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  
Universite 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

Racouf 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  
Universite 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 ± 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-CR29 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’ HRQL 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
CRC: Colorectal cancer

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
|                      | 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         |
| **Age**              | Mean      | SD         |
|                      | 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 |
|-------------------|-------|----|------|-----|-------|---------|-------|-----|
| 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| 50,50 |      | 42,17 | 36,49| 32,7  | 16,3    | 0-100 | .889|
| 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|
| Bloat 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    | 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       | 52,53s| 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          | 49-54s| 50   | 37,41 | 20,18| 4,1   | 4,1     | 0-100 | .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|
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 | -0.00 - .21 | .66    | .91 - .92 | -.12 - .25 | .82    |
| BMS              | .74 - .89   | -0.27 - .35        | .615              | .62 - .96 | -.44 - .35 | .581   | .79 - .87 | -.20 - .30 | .65    |
| BI               | -.66 - -.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

| Scales/Single Items | Functional scales | Symptom scales |
|---------------------|-------------------|----------------|
| **Body Image**      | 0.294**           | -0.121         |
| **Anxiety**         | 0.327**           | 0.101          |
| **Sexual Function:**| -0.017            | 0.138          |
| Male                |                   |                |
| Female              |                   |                |
| **Urinary Frequency**| -0.137*          | 0.183          |
| **Blood and mucus in stool**| -0.241**     | 0.091          |
| **Urinary Incontinence**| -0.009          | 0.093          |
| **Dysuria**         | -0.017            | 0.093          |
| **Abdominal Pain**  | -0.138*           | 0.092          |
| **Buttock Pain**    | -0.012*           | 0.092          |
| **Bloating Feeling**| -0.206*           | 0.091          |
| **Dry mouth**       | -0.306*           | 0.091          |
| **Hair loss**       | -0.036            | 0.091          |
| **Trouble with taste**| -0.099*         | 0.091          |
| **Weight**          | 0.162*            | 0.091          |
| **Flatulence**      | 0.124*            | 0.091          |
| **Leakage**         | 0.083*            | 0.091          |
| **Sore skin around stoma**| -0.041*       | 0.091          |
| **Bags changes**    | -0.085*           | 0.091          |
| **Embarassment**    | -0.407*           | 0.091          |
| **Stoma care problems**| -0.502**       | 0.091          |
| **Stoma problems**  | -0.077            | 0.091          |
| **Flatulence**      | -0.160*           | 0.091          |
| **Faecal incontinence**| -0.036          | 0.091          |
| **Sore skin around anus**| -0.081*        | 0.091          |
| **Stool Frequency** | 0.002             | 0.091          |
| **Embarassment**    | -0.101*           | 0.091          |
| **Defaecation**     | -0.111            | 0.091          |
| **Impotence**       | 0.019             | 0.091          |
| **Dyspareunia**     | -0.083            | 0.091          |
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                      | 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    |
| Blood and mucus in stool  | 27,6(28,8)   | 23,8(29,1)      | .247                         | 20,2(26,8) | 27,4(30,2) | .086    |
| Body Image                | 66,6(27,5)   | 81,1(23,0)      | 0,000                        | 77,4(24,8) | 77,7(25,0) | .938    |
| Urinary Incontinence      | 24,0(35,0)   | 20,0(31,4)      | .451                         | 18,3(28,7) | 21,5(33,0) | .788    |
| Dysuria                   | 21,3(29,1)   | 20,4(31,9)      | .469                         | 18,8(30,6) | 22,3(31,9) | .120    |
| Abdominal Pain            | 28,0(32,5)   | 31,3(34,6)      | .590                         | 28,6(34,2) | 32,1(34,3) | .440    |
| Buttock Pain              | 28,6(33,6)   | 26,7(34,9)      | .563                         | 17,0(30,2) | 32,3(36,1) | .001    |
| Bloat feeling             | 30,6(33,5)   | 28,2(39,9)      | .545                         | 27,7(32,4) | 29,0(34,2) | .892    |
| Dry mouth                 | 30,0(36,4)   | 23,0(33,4)      | .183                         | 20,5(29,0) | 26,6(36,5) | .477    |
| Hair loss                 | 17,3(28,7)   | 16,1(29,1)      | .608                         | 10,6(24,9) | 19,4(31,5) | .027    |
| Trouble with taste        | 27,3(36,0)   | 18,5(31,7)      | .069                         | 13,2(27,5) | 24,4(35,1) | .016    |
| Anxiety                   | 52,6(40,4)   | 67,8(36,1)      | .016                         | 63,2(37,8) | 65,4(37,0) | .658    |
| Weight                    | 69,3(38,6)   | 77,3(30,6)      | .305                         | 79,4(30,4) | 73,8(33,2) | .194    |
| 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                         | 421(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(28,4)   | 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       | 16,1(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    |
| Impotence                 | 47,2(39,2)   | 35,6(38,5)      | .021                         | 31,5(34,6) | 41,6(40,6) | .248    |
| Sexual Function: Female   | 56,8(38,6)   | 69,6(36,1)      | .064                         | 65,4(33,3) | 66,6(39,6) | .770    |
| Dyspareunia               | 33,3(39,1)   | 24,8(34,9)      | .156                         | 20,2(33,1) | 29,4(37,1) | .240    |

Table 6: Known-group comparisons using the EORTC QLQ-CR29 according to: Gender-Age
| Table 6 | 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)   | .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    |
|         |        |     | Bloating 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(40,8) | .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)   | .458    | 48,5(36,5) | 45,8(36,5)  | 575      |
|         |        |     | Impotence                  | 48,7(44,3)  | 35,2(38,5)   | .420    | 42,0(35,1) | 46,5      |
|         |        |     | Sexual Function: Female    | 57,5(36,7)  | 63,5(37,7)   | .823    | 83,1(31,4) | 109       |
|         |        |     | Dyspareunia                | 33,3(36,5)  | 27,6(36,8)   | .98     | 9,2(22,8)  | 996       |

0.000: p<0.001

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