Validation of the Arabic version of the EORTC Colorectal (CR29) module in Moroccan colorectal cancer patients

Yacir El Alami

Mohammed V University of Rabat - Souissi: Universite Mohammed V de Rabat - Souissi

Houda Bachri

Mohammed V University of Rabat: Universite Mohammed V de Rabat

Hajar Essangri

Université Mohammed V de Rabat: Universite Mohammed V de Rabat

Said Benamer

Mohammed V University of Rabat: Universite Mohammed V de Rabat

Amine Benkabbou

Mohammed V University of Rabat: Universite Mohammed V de Rabat

Raouf Mohsine

Mohammed V University of Rabat: Universite Mohammed V de Rabat

Mohammed Anass Majbar

Mohammed V University of Rabat: Universite Mohammed V de Rabat

Amine Souadka (✉ a.souadka@um5s.net.ma)

Université Mohammed V de Rabat <https://orcid.org/0000-0002-1091-9446>

Research

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Abstract

Purpose: Quality of life outcomes are a focal endpoint of cancer treatment strategies which can be evaluated through patient-related outcome measures (PROMs). We aim to validate the Moroccan Arabic version of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire for Colorectal cancer patients (EORTC QLQ CR-29).

Methods: Following translation to Moroccan Arabic, the QLQ CR-29 was administered to patients treated for colorectal cancer (CRC) in the national institute of oncology. Psychometric properties were tested 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 the ability to discriminate between different patient groups was tested using known-groups comparison.

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, whereas the coefficient was 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 and can be used for research and clinical purposes in Moroccan CRC patients.

Introduction

Colorectal cancer (CRC) is a global challenge [1] representing the third malignancy in terms of incidence and second in terms of mortality according to the GLOBOCAN database. [2]. Even with increasing incidence trends, early detection screening and the large array of advancing treatment modalities is effectively reducing mortality in a large number of countries worldwide. [3] However, colorectal cancer survivors may suffer physical functioning impairment and physical and psychological manifestations such as pain, bowel dysfunction, anxiety, sleep disruption, and depression [4]. While these symptoms negatively reflect on the quality of life [5], the latter can independently act on survival [6]. Furthermore, as CRC is increasingly diagnosed in younger patients [7], the psychosocial burden the early disease may imply, requires looking beyond oncological outcomes. Accordingly, quality of life (QoL) is an important endpoint both in clinical practice and cancer research [8, 9].

Health-related quality of life (HRQL) is an abstract and multidimensional concept [10] 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 treatments and can be used as a stand-alone questionnaire or in combination with disease specific modules [11], while survivorship core questionnaires are in the process of being developed. [12] The EORTC QLQ-CR29 questionnaire specific to colorectal cancer was developed based on the revision of the QLQ-CR38 [13] during an international study where the clinical and psychometric validity of this HRQL questionnaire were examined [14]. Following, the psychometric properties of the EORTC QLQ-C29 were tested in several languages and contexts. [8, 15–22]

Up to date, The QLQ-CR29 has not yet been validated for Arabic speaking populations. According to the EORTC QL Study Group recommendations that validation studies of QoL instruments be carried out in individual countries [23], the aim of this study is to assess the psychometric properties of the EORTC QLQ-CR 29 questionnaire and test its reliability and validity in Moroccan colorectal cancer patients.

Materials And Methods

We followed the STROBE (Strengthening the Reporting of Observational studies in Epidemiology) directive guidelines for observational studies [24]. The Approval of the study protocol was obtained from the institutional ethics review board (number : 79/17) and all patients enrolled in the study provided a written, informed consent allowing the use of their data for clinical studies at the time of their initial visit.

Description of the instruments

The participants completed in addition to a general information section including sociodemographic and clinical data, the EORTC QLQ-CR29 [14], and the validated Moroccan Arabic version of the QLQ-C30 (version 3.0). [25]

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/quality of life and the other scales. High scores represent better functioning and worse symptoms. [26]

The EORTC QLQ-CR29:

The EORTC QLQ-CR29 is a colon and rectum site-specific quality of life 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 and 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 [14].

Translation process :

The translation process followed the European Organisation for Research and Treatment of Cancer (EORTC) guidelines [27]. Two different translators independently translated the questionnaire from English to Moroccan Arabic and a consensual version was attained following the discussion of both translations. Back translation into English was then performed by two different translators who had no prior knowledge of the original English version. An expert committee including surgeons, oncologists, epidemiologists and the four translators reviewed all translations and a provisional version was developed. To examine patients' understanding of the translated version, the provisional Moroccan Arabic EORTC QLQ-CR29 underwent a preliminary test on a group of 34 patients with colon or rectal malignancies after which the final version of the instrument was generated.

Study population and data collection :

Patients were prospectively recruited from the national oncology institute during the period between November 2019 and January 2020. Patients aged over 18 years with a pathologically confirmed cancer of the colon and/or the rectum who had undergone surgery at least 6 months prior to the enrollment in the study were included. Patients were excluded if they were unable to understand the questionnaire, presented cognitive and/or medical complications that hindered the interview completion and the submission of an uncompleted 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 localisation (colon vs rectum), neoadjuvant radiochemotherapy and adjuvant chemotherapy.

As the sample size determination for psychometric validation studies lacks clear recommendations [28], we determined the required sample by allocating a number of observations 5 to 10 times greater than the variables. [29] Accordingly, the sample needed size ranged between 150 and 300 participants.

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. [26]

Descriptive statistics were generated through mean, median, standard deviation (SD), and floor and ceiling effects and age was categorized in 3 groups: < 40 years ; 41- 65 years and > 65 years.

There are two different levels of reliability; 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.

As for reproducibility, a random subgroup of patients was selected to retake the QLQ CR-29 questionnaire after 7 to 14 days from the first interview 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. [30] 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, USA). 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 patients completed the questionnaire among which 123 were males and 98 were females with a mean age of $55,6 \pm 12,7$ years. Seventy eight (35,9%) participants had colonic cancer and 138 (64,1%) had rectal cancer, 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 twenty-one dimensions except the bags change which ranged from 0 to 83.

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 a 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**.

The reproducibility (test-retest reliability) of the Arabic version of the QLQ-CR29 was tested using the intraclass correlation coefficient (ICC) after administering the instrument twice to 34 patients. For each item, the ICCs ranged from 0,889 to 1 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 quality of life 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 was able to distinguish patients based on differences between known groups. **Table 5 and Table 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.

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

Discussion

Health-related quality of life (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 [31]. 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 quality of life of Moroccan colorectal cancer 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 [20]. 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. [18, 32] On the other hand, as suggested by Arraras et al [18], 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 [17] and mostly similar to those in the original psychometric validation study. [15] 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.

In the assessment of construct 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 [15]. 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. Similar results were reported by the Dutch and Spanish Validation studies [17, 18]. 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. [20, 22] 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. [33] 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 a 150 and other EORTC QLQ-CR29 validation were performed on a smaller population. 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 charge of reading the questions and different options for the answer. Furthermore, although the use of confirmatory factor analysis may be an option, the multitrait scaling analysis is the most frequently used method for the EORTC tools transcultural validations. Notwithstanding the foregoing, this is, to our knowledge, the first Arabic validation of the EORTC QLQ-CR29 questionnaire.

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 quality of life of colorectal cancer 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 quality of life impact.

Abbreviations

HRQOL: health-related quality of life

EORTC: European Organization for Research and Treatment of Cancer

QoL: Quality of life

ICC: intraclass correlation coefficient

PROMs: patient-related outcome measures

Declarations

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Conflicts of interest:

The authors declare no conflict of interest.

Availability of data and materials:

Derived data supporting the findings of this study are available from the corresponding author [AS] upon reasonable request.

Authors' contributions:

YEA, AS and HB have contributed to the conception and design of the study, acquisition of the data, the analysis and the interpretation of data. YEA, AS, HB and HE wrote the first draft. MAM and AB critically reviewed the draft for important intellectual content. SB and RM were involved in revising critically the corrected manuscript and all authors read and gave the final approval of the version to be published.

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Ethics approval and consent to participate

This study N° 79/17 was approved by the ethics committee of the Faculty of the medicine and pharmacy - University Mohammed V Rabat - Morocco. All the subjects were informed of the conditions related to the study and gave their written, informed consent.

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Tables

Table 1: Patients sociodemographic characteristics

*Doesn't add up to 221 because of missing data

N patients	221	
	Frequency	Percentage
Gender		
Female	98	44,5
Male	123	55,5
Stoma status		
Definitive Stoma	50	22,6
No Stoma	171	77,4
Localization N=216		
Colon	78	35
Rectum	139	62
Neoadjuvant Chemo-radiotherapy*		
Yes	89	45,5
No	107	54,6
Adjuvant Chemotherapy*		
Yes	91	70
No	39	30
	Mean	SD
Age	55,65	12,87

Table 2: Quality of life scores according to EORTC QLQ-C30 and QLQ-CR29 structure and reliability

Scale/Single Item	Items	N	Mean	SD	Floor	Ceiling	Range	ICC
C30								
Physical Function	1 - 5		73,64	23,85	,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	,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	,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	-
CR29								n=34
Urinary Frequency	31,32	221	39,89	33,46	26,2	10,9	0-100	,961
Blood & mucus in stool	38,39	221	24,73	29,02	43,4	4,1	0-100	,969
(F)Body image	45-47	221	77,82	24,83	1,8	38	0-100	,950
Defecation/stoma pb		-	-	-	-	-	-	
Urinary Incontinence	33	221	20,96	32,22	64,7	7,2	0-100	,982
Dysuria	34	221	20,66	31,30	63,3	6,8	0-100	,950
Abdominal pain	35	221	30,61	34,12	48	8,6	0-100	,922
Buttock pain	36	221	27,14	34,62	55,7	9	0-100	,921
Bloated feeling	37	221	28,80	33,77	50,2	8,6	0-100	,945
Dry mouth	40	221	24,58	34,14	60,2	8,6	0-100	,979
Hair Loss	41	221	16,44	29,57	71,5	5,9	0-100	,968
Trouble with taste	42	221	20,51	32,89	67,0	8,1	0-100	,975
(F)Anxiety	43	221	64,67	37,60	16,7	43,4	0-100	,951
(F)Weight	44	221	75,56	32,66	8,1	56,6	0-100	,960
Flatulence	49s	50	41,49	33,00	28,6	10,2	0-100	,908
Leakage	50 s	50	42,17	36,49	32,7	16,3	0-100	,889
Sore skin around stoma	51s	50	42,85	38,49	34,5	20,4	0-100	,965
Bags change	52,53 s	50	18,36	22,62	49	2	0-83	,969
Embarrassed	54s	50	45,56	43,09	41,8	29,1	0-100	,956
Stoma care pb.	55s	50	40,08	41,47	46,8	21,5	0-100	,912
Stoma pb	49-54 s	50	37,41	20,18	4,1	4,1	0-100	0.999
Flatulence	49	172	30,62	37,01	52,9	12,8	0-100	,980
Faecal Incontinence	50	172	26,16	37,38	61,6	14,0	0-100	,970
Sore skin around anus	51	172	20,34	31,72	64,5	7,6	0-100	,979
Stool Frequency	52,53	172	29,65	32,33	38,4	7,6	0-100	,977
Embarrassment	54	172	31,20	38,51	54,7	15,1	0-100	,975
Defecation pb	49-54	172	28,79	25,84	16,1	,7	0-100	,969

Sexual functioning Male	56	42,85	37,81	33	20,5	0-100	,928
Impotence	57	38,18	38,79	40,9	20	0-100	,966
Sexual functioning female	58	67,06	36,76	11,9	48,8	0-100	,933
Dypareunia	59	26,58	35,75	58,3	10,7	0-100	,985

Table 3: Convergent and discriminant validity of the EORTC QLQ-CR29

	Total n= 221			Without stoma n=50			With Stoma n= 171		
	Convergent	Discriminant	alpha	Convergent	Discriminant	alpha	Convergent	Discriminant	alpha
UF	,905 - ,907	-0,00 - 0,25	,795	,83-,84	-,00 - ,21	,66	,91 - ,92	-,12 - ,25	,82
BMS	,74-,89	-,27 - ,35	,615	,62 - ,96	-,44 - ,35	,581	,79 - ,87	-,20 - ,30	,65
BI	-0,66 - -0,75	-,00 - ,36	,672	-,51 - -,89	-,20 - ,39	,690	-,63 - -,72	-,07 - ,19	,64
SF	,83 - ,96	-,30 - ,39	0,835*	,83 - ,96	-,31 - ,39	,804	-,85 - ,91	-,14 - ,34	,87

UF: Urinary Frequency, BMS: Blood & Mucus in stool, BI : Body Image, SF: Stool Frequency.

Multitrait scaling analysis' summary of the results ; ranges for convergent and discriminant validity of each multi item scale and their internal consistency using cronbach's alpha.

* mean of cronbach's alpha coefficient for patients without and with stoma.

Table 4: Scale correlation between the QLQ-CR29 and QLQ-C30

EORTC QLQ C30														
CR-29	Functional scales					Symptom scales								
Scales/Single Items	QL	PF	RF	EF	CF	SF	FA	NV	PA	DY	SL	AP	CO	DI
<i>Functional scales</i>														
Body Image	,294**	,279**	,370**	,214**	,244**	,403**	-,298**	-,256**	-,161*	-,250**	-,151*	-,278**	-,221**	-0.00
Anxiety	,297**	,314**	,264**	,315**	,273**	,285**	-,294**	-,160*	-,210**	-,169*	-,138*	-0.117	-0.029	-0.00
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	0.04
Sexual Function: Female	-,299**	-0.192	-0.115	-0.079	-,256*	0.040	0.082	-0.033	,221*	-0.001	,230*	0.040	0.017	0.11
<i>Symptom Scales</i>														
Urinary Frequency	-,137*	-,247**	-,201**	-,237**	-0.089	0.029	,244**	0.070	,218**	,230**	,176**	,165*	0.042	,221*
Blood and mucus in stool	-,241**	-,283**	-,269**	-,190**	-0.110	-0.123	,359**	,215**	,349**	,190**	,277**	,268**	,152*	,302*
Urinary Incontinence	-0.009	-0.128	-0.060	-,237**	-,152*	-0.050	0.102	0.014	0.108	,150*	,195**	0.030	,135*	0.03
Dysuria	-0.017	-0.103	-,161*	-0.069	-0.065	-0.047	,153*	0.012	,172*	0.058	,133*	0.086	0.091	0.10
Abdominal Pain	-,138*	-,161*	-0.099	-0.125	-0.099	-0.055	,232**	,143*	,443**	,140*	,254**	0.122	,168*	0.10
Buttock Pain	-,212**	-,265**	-,270**	-0.103	-0.098	-0.074	,363**	,149*	,469**	,194**	,253**	,190**	0.025	,149*
Bloated Feeling	-,206**	-,213**	-,138*	-,213**	-,145*	-0.084	,292**	,171*	,377**	,256**	,380**	0.058	,253**	0.04
Dry mouth	-,309**	-,341**	-,257**	-,266**	-,283**	-0.125	,340**	,390**	,205**	,202**	,141*	,329**	,211**	,145*
Hair loss	-0.036	-,195**	-,133*	-,337**	-,242**	-0.131	,183**	,217**	0.084	0.080	,141*	,182**	,200**	,135*
Trouble with taste	-0.099	-,247**	-,236**	-,134*	-,173*	-0.125	,243**	,343**	0.036	,202**	0.010	,271**	,173*	0.10
Weight	,176**	,280**	,291**	,157*	0.121	,179**	-,238**	-0.128	-0.081	-0.060	-,143*	-,165*	-,169*	-0.06
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	0.14
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	0.12
Sore skin around stoma	-0.041	-0.190	0.025	-,600**	-,402**	-,330*	,295*	0.261	,297*	0.247	,380**	0.073	0.172	0.00
Bags changes	-0.085	-0.169	0.002	-,404**	-0.025	-0.273	0.228	-0.018	0.155	0.218	,344*	0.192	-0.003	0.01
Embarrassment	-,407**	-,312**	-,394**	-,272*	-0.150	-0.164	,476**	0.155	,419**	,325**	,353**	0.156	-0.079	0.03
Stoma care problems	-,502**	-,391**	-,458**	-,277*	-0.182	-,228*	,529**	,239*	,587**	,328**	,468**	,239*	0.093	-0.06
Stoma problems	-0.077	-0.142	-0.009	-,580**	-0.277	-,364*	,336*	0.108	0.181	0.264	,301*	0.138	0.104	0.17
Flatulences	-,160*	-,151*	-0.034	-0.149	-0.137	-0.112	0.144	0.032	,177*	,269**	,173*	-0.003	0.008	,252*
Faecal incontinence	-0.036	-0.081	-0.040	-0.142	-0.122	-0.117	,153*	0.084	,190*	0.141	0.111	-0.017	-0.140	,403*
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	0.14
Stool Frequency	0.002	-0.019	-0.024	-0.071	0.002	0.024	0.083	-0.044	,259**	0.092	0.123	0.004	-0.035	,452*
Embarrassment	-0.101	-0.133	-0.135	-,207**	-,167*	-,208**	,178*	0.141	0.149	,276**	,152*	0.062	0.146	,224*
Defecation	-0.111	-0.116	-0.038	-,202*	-0.159	-,173*	,190*	0.157	,280**	,316**	,181*	0.040	0.106	,379*
Impotence	0.019	-0.065	-0.149	-0.104	-0.170	-,218*	0.075	,243*	-0.104	,313**	0.065	,308**	0.175	0.00
Dyspareunia	-0.083	-0.096	-0.118	-0.174	-,243*	-,345**	0.108	0.025	,260*	0.163	0.162	0.156	0.045	0.15

*: $p < 0.05$

** : $p < 0.01$

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.

Table 5 : Known-group comparisons using the EORTC QLQ-CR29 according to : Stoma status-Tumour Site- Neoadjuvant radiochemotherapy usage.

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)	,412	35,4(31,2)	42,2(34,8)	,215	45,5(33,9)	35,0(32,2)	,031
Blood and mucus in stool	27,6(28,8)	23,8(29,1)	,247	20,2(26,8)	27,4(30,2)	,086	29,9(30,3)	19,3(27,1)	,004
Body Image	66,6(27,5)	81,1(23,0)	,000	77,4(24,8)	77,7(25,0)	,938	77,6(24,1)	78,9(24,5)	,625
Urinary Incontinence	24,0(35,0)	20,0(31,4)	,451	18,3(28,7)	21,5(33,0)	,788	20,2(32,0)	21,4(32,1)	,592
Dysuria	21,3(29,1)	20,4(31,9)	,469	18,8(30,6)	22,3(31,9)	,120	23,2(32,3)	18,3(29,7)	0,299
Abdominal Pain	28,0(32,5)	31,3(34,6)	,590	28,6(34,2)	32,1(34,3)	,440	34,4(34,6)	26,7(33,4)	,095
Buttock Pain	28,6(33,6)	26,7(34,9)	,563	17,0(30,26)	32,3(36,1)	,001	38,5(36,2)	14,3(27,5)	,000
Bloated Feeling	30,6(33,5)	28,2(33,9)	,545	27,7(32,4)	29,0(34,2)	,892	35,2(35,6)	23,6(31,7)	,017
Dry mouth	30,0(36,4)	23,0(33,4)	,183	20,5(29,0)	26,6(36,5)	,477	30,7(38,3)	19,0(28,9)	,055
Hair loss	17,3 (28,7)	16,1(29,1)	,608	10,6(24,9)	19,4(31,5)	,027	18,7(30,1)	14,6(28,6)	,222
Trouble with taste	27,3(36,0)	18,5(31,7)	,069	13,2(27,5)	24,4(35,1)	,016	20,5(31,1)	17,7(31,8)	,375
Anxiety	52,6(40,4)	67,8(36,1)	,016	63,2(37,8)	65,4(37,0)	,658	65,9(36,5)	63,5(38,4)	,725
Weight	69,3(38,6)	77,3(30,6)	,305	79,4(30,4)	73,8(33,2)	,194	75,6(30,4)	76,3(33,9)	,492
Flatulence				45,8(31,9)	39,3(32,7)	,601	35,0(34,1)	45,6(33,7)	,361
Leakage				45,8(31,9)	40,4(38,8)	,558	42,1(39,8)	45,6(31,8)	,705
Sore skin around stoma				39,5(32,7)	44,4(41,3)	,748	50,8(43,5)	43,8(33,4)	,598
Bags changes				21,8(27,0)	16,6(20,4)	,584	17,5(19,6)	26,3(27,3)	,351
Embarrassment				64,5(28,46)	40,7(44,9)	,056	56,3(46,3)	36,9(39,8)	,055
Stoma care problems				37,5(38,2)	40,7(42,5)	,804	54,0(42,1)	23,4(36,7)	,003
Stoma problems				39,9(17,1)	36,1(21,6)	,499	37,1(23,4)	41,8(16,4)	,387
Flatulences				21,5(33,6)	34,5(37,3)	,017	43,8(39,1)	19,6(31,8)	,000
Faecal incontinence				16,12(30,6)	31,4(39,5)	,009	35,7(41,0)	17,0(31,5)	,001
Sore skin around anus				11,8(24,2)	25,1(34,6)	,012	29,5(36,1)	13,6(26,0)	,002
Stool Frequency				19,3(26,8)	35,8(34,2)	,002	37,6(36,1)	21,5(26,8)	,008
Embarrassment				23,1(35,4)	34,9(39,1)	,053	40,4(39,2)	23,4(35,7)	,004
Defecation pb				18,8(21,5)	36,5(36,5)	,000	37,8(27,4)	19,5(21,0)	,000
(F) Sexual Function: Male	54,1(39,1)	39,7(37,1)	,162	32,4(32,4)	48,1(39,4)	,047	46,3(39,4)	36,0(32,8)	,211
Impotence	47,2(39,2)	35,6(38,5)	,021	31,5(34,6)	41,6(40,6)	,248	43,9(39,2)	33,3(36,8)	,167
Sexual Function: Female	56,8(38,6)	69,6(36,1)	,064	65,4(33,3)	66,6(39,6)	,770	69,4(35,9)	70,0(35,2)	,928
Dyspareunia	33,3(39,1)	24,8(34,9)	,156	20,23(33,1)	29,4(37,1)	,240	26,8(32,6)	23,3(35,5)	,459

Table 6 : Known-group comparisons using the EORTC QLQ-CR29 according to: Gender- Age

Table6	Gender		Age				
CR-29Scales/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)	,862	28,2(30,4)	42,4(33,3)	38,1(34,1)	,115
Blood and mucus in stool	24,6(27,8)	24,8(30,5)	,794	25,6(29,5)	26,7(29,4)	19,2(27,5)	,183
Body Image	77,4(25,0)	78,3(24,7)	,777	74,3(23,2)	76,6(26,1)	80,7(21,8)	,481
Urinary Incontinence	19,5(31,9)	22,7(32,6)	,385	19,2(28,5)	19,6(32,3)	26,6(33,0)	,273
Dysuria	23,3(32,2)	17,3(29,9)	,101	23,0(36,2)	20,8(31,5)	20,7(29,5)	,978
Abdominal Pain	27,6(33,5)	34,3(34,6)	,172	32,0(34,6)	31,9(35,2)	26,6(29,8)	,772
Buttock Pain	28,1(34,9)	25,8(34,3)	,478	32,0(34,6)	27,7(36,1)	22,2(30,1)	,500
Bloated Feeling	27,3(32,8)	30,6(35,0)	,495	26,9(32,6)	31,9(35,0)	22,9(30,8)	,293
Dry mouth	17,3(28,7)	33,6(38,1)	,001	23,0(33,6)	24,7(33,8)	25,1(36,3)	,967
Hair loss	8,6(21,7)	26,2(34,9)	,000	12,8(28,4)	19,6(32,3)	10,3(19,8)	,228
Trouble with taste	16,8(31,4)	25,1(34,2)	,040	30,7(38,7)	20,6(33,4)	14,8(27,1)	,282
Anxiety	69,6(34,9)	57,8(39,9)	,032	65,3(38,2)	60,1(38,2)	73,3(34,5)	,116
Weight	75,3(33,3)	75,8(32,0)	,920	75,6(30,6)	74,5(33,6)	77,0(31,6)	,933
Flatulence	43,6(32,2)	38,3(34,6)	,566	38,8(32,7)	44,7(33,2)	33,3(36,5)	,667
Leakage	47,1(36,2)	35,0(36,6)	,241	61,1(44,3)	41,9(34,6)	27,7(38,9)	,299
Sore skin around stoma	44,8(39,1)	40,0(38,3)	,650	66,6(42,1)	42,8(37,5)	33,3(36,5)	,287
Bags changes	20,1(22,4)	15,8(23,2)	,427	22,2(25,0)	20,9(23,6)	5,5(8,6)	,328
Embarrassment	46,3(42,4)	44,4(44,6)	,680	51,8(50,3)	51,3(41,8)	31,4(40,3)	,230
Stoma care problems	42,7(43,1)	36,3(39,4)	,481	66,6(50,0)	40,9(40,2)	29,6(37,7)	,093
Stoma problems	39,8(20,0)	33,8(20,3)	,336	48,1(31,7)	38,8(16,9)	23,1(20,9)	,183
Flatulences	29,0(38,5)	32,4(35,2)	,452	36,6(41,7)	33,6(37,8)	20,5(31,1)	,142
Faecal incontinence	23,4(35,8)	29,4(39,1)	,391	40,0(44,0)	28,7(38,3)	14,5(28,4)	,050
Sore skin around anus	17,3(29,6)	23,9(33,9)	,300	26,6(36,8)	21,7(32,8)	12,8(24,9)	,266
Stool Frequency	27,8(30,2)	31,8(34,7)	,836	35,8(34,7)	33,0(33,7)	18,3(25,0)	,029
Embarrassment	27,3(36,5)	35,8(40,4)	,179	41,6(38,8)	36,0(40,8)	14,5(26,2)	,005
Defecation pb	26,9(25,3)	30,9(26,4)	,499	37,5(33,0)	30,3(25,5)	17,5(19,0)	,032
Sexual Function: Male				33,3(36,9)	42,7(37,8)	45,8(36,5)	,575
Impotence				48,7(44,3)	35,2(38,5)	42,0(35,1)	,465
Sexual Function: Female				57,5(36,7)	63,5(37,7)	82,3(31,4)	,109
Dyspareunia				33,3(36,5)	27,6(36,8)	9,8(22,8)	,098

0,000: p<0.0001

Higher scores represent higher functioning or a worse lever of symptoms.