KINGDOM OF MOROCCO
MOHAMMED V UNIVERSITY OF RABAT
FACULTY OF MEDECINE AND PHARMACY
RABAT

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VALIDATION OF THE MOROCCAN VERSION OF THE EORTC QUALITY OF LIFE QUESTIONNAIRE COLORECTAL MODULE (CR29) IN COLORECTAL CANCER PATIENTS

THESIS

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BY

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بسم الله الرحمن الرحيم
"سبحانك لا علم لنا
إلا ما علمتنا
إنك أنت العليم الحكيم"
سورة البقرة: الآية: 31
صدق الله العظيم

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Dedication

To my parents:

Meriem El Beghdadi & Mohammed Bachri

Words fail me to express how I feel. You have always been my compass and my anchor in life. For raising me in your image, for trusting me to make my own choices, for always supporting me and encouraging me throughout those many years and for never allowing doubt and failure to get the best of me, I am forever indebted to you.

My only wish is to make you proud.

To our ray of sunshine, my sister :

Salma Bachri

I am very proud of the woman that you've become. Your energy, and joie de vivre is truly amazing. I am happy to watch you grow and prosper on your own.

To my sweet little sister Hajar Bachri:

I am in awe of the smart, wise and silently powerful person you are becoming. But no matter how much you grow up you will forever be my little sister.

To my uncle Boubker El Beghdadi

Thank you for your never ending support

and for believing in me.

To the El Beghdadi And Bachri families:

Grand-parents, grand-mothers, uncles,

aunts and cousins; I dedicate this work to you,

our strong bond is something I take great pride in.

To Jihanne and Amina:

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You are my soul sisters and I am so lucky to have you
in my life, you lift me up and keep me grounded when I need it. Thank
you and may we forever stay this close.

To Najlaa Belharty :

Your friendship has brought me so much joy,
I am grateful for your kindness, strength and unwavering faith
in me. I deeply admire your work ethic and I was so privileged
to watch you become the doctor you are today,
the best is yet to come! Thank you for being you.

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and prosper supporting each other.

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Director of Thesis

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To General Surgery Professor

Majbar Mohammed Anass

Jury of thesis

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To Medical Oncology

Professor Boutayeb Saber

Jury of thesis

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To Oncology-Radiotherapy Professor El Kacemi Hanan

Jury of thesis

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To Gastroenterology Professor Amrani Laila

Jury of thesis

Thank you Professor for giving me the honor of taking part in my thesis Jury. Please accept the expression of my utmost respect

To General Surgeon Dr El Alami Yacir

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To Dr Hajar Essangri

I thank you for your help, valuable input and the time you have devoted to this work.

Abbreviation

ABBREVIATIONS:

- **CRC**: Colo-Rectal Cancer
- **QoL**: Quality of Life
- **HRQL**: health-related quality of life
- **EORTC**: European Organization for Research and Treatment of Cancer
- **QLQ**: Quality of life Questionnaire
- **QLG**: Quality of Life Group
- **CT scan** : Computerized tomography
- **MRI** : Magnetic resonance imaging
- **CRM** : Circumferential Resection Margin
- **TME**: Total mesorectal Excision
- **APR**: Abdominoperineal Resection
- **RCT**: Radiochemotherapy
- **SCPRT** : Short-course radiotherapy
- **OS**: Overall Survival
- **PFS:** Progression-free survival
- **PROM:** Patient-reported outcome measures
- **LARS**: Low Anterior Resection Syndrome
- **ICC:** Intraclass correlation coefficient
- **COSMIN**: Consensus-based Standards for the selection of health Measurement INstruments
- **Pb**.: Problem

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Introduction

Colorectal cancer (CRC) is one of the most prevalent forms of cancer worldwide. The incidence rates are constantly increasing both in western and developing countries. In contrast, decreasing colorectal cancer mortality rates have been observed in a large number of countries worldwide. The 5-year survival rate for patients at the early stages of CRC (stages I and II) is above 60%, and for stage III patient 5-year survival rate is 10%. (1) (2)

The above-cited increase in survival rates is most likely attributed to colorectal cancer screening, reduced prevalence of risk factors, and improved treatments as well as a result of the aging population. The quality of cancer care has considerably improved as well, benefiting from prevention strategies, early detection, and the multidisciplinary approach to treatment by the establishment of adjuvant and neoadjuvant radiochemotherapy. Which has led to decreases in CRC mortality even in the face of increased incidence. (3)

As survival rates for CRC have increased, quality of life (QoL) has grown to become an important endpoint both in clinical practice and in clinical cancer research. (4) It is now crucial to properly understand the patient's health related quality of life (HRQL) and the treatment's cost in real life when evaluating whether future interventions should be implemented and tailor services accordingly. (5) CRC survivors may be impaired in physical functioning and in everyday life by multiple disease-related and treatment-related symptoms such as pain, bowel dysfunction, and fatigue. They may be negatively affected in psychological, emotional, and social life because of fear, anxiety, sleep disruption, and depression. (6)

These HRQL issues are abstract and multidimensional concepts in nature, which makes them hard to measure and observe, therefore HRQL should be evaluated using a variety of multi-item scales. No consensus over a standard tool to measure satisfaction has been obtained, thus the significance of results is often uncertain. (7) Nonetheless, standardized and universally accepted tools are paramount to the assessment of the QoL of CRC survivors.

The European Organization for Research and Treatment of Cancer (EORTC) aims to measure the QoL of cancer patients by elaborating questionnaires.

To that end, the EORTC QoL Group (QLG) - a multinational, multidisciplinary group- has adopted, in its questionnaire system a modular approach, with a cancer-specific core questionnaire (QLQ-C30) that covers symptoms and problems experienced by cancer patients and modules supplementing the core questionnaire that are site-, symptom- or treatment-specific.(8)

The EORTC QLQ-C30 was released in 1993(9) and has been ever since broadly used as a HRQL measurement tool specifically for cancer patients in clinical trials. (10) General aspects related to the physical and psychosocial health of cancer patients are covered by this core questionnaire. Specific issues related to particular malignancies are addressed by module questionnaires that complement the QLQ-C30.(11) Moreover, the EORTC QoL Group Study's strategy of developing questionnaires is unique and widely adopted by guidelines that have proved the efficiency of the modular approach. The EORTC's proficiency is traced back to its multi-linguistic and multicultural attributes that ensure a robust and high-quality module development strategy.(12) The EORTC QLQ-C30 core questionnaire, as well as several site-specific modules, have successfully been translated and culturally adapted to the Moroccan population as we detailed in Table 1.

As for the EORTC QLQ-CR29, it is an updated and shorter version of the QLQ-CR38 that dates from the 1990s. This update was made in response to the progress achieved in CRC treatment at both surgical and radiochemotherapy levels- new radiochemotherapy protocols, ultra-low resections, and minimally invasive surgery techniques-.(13) In addition to redundant scales being removed, the CR29 also addresses other aspects of QoL such as sexual issues, and the ano-rectal function.(8) (13,14)

Furthermore, the improvements of the CRC-specific module to "CR29" allows international multi-lingual psychometric studies to be conducted and thus allowing a broader field-testing of the questionnaire more. Fittingly, the original validation of the CR29 was obtained after an international multicenter study was conducted, nevertheless, the EORTC recommends that countries translate and validate individually the questionnaire module. (15) To date, the QLQ- CR29 has not been evaluated nor validated with a Moroccan population. In our study, we applied the Moroccan Dialect translated version of the QLQ CR-29 to CRC patients and aim to show its validity and reliability as a measurement tool for QoL of CRC patients.

EORTC questionnaire	Characteristics	Moroccan translation
QLQ-C30	Core questionnaire-Cancer-specific	Available (21)
QLQ-H&N35	ENT Cancer -Module	Available (16)
QLQ-BR23	Breast Cancer -Module	Available (17)
QLQ-CX24	Cervical Cancer -Module	Available (31)
QLQ-PR25	Prostate Cancer - Module	Available (17,18)
STO 22	Stomach Cancer- Module	Ongoing

***Table 1**: Available Moroccan versions of EORTC questionnaires*

Background

EPIDEMIOLOGY

Incidence and mortality rates:

Colorectal cancer refers to a malignant tumour arising from the inner wall of the colon and/ or the rectum. Incidence and mortality rates vary around the world. Globally, CRC is the third most commonly diagnosed cancer in males and the second most commonly diagnosed in females, with 1.8 million new cases and almost 861,000 deaths in 2018 according to the World Health Organization (WHO) GLOBOCAN database. (19)

CRC incidence rates are substantially higher in males than in females and are steadily rising in developing nations. As such, the WHO estimates an increase of 77% in the number of newly diagnosed cases of CRC and an increase of 80% in deaths from CRC by 2030. (20)

In Morocco, CRC cancer incidence is lower compared to developed countries, however, these numbers are constantly increasing as elucidated by the incidence rates registered in the Casablanca region going from 7,3 case/100.000 in 2004-2007 to 9,6 case/100.000 habitants in 2008-2012. (11) These rates also steadily increase with age, while being the highest in the age group of 65 to 74.

Colon cancer is the first most common malignancy among digestive cancers in both males and females. Whereas rectal cancer comes in 3rd place among digestive cancers.

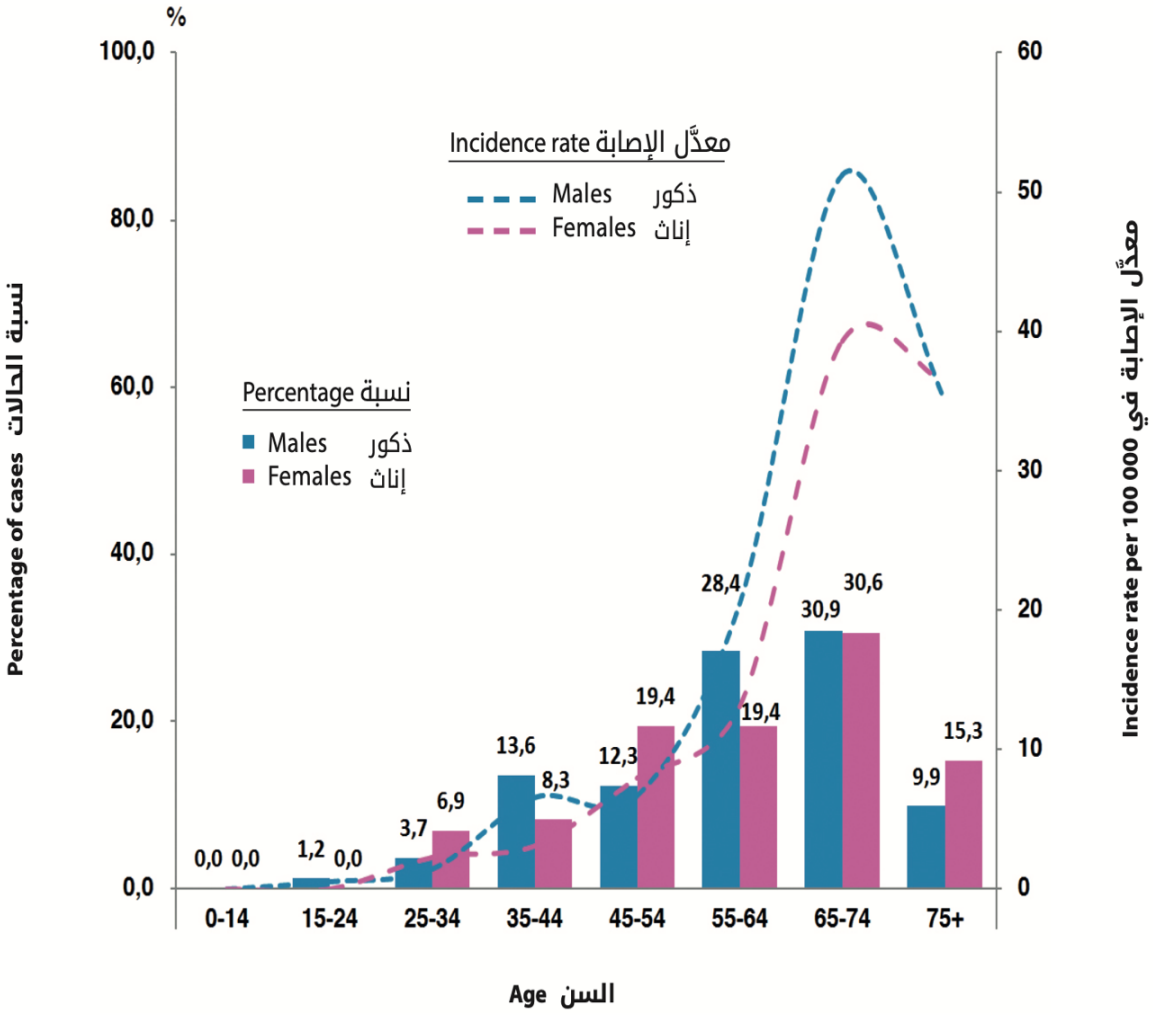


Figure 1 *: Distribution and incidence rate of colon cancer. -Rabat's registry*

MANAGEMENT OF COLORECTAL CANCER :

As with all cancer treatment strategies today, a multidisciplinary team (MDT) approach is paramount to ensure the best possible decision and outcome for each patient. (21) Evidence-based guidelines should be followed for the screening, diagnosis, and treatment of CRC. (22)

I. Screening principles:

The stepwise evolution of CRC from normal mucosa to an invasive tumour passing through different stages of premalignant lesions facilitates primary and secondary prevention. (22)

The gold standard of excellence for the diagnosis of colorectal pathologies is the colonoscopy (20) which has the advantage of being both a diagnostic and therapeutic tool. (22) Currently, available guidelines recommend a complete colonoscopy for CRC screening in moderate-risk populations based on higher sensitivity and specificity when compared to other tests (3,22,23), with the optimal age for testing ranging between 50 and 74 years and a screening interval of 10 years for negative tests. (22)

II. Diagnosis work-up:

The stage of cancer at presentation is the single most important determinant of outcome. (21) Therefore, a full diagnostic workup must be performed to attain an accurate histological diagnosis of the primary tumour, as well determining the extent of the disease. (22) In the absence of complications, guidelines recommend a total colonoscopy with multiple endoscopic biopsies (12 minimum). (23) Accordingly, endoscopy determines the exact location of the primary tumour, its macroscopic aspect while allowing for the detection and removal of synchronous precancerous or cancerous lesions. (22)

III. Assessment of tumour extension:

Following a comprehensive physical examination, a CT of the thoracic, abdominal, and pelvic cavities with intravenous contrast administration constitutes the reference radiological method for the evaluation of the presence of distant metastases of CRC. (22) Endoscopic ultrasound may offer better staging of early detected lesions (T1) by determining whether the tumour extends to the submucosa (sm) or is limited to the mucosa. High-resolution MRI has a proven ability to accurately stage patients for rectal cancer (T) as well as determining preoperative prognostic features such as the spread into the mesorectum, the relationship to the mesorectal fascia, and the Circumferential resection margin (CRM).(24)

❖ ***Treatment of colorectal cancer:***

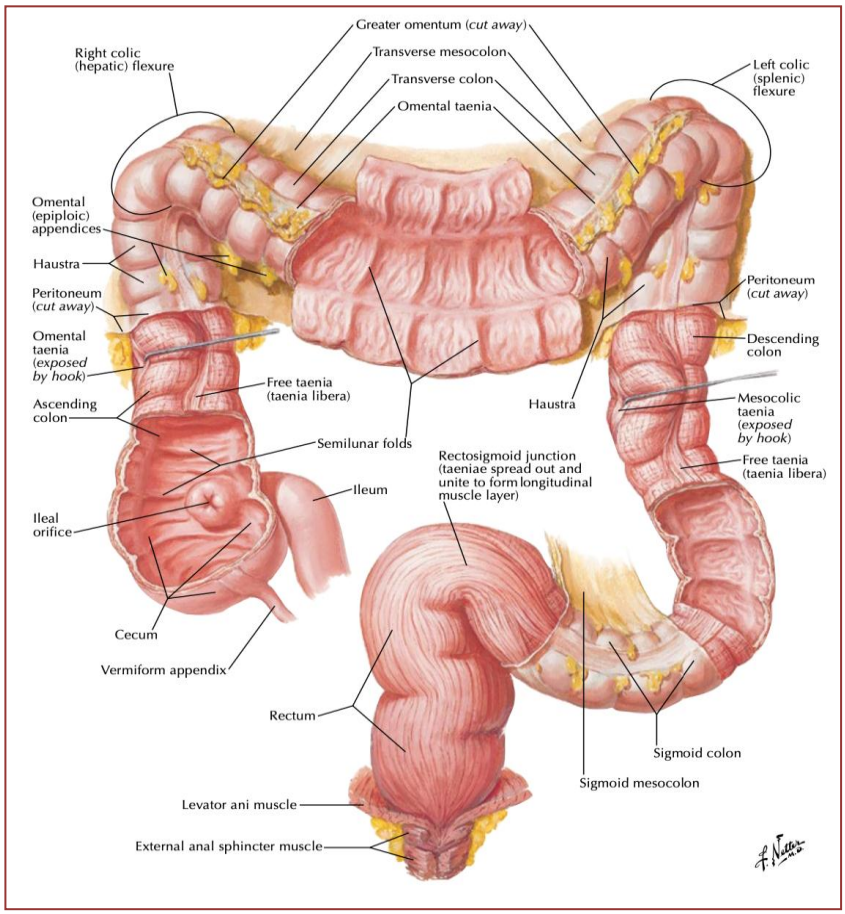


***Figure 2**: Overview of the Colon-Rectum anatomy (25)*

Surgery for colorectal cancer

Surgery remains the cornerstone of curative treatment for lower GI tract malignancies, (26) and the operative strategy should be based on the fundamental principles of oncological surgery. As outlined by the guidelines, this includes an *en bloc* lymphadenectomy, ligation at the origin of feeding vessels, and adequate proximal and distal resection margins. (27)

On the other hand, the surgical approach is based on the site of the tumor and the vascular territories involved.

Right hemicolectomy is performed for tumors extending from the cecum to the hepatic flexure and transverse colonic cancers require a transverse colectomy. However, an extended right hemicolectomy, with the ligation of the middle colic artery, the preservation of the left colic artery, and an ileo descending colon anastomosis, is often preferred because of concerns over tension or inadequate blood supply. Cancers in the descending and sigmoid colon should be managed by a left hemicolectomy.(28)

The treatment strategy of rectal cancer is based on the clinical stage, the local advancement, and the MRI predicted circumferential resection margin (CRM). (22)

Treatment of low-risk, early-stage tumours is primary surgical therapy, whereas patients presenting advanced or high-risk disease require neoadjuvant radiation or chemoradiation before surgery. (29)

As such, the indications for curative resection techniques recommended are as follows:

Upper rectal tumours: Partial mesorectal excision (PME) can be performed without compromising the oncological results.(30) The tumour-specific mesorectal excision requires no less than a 5 cm distal margin. (31) The continuity is restored by a

colorectal anastomosis which helps avoid the functional disturbances associated with coloanal anastomosis. (30)

Mid-rectal tumours: Total mesorectal resection, (TME) is considered the standard resection technique to avoid recurrence as well as the preservation of the anal sphincters. (32) This technique consists of the total excision of the rectum vascular pedicle alongside the fascia anatomic planes. (33) Coloanal anastomosis associated with colonic J pouch reservoir to restore continuity is recommended in addition to a diverting ostomy (ideally a loop ileostomy). (29)

Lower-rectal tumours: TME is performed when a 1 cm distal margin clearance is possible as well as a CRM<1mm. Rullier's classification for lower rectal cancer and the standardization of surgery permits the preservation of anal sphincters without compromising the oncologic outcomes. (34)

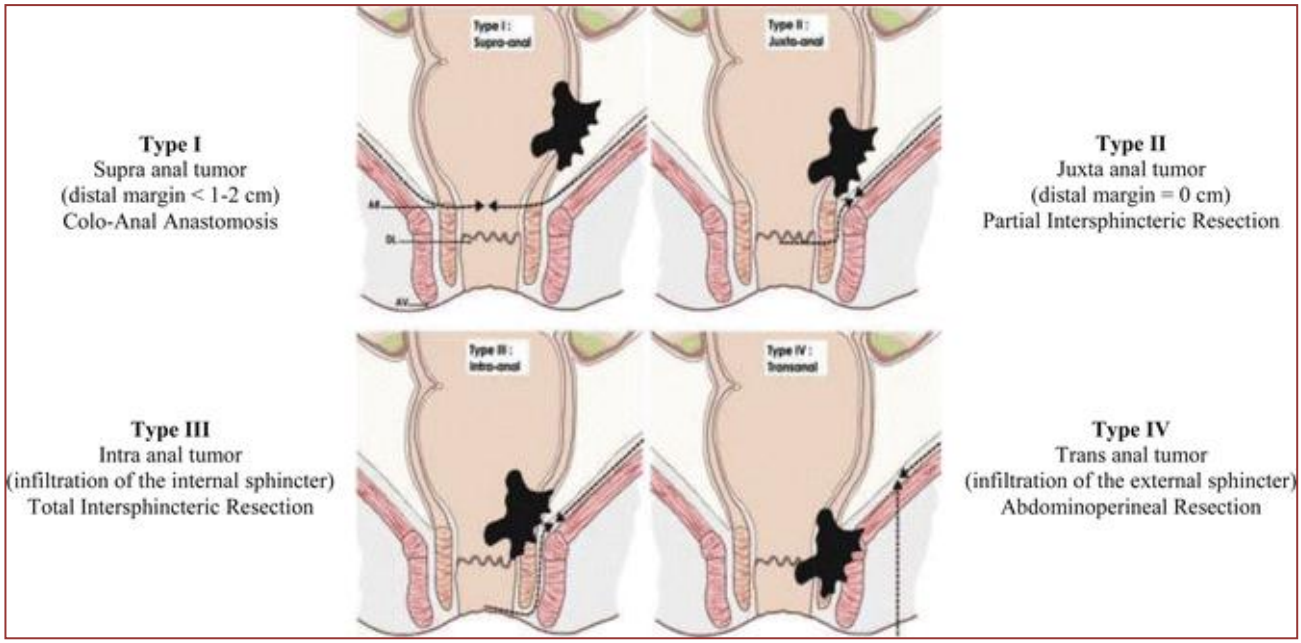


***Figure 3**: Rullier's Surgical Classification of low rectal cancer (34)*

Sphincter-sparing surgery for the lower rectum consists of intersphincteric resection and a manual colonic J-pouch anastomosis. (31) However, an Abdominoperineal resection (APR) may be required in very low tumours where the sphincters cannot be preserved. Perianal tissue and anal channel are resected en bloc with the whole rectum and mesorectum. (31)

- ***Adjuvant radiochemotherapy:***

A detailed explanation of radiation and chemotherapy protocols is beyond the scope of this study. Nonetheless, we present some basic notions necessary to comprehend the outcomes and consequent HRQL.

Given the anatomic complexity of the pelvis which complicates rectal surgery, as well as the absence of serosa in the rectum, risks of local recurrence are higher when dealing with rectal cancer compared to colon cancer. (35)

Concurrent neoadjuvant radiochemotherapy (RCT) reduces the risks of local recurrence when associated with an optimal resection of the mesorectum. (36) (37) As such, guidelines recommend neoadjuvant RCT for T3-T4 and/or N+ in mid and lower rectal tumours or MRI predicted CRM (<1mm). (38) Standard CRT protocols consist of 50 Gy (25 × 2 Gy on weekdays) associated with capecitabine with targeted volumes being decided according to CT scans and MRIs.(39)

Short-course preoperative radiotherapy (SCRT) (25 Gy in 5 fractions) is more efficient for operable rectal cancers than post-operative RCT. (40) The ultimate decision should be made by the multidisciplinary team. Radiotherapy negatively impacts sexual and digestive functions and when associated to surgery, adverse effects such as impotence dyspareunia and anal incontinence can be more prominent. (41)

❖ ***Determinants of Quality of Life:***

Addressing HRQL issues requires a good understanding of the multiple factors influencing it. In addition to the stage and site of the tumour, HRQL is heavily affected by the physical, psychological, and social consequences of the CRC diagnosis and its treatment. (42) In an attempt to facilitate the discussion, *Marventano et al.,* suggests dividing QoL factors into the following categories :

Socio-demographic characteristics :

Gender is a determinant for specific HRQL problems such as sexual dysfunction in men while age remains a subject of controversy (42) in light of the conflicting reports either describing the worsening or improvement in QoL with increased age in different studies. (43,44) Other factors such as low-income and a narrow social network have been linked to a worse QoL in its physical, emotional and social aspects.(43,45)

Health-related factors:

Comorbidities such as heart disease, obesity, urinary disorders, and depression/anxiety significantly influence the overall QoL of CRC patients. (46,47) The higher rate of depression and anxiety reported compared to the general population of the same age may be explained by worries of recurrence or a second cancer.(48)

Cancer-related and surgical procedures factors :

The functional results of surgical procedures as well as neoadjuvant and adjuvant therapies such as genitourinary dysfunction, LARS, and LARS-like symptoms also heavily affect the QoL.(28) (49) In fact, cohort studies show that patients undergoing surgery suffer from a decline in QoL with gradual improvement 3 months after the surgery. (50)

Another major consequence of CRC surgery is the creation of a stoma which may negatively impact QoL compared to sphincter-sparing resections although some reports did not find a significant difference.(51–54) In fact, a systematic review linked ostomized patients' altered Qol to its influence on social aspects of HRQL. (52) Variations of physical and psychological disorders according to gender have also been recorded in stoma patients. (55)

By encapsulating all these different factors, we were able to pre-establish hypothesized comparison elements, test them in our study, and finally draw conclusions about the instrument's ability to evaluate HRQL in our context.

Materials & Methods

Traditionally, clinical studies use tools such as overall survival (OS) or more recently tumor-based endpoints such as progression-free survival (PFS) to study the efficiency of treatment for advanced or metastatic colorectal cancer (mCRC). (56)

In the current situation however, these traditional endpoints do not seem to be relevant. Demonstrating clinical efficiency requires alternative outcomes for the OS. Adequately measuring the effects of therapeutic interventions with appropriate primarily patient-oriented and patient-reported endpoints is therefore crucial to the advancement of clinical research in mCRC in order to complement the results of tumor-based endpoints. (57,58)

Over the past two decades, treatment trials for CRC started focusing on supplementing traditional clinical outcomes -toxicity scores, surgical-related morbidity, local recurrence rates, OS…- with outcomes reported by the patients themselves. (59)

Assessing the patient's perspective of the outcome can be achieved with patient-reported outcome measures (PROMs) including health-related quality of life (HRQL) questionnaires. (15) HRQL can be defined as the evaluation of the QoL and its relationship with health over time and includes the patient's perspective of the way a disease or its treatment affects his or her physical, emotional and social well-being. (57)

In the era of globalization, using a standard measurement that has been culturally adapted comes with many advantages; it allows cross-cultural comparisons, as well as international multi-center clinical trials while avoiding the costs and time-consuming process of developing a new test. (60)

A frequently used PROM to evaluate HRQL in cancer patients is the EORTC QLQ-C30 (10) which can either be used alone or alongside tumor-specific questionnaire modules. The developing process of these cancer-specific modules - including the QLQ CR29- is outlined by the EORTC quality of life group (QLG) as well as the cultural adaptation procedure. (61)

SYSTEMATIC LITERATURE REVIEW :

We performed a systematic search of SpringerLink, PubMed, and ScienceDirect databases to identify studies about the EORTC-QLQ CR29. The MeSH-terms (Medical SubHeadings) used were: “Quality of Life” combined with “Colorectal Neoplasms/psychology”, “Colorectal Neoplasms/therapy”, “Psychometrics/methods” and the PROM’s name.

After a preliminary screening, we included articles based on the following criteria: Available abstracts, Data reports on the QLQ-CR29 properties, and studies answering to COSMIN’s (Consensus-based Standards for the selection of health Measurement Instruments) guidelines to examine the methodological quality of studies conducted on the measurement properties (62,63). Articles with no available abstracts, non english publications, as well as studies with no data about CRC patients were excluded.

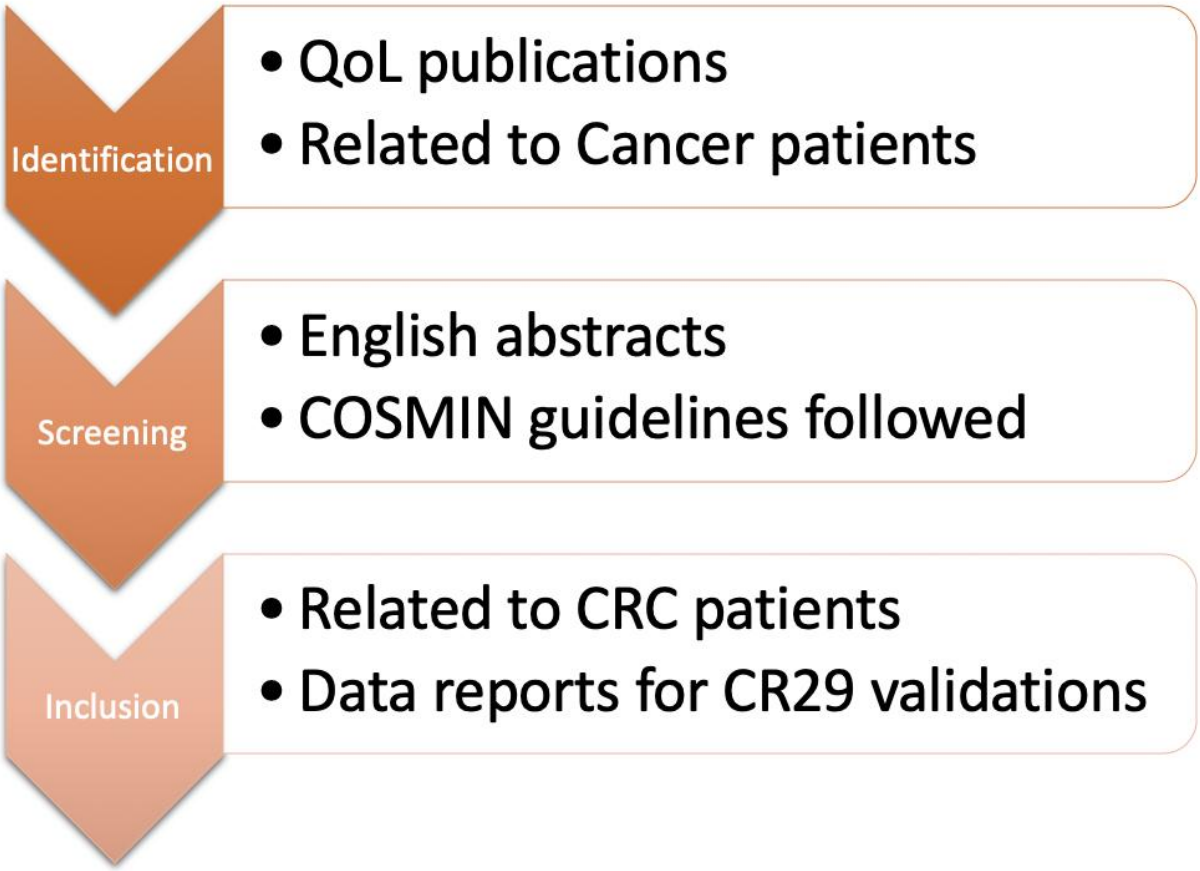


***Figure 4**: Flow-chart of the systematic literature review and selection process:*

CROSS-CULTURAL ADAPTATION PROCEDURE:

As aforementioned, clinicians and researchers are devoted to the development of HRQL measures. Nevertheless, as most measurement tools are developed in the English language, transcribing these dimensions to other languages and cultures may be impeded by cultural differences in disease expression as well as in the expression of QoL issues. (64) (65) Consequently, two options may be considered: the development of a new measure - which is time-consuming with the main task being the conceptualization of the measure's items - , or the use of a previously validated measure in another language after validating it in the targeted population - also known as cross-cultural adaptation-. Today, with the increase of multicentre multicountry trials, the need for culturally adapted HRQL measurement tools has never been greater. (64,66)

Previous efforts were made to raise the issues encountered during the adaptation process and how to tackle them using systematic methods (67) which led to standardized guidelines (66,68) based on social and psychological research.(69–71) In addition to a good linguistic translation, measurement tools to be used across cultures must also be adapted with unique standardized methods to maintain the content's validity across different cultures. (68) Accordingly, cross-cultural adaptation refers to the process of preparing a questionnaire to be used in a different setting by adapting it both at a linguistic and cultural level. (72)

The quality of the adapted instrument with regard to the cultural context and lifestyle is then assessed according to its sensibility. The elements of sensibility that must be considered include the purpose of the measure, comprehensibility, content, replicability and the suitability of the scales forming the instrument of measure.(66)

In our study, we translated the EORTC QLQ-CR29 to the most commonly spoken language in Morocco -Moroccan Arabic. The Moroccan dialect greatly differs from the official language in Morocco - Classical Arabic - that is only mastered by Moroccans with a certain level of education.

I. Translation process:

Translation abides to standardized steps. The translation process was conducted according to the following steps as laid by the EORTC translation manual (73,74):

- *Forward translation*: Two translations from the English version made by two separate translators who are native speakers of the Moroccan Arabic Dialect.
- *Reconciliation:* The two translations are then reconciled by a third person who chooses the best version or combines the two in order to have the most accurate translation.
- *Backward translations:* Two translators who must have an excellent understanding of the English language translate the Moroccan dialect version back to English.
- *Review*: This step consists of proofreading the preliminary translation with discussions of the corrections until a consensus is reached.
- The result was a provisional Moroccan Arabic Version of the EORTC QLQ-CR29.
- *Pilot-testing:* This is the final step of the translation process. A small group of the targeted population completes the provisional Moroccan Arabic questionnaire and gives remarks about the meaning of the questions and ways to improve it thereby ensuring that the translated version retains its equivalence when applied.

The purpose of the aforementioned steps is to raise and address all the inconsistencies that may occur during the translation process. Once the issues resolved, the final translated version of the EORTC QLQ-CR29 was ready for use.

The final translated version was then validated and adapted to its aimed population.

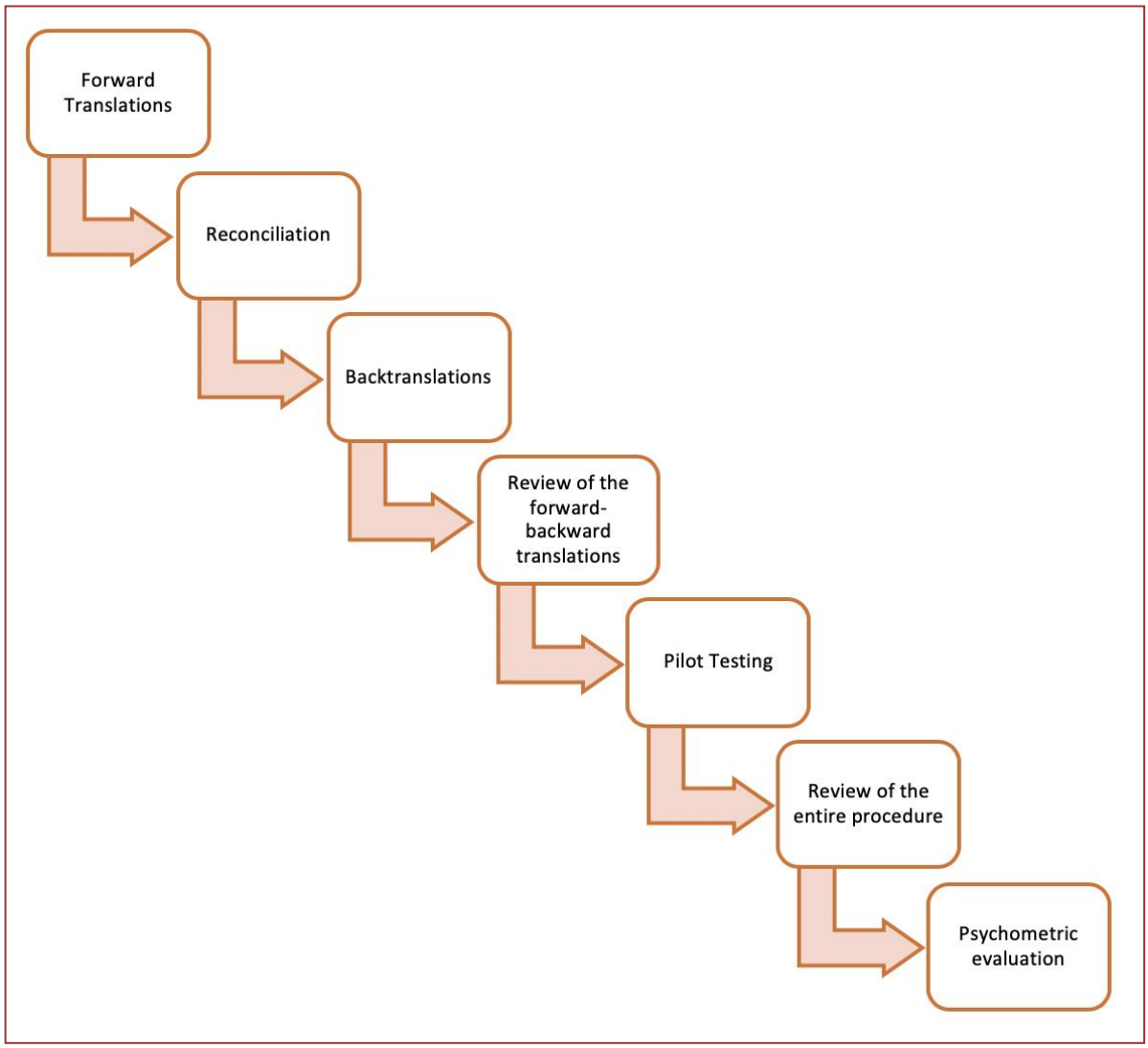


Figure 5*: The reconciliation process: guidelines for translating QoL questionnaires*

II. Validation process:

1. Study Design:

We followed the STROBE (Strengthening the Reporting of Observational studies in Epidemiology) directive guidelines for observational studies (75).

Patients were prospectively recruited from The National Oncology Institute of Rabat during the period between January 2017 up until December 2019. We resorted to the database of the Department of Surgical Oncology to enlist participants according to predetermined inclusion criteria. The participant's list contained basic information related to the patient such as: the entry number, the exact diagnosis, and the type of intervention.

Enlisted participants responded to the following criteria:

Inclusion criteria:

The patients considered eligible for the study were:

- Aged over 18,
- Patients with histologically confirmed cancer of the colon and/or rectum,
- Surgery 6 months prior to the interview.

A severe decrease in QoL occurs immediately after the surgical with a gradual recuperation 3 months after, whereas older patients need more time to restore their QoL. (42) Accordingly, a postoperative interval of 6 months was required to truly appreciate the patients' QoL as conducted in previous studies of QoL for CRC patients. (76–78)

Exclusion criteria:

The exclusion criteria were:

- The inability to understand and speak Moroccan arabic dialect,
- Debilitating comorbidities such as dementia that rendered the interview unfeasible.
- Uncompleted questionnaires.

The cases were divided into known-groups according to:

- Age,
- Gender,
- Stoma status
- Tumor site
- Radio/chemotherapy

Sample Size Considerations:

As the sample size determination for psychometric validation studies lacks clear recommendations (79), we determined the required sample by allocating a number of observations 5 to 10 times greater than the variables.(80) Accordingly, the sample size ranged between 150 and 300 participants.

2. Interview process:

Eligible patients were approached during their follow up visits to the Institute and asked to complete the questionnaires without offering them any interpretation of the questions. For those unable to read, an interviewer read the questions and noted down the participant's answers. We also contacted participants unable to present to the hospital, and conducted the interview via phone calls.

Each patient completed forms containing:

◊Clinical and socio-demographic characteristics.

◊The Moroccan Dialect version of the EORTC QLQ C30 and the QLQ-CR29 module.

3. Description of the instruments:

EORTC QLQ-C3O:

The EORTC QLQ-C30 *version 3.0* is a core questionnaire composed of both multi-item scales and single items that reflect the multidimensionality of the quality-of-life construct and which incorporates the following:

◊Five functional scales: for physical, role, cognitive, emotional, and social.

◊Three symptom scales : for fatigue, pain, and nausea and vomiting.

◊A global health and quality-of-life scale.

◊Lastly, the single items examine additional symptoms that are commonly reported by cancer patients (dyspnea, appetite loss, sleep disturbance, constipation, and diarrhea), in addition to the perceived financial impact of the disease and its treatment. (10)

These items are scored using a 1-to 4-point Likert scale, the possible answers are:

- 1 = “Not at all”,
- 2 = “A little”,
- 3= “Quite a bit”,
- 4= “Very much”.

As for the items 29 and 30, seven different responses are possible and are awarded a score of 1 to 7 points. (81)

The Moroccan version of the QLQ C30 we used has already been validated in a previous study. (60)

EORTC QLQ-CR29:

The EORTC QLQ-CR29 is a tumor-specific questionnaire module that supplements the QLQ C30, it contains 29 items composed of multi-item scales and single items that evaluate both symptomatic and functional areas;

◊Multi-item scales are: Urinary frequency (UF), Blood and mucus in the stool (BMS), Body image (BI), Stoma problems and defecation problems (Stoma pb. & Def pb)

◊Single items are: anxiety, weight, sexual interest, urinary incontinence, dysuria, abdominal pain, buttock pain, bloating, dry mouth, hair loss, taste loss, flatulence, fecal incontinence, sore skin, embarrassment, stoma care problem, impotence or dyspareunia.

An item (Q48) indicates the stoma status, separate items are designed for patients with/without a stoma:

◊With stoma (Q49s-55s): bags change, flatulence, leakage, sore skin around the stoma and stoma care problems

◊Without stoma: (Q49-54) stool frequency, flatulence, fecal incontinence, sore skin, and embarrassment.

The last four items are separated according to gender;

◊Sexual interest and impotence for males (Q56-57),

◊Sexual interest and dyspareunia for females (Q58-59).

The EORTC QLQ-CR29 multi-item scales and single items are also scored using a 1- to 4-point Likert scale (“not at all”, “a little”, “quite a bit”, “very much”).

Additional data collected:

Socio-demographic characteristics:

- Name
- Entry Number
- Social security status
- Age
- Gender

Clinical data:

- Site
- Stoma status
- Anastomoses' type
- Fistula
- Adjuvant radiochemotherapy

4. Statistical Analysis:

Scale structure:

Given the multidimensional aspect of QoL and the QLQ C30&CR29, multitrait scaling analysis was used to examine the extent to which the items of the module can be combined into the hypothesized multi-item scales. (82)

As advised by the EORTC guidelines, when items are related to the same clinical or psychosocial concept, they are combined into scales with each one dealing with a different domain of QoL. (61)

Scores were calculated for the two questionnaires (C30 & CR29) by transforming raw scores (RS) linearly into a 0 to 100 score, as stated by the EORTC scoring manual. (83) A raw score (RS) is the estimated average of the items that contribute to the scale.

The linear transformation: RS is standardized so that scores (S) range from 0 to 100; a higher score represents a higher ("better") level of functioning or a higher ("worse") level of symptoms. (83) Meaning; the higher the score for a functional scale, the higher/healthier level of functioning, but the higher the score for a symptom scale or item the higher the level of symptomatology/ problems.

In practical terms, if I_1, I_2, ... I_n are items included in a scale, the scores are calculated as follows:

◊RS= $(I_1 + I_2 + ... + I_n)/n$

◊Linear transformation depends on the nature of the scale:

- Functional scales: $S=\left\{1-\frac{(RS-1)}{range}\right\}\times 100$
- Symptom scales/ items: $S=\left\{\frac{(RS-1)}{range}\right\}\times 100$

Range is the difference between the maximum value possible of the raw score (RS) and the minimum possible value.

Descriptive Analysis:

Descriptive statistics were generated through: Means, Medians, and Standard Deviations (SD) of scores as well as a floor and ceiling effect for both questionnaires.

The percentage of responders who achieved the lowest (floor) or highest (ceiling) possible limits for potential responses was examined for each scale. Similar to previous studies (4,84), such effects were considered to have occurred if more than 50% of respondents achieved the lowest or highest possible score, respectively.

Psychometric properties:

Psychometric properties are defined as the assessment if the instrument is a reliable and valid form of measurement.(25) To state that a questionnaire has excellent

psychometric properties it must be evaluated extensively. A single attribute is measured with multiple items, and validation methods are used to demonstrate that the multiple component items are all measuring (more or less) the same single attribute. (26)

CoSMIn taxonomy offers evidence-based consensus on definitions and terminology for examining methodology of measurement properties. (62) As such, we used CoSMIn taxonomy to define the following properties :

***A. Reliability*:**

The assessment of reliability consists of determining that a scale or measurement yields reproducible and consistent results. There are two different levels of reliability; internal reliability and reproducibility (82) :

A. 1.Internal Reliability:

Also known as internal consistency, states that the items belonging to the same scale should be consistent in the sense that they should all measure the same thing. (85)

The internal consistency was evaluated for multi-item scales using Cronbach's alpha reliability coefficient. Cronbach's alpha coefficient ranges from 0 to 1. The closer the coefficient is to 1, the greater the internal consistency and homogeneity of the items in the scale, correspondingly results can be interpreted along these lines (27):

> .9 – Excellent,

> .8 – Good,

> .7 – Acceptable,

> .6 – Questionable,

> .5 – Poor, and

< .5 – Unacceptable"

A value of 0,7 or greater was considered as an indicator of high internal consistency. As suggested by *Nunnally et al.* (86)

A. 2. Reproducibility:

The questionnaire should yield reproducible or similar values if used repeatedly on the same patient while the patient's condition has not substantially changed(62) which can be assessed by repeating measurements over a period of time (test-retest reliability). The appropriate time period should be long enough to prevent the participant from remembering the first answer but short enough to avoid any clinical change. Accordingly, psychometricians recommend a time interval of 1 to 2 weeks. (85)

A random subset of patients was selected to retake the QLQ-CR29 questionnaire after 7-14 days of the first interview. No procedures were performed between the two interviews.

The results of the two measurements were correlated using the Intraclass Correlation Coefficient (ICC). A 0.9 coefficient or higher translates excellent test-retest reliability and a minimum of 0,7 is considered acceptable. (87)

B. Validity:

Validity is determining whether there are grounds for believing that the instrument measures what it is intended to measure and that it is useful for its intended purpose. (88)

In our case; this translates to asking to what extent is it reasonable to claim that the Moroccan Dialect version of the EORTC QLQ CR-29 really is assessing the QoL of CRC patients?

The validation process covers content, construct and criterion validity: (82)

B.1. Content validity:

Content Validity concerns the extent to which the items are sensible and reflect the intended domain of interest. To be able to claim content validity, expert panels (clinicians) should assess the clarity, comprehensiveness, and explicitness of the different items and scales forming the instrument of measure. (88) Participants also conducted this critical examination of the questionnaire's content. Contrary to the other forms, no correlation coefficient or other statistical tests can be used to determine content validation. (87,88)

B.2. Construct validity:

Construct validity is one of the most important characteristics of a measurement instrument. It is an assessment of the degree to which an instrument measures the construct that it was designed to measure. (82) Of the three types of validity, construct validity is the most amenable to exploration by numerical analysis. The numerical analyses evaluate the following correlations :

a. Convergent validity:

Convergent validity states -in the matter of multi-item scales- that items comprising any one scale should correlate with each other. If items belong hypothetically to the same scale, they should strongly correlate to the scale score, if they do not it may imply that an item or another is not contributing to the scale it was meant to measure. (62)

The convergent validity of each item was determined by calculating the correlation between each item and its own dimension. Spearman Correlation test was used to evaluate the correlation. A correlation of $r > 0.40$ of an item with its own scale was considered acceptable.

b. Discriminant validity:

Discriminant validity of an instrument that has multiple scales stipulates that the items within one scale should not correlate too highly with external items and other scales. Strictly speaking, we expected that the correlation between each item and its own dimension to be greater than the correlation between the item and the other dimensions. Correlations were generated through Spearman's Correlation test. (26) (82)

- ***Multitrait-multimethod & Multitrait scaling analysis:***

One way to study these correlations is the Multitrait-multimethod (MTMM) correlation matrix. MTMM correlation matrix is generated through examining multiple traits by using different methods.(89) To that end, the traits are the items and the scales make up for the methods. However, when dealing with questionnaires containing multi-item scales such as the CR29, MTMM analysis yields a large number of item-to-item correlations that are onerous to present. (82)

Alternatively, we can focus on item-to-scale correlations which are known as multitrait scaling analysis. (MSA) Multitrait scaling analysis is a simple yet efficient way to examine the convergent and divergent validity of measurements with multi-item scales such as the CR29. (82) Multitrait scaling analysis(MSA) was therefore used to assess the structure of CR29.

For a better understanding of the multitrait scaling analysis let us consider the following template for the MSA correlation matrix:

	Hypothesized Scales			
	items	Scale 1	Scale 2	Scale 3
Scale 1	Item 1	C		
	Item 2	C		
Scale 2	Item 3		C	
	Item 4		C	
Scale 3	Item 5			C
	Item 6			C

***Table 2**: Template of multitrait scaling analysis*

Grey "C" cells represent the convergent validity correlations. Multitrait- scaling analysis aims to confirm that items are included in the scale which they correlate most strongly with, thus the grey cells should have higher correlations (Spearman's r >0,4) when compared to the other cells. (82)

- ***Example from literature:***

In this example, the construct validity of the QLQ-C3O was examined using MSA. The QLQ-C30 is made of multiple scales and each scale contains multiple items. The framed cells show the correlation between the items and their own scales. We notice that overall, these correlations are higher than the correlation between the items and other scales. Therefore, we can conclude that QLQ-C3O yields good convergent and divergent validity.

Item no	Description	PF	RF	EF	CF	SF	FA	NV	PA	QL
1	Strenous activity	−0.75	−0.41	−0.04	−0.05	0.08	0.22	0.07	−0.01	0.03
2	Long walk	−0.75	−0.32	−0.11	−0.09	0.08	0.12	−0.03	−0.02	0.09
3	Short walk	−0.69	−0.40	−0.09	−0.11	−0.08	0.31	0.05	0.08	0.03
4	Stay in bed/chair	−0.61	−0.30	−0.22	−0.05	−0.03	0.43	0.17	0.15	−0.15
5	Needed help in eating/dressing/ washing	***−0.38***	−0.37	−0.45*	−0.21	−0.17	0.25	0.05	0.34	−0.13
6	Limited work	−0.34	−0.65	−0.25	−0.12	−0.35	0.25	−0.06	0.28	0.09
7	Limited hobbies	−0.30	−0.57	−0.18	0.02	−0.27	0.31	0.13	0.28	−0.04
21	Tense	−0.14	−0.17	−0.65	−0.08	−0.25	0.14	0.10	0.25	−0.05
22	Worried	−0.11	−0.17	−0.64	−0.12	−0.25	0.16	0.06	0.21	−0.08
23	Irritable	−0.15	−0.15	−0.54	−0.05	−0.12	0.12	0.05	0.14	−0.10
24	Depressed	−0.03	−0.03	−0.49	−0.11	−0.13	−0.12	0.01	0.13	−0.12
20	Concentration	−0.10	−0.09	−0.25	−0.58	−0.07	−0.11	−0.01	−0.26	−0.14
25	Memory	−0.08	−0.01	−0.01	**−0.34**	−0.18	−0.04	−0.17	0.04	−0.04
26	Family life	0.28	−0.01	−0.12	−0.12	−0.75	−0.03	−0.01	0.05	−0.11
27	Social life	−0.16	−0.33	−0.09	−0.02	−0.71	0.17	−0.06	0.24	0.02
10	Need rest	−0.14	−0.17	−0.14	−0.10	−0.21	**0.28**	−0.04	0.05	−0.08
12	Feel weak	−0.30	−0.27	−0.29	−0.04	−0.19	0.40	0.03	0.29	−0.10
18	Tired	−0.34	−0.26	−0.32	−0.11	−0.17	0.50	0.14	0.31	−0.10
14	Nausea	−0.08	−0.09	−0.21	−0.02	−0.24	−0.06	0.40	0.15	−0.15
15	Vomiting	−0.05	−0.11	−0.21	−0.09	−0.19	0.13	**0.34**	0.14	−0.15
9	Pain	−0.20	−0.27	−0.26	−0.14	−0.07	0.16	0.09	0.59	0.07
19	Relation of pain with daily activities	−0.29	−0.38	−0.33	−0.19	−0.15	0.27	0.03	0.60	−0.29
29	Overall physical condition	0.07	0.06	0.23	0.03	0.14	−0.07	−0.20	−0.05	0.62
30	QoL	0.14	0.07	0.25	−0.07	0.03	−0.19	−0.22	−0.19	0.65

EORTC QLQ-C30, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-C30; PF, physical function; RF, role function; EF, emotional function; CF, cognitive function; SF, social function; FA, fatigue; NV, nausea and vomiting; PA, pain; QL, quality of life.

Table 3*: Multitrait scaling analysis of EORTC-QLQ C30* (90)

- ***Known*-group comparisons:**

Known group validity -also called clinical validity is another way to test the construct validity of the instrument. It is based on the principle that a specified subgroup of patients is anticipated to score differently from another given their different clinical statuses, and the instrument should be sensitive to these differences. (63)

In this study, the compared subgroups were pre-established based on the determinants of QoL we developed in the previous chapter. Subsequently the subgroups were :

- Stoma status: permanent stoma vs. no stoma,
- Age: <65 years old vs. ≥65 years old,
- Gender: Male vs. Female
- Tumor site: Colon cancer vs. Rectal cancer
- Neoadjuvant Radiochemotherapy usage: used vs. not used.

B.3. Criterion validity:

Criterion validity considers whether the scale has an association with external criteria, such as other established instruments.

This was performed by comparing scales of the EORTC QLQ-C30 and those of the EORTC QLQ-CR29 to assess whether a clinical overlap between the two questionnaire scales existed and its extent. (4)

Spearman's correlation test was also used for this comparison.

We analyzed all the data using SPSS 26.0. For all analyses, a statistically significant result was defined as $p < .05$.

III. ***Ethical considerations:***

Approval for this study was obtained from the Ethics Committees of the Faculty of Medicine and Pharmacy, Mohammed V University, and the National Institute of Oncology in Rabat, Morocco. (79/17)

All patients enrolled in the study provided written, informed consent allowing the use of their data for clinical studies at the time of their initial visit.

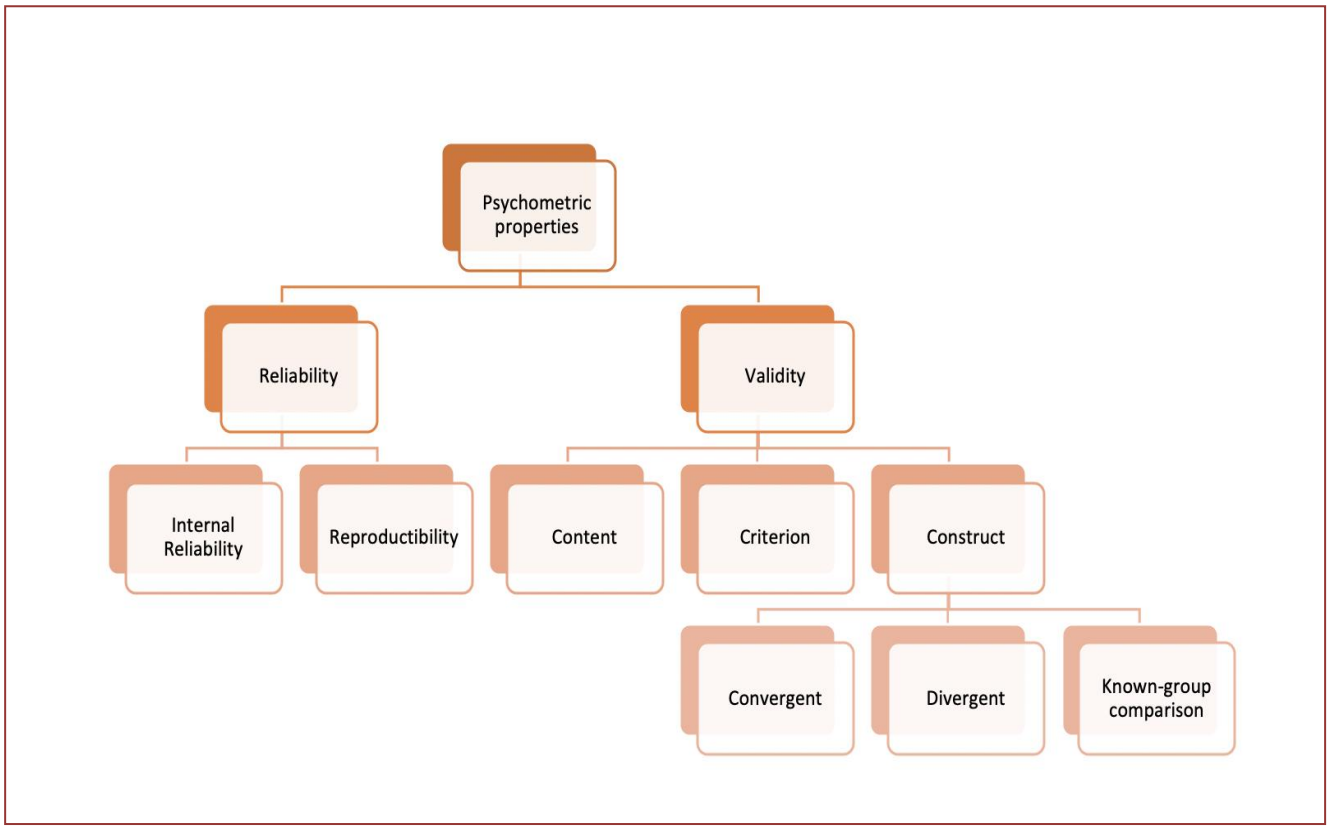


Figure 6: *Psychometric properties of the measurement*

Results

SYSTEMATIC LITERATURE REVIEW:

We reviewed all available previous validation studies of the different versions of the questionnaire and the results of the systematic literature review are detailed in Table 4. The CR29 has been translated and/or culturally adapted into 56 languages or dialects, namely, Danish, Polish, Persi, Spanish, Taiwanese, Chinese, Japanese, Korean… (15)

Reference	Publication Year	Research Aim	Sample size	Language
Gujral et al. (8)	2007	Updating the EORTC QLQ module for CRC patients	120 patients	English
Whistance et al. (9)	2009	Validation of the clinical and psychometric properties of the EORTC QLQ-CR29	351 Patients	English, French, German, Spanish, Italian, Taiwanese
Arras et al. (34)	2010	Validation of the Spanish version	84 Patients	Spanish
Stiggelbout et al. (33)	2015	Validation of Dutch version	236 Patients	Dutch
Magagi et al. (91)	2015	Validation of the Bahasa-Malasia version	93 Patients	Bahasa-Malaysian
Sanna et al.(3)	2017	Large scale validation of the Polish version	150 Patients	Polish
Sadighi et al. (92)	2017	Properties of the Iranian version	100 Patients	Persi
Lin et al. (36)	2017	Validation of the Chinese version	356 Patients	Chinese
Shen et al. (37)	2018	Validation of the Taiwan Chinese version	108 Patients	Taiwan Chinese

Table 4*: Literature review of the available validations of The EORTC QLQ-CR29*

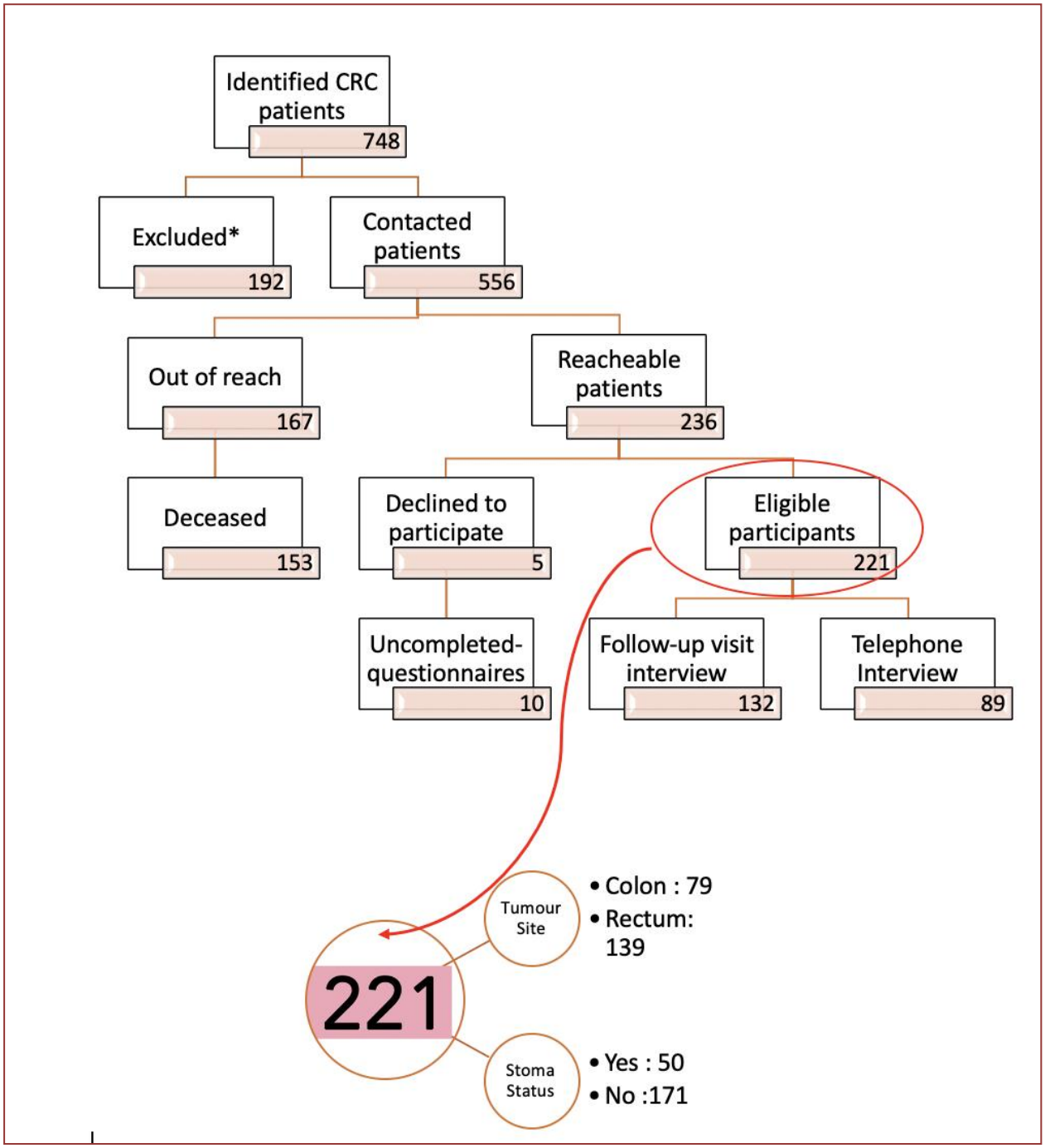
CULTURAL ADAPTATION:

After rigorously following the translation steps, the provisional Moroccan Arabic EORTC QLQ-CR29 underwent a preliminary test on a group of 50 patients with colon or rectal malignancies which resulted in the final version of the instrument.

The final version of the cultural adaptation is showcased in the appendix along with the Moroccan version of the QLQ-C30.

PARTICIPANTS' COMPLIANCE AND CHARACTERISTICS :

We first registered 748 cases of colorectal cancer, based on our selection criteria, 192 patients were excluded for non-eligibility, and out of the 556 contacted patients; 167 patients were out of reach and 153 patients were deceased (20,4%). Additionally, 5 patients declined the invitation to participate and 10 returned incomplete questionnaires and were consequently excluded. We were able to enroll a total of 221 participants with complete questionnaires - the EORTC QLQ-C30 and the QLQ-CR29-. Overall, 132 patients filled the questionnaire forms during their follow-up visits and 89 were interviewed via phone calls.



*Exclusion for non-eligibility : debilitating comorbidities (i.e dementia…) - No postoperative 6 months interval-

***Figure 7**: Flow-chart of enlisted participants*

The socio-demographic and clinical properties of the patients enrolled in the study are detailed in Table 4. 123 were males and 98 were females. The mean age was 55,6 (+/- 12,7) years and 78 patients had colic cancer (35,9%), 138 had rectal cancer (64,1%) and 50 patients had a stoma (22,6%). 34 patients retook the QLQ-CR29 for a second time after a period of one to two weeks to evaluate reproducibility.

The mean time for completion of both questionnaires (C30 & CR29) was 15 mins when no help was provided, otherwise, the mean completion time was 20 mins. Help was essentially required to read the questions. (31,2%) Participants considered the questionnaire to be clear and had no trouble responding to the questions, except for sexuality related items. Missing answers were amidst the sexual items with a miss rate of 9% for males and 23% for females. Those patients reported that questions about sexual activity were not relevant to them.

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*		
Colon	78	35
Rectum	139	62
Neoadjuvant ChemoRadiotherapy*		
Yes	89	45,5
No	107	54,6
Adjuvant Chemotherapy*		
Yes	91	70
No	39	30
	Mean	SD
Age	55,65	12,87

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

Table 5 *Patients sociodemographic characteristics :*

DESCRIPTION OF THE QLQ-CR29 SCORES:

The distributions of the EORTC QLQ-C30 and QLQ-CR29 scale scores are detailed in Table 5 .

The above-cited scale scores were mixed with a high score for a functional scale being equivalent to a better level of functioning, whereas a high score for a symptom scale meant a higher level of symptoms. The mean values for the different dimensions of the QLQ-CR29 scores ranged from 16,44 to 75,56 and the single item “Hair loss” scored the lowest while the “Weight” item scored the highest.

The range of scores was broad in all the dimensions. Other than one item (the single item “Bag change” that ranged from 0 to 83), the whole range of scores was represented (0 to 100) in all the items of the QLQ-C30 and the QLQ-CR29.

The percentage of patients scoring low was high in 12 single items (>50%) which indicates the presence of a floor effect.

A ceiling effect was observed for one single item where the percentage of patients scoring high exceeded 50%.

Scale/Single Item	Items	N	Mean	SD	Floor	Ceiling	Range	ICC
C30 :								
Physical Function	1 - 5	221	73,64	23,85	,9	23,9	0-100	-
Role Function	6,7	221	62,92	37,00	13,3	39,0	0-100	-
Emotional Function	21-24	221	67,24	30,77	4,1	30,7	0-100	-
Cognitive Function	20, 25	221	83,94	23,45	,5	58,3	0-100	-
Social Function	26 , 27	221	79,58	28,93	3,7	57,3	0-100	-
Fatigue	10,12,18	221	30,98	29,17	27,1	2,8	0-100	-
Nausea and vomiting	14,15	221	7,79	17,16	78,0	,5	0-83	-
Pain	9,19	221	24,31	29,72	46,8	3,7	0-100	-
Dyspnoea	8	221	21,10	30,59	62,4	4,6	0-100	-
Insomnia	11	221	27,67	35,25	56,4	9,2	0-100	-
Appetite loss	13	221	20,48	30,99	63,3	6,4	0-100	-
Constipation	16	221	27,52	33,97	53,8	1,4	0-100	-
Diarrhea	17	221	27,67	34,67	53,2	10,6	0-100	-
Financial difficulties	28	221	51,22	40,61	30,7	30,7	0-100	-

CR29 :	Items	N	Mean	SD	Floor	Ceiling	Range	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		-	-	-	-	-	-	,969
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	1
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 Fq	52,53	172	29,65	32,33	38,4	7,6	0-100	,977
Embarrassed	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	
(F)Sexual functioning Male	56	111	42,85	37,81	33	20,5	0-100	,928
Impotence	57	111	38,18	38,79	40,9	20	0-100	,966
(F)Sexual functioning female	58	75	67,06	36,76	11,9	48,8	0-100	,933
Dypareunia	59	75	26,58	35,75	58,3	10,7	0-100	,985

Table 6 *Quality of life scores according to EORTC QLQ-C30 and QLQ-CR29, structure and reliability.*

RELIABILITY

Internal Consistency:

Internal consistency was assessed using Cronbach's alpha coefficient.

Table 9 shows the results of the alpha Cronbach's coefficient calculations.

In addition to calculating it for the total study populations, Cronbach's alpha coefficient was also calculated separately for patients with and without a stoma.

The criterion of 0,7 was exceeded for the Urinary Frequency scale (0,79) and the Stool Frequency scale (0,83) which indicates acceptable and good internal consistency.

The Cronbach's alpha coefficient was moderately lower for the Blood and Mucus in Stool (BMS) scale (0,615) and the Body Image (BI) Scale (0,672).

Besides the Body image scale (0,64 with vs. 0,69 without), cronbach's alpha coefficients were higher for patients without stoma in comparison to those with a stoma therefore indicating higher reliability for patients without stoma.

Reproducibility:

The QLQ CR29 was administered twice for 34 patients to assess the test-retest reliability using the intraclass correlation coefficient (ICC).

The ICCs ranged from 0,889 to 1 for each item of the QLQ CR29 indicating good to excellent reproducibility for all the items of the EORTC QLQ CR29.

ICC results are detailed in Table 5.

VALIDITY:

Multitrait scaling analysis:

Convergent and divergent validity of the multi-item scales included in the QLQ-CR29 were tested for the full sample as well as independently for patients with and without stoma.

The results of multitrait scaling analysis- which evaluates convergent and divergent validity- are detailed in the three Tables below.

The 0,40 criterion for Spearman's correlation coefficient between single items and their own scale was exceeded for all the dimensions.

All these correlations were statistically significant with $p<0,01$ for all convergent validity correlations.

Furthermore, the items correlated better with their own scales than with other scales showing good divergent validity.

Item nb	Description	Urinary Frequency	Blood & Mucus in Stool	Body Image	Stool frequency	Urinary Frequency
31	Urinary Frequency -Day-	,905**	,199**	-,067	,210	,252**
32	Urinary Frequency -Night	,907**	,138*	-,055	-,005	,190*
38	Blood in stool	,072	,745**	-,182**	,215	,279**
39	Mucus in stool	,188**	,891**	-,277**	,350*	,308**
45	Body Image - Feeling attractive	-,005	,231**	-,711**	,188	,111
46	Body Image – Masculinity/ Femininity	,036	,163*	-,759**	,128	,020
47	Body Image - Contentement	-,050	,202**	-,665**	,364*	,012
52s	Bag Change- Day	,086	,393**	-,300*	,966**	-
53s	Bag Change- Night	,173	,151	-,107	,830**	-
52	Stool Frequency -Day	,262**	,347**	-,071	-	,914**
53	Stool Frequency - Night	,271**	,293**	-,142	-	,850**

**p<0,05*

***p<0,01*

Grey cases show the convergent validity correlations

***Table 7**: Multitrait scaling analysis*

Item nb	Description	Urinary Frequency	Blood & Mucus in Stool	Body Image	Stool frequency
31	Urinary Frequency -Day-	,917**	,205**	-,120	,252**
32	Urinary Frequency -Night	,923**	,132	-,125	,190*
38	Blood in stool	,057	,791**	-,201**	,279**
39	Mucus in stool	,193*	,875**	-,182*	,308**
45	Body Image - Feeling attractive	-,008	,191*	-,723**	,111
46	Body Image – Masculinity/ Femininity	,112	,085	-,707**	,020
47	Body Image - Contentement	-,079	,151*	-,630**	,012
52	Bag Change- Day	,262**	,347**	-,071	,914**
53	Bag Change- Night	,271**	,293**	-,142	,850**

**p<0,05*

***p<0,01*

***Table 8**: Multitrait scaling analysis -No Stoma Patients*

Item nb	Description	Urinary Frequency	Blood & Mucus in Stool	Body Image	Stool frequency
31	Urinary Frequency -Day-	,849**	,185	,146	,210
32	Urinary Frequency -Night	,836**	,166	,171	-,005
38	Blood in stool	,147	,626**	-,317*	,215
39	Mucus in stool	,210	,964**	-,447**	,350*
45	Body Image - Feeling attractive	,025	,339*	-,515**	,188
46	Body Image – Masculinity/ Femininity	-,205	,393**	-,893**	,128
47	Body Image - Contentement	,069	,342*	-,748**	,364*
52s	Bag Change- Day	,086	,393**	-,311*	,966**
53s	Bag Change- Night	,173	,151	-,059	,830**

**p<0,05*

***p<0,01*

***Table 9**: Multi-trait scaling analysis -Stoma Patients*

	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 10**: Convergent and discriminant validity of the EORTC QLQ-CR29:*

CRITERION VALIDITY: C30 VS CR29

The results of the correlation scores between the two questionnaires are detailed in Table 10.

Correlations between the scales of the QLQ-CR29 and QLQ- C30 using Spearman's rho (r) were low ($r<0.40$) in most cases, showing there is no overlap between the two questionnaires.

Nevertheless, in certain areas with more similar content, higher correlations were noted; e.g: "Body Image" and "Social Functioning" correlated at 0,403, whereas in symptom scales, CR29's "Abdominal Pain" scale correlated at 0,443 with C30's "Pain" scale. "Stoma care problems" correlated at 0,502 with the "Global quality of life scale". The C3O's "Diarrhea" scale correlated with the "Stool frequency" and "Fecal incontinence" from the CR29.

Functional scales of the QLQ-CR29 correlated for the most part positively with functional scales of the QLQ-C30 and negatively with symptom scales of the QLQ-C30. Furthermore, 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).

	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	FI
Functional scales															
Body Image	,294**	,279**	,370**	,214**	,244**	,403**	-,298**	-,256**	-,161*	-,250**	-,151*	-,278**	-,221**	-0.003	-0.079
Anxiety	,297**	,314**	,264**	,315**	,273**	,285**	-,294**	-,160*	-,210**	-,169*	-,138*	-0.117	-0.029	-0.008	-,167*
Sexual Function: Male	-0.121	-0.133	-0.058	-0.011	-0.034	-0.111	0.009	-0.010	0.084	0.089	0.124	0.109	0.049	0.049	0.018
Sexual Function: Female	-,299**	-0.192	-0.115	-0.079	-,256*	0.040	0.082	-0.033	,221*	-0.001	,230*	0.040	0.017	0.112	0.033
Symptom Scales															
Urinary Frequency	-,137*	-,247**	-,201**	-,237**	-0.089	0.029	,244**	0.070	,218**	,230**	,176**	,165*	0.042	,221**	0.122
Blood and mucus in stool	-,241**	-,283**	-,269**	-,190**	-0.110	-0.123	,359**	,215**	,349**	,190**	,277**	,268**	,152*	,302**	,256**
Urinary Incontinence	-0.009	-0.128	-0.060	-,237**	-,152*	-0.050	0.102	0.014	0.108	,150*	,195**	0.030	,135*	0.032	0.044
Dysuria	-0.017	-0.103	-,161*	-0.069	-0.065	-0.047	,153*	0.012	,172*	0.058	,133*	0.086	0.091	0.100	0.025
Abdominal Pain	-,138*	-,161*	-0.099	-0.125	-0.099	-0.055	,232**	,143*	,443**	,140*	,254**	0.122	,168*	0.107	-0.039
Buttock Pain	-,212**	-,265**	-,270**	-0.103	-0.098	-0.074	,363**	,149*	,469**	,194**	,253**	,190**	0.025	,149*	,280**
Bloated Feeling	-,206**	-,213**	-,138*	-,213**	-,145*	-0.084	,292**	,171*	,377**	,256**	,380**	0.058	,253**	0.040	0.073
Dry mouth	-,309**	-,341**	-,257**	-,266**	-,283**	-0.125	,340**	,390**	,205**	,202**	,141*	,329**	,211**	,145*	0.113
Hair loss	-0.036	-,195**	-,133*	-,337**	-,242**	-0.131	,183**	,217**	0.084	0.080	,141*	,182**	,200**	,135*	0.033
Trouble with taste	-0.099	-,247**	-,236**	-,134*	-,173*	-0.125	,243**	,343**	0.036	,202**	0.010	,271**	,173*	0.101	0.072
Weight	,176**	,280**	,291**	,157*	0.121	,179**	-,238**	-0.128	-0.081	-0.060	-,143*	-,165*	-,169*	-0.083	-0.017
Flatulences	0.124	-0.023	0.139	-0.126	-0.180	-0.260	0.077	0.056	-0.062	0.262	0.042	0.065	0.131	0.147	0.117
Leakage	0.083	0.142	0.046	-0.271	-0.128	-0.146	0.033	0.059	-0.023	0.114	-0.004	0.093	0.029	0.127	0.240
Sore skin around stoma	-0.041	-0.190	0.025	-,600**	-,402**	-,330*	,295*	0.261	,297*	0.247	,380**	0.073	0.172	0.002	0.133
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	0.019	-0.098
Embarrassement	-,407**	-,312**	-,394**	-,272*	-0.150	-0.164	,476**	0.155	,419**	,325**	,353**	0.156	-0.079	0.030	,361**
Stoma care problems	-,502**	-,391**	-,458**	-,277*	-0.182	-,228*	,529**	,239*	,587**	,328**	,468**	,239*	0.093	-0.064	,343**
Stoma problems	-0.077	-0.142	-0.009	-,580**	-0.277	-,364*	,336*	0.108	0.181	0.264	,301*	0.138	0.104	0.179	0.139
Flatulences	-,160*	-,151*	-0.034	-0.149	-0.137	-0.112	0.144	0.032	,177*	,269**	,173*	-0.003	0.008	,252**	,200**
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**	,203**
Sore skin around anus	-0.081	-0.012	-0.045	-0.057	-0.047	-0.102	0.049	0.113	0.086	0.121	0.027	0.027	-0.006	0.149	,195*
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**	,189*
Embarrassement	-0.101	-0.133	-0.135	-,207**	-,167*	-,208**	,178*	0.141	0.149	,276**	,152*	0.062	0.146	,224**	,203**
Defecation	-0.111	-0.116	-0.038	-,202*	-0.159	-,173*	,190*	0.157	,280**	,316**	,181*	0.040	0.106	,379**	,290**
Impotence	0.019	-0.065	-0.149	-0.104	-0.170	-,218*	0.075	,243*	-0.104	,313**	0.065	,308**	0.175	0.008	0.064
Dyspareunia	-0.083	-0.096	-0.118	-0.174	-,243*	-,345**	0.108	0.025	,260*	0.163	0.162	0.156	0.045	0.157	,236*

Table 11*: Scale correlation between the QLQ-CR29 and QLQ-C30*

CLINICAL VALIDITY:

The clinical validity of the QLQ-CR29 was evaluated by comparing the scores in pre-established subgroups of patients with clinically different status.

The compared groups were:

- Stoma status: permanent stoma vs. no stoma,
- Age Groups: <=40 vs. 41-65 vs. >65
- Gender: Male vs. Female
- Tumor site: Colon cancer vs. Rectal cancer
- Neoadjuvant radiochemotherapy: used vs. not used.

The results of known-groups comparisons are presented in Table 11.

Overall, patients with a stoma had worse QoL compared with patients without and also reported significantly more Anxiety (p=0,021) and Body Image (p=,000303). On the other hand, male patients with stoma reported higher impotence symptom scores.

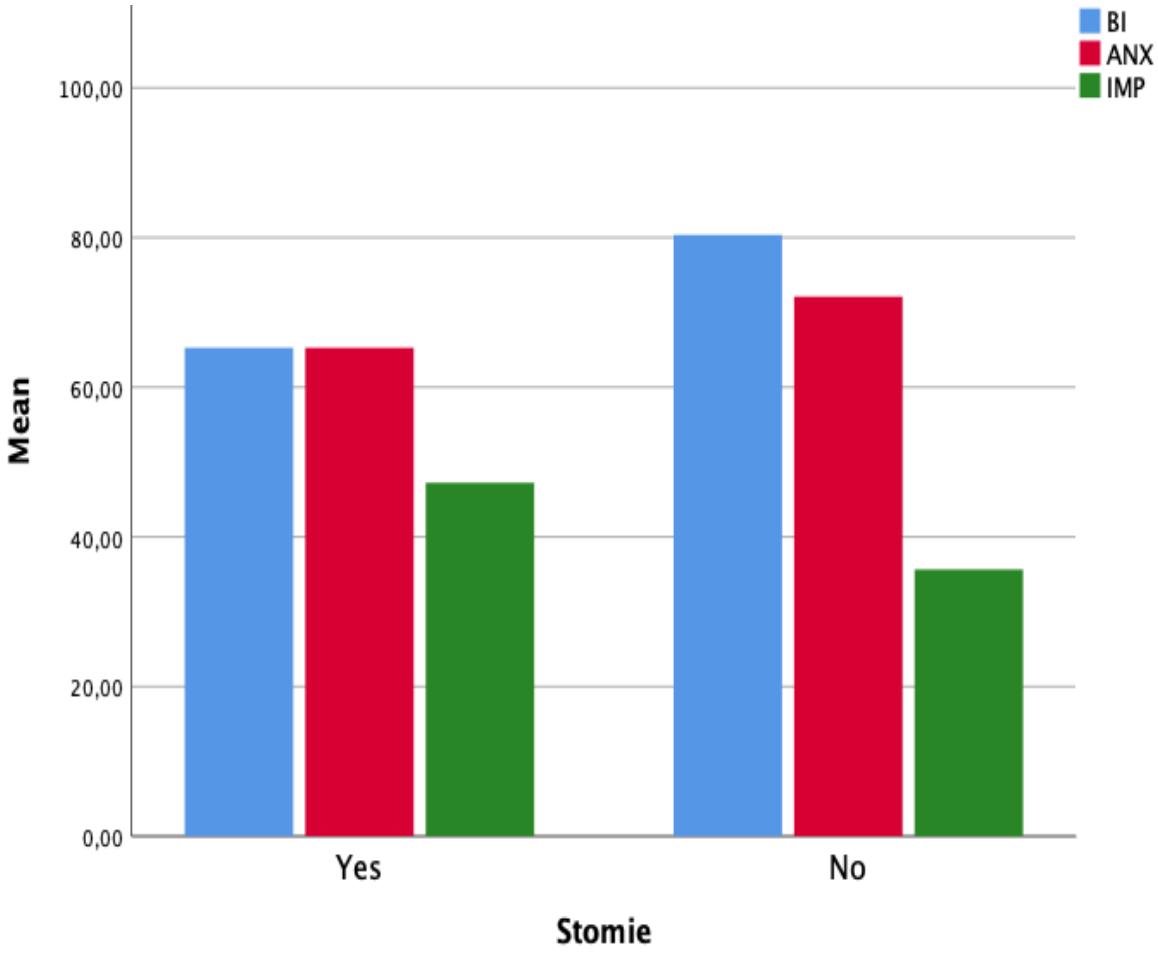
Patients with rectal cancer had a worse QoL than patients with colon cancer with those with rectal cancer having significantly higher symptom scores for flatulence, fecal incontinence, sore skin around the anus, stool frequency, and defecation problems . Additionally, males with rectal cancer significantly reported more sexual function issues than those with colon cancer.

We also compared patients who received neoadjuvant radiochemotherapy with those who did not. Accordingly, patients who underwent neoadjuvant treatment reported significantly higher symptom scores related to Blood & Mucus in stool, Buttock pain, Bloated feeling, Stoma care problems, Flatulence, Fecal incontinence, Sore skin, Stool frequency, Embarrassment and Defecation problems.

	Stoma status			Colon vs Rectum			Neoadjuvant therapy		
CR-29Scales/Single Items	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	35,66(41,13)	41,13(34,60)	,412	35,47(31,25)	42,20(34,88)	,215	45,50(33,96)	35,04(32,28)	**,031**
Blood and mucus in stool	27,66(28,88)	23,87(29,10)	,247	20,29(26,81)	27,45(30,28)	,086	29,96(30,37)	19,31(27,19)	**,004**
Body Image	66,66(27,5)	81,10(23,05)	**,000**	77,49(24,87)	77,77(25,02)	,938	77,65(24,12)	78,92(24,55)	,625
Urinary Incontinence	24,00(35,01)	20,07(31,41)	,451	18,37(28,75)	21,58(33,05)	,788	20,22(32,02)	21,49(32,13)	,592
Dysuria	21,33(29,16)	20,46(31,98)	,469	18,80(30,66)	22,30(31,94)	,120	23,22(32,33)	18,38(29,75)	0,299
Abdominal Pain	28,00(32,54)	31,38(34,62)	,590	28,63(34,28)	32,13(34,38)	,440	34,45(34,61)	26,79(33,47)	,095
Buttock Pain	28,66(33,67)	26,70(34,98)	,563	17,09(30,26)	32,37(36,10)	**,001**	38,57(36,20)	14,33(27,51)	**,000**
Bloated Feeling	30,66(33,56)	28,26(33,92)	,545	27,77(32,41)	29,01(34,24)	,892	35,20(35,66)	23,67(31,72)	**,017**
Dry mouth	30,00(36,42)	23,00(33,40)	,183	20,51(29,04)	26,61(36,59)	,477	30,71(38,34)	19,00(28,99)	,055
Hair loss	17,33 (28,76)	16,17(29,10)	,608	10,68(24,90)	19,42(31,57)	**,027**	18,72(30,13)	14,64(28,65)	,222
Trouble with taste	27,33(36,07)	18,51(31,74)	,069	13,2(27,5)	24,46(35,11)	**,016**	20,59(31,18)	17,75(31,82)	,375
Anxiety	52,67(40,45)	67,84(36,13)	**,016**	63,2(37,8)	65,47(37,08)	,658	65,92(36,57)	63,55(38,45)	,725
Weight	69,33(38,60)	77,38(30,60)	,305	79,48(30,49)	73,86(33,27)	,194	75,65(30,46)	76,32(33,96)	,492
Flatulence				45,83(31,91)	39,39(32,76)	,601	35,08(34,19)	45,61(33,72)	,361
Leakage				45,83(31,91)	40,40(38,87)	,558	42,10(39,81)	45,61(31,83)	,705
Sore skin around stoma				39,5(32,7)	44,44(41,38)	,748	50,87(43,55)	43,85(33,43)	,598
Bags changes				21,87(27,02)	16,66(20,41)	,584	17,54(19,62)	26,31(27,39)	,351
Embarrassement				64,58(28,46)	40,74(44,97)	,056	56,32(46,37)	36,93(39,89)	,055
Stoma care problems				37,50(38,24)	40,74(42,52)	,804	54,02(42,17)	23,42(36,73)	**,003**
Stoma problems				39,93(17,11)	36,19(21,65)	,499	37,13(23,42)	41,81(16,49)	,387
Flatulences				21,50(33,65)	34,59(37,35)	**,017**	43,80(39,13)	19,69(31,81)	**,000**
Faecal incontinence				16,1230,62)	31,44(39,52)	**,009**	35,71(41,04)	17,04(31,55)	**,001**
Sore skin around anus				11,82(24,21)	25,15(34,67)	**,012**	29,52(36,13)	13,63(26,08)	**,002**
Stool Frequency				19,35(26,85)	35,84(34,25)	**,002**	37,61(36,19)	21,59(26,88)	**,008**
Embarrassement				23,11(35,49)	34,90(39,13)	,053	40,47(39,27)	23,48(35,79)	**,004**
Defecation pb				18,85(21,57)	36,57(36,57)	**,000**	37,85(27,42)	19,52(21,04)	**,000**
Sexual Function: Male	54,16(39,10)	39,77(37,10)	,162	32,45(32,40)	48,19(39,45)	**,047**	46,37(39,42)	36,00(32,88)	,211
Impotence	47,22(39,21)	35,65(38,53)	**,021**	31,57(34,61)	41,66(40,63)	,248	43,93(39,22)	33,33(36,88)	,167
Sexual Function: Female	56,86(86)	69,65(36,11)	,064	65,47(33,31)	66,66(39,60)	,770	69,44(35,96)	70,00(35,24)	,928
Dyspareunia	33,33(39,10)	24,87(34,98)	,156	20,23(33,13)	29,48(37,13)	,240	26,85(32,67)	23,33(35,56)	,459

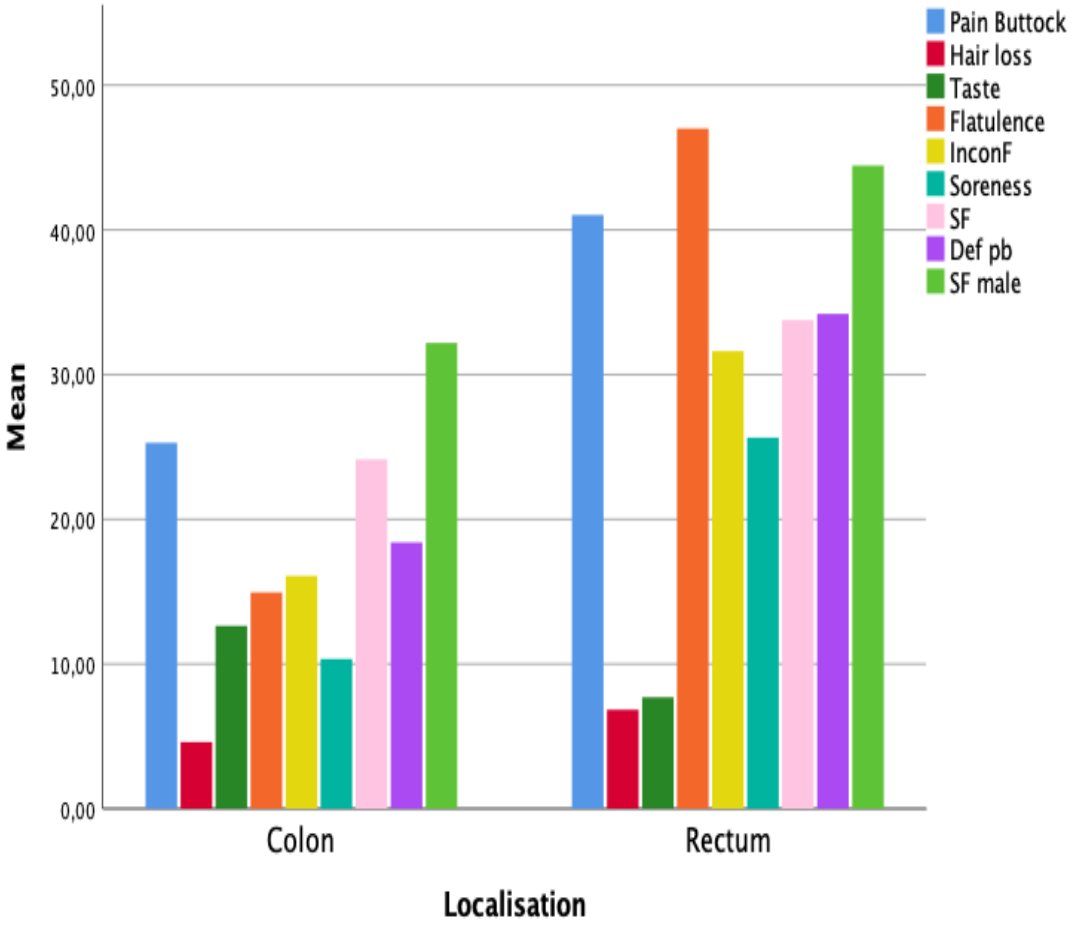
,000: p<0,0001

***Table 12**: Known-group comparisons using the EORTC QLQ-CR29: Stoma Status ; Tumour Site; Neoadjuvat therapy.*



BI: Body Image, ANX: Anxiety, IMP: Impotence.

***Figure 8** : Bar chart for items means according to Stoma Status.*

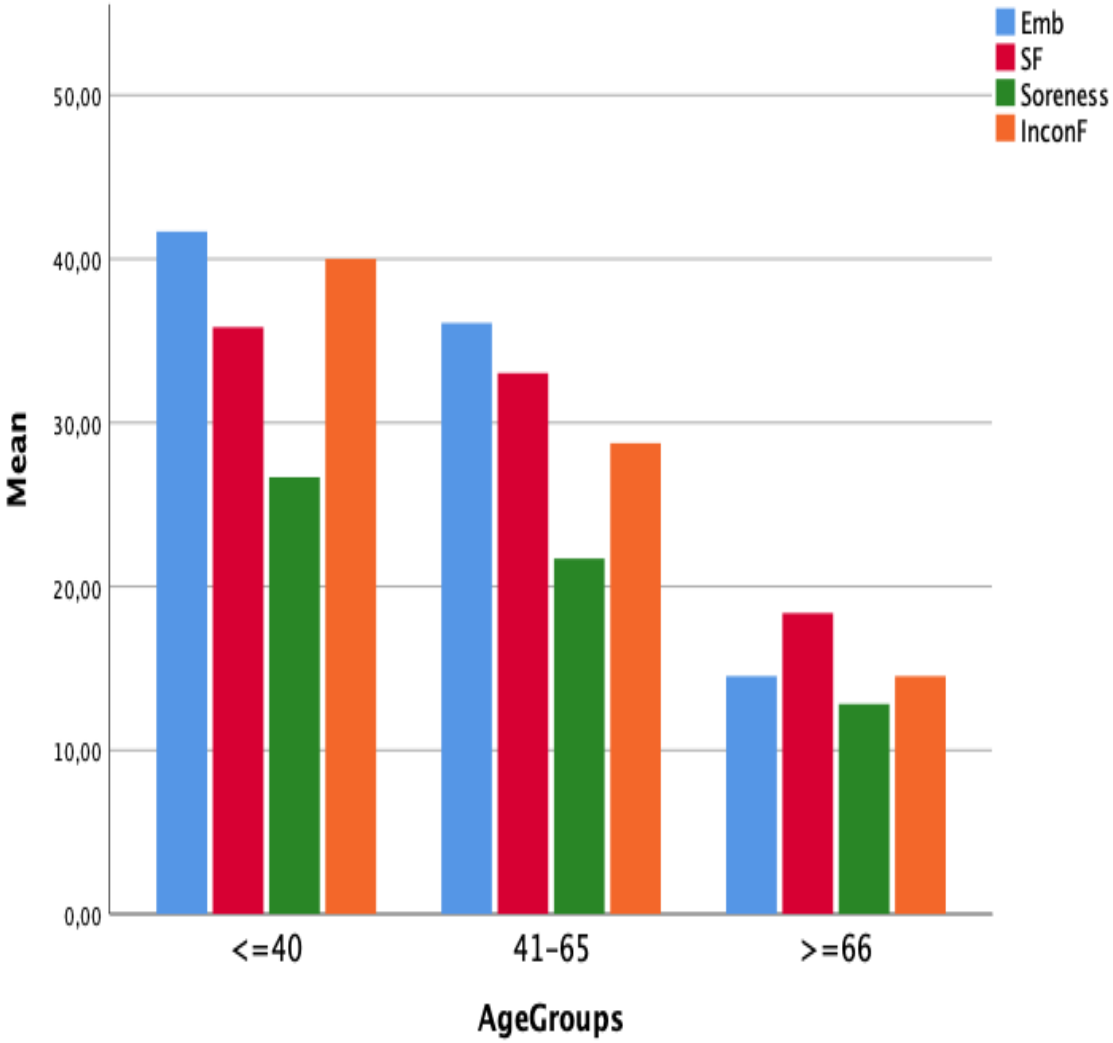


InconF: Faecal Incontinence, SF: Stool Frequency, Def pb: Defecation problems, SF male : Sexual Function Male

***Figure 9**: Bar chart for items' means according to Tumor Site.*

	Gender				Age Groups		
CR-29Scales/Single Items	Male(n=123)	Female(n=98)	p-value	<=40	41-65	>=66	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)	38,33(34,66)	,566	38,8(32,7)	44,7(33,2)	33,3(36,5)	,667
Leakage	47,1(36,2)	35,00(36,63)	,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	20,11(22,44)	15,83(23,24)	,427	22,2(25,0)	20,9(23,6)	5,5(8,6)	,328
Embarrassement	46,37(42,44)	44,44(44,61)	,680	51,8(50,3)	51,3(41,8)	31,4(40,3)	,230
Stoma care problems	42,75(43,12)	36,36(39,40)	,481	66,6(50,0)	40,9(40,2)	29,6(37,7)	,093
Stoma problems	39,84(20,03)	33,88(20,38)	,336	48,1(31,7)	38,8(16,9)	23,1(20,9)	,183
Flatulences	29,07(38,56)	32,47(35,21)	,452	36,6(41,7)	33,6(37,8)	20,5(31,1)	,142
Faecal incontinence	23,40(35,86)	29,48(39,10)	,391	40,0(44,0)	28,7(38,3)	14,5(28,4)	,050
Sore skin around anus	17,37(29,62)	23,93(33,93)	,300	26,6(36,8)	21,7(32,8)	12,8(24,9)	,266
Stool Frequency	27,83(30,27)	31,83(34,73)	,836	35,8(34,7)	33,0(33,7)	18,3(25,0)	**,029**
Embarrassement	27,30(36,56)	35,89(40,47)	,179	41,6(38,8)	36,0(40,8)	14,5(26,2)	**,005**
Defecation pb	26,95(25,31)	30,95(26,48)	,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

***Table 13**: Known-group comparisons using the EORTC QLQ-CR29: Gender and Age Groups*



Emb: Embarrassment, SF: Stool Frequency, Soreness: Soreness around the anus, InconF: Faecal Incontinence.

***Figure 10**:: Bar chart for items means according to Age.*

Discussion

The health-related quality of life (HRQL) of CRC patients is gaining prominence both in day to day practice and clinical research and the proper understanding of the patient's HRQL in real life is increasingly becoming crucial to the evaluation of current and future therapies. (5) As such, patient satisfaction questionnaires are becoming more commonplace as a measure and comparator of quality care. (14)

The EORTC's questionnaire module specifically developed for CRC was assessed in an international multi-center study. (15) However, QLQ-CR29 has not yet been validated and culturally adapted to the Moroccan population. The present study is the first validation study of the Moroccan Arabic version of the QLQ-CR29 questionnaire.

Our study largely replicates the findings of the original international study, as well as the previously published validation studies conducted by different countries (Dutch, Polish, Chinese, Spanish, Taiwanese…).

THE PARTICULARITIES OF QOL MEASUREMENT:

QoL is a unique construct that encompasses physical, functional, emotional as well as social aspects of the patient's well-being and it is multidimensional and dynamic by nature.(42) Measuring QoL today is made easier owing to the cohesive framework and widely accepted methods which allow large applications.(88) To validate the Moroccan version of QLQ-CR29, we strictly followed the standardized tools and attributes used to assess QoL instruments. (62,82,88) systematic review of previously published studies also elucidates that these attributes have been widely used by multiple cross-cultural validations of the CR29. (4,15,81,84,91,93) .

THE QLQ-CR29 ACCEPTABILITY AND PATIENT'S COMPLIANCE:

During the interview, the high level of illiteracy among the Moroccan population represented the major difficulty which made self-administration limited to a minority of participants.To address this issue, an investigator read the questions without offering any interpretation or explanation to avoid compromising the results. Resorting to the investigator's administration of the questionnaire was also the case for multiple validation studies conducted on Moroccan patients (18,60,94), nonetheless, it is recommended to involve patients with low-literacy in developing future PROMs. (95)

As each region of Morocco has its own vocabulary, the linguistic and cultural particularities of the Moroccan Arabic Dialect were another difficulty faced during the interview process. Although the participants' accent and expression reflected these cultural differences, the questionnaire's comprehensiveness was not affected, and participants were able to report their answers according to the standardized Likert Scale of the QLQ-CR29.

PSYCHOMETRIC PROPERTIES:

Reliability

1. <u>Internal Consistency:</u>

The multi-item scales showed adequate internal consistency reliability. In fact, the cronbach's alpha was satisfactory 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 (81). 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. (84,96)

As suggested by *Arraras et al.* (84), some differences may be due to the fact that the EORTC sample had a greater variety in the patients' clinical situations and in the assessment points (six groups of patients were enrolled), whereas the sample in our study was much more homogeneous.

2. Reproducibility:

All ICCs were greater than 0.8, thus indicating good to excellent reproducibility for both single item and multi-item scales. As such, the Moroccan Arabic translation of the QLQ-CR29 can be considered a stable instrument.

The ICC in the original psychometric validation study were greater than 0,55 for single items and greater than 0,68 for multi-item scales indicating good reproducibility (15). In addition, ICCs were higher in our study in comparison to the Dutch (76) and Polish (4) validation studies where poor *test-retest* reliability for the urinary incontinence and dysuria items were found.

Validity:

1. Construct Validity:

The multitrait scaling analyses showed that all item and item-own scale correlations were greater than 0.40 and greater than item-other scale correlations. No inconsistent results were noted thus confirming the structures of the scales forming the QLQ-CR29 and being in agreement with the previous validations where multitrait scaling analysis was also used to assess convergent and divergent validity. *(Sanna et al.; Lin et al.; Arraras et al.; Whistance et al.)* (4,15,81,84) As a result, we conclude that the Moroccan Arabic translation of the QLQ-CR29 has a valid construct.

2. Criterion Validity:

In the assessment of criterion validity, correlations between the scales of the QLQ-C30 and those of the QLQ-CR29 were low (<0.4) indicating that the two

questionnaires measure different concepts. In certain areas with related content, higher correlation scores were noted given the similar concepts of these particular scales. Nonetheless, the results show that the two questionnaires are independent and do not overlap.

The QLQ-C30 as a comparator instrument was used in previous investigation studies as well, reporting similar results.(81,84,93)

3. Clinical Validity

To evaluate clinical validity, we hypothesized that patients with a stoma had worse symptoms than patients without, that patients with Colon cancer had a better QoL than patients with Rectal cancer, and that patients with radiotherapy experienced worse QoL from treatment side effects or psychological distress.

We found less significant differences related to stoma status than the original study. (15)

Body Image issues were also significantly more prevalent in patients with a stoma and impotence scores were higher among males with a stoma. Therefore, the questionnaire differentiates between patient according to their stoma status

Regarding the distinction according to the tumor site, colon cancer patients had better functions and fewer symptoms, including stool frequency and sexual interest in males, as opposed to rectal cancer patients which suggests a convincing clinical validity. It is noteworthy that 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 ones. Similar results were reported by the Dutch and Spanish Validation studies. (76,84) In fact, age as a determinant of QoL is controversial; although it was clearly established that older patients require a longer postoperative recovery period (78), we may notice a better QoL in both its physical and psychological aspects in elderly

patients. (45) In our context, 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 and this ability to discriminate between different clinical groups is encouraging and allows further research to be conducted based on this instrument.

Interventions to improve the questionnaire:

A higher missing data rate was registered for sexual dimensions compared to other items as patients were more reticent about answering sex-related questions. This makes the results interpretation for this dimension more difficult as missing values were excluded when correlation analysis was run. Similar observations were made in the Chinese and Iranian studies, with discussions regarding sexual activity and even ostomy considered to be difficult. (81,92) In order to obtain as accurate and comprehensive results as possible, explanations from medical professionals were required when the patients answered the questionnaire. In our context, this issue may be explained by the cultural and religious particularities of the Moroccan population where sexual practices are taboo. We suggest that more studies addressing this problem be conducted to determine the reliability and validity of the CR29 in evaluating sexual aspects of QoL according to cultural contexts.(97)

As first suggested by the Dutch study (33) and confirmed by the Taiwanese validation(77,97), having fewer single items could help improve the scale and increase the reliability of the entire questionnaire by improving alpha Cronbach’s coefficient. As the QLQ-CR29 is composed of 17 single items and 4 multi-item scales, measuring performance of the QLQ-CR29 can substantially be compromised by the excessive number of single items which hinders the module’s ability to detect all differences under high dimensionality and may raise concerns about its sensitivity.

Study limitations:

This study has some limitations; one of which is the limited sample size of patients. However, the minimum sample size was set at 150 and other EORTC QLQ-CR29 validations were performed on smaller populations. (98)

Self-administration was not possible with the entire population 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 the different options for the answer.

The Arabic language is commonly spoken across the country, however, there are some other regional languages such as “Tarifit”, “Tachelhit”, and “Tamazight” that are more popular in some Moroccan regions. Nonetheless, the majority of these people also have a good grip of the Moroccan Arabic dialect. Further validation should be specifically performed in these regions for a better inclusion of these patient groups in local or national clinical studies.(21) (60)

Moreover, 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-CR29 show that it is a reliable and valid instrument to measure the QoL of colorectal cancer patients. Therefore, this tool can be used to supplement the EORTC QLQ-C30 in assessing HRQL.

This association, alongside other more traditional outcome measures like mortality and morbidity, provide an effective way to measure quality of life with excellent sensitivity and specificity facilitating hereafter colorectal cancer therapy and enhancing comprehensive outcomes research.

Abstract

Abstract

Title: Validation of the Moroccan version of the EORTC Colorectal (CR29) module in Moroccan colorectal cancer patients.

Author: BACHRI HOUDA

Keywords: *Neoplasm; Colorectal cancer; Health-related quality of life; Patient Reported Outcome Measures; EORTC QLQ-CR29.*

Background: Colorectal cancer incidence rate is constantly increasing. With the oncologic outcomes improving, the quality of life outcome is becoming a focal endpoint to ensure quality of cancer care.

Purpose: Validation of the Moroccan version of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire for Colorectal cancer patients (EORTC QLQ-CR29).

Methods*:* We translated the original questionnaire to Moroccan Arabic according to the EORTC guidelines. The QLQ CR-29 was then administered along with the EORTC core questionnaire QLQ-C30 to recruited patients from the national institute of oncology. Psychometric properties were then tested by measuring Cronbach's alpha coefficient of the scales to evaluate reliability. Test-retest correlations were measured using Intraclass correlation coefficient (ICC) to evaluate reproducibility. The validity was tested by performing multi-trait scaling analyses and the questionnaire's ability to discriminate between different clinical patient's groups was tested using Known-Groups comparisons.

Results: 221 patients completed the EORTC QLQ C30 with the QLQ- CR29, and 34 patients completed the QLQ-CR29 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 (0,61) and the body Image scale (0,67). The ICCs ranged from 0,88 to 1 for the scales of the QLQ CR29 indicating good to excellent reproducibility. In multi-trait scaling analysis, the criterion for item convergent and divergent validity was met. The known-group comparison showed statistically significant differences between patients according to age, gender, stoma status, tumor location, and radiotherapy.

Conclusion: The Moroccan version of the EORTC QLQ-CR29 is a psychometrically valid and reliable tool and can be used for research and clinical purposes with Moroccan CRC patients.
Keywords: Colorectal cancer; Health-related quality of life; Patient Related Outcome Measures; Neoplasm; EORTC QLQ-CR29.

RÉSUMÉ

Titre : Traduction et validation de la version en arabe dialectale marocaine du module colorectal (CR29) de l'EORTC chez les patients atteints de cancer colorectal.

Auteur : BACHRI HOUDA

Mots-clés : Néoplasme, Cancer colorectal, Qualité de vie, EORTC-CR29.

Contexte : Avec l'amélioration des résultats oncologiques du traitement du cancer colorectal, les résultats concernant la qualité de vie des patients sont maintenant considérés comme élément central de la stratégie thérapeutique. Les mesures des résultats liés aux patients constituent un bon outil de l'évaluation de cet aspect de la prise en charge des patients cancéreux.
Objectif **:** Validation de la version dialectale arabo-marocaine du questionnaire de l'Organisation européenne pour la recherche et le traitement du cancer sur la qualité de vie des patients atteints de cancer colorectal (EORTC QLQ-CR29).

Matériels et méthodes : Après la traduction en arabe dialectale du QLQ-CR29, le questionnaire a été administré aux patients traités pour cancer colorectal à l'Institut Nationale d'Oncologie (INO). Les propriétés psychométriques ont ensuite été testées en mesurant le coefficient alpha de Cronbach pour évaluer la fiabilité, et le coefficient de corrélation instraclasse (CCI) pour examiner la reproductibilité. Pour vérifier la validité du construit, on a évalué la validité convergente et la validité divergente des différentes échelles. La capacité du questionnaire à discriminer entre différents groupes a été testé en comparant des groupes différents sur le plan clinique et pathologique.

Résultats : Au total, 221 patients étaient inclus dans notre études et 34 patients ont complété le questionnaire une deuxième fois. Les échelles « Fréquence urinaire » et « Fréquence des selles » avaient une bonne fiabilité interne avec un coefficient alpha de Cronbach respectivement à 0,79 et 0,83. Cependant le coefficient était légèrement plus faible pour les échelles « Sang et mucosités dans les selles » (0,61) et « Image Corporelle » (0,67). Le CCI allait de 0,88 à 1 indiquant une bonne à excellente reproductibilité. Le critère pour la validité convergente et pour la validité divergente a été satisfait. La validité clinique a montré des différences statistiquement significatives entre les patients selon l'âge, le sexe, le statut de la stomie, le site tumoral et la radiothérapie.

Conclusion : La version Marocaine de l'EORTC QLQ-CR29 est un outil valide et fiable et peut être utilisé à des fins cliniques et de recherche chez des patients Marocains atteints de cancer colorectal.

ملخص

العنوان : المصادقة على النسخة العربية المغربية لاستبيان المنظمة الأوروبية للبحث وعلاج نوعية الحياة لمرضى سرطان القولون والمستقيم س ر 29

المؤلفة :هدى باشري

الكلمات الأساسية :ورم سرطان قولون مستقيم؛ جودة الحياة؛

مقدمة: معدل الإصابة بسرطان القولون والمستقيم في تزايد مستمر. أصبحت جودة الحياة هدفًا مهمًا لضمان جودة رعاية مرضى السرطان

الهدف: التحقق من صحة النسخة العربية من استبيان المنظمة الأوروبية للبحث وعلاج نوعية الحياة لمرضى سرطان القولون والمستقيم س ر29

المناهج بعد ترجمة الإستبيان إلى العربية المغربية الدارجة وفقا لمعايير الترجمة والترجمة المضادة تم إستجواب المرضى الذي تم علاجهم من سرطان القولون او المستقيم مع تقديم الاستبيان لمجموعة فرعية لمراجعة الموثوقية عبر طريقة الإختبار وإعادة اختبار. تم اختبار خصائص الإستبيان السيكومترية بإثبات الاتساق الداخلي من خلال قياس معامل ألفا كرونباخ كما اعتمدنا دراسة الارتباط بين كل من المعيار واستبيان جودة الحياة س30 لإثبات الصدق التقاربي. مكنت قدرة المعيار على التمييز بين مجموعات من المرضى ذوي خواص سريرية و علاجية مختلفة من إثبات الصدق التمييزي

النتيجة: تم ضم221 مريضا في دراستنا و مجموعة فرعية مكونة من 34 مريضا أكملت الاستبيان مرتين. كان لمقياس التردد البولي ومقياس تردد البراز اتساقًا داخليًا جيدًا مع معاملات ألفا كرونباخ تساوي 0،79 و 0،83 على التوالي ، في حين كان المعامل أقل بشكل معتدل لمقياسي الدم والمخاط في البراز 0،61 و صورة الجسم0،67
تراوحت معاملات إعادة الاختبار من 0،88 إلى 1 لمقاييس الاستبيان التي تشير إلى إمكانية استنساخ جيد إلى ممتاز صحة نتائج البناء كانت مرضية أيضا. تم إثبات الصدق التمييزي من خلال قدرة المعيارين على التمييز بين مجموعات فرعية من المرضى وفقا لموقع الورم،العلاج الإشعاعي وكذلك نوع المفاغرة.

الخاتمة للنسخة العربية المغربية من استبيان سر29 خصائص سيكومترية صالحة وموثوقة و يمكن استعمال في كل من لإجراءات السريرية والبحث الطبي.

Appendix

EORTC-QLQ C30:

EORTC QLQ-C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Please fill in your initials: ⌊ ⌋⌊ ⌋⌊ ⌋⌊ ⌋

Your birthdate (Day, Month, Year): ⌊ ⌋⌊ ⌋ ⌊ ⌋⌊ ⌋ ⌊ ⌋⌊ ⌋⌊ ⌋⌊ ⌋

Today's date (Day, Month, Year): 31 ⌊ ⌋⌊ ⌋ ⌊ ⌋⌊ ⌋ ⌊ ⌋⌊ ⌋⌊ ⌋⌊ ⌋

	Not at All	A Little	Quite a Bit	Very Much
1. Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2. Do you have any trouble taking a long walk?	1	2	3	4
3. Do you have any trouble taking a short walk outside of the house?	1	2	3	4
4. Do you need to stay in bed or a chair during the day?	1	2	3	4
5. Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4

During the past week:	Not at All	A Little	Quite a Bit	Very Much
6. Were you limited in doing either your work or other daily activities?	1	2	3	4
7. Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8. Were you short of breath?	1	2	3	4
9. Have you had pain?	1	2	3	4
10. Did you need to rest?	1	2	3	4
11. Have you had trouble sleeping?	1	2	3	4
12. Have you felt weak?	1	2	3	4
13. Have you lacked appetite?	1	2	3	4
14. Have you felt nauseated?	1	2	3	4
15. Have you vomited?	1	2	3	4
16. Have you been constipated?	1	2	3	4

Please go on to the next page

During the past week:	Not at All	A Little	Quite a Bit	Very Much
17. Have you had diarrhea?	1	2	3	4
18. Were you tired?	1	2	3	4
19. Did pain interfere with your daily activities?	1	2	3	4
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21. Did you feel tense?	1	2	3	4
22. Did you worry?	1	2	3	4
23. Did you feel irritable?	1	2	3	4
24. Did you feel depressed?	1	2	3	4
25. Have you had difficulty remembering things?	1	2	3	4
26. Has your physical condition or medical treatment interfered with your family life?	1	2	3	4
27. Has your physical condition or medical treatment interfered with your social activities?	1	2	3	4
28. Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

For the following questions please circle the number between 1 and 7 that best applies to you

29. How would you rate your overall health during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

30. How would you rate your overall quality of life during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

EORTC QLQ – CR29

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week. Please answer by circling the number that best applies to you.

During the past week:	**Not at All**	**A Little**	**Quite a Bit**	**Very Much**
31. Did you urinate frequently during the day?	1	2	3	4
32. Did you urinate frequently during the night?	1	2	3	4
33. Have you had any unintentional release (leakage) of urine?	1	2	3	4
34. Did you have pain when you urinated?	1	2	3	4
35. Did you have abdominal pain?	1	2	3	4
36. Did you have pain in your buttocks/anal area/rectum?	1	2	3	4
37. Did you have a bloated feeling in your abdomen?	1	2	3	4
38. Have you blood in your stools?	1	2	3	4
39. Have you had mucus in your stools?	1	2	3	4

During the past week:	**Not at All**	**A Little**	**Quite a Bit**	**Very Much**
40. Did you have a dry mouth?	1	2	3	4
41. Have you lost hair as a result of your treatment?	1	2	3	4
42. Have you had problems with your sense of taste?	1	2	3	4
43. Were you worried about your health in the future?	1	2	3	4
44. Have you worried about your weight?	1	2	3	4
45. Have you felt physically less attractive as a result of your disease or treatment?	1	2	3	4
46. Have you been feeling less feminine/masculine as a result of your disease or treatment?	1	2	3	4
47. Have you been dissatisfied with your body?	1	2	3	4
48. Do you have a stoma bag (colostomy/ileostomy)? (please circle the correct answer)	Yes		No	

During the past week:	**Not at All**	**A Little**	**Quite a Bit**	**Very Much**
Answer these questions ONLY IF YOU HAVE A STOMA BAG, if not please continue below:				
49. Have you had unintentional release of gas/flatulence from your stoma bag?	1	2	3	4
50. Have you had leakage of stools from your stoma bag?	1	2	3	4
51. Have you had sore skin around your stoma?	1	2	3	4
52. Did frequent bag changes occur during the day?	1	2	3	4
53. Did frequent bag changes occur during the night?	1	2	3	4
54. Did you feel embarrassed because of your stoma?	1	2	3	4
55. Did you have problems caring for your stoma?	1	2	3	4

Answer these questions ONLY IF YOU DO NO T HAVE A STOMA BAG:				
49. Have you had unintentional release of gas/flatulence from your back passage?	1	2	3	4
50. Have you had leakage of stools from your back passage?	1	2	3	4
51. Have you had sore skin around your anal area?	1	2	3	4
52. Did frequent bowel movements occur during the day?	1	2	3	4
53. Did frequent bowel movements occur during the night?	1	2	3	4
54. Did you feel embarrassed because of your bowel movement?	1	2	3	4

During the past 4 weeks:	**Not at All**	**A Little**	**Quite a Bit**	**Very Much**
For men only:				
56. To what extent were you interested in sex?	1	2	3	4
57. Did you have difficulty getting or maintaining an erection?	1	2	3	4

For women only:				
58. To what extent were you interested in sex?	1	2	3	4
59. Did you have pain or discomfort during intercourse?	1	2	3	4

EORTC-C30: Moroccan Arabic Version

سميتك.....

تاريخ الازدياد (النهار، الشهر، العام).....

التاريخ ديال اليوم (النهار، الشهر، العام).....

	لا	غير شويا	مرة مرة	ديما
1. واش كيجيك شي مشكل مني كدير شي مجهود بحال تهز شي شانطة أو قفة ثقيلة	1	2	3	4
2. واش كتعيا فاش كتمشا بزاف	1	2	3	4
3. واش كتعيا فاش كتمشا غير شويا خارج الدار	1	2	3	4
4. واش كتحتاج تبقا فلفراش أو تكلس فاش كتكون فالدار	1	2	3	4
5. واش كتحتاج شي واحد يعاونك فلماكلا، فلباس، فلغسيل، باش تمشي لمرحاض (بيت الما) **فالسيمانا اللي فاتت**	1	2	3	4
6. واش حسيتي براسك ما قادرش ديرالخدمة ديالك أوشغالات ديال كل نهار	1	2	3	4
7. واش حسيتي براسك ما قادرش ديرداكشي اللي عزيز عليك تدير محيت كيكون عندك الوقت (الهوايات ديالك)	1	2	3	4

8. واش جاك ضيق فالتنفس (النهجة، القذفة)	1	2	3	4
9. واش جاك لحريق (الوجع)	1	2	3	4
10. واش حتاجيتي ترتاح	1	2	3	4
11. واش كان عندك شي مشكل فنعاس	1	2	3	4
12. واش كنت حاس براسك مرخي (ضعيف)	1	2	3	4
13. واش نقصاتلك الشهية	1	2	3	4
14. واش كتحس بترويعا	1	2	3	4
15. واش تقييتي (رديتي)	1	2	3	4
16. واش كنت مقبوط (معصوم)	1	2	3	4
17. واش كانت كرشك جارية (طايحة عليك الكرش)	1	2	3	4
18. واش كنت عيان	1	2	3	4
19. واش لحريق كان كيأثرعلى الشغالات ديالك ديال كل نهار	1	2	3	4
20. واش جاك شي مشكل فالتركيز فا ش كتقرا شي جورنال أو فا ش كتفرج فتيليفيزيون	1	2	3	4
21. واش حسيتي براسك معصب	1	2	3	4
22. واش حسيتي براسك مقلق (موسوس)	1	2	3	4
23. واش حسيتي براسك منفعل (كتقلق دغيا، على سبة)	1	2	3	4
24. واش حسيتي براسك مكتئب (مغموم)	1	2	3	4
25. واش كان عندك مشكل تعقل على شي حوايج (مشكل النسيان)	1	2	3	4
26. واش هاد المرض ديالك أو دوا اللي كتاخذ أثر على علاقتك مع العائلة	1	2	3	4
27. واش هاد المرض ديالك أو دوا اللي تاتاخذ أثر على علاقتك مع	1	2	3	4

الناس

28. واش هاد المرض ديالك أو دوا اللي كتاخذ سبب ليك شي مشاكل فلمصروف (مشاكل مادية) 1 2 3 4

بالنسبة لأسئلة اللي جايا اختار الجواب اللي يناسبك من 1 حتال 7

29. شحال تقدر (تعطي) صحتك فالسيمانا اللي فاتت

1 2 3 4 5 6 7

ضعيفة

ممتازة

30. شحال تقدر (تعطي) الجودة ديال حياتك فالسيمانا اللي فاتت (كيفاش كتبانلك حياتك)

1 2 3 4 5 6 7

خايبة (مكرفسة)

مزيانة

EROTEC QLQ-CR29

المرضى كيتشكاو شي مرات من بعض الاعراض او المشاكل الجانبية للعلاج. بيين لينا من فضلك الى عانيت من شي اعراض او مشاكل فالسيمانا اللي فات. باش تجاوب دير دوارة على الرقم الي كيناسبك.

فالسيمانا اللي فات	لا	غير شوية	مرة مرة	ديما
31. واش كنت كتبول بزاف فالنهار	1	2	3	4
32. واش كنت كتبول بزاف فالليل	1	2	3	4
33. واش كانت كتزهق (كتفلت) ليك البولة بلا متحس	1	2	3	4
34.واش كنت كتحس بلحريق (لوجع) فاش كتبول	1	2	3	4
35. واش كان عندك لحريق (لوجع) فكرشك	1	2	3	4
36. واش كان تيجيك لحريق (لوجع) فلمخرج ديالك	1	2	3	4
37. واش كنت كتحس بالنفخ فكرشك	1	2	3	4
38. واش كان عندك الدم فلخروج ديالك	1	2	3	4
39. واش كان عندك تكراط لمصارن (بحال لخنونة أو لبيض ديال البيض فلخروج ديالك)	1	2	3	4

فالسيمانا اللي فات	لا	غير شوية	مرة مرة	ديما
40. واش كان كينشف ليك فمك	1	2	3	4
41. واش كان كيطيح ليك شعرك	1	2	3	4

42. واش تبدل ليك الدوق	1	2	3	4
43. واش كان مستقبل (او كيف غدي تولي) صحتك مقلقك	1	2	3	4
44. واش كان مستقبل (او كيف غدي يولي) الوزن ديالك مقلقك	1	2	3	4
45. واش حسيتي بالجسم ديالك مبقاش تيجلب (او تيعجب الناس)مع هاد المرض او الدوا لي تتاخذ	1	2	3	4
46. واش حسيتي بالأنوثة أو الذكورة/الرجولة ديالك نقصات مع هاد المرض اوالدوا لي تتاخذ	1	2	3	4
47. واش مابقيتيش راض على (او ما عاجبكش) الجسم ديالك	1	2	3	4
48. واش عندك المصران خارج فالجنب (الخنشة ديال لخروج)	**نعم**	**لا**		

فالسيمانا اللي فات	**لا**	**غير شوية**	**مرة**	**ديما مرة**

<u>جاوب غير الى عندك المصران خارج فالجنب او (الخنشة ديال المصران)</u>

(لي ماعندوش الخنشة مايجوبش)

49. واش تيزهق (كيفلت) ليك الريح من الخنشة بلا متحس	1	2	3	4
50. واش تيزهق (كيفلت) ليك الخروج من الخنشة بلا متحس	1	2	3	4

51. واش عندك شي التهاب (طايب ليك اللحم) فبلاصت الخنشة	1	2	3	4
52. واش كتبدل الخنشة بزاف ديال المرات بالنهار	1	2	3	4
53. واش كتبدل الخنشة بزاف ديال المرات بالليل	1	2	3	4
54. واش كتحس بشي احراج (ازعاج) بسبب المصران الخارج	1	2	3	4
55. واش عندك شي مشاكل باش تكلف (تقوم) بالمصران الخارج	1	2	3	4

خاص بالناس لي ما عندهمش المصران الخارج فالجنب

49. واش تيزهق (كيفلت) ليك الريح من لور (الدبور/ المخرج) بلا متحس	1	2	3	4
50. واش تيزهق (كيفلت) ليك الخروج من لور (الدبور/المخرج) بلاتحس	1	2	3	4
51. واش عندك شي التهاب (طايب ليك اللحم) فبلاصت المخرج	1	2	3	4
52. واش كدير الخروج ديالك (كرشك) بزاف ديال المرات بالنهار	1	2	3	4
53. واش كدير الخروج ديالك بزاف ديال المرات بالليل	1	2	3	4
54. واش كتحس بشياحراج (ازعاج) (كرشك) بسبب الخروج المرحاض	1	2	3	4

فالشهر اللي فات (4 دسيمانات)	لا	غير شوية	مرة	ديما مرة

خاص بالرجال

56. الى اي حد كنت مهتم بالممارسة الجنسية	1	2	3	4
57. واش عندك شي صعوبات فالانتصاب او الحفاظ على انتصاب الذكر ديالك	1	2	3	4

خاص بالنساء

58. الى اي حد كنت مهتمة بالممارسة الجنسية	1	2	3	4
59. واش عندك شي ألم /حريق أوما مرتاحاش فالجماع مع الرجل	1	2	3	4

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Serment d'Hippocrate

Au moment d'être admis à devenir membre de la profession médicale, je m'engage solennellement à consacrer ma vie au service de l'humanité.

- *Je traiterai mes maîtres avec le respect et la reconnaissance qui leur sont dus.*
- *Je pratiquerai ma profession avec conscience et dignité. La santé de mes malades sera mon premier but.*
- *Je ne trahirai pas les secrets qui me seront confiés.*
- *Je maintiendrai par tous les moyens en mon pouvoir l'honneur et les nobles traditions de la profession médicale.*
- *Les médecins seront mes frères.*
- *Aucune considération de religion, de nationalité, de race, aucune considération politique et sociale ne s'interposera entre mon devoir et mon patient.*
- *Je maintiendrai le respect de la vie humaine dés la conception.*
- *Même sous la menace, je n'userai pas de mes connaissances médicales d'une façon contraire aux lois de l'humanité.*
- *Je m'y engage librement et sur mon honneur.*

قسم أبقراط

بسم الله الرحمان الرحيم

أقسم بالله العظيم

في هذه اللحظة التي يتم فيها قبولي عضوا في المهنة الطبية أتعهد علانية:

- بأن أكرس حياتي لخدمة الإنسانية .
- وأن أحترم أساتذتي وأعترف لهم بالجميل الذي يستحقونه .
- وأن أمارس مهنتي بوازع من ضميري وشرفي جاعلا صحة مريضي هدفي الأول .
- وأن لا أفشي الأسرار المعهودة إلي .
- وأن أحافظ بكل ما لدي من وسائل على الشرف والتقاليد النبيلة لمهنة الطب .
- وأن أعتبر سائر الأطباء إخوة لي .
- وأن أقوم بواجبي نحو مرضاي بدون أي اعتبار ديني أو وطني أو عرقي أو سياسي أو اجتماعي .
- وأن أحافظ بكل حزم على احترام الحياة الإنسانية منذ نشأتها .
- وأن لا أستعمل معلوماتي الطبية بطريق يضر بحقوق الإنسان مهما لاقيت من تهديد .
- بكل هذا أتعهد عن كامل اختيار ومقسما بالله .

والله على ما أقول شهيد .

المملكة المغربية
جامعة محمد الخامس بالرباط
كلية الطب والصيدلة
الرباط

سنة : 2020 أطروحة رقم: 193

المصادقة على النسخة العربية المغربية لاستبيان المنظمة الأوروبية للبحث CR29وعلاج نوعية الحياة لمرضى سرطان القولون

أطروحة

قدمت ونوقشت علانية يوم : / /2020

من طرف

السيدة هدى باشري

المزدادة في 01 نونبر 1994 بالرباط

لنيل شهادة

دكتور في الطب

الكلمات الأساسية : ورم؛ سرطان القولون المستقيم؛ جودة الحياة

أعضاء لجنة التحكيم:

السيد محسن رؤوف أستاذ في الجراحة العامة	رئيس
السيد أمين صوادقة أستاذ في الجراحة العامة	مشرف
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السيدة ليلى العمراني أستاذة في أمراض الجهاز الهضمي	عضو