bottomley A, Holzner B, et al (2016). Development of a Guidance on the Implementation and use of EORTC Instruments in Electronic Applications. *Value Health*, **19**, A391.
- Lin JB, Zhang L, Wu DW, et al (2017). Validation of the chinese version of the EORTC QLQ-CR29 in patients with colorectal cancer. *World J Gastroenterol*, **23**, 1891-8.
- Magaji BA, Moy FM, Roslani AC, et al (2015). Psychometric validation of the Bahasa Malaysia version of the EORTC QLQ-CR29. *Asian Pac J Cancer Prev*, **16**, 8101–5.
- Magaji B, Moy F, Law C, Sii H, Roslani A (2019). Pattern of Health-related quality of life and its association among patients with colorectal cancer. *Asian Pac J Cancer Care*, **4**, 45-52.
- Mrabti H, Amziren M , ElGhissassi I, et al (2016). Quality of life of early stage colorectal cancer patients in Morocco. *BMC Gastroenterol*, **16**, 131.
- Nejjari C, El Fakir S, Bendahhou K, et al (2014). Translation and validation of European organization for research and treatment of cancer quality of life questionnaire -C30 into Moroccan version for cancer patients in Morocco. *BMC Res Notes*, **7**, 228.
- Nowak W, Tobiasz-Adamczyk B, Brzyski P, et al (2011). Adaptation of quality of life module EORTC QLQCR29 for Polish patients with rectal cancer: initial assessment of validity and reliability. *Pol Przegl Chir*, **83**, 502-10.
- Pachler J, Wille-Jorgensen P (2012). (Quality of life after rectal resection for cancer. with or without permanent colostomy. *Cochrane Database Syst Rev*, **12**, 4323.
- Peng J, Shi D, Goodman KA, 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.
- Sanna B, Bereza K, Paradowska D (2017). A large-scale prospective clinical and psychometric validation of the EORTC colorectal (QLQ-CR29) module in Polish patients with colorectal cancer. *Eur J Cancer Care*, **2017**, e12713
- Souadka A, Majbar MA, El Harroudi T, Benkabbou A, Souadka A (2015). Perineal pseudocontinent colostomy is safe and efficient technique for perineal reconstruction after abdominoperineal resection for rectal adenocarcinoma *BMC Surg*. **15**, 40.
- Stiggelbout AM, Kunneman M, Baas-Thijssen MC, et al (2016). The EORTC QLQ-CR29 quality of life questionnaire for colorectal cancer: validation of the Dutch version. *Qual Life Res*, **25**, 1853-8.
- Whistance RN, Conroy T, Chie W, et al (2009). European organisation for the research and treatment of Cancer quality of life group: Clinical and psychometric validation of the EORTC QLQ-CR29 questionnaire module to assess health-related quality of life in patients with colorectal cancer. *Eur J Cancer*, **45**, 3017–26.
- Wickramasinghe DP, Dayasena P, Seneviratne S, Samarasekera DN (2020). Translation and Validation of the Sinhala Version of the EORTC-QLQ-CR29 Questionnaire. *Asian Pac J Cancer Prev*, **21**, 31-6.



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