**Arabic Language Translation and Initial Validation of the Functional Assessment of Cancer Therapy Quality of Life Questionnaire (FACT-C) in Egyptian Patients with Colorectal Cancer**

Sara M. El-Badawy1, Mohamed A. Alm El-Din1, Ibrahim A. Kabbash2 and Ashraf F. Barakat1

1 Department of Clinical Oncology, Faculty of Medicine, Tanta University, Egypt

2 Department of Public Health, Faculty of Medicine, Tanta University, Egypt

[almeldin@gmail.com](mailto:almeldin@gmail.com)

**Abstract: Background:** The aim of this study is translation of functional assessment of cancer therapy-colorectal questionnaire version 4 (FACT-C) into Arabic language and its Initial validation and correlation with psychometric properties of the Arabic version of the European Organization for Research and Treatment (EORTC) quality-of-life colorectal questionnaire (QLQ-CR29). **Method:** This cross sectional study included 80 patients with colorectal cancer. The FACT-C, version4 questionnaire was translated according to EORTC guidelines into its Arabic form through forward- backward translation and harmonization then pilot study of translated questionnaire was done on first 10 patients. The order of administration of the FACT-C and EORTC questionnaires was randomized to avoid any effects of order of presentation. **Results:** The FACT-C showed good acceptability, good reproducibility and excellent internal consistency 0.839 using Cronbach alpha statistics as compared to EORTC QLQ 29. The relative high internal consistency of FACT-C confirms the reliability of Arabic version of the questionnaire. Patients did not express a preference for one survey over another. **Conclusion:** Arabic version of FACT-C can be used to assess quality of life in colorectal patients. Validation on larger number of patients & future studies for the appropriate use of these measures in clinical research is recommended.

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**Key words:**Quality of life, FACT-C, colorectal cancer, Egyptian patients

**1. Introduction**

Colorectal cancer (CRC) is the third most commonly diagnosed cancer, with over one million new cases (1). CRC is the 6th cancer in Egypt, representing 4% of the totalcancers and 53% of GIT cancers. The median age was 53 years withmale predominance. (2) In the past twenty years mortality rates have fallen due to improvements in early detection and cancer treatment (3-5). Five years survival is 66% in the United States of America and 56% in Europe. (6) The rise of patients living with the consequence of cancer and its treatment has increased greatly the interest of their effect on health-related quality of life (HRQoL). (7)

HRQoL has been became an important aspect of the cost to benefit ratio in evaluating treatment recommendations. Recently, more studies are incorporating HRQoL as clinical trial end point parallel to free survival and even actual survival time. (8) Therefore, accurate HRQoL information could make a major contribution to improving the management of cancer patients. (8) HRQoL is a multi-dimensional, dynamic, subjective and centered on patient construct, comprising physical, functional, emotional, and social well-being. (9) Several studies assess the impact of CRC in the HRQoL, both in short-term (10, 11) and long-term periods. HRQoL, being a subjective, patient-related concept, is difficult to quantify. (12)

The FACT-C is the most used CRC specific questionnaire, although the EORTC has a CRC-specific module, the QLQ-CR29. (13) The FACT-C has been validated in English, (14) Spanish, (15) Korean, (16) French (17) and Chinese patients. (18)

The FACT scales are designed for patient self-administration, but can also be administered by interview format. Interview administration is considered appropriate given adequate training of interviewers so as to elicit non-biased patient responses. Foreign language versions of the FACT questionnaires are now available in more than 50 different languages, permitting cross-cultural comparisons of people from different backgrounds. (19) The objective of the current study is Arabic language translation and initial validation of the functional assessment of FACT-C in Egyptian colon cancer patients.

**2. Patients and Methods**

This cross-sectional study was carried out at the department of Clinical Oncology, Tanta University Hospitals on 80 patients with colorectal carcinoma (CRC) who were informed of their diagnosis. Eligibility criteria include pathologic confirmation of CRC, age older than 18 years and life expectancy of at least 3 months. Exclusion Criteria were patients with meningeal or cerebral metastases, previous or concomitant other cancer, overt psychosis and cognitive impairment. Patients were recruited according to four treatment groups:

1. Surgery with curative intent.

2. Chemotherapy as adjuvant treatment or for metastatic disease.

3. Preoperative radiotherapy delivering 45 Gy (Gray) in 25 fractions with or without concomitant chemotherapy for rectal cancer.

4. Disease-free survivors with follow-up more than 3 years.

Assessment of HRQoL tools include:

1. EORTC (European Organization for Research and Treatment of Cancer*)* questionnaires QLQ-C30 (Quality of Life Questionnaire in Cancer patients), version 3.0, The Arabic version of EORTC questionnaires was provided by the EORTC quality-of-life unit and its Arabic translation had been performed along the lines of their current forward-backward procedures (20).
2. The EORTC colorectal questionnaire (QLQ-CR29) (Quality of Life Questionnaire in Colorectal patients) was developed to be used in conjunction with the QLQ-C30. It incorporates two functional scales (body image and sexuality) and seven symptom scales (micturation problems, symptoms in the area of the gastrointestinal tract, chemotherapy side effects, and problems with defecation, stoma-related problems, male and female sexual problems). The remaining single items assess future perspective and weight loss.

3- FACT questionnaire (Functional Assessment of Cancer Therapy) was developed in North America and it has been translated into many languages. The FACT questionnaire was translated according to EORTC guidelines into its Arabic form through forward-backward translation and harmonization then pilot study of translated questionnaire was done on first 10 patients as a sample to:

* Test and evaluate the adequacy of the translated questionnaire.
* Estimate the time needed for assessment of each study subject and filling the questionnaire.
* Determine the potential obstacles that might be met during the study.

Patients completed the FACT-C version 4 and the EORTC questionnaires (QLQ-C30 first, then QLQ-CR29). The order of administration of the FACT-C and EORTC questionnaires was randomized to avoid any effects of order of presentation. (21)

**3. Results**

A total number of 80 patients with colorectal cancer had completed the EORTC QLQ30, 29 & FACT-C questionnaires. Their age was from 27 to 81 years with mean age of 49 years. There were 46 females and 34 males who completed the questionnaire.

Most of them were rural 53.8% & married 78.8%. Number of children they had range from 3 to 4 children with only 8 patients had no children. Thirty-nine patients were illiterate while only 6 patients were highly educated. Among female participants, 52.5% were house wives and 30.1% of them were manual workers.

**Table 1:** **Characteristics of studied patients**

| **Character** | **Number (n=80)** | **%** |
| --- | --- | --- |
| **Age in year:** |  |  |
| <30 | 1 | 1.2 |
| 30- | 21 | 26.3 |
| 40- | 17 | 21.2 |
| 50- | 19 | 23.8 |
| 60- | 19 | 23.8 |
| 70+ | 3 | 3.7 |
| **Range** | 27-81 | |
| **Mean + SD** | 49.54+12.81 | |
| **Sex:** |  |  |
| Males | 34 | 42.5 |
| Females | 46 | 57.5 |
| **Residence:** |  |  |
| Urban | 37 | 46.2 |
| Rural | 43 | 53.8 |
| **Marital status:** |  |  |
| Single | 4 | 5.0 |
| Married | 63 | 78.8 |
| Divorced | 1 | 1.2 |
| Widow | 12 | 15.0 |
| **Number of children:** |  |  |
| None | 8 | 10.0 |
| 1-2 | 15 | 18.8 |
| 3 | 28 | 35.0 |
| 4 | 17 | 21.2 |
| 5+ | 12 | 15.0 |
| **Educational level:** |  |  |
| Illiterate | 39 | 48.7 |
| Primary & secondary | 35 | 43.8 |
| University | 6 | 4.5 |
| **Job:** |  |  |
| Unemployed | 3 | 3.8 |
| Housewife | 42 | 52.5 |
| Unskilled manual workers | 11 | 13.8 |
| Skilled manual worker | 13 | 16.3 |
| Employee | 5 | 6.2 |
| Professional | 5 | 6.2 |

There were 29 patients received chemotherapy, 17 patients finished radiotherapy, 6 patients did surgical resection and 28 survivors under follow up. Only 16 patients had stoma. Duration since diagnosis in months ranged from 6 to 150 months with mean time of 22 months. Co morbidity charlson score for 38.7% of patients was 2 and for 43.7% of them was 3:4.

**Table 2:** **Clinical characteristics of studied patients**

|  |  |  |
| --- | --- | --- |
| **Variables** | **Number (n=80)** | **%** |
| **Treatment:** |  |  |
| Follow up | 28 | 35.0 |
| Surgery | 6 | 7.5 |
| Chemotherapy | 29 | 36.3 |
| Radiotherapy | 17 | 21.3 |
| **Presence of stoma:** |  |  |
| None | 64 | 80.0 |
| Yes | 16 | 20.0 |
| **Duration since diagnosis in months:** |  |  |
| 6- | 19 | 23.7 |
| 12- | 36 | 45.0 |
| 24+ | 25 | 31.3 |
| Range | 6-150 | |
| Mean+SD | 22.51+19.91 | |
| **Charlson’s score** |  |  |
| 2 | 31 | 38.7 |
| 3 | 16 | 20.0 |
| 4 | 19 | 23.7 |
| 5 | 5 | 6.3 |
| 6 | 5 | 6.3 |
| 7 | 4 | 5.0 |

The level of performance is significantly decreased by treatment over time; at the baseline, 36.3% of patients had performance of 70% using [Karnofsky performance status scale](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=2ahUKEwiR8fSR3bvdAhWjs4sKHWSMA08QFjAAegQICRAC&url=http%3A%2F%2Fwww.npcrc.org%2Ffiles%2Fnews%2Fkarnofsky_performance_scale.pdf&usg=AOvVaw2-FolNWjV4HAtp9SlRjngp) where 28.8% and 17.2% had this level of performance at the first and second follow up, respectively. The EORTC questionnaire showed statistically significant differences at different periods of follow up when comparing the baseline to the time before fourth cycle of chemotherapy in terms of global health status, pain, having stoma & total score.

**Table (3): Comparison of EORTC at different periods of follow up**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **EORTC score** | **Baseline** | **Before third cycle** | **Before fourth cycle** | **p** |
| **Global health** | 66.56+20.35 | 66.83+17.58 | 64.37+20.76 | **0.001\*** |
| **Physical function** | 61.58+24.33 | 61.15+24.72 | 64.60+26.97 | 0.470 |
| **Role functioning** | 54.17+31.99 | 51.92+35.49 | 62.07+35.61 | 0.670 |
| **Emotional functioning** | 85.63+23.12 | 87.98+19.49 | 89.37+19.91 | 0.152 |
| **Social functioning** | 70.42+31.93 | 72.76+33.17 | 77.01+32.86 | 0.623 |
| **Fatigue** | 44.31+26.02 | 44.44+25.38 | 37.55+24.38 | 0.607 |
| **Nausea and vomiting** | 8.96+22.49 | 5.45+13.09 | 8.05+15.82 | 0.623 |
| **Pain** | 37.50+31.32 | 37.18+32.44 | 29.31+31.39 | **0.001\*** |
| **Dyspnea** | 5.83+19.68 | 4.49+13.25 | 0+0.0 | 0.326 |
| **Insomnia** | 16.25+30.92 | 13.46+24.93 | 11.49+31.21 | 0.272 |
| **Appetite loss** | 24.17+26.51 | 27.56+29.31 | 24.14+28.03 | 0.243 |
| **Constipation** | 9.58+21.99 | 11.54+23.69 | 5.75+15.61 | 0.243 |
| **Diarrhea** | 24.17+28.05 | 25.64+25.24 | 28.74+29.17 | 0.421 |
| **Financial difficulties** | 34.58+34.14 | 34.62+35.52 | 33.33+28.17 | 0.381 |
| **Questions 31-47** | 35.31+8.76 | 34.70+8.10 | 33.87+6.59 | 0.465 |
| **Stoma (n=13)** | 39.56+17.77 | 48.05+16.24 | 52.98+19.09 | **0.001\*** |
| **Male sexual life** | 65.79+10.90 | 68.33+10.42 | 72.22+5.51 | 0.347 |
| **Female sexual life** | 54.69+12.12 | 61.72+15.46 | 59.09+15.90 | 0.239 |
| **Total score** | 639.74+93.84 | 643.10+85.01 | 603.01+71.55 | **0.001\*** |

In contrast, FACT-C did not show any statistically significant differences at different periods of follow up Table (4). Most of studied patients reported fair HRQoL by both questionnaires; also there were statistically significant differences in emotional and social wellbeing in correlation between subscales & total score of both EORTC and FACT-C.

**Table (4): Comparison of FAT- C at different periods of follow up**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **EORTC score** | **Before** | **Before third cycle** | **Before fourth cycle** | **p** |
| **Physical function** | 51.92+17.29 | 51.51+16.16 | 48.03+16.44 | 0.239 |
| **Role functioning** | 69.96+15.42 | 69.64+14.76 | 74.75+14.69 | 0.192 |
| **Emotional functioning** | 44.95+8.43 | 43.11+7.82 | 42.67+9.02 | 0.036 |
| **Social functioning** | 87.24+13.75 | 88.46+12.96 | 88.36+13.66 | 0.091 |
| **Others** | 62.05+9.63 | 62.50+9.02 | 63.30+7.98 | 0.371 |
| **Total score** | 316.12+20.45 | 315.22+20.79 | 317.12+20.79 | 0.669 |

### Using Cronbach’s alpha for measurement of reliability of internal consistency of subscales of the EORTC and FACT-C; both had relatively high internal consistency. The relative high internal consistency of FACT-C confirmed the reliability of Arabic version of the questionnaire.

**Table (5):** **Comparison of internal consistency of subscales of the EORTC and FACT**

|  |  |
| --- | --- |
| **Subscale** | **Cronbach’s alpha** |
| **EORTC** |  |
| Physical functioning | 0.819 |
| Role functioning | 0.867 |
| Emotional functioning | 0.878 |
| Social functioning | 0.935 |
| EORTC (1-30) | 0.921 |
| EORTC (31-47) | 0.845 |
| EORTC (94-55) | 0.915 |
| **FACT** |  |
| Physical function | 0.886 |
| Role functioning | 0.851 |
| Emotional functioning | 0.435 |
| Social functioning | 0.885 |
| Others | 0.337 |
| Total | 0.839 |

**4. Discussion**

Assessment of HRQoL is important to judge overall treatment efficacy, educate patients and clinicians about the treatment outcomes, and to facilitate medical decision-making. (22) We found that three main factors would affect patients' quality of life including socio-demographic characteristics, health-related factors and cancer-related and surgical procedures factors.

In regards to Socio-demographic characteristics, Gender has not been reported as significant determinant in patients’ HRQoL (22). However, this is might not be true for specific problems like poor sexual functioning in man. Results on age and CRC HRQoL are controversial. Zahran et al. reported that age did not play a significant role in patients’ HRQoL. Nevertheless, in some studies HRQoL increase with age, whereas others reported a lower HRQoL with increasing age. (22)

Education level is not a determinant for HRQoL, because its role is subordinated to income. With regards to income, there is evidence that low income correlates with worse physical, social and emotional well-being dimensions of HRQoL. (23) 50% of studied patients reported fair financial problems.

For health-related factors, patient with CRC reported poor physical HRQoL. Co morbidity affects HRQoL by decreasing performance. Regarding cancer-related and surgical procedures factors, the stage and site of colorectal cancer at diagnosis are important in determining HRQoL, as they determine symptoms, treatment modalities and therapy duration. (22)

Surgical procedures can affect various aspects of HRQoL due to physical and psychological consequences. (23) An important consequence of colorectal surgery is stoma. The presence of stoma influenced negatively the HRQoL if compared with patients undergoing a sphincter saving resection, but not all authors found a significant difference. The most important aspect influenced by the presence of stoma was the social component of HRQoL as assessed by a recent systematic review conducted on 10 studies. (22)

Patients with a stoma (19%of studied patients) reported a significantly poorer body image and a higher level of micturition problems than patients without stoma. (24) Only 20% of studied patients had stoma showing fair HRQoL. Our study has compared the QLQ-CR29 and the FACT-C in attempts to distinguish their responsiveness, reliability, and validity in determining HRQoL in the CRC patient population.

The EORTC colorectal-specific modules are administered alongside the core QLQ-C30, and therefore, take longer on average to complete. In spite of this, no preferential difference between the QLQCR29 and FACT-C among patients has been reported. HRQoL can definitely be assessed by both EORTC & FACT-C, proved by the high internal consistency of both questionnaires, & that most of studied patients reported fair HRQoL by both questionnaires, also there are statically significant differences in emotional and social in correlation between subscales & total score of both EORTC and FACT-C.

It was shown that FACT-C English, Spanish, and Korean versions were also a reliable, valid HRQoL instrument for CRC with Cronbach’s alpha coefficients ranging from 0.71 to 0.89, from 0.56 to 0.87 and from 0.70 to 0.93 for the three versions, respectively. (25, 26) The FACT-C French version had a high degree of internal consistency (Cronbach’s alpha = 0.77–0.92), with Physical well-being 0.77, Social/family well-being 0.82, Emotional well-being 0.8, Functional well-being 0.85, FACT-C total score 0.92. (24) Our Arabic version had a high internal consistency (0.89), with Physical well-being 0.89, Social/family well-being 0.89, Emotional well-being 0.44, Functional well-being 0.85, FACT-C total score 0.84.

**Conclusion and Recommendations**

Arabic version of FACT-C could be used to assess quality of life in Egyptian patients with colorectal carcinoma. Validation on larger number of patients in other Arabic-speaking countries is recommended for the appropriate use of these measures in clinical research.

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