

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

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

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

[Sara M. El-Badawy, Mohamed A. Alm El-Din, Ibrahim A. Kabbash and Ashraf F. Barakat. **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.** *Cancer Biology* 2018;8(2):114-119]. ISSN: 2150-1041 (print); ISSN: 2150-105X (online). <http://www.cancerbio.net>. 16. doi:[10.7537/marscbj080218.16](https://doi.org/10.7537/marscbj080218.16).

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 total cancers and 53% of GIT cancers. The median age was 53 years with male 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 become 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 (micturition 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 \pm SD	49.54 \pm 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 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.

References

1. Jemal A, Bray F, Center MM, et al: Global cancer statistics. *CA: a cancer journal for clinicians* 2011, 61(2):69-90.
2. Ahmed A. Zeeneldin 1, Magdy M. Saber 1, Ibrahim A. Seif Eldin 2, et al: Medical Oncology/Hematology Department, National Cancer Institute, Cairo University, Cairo, Egypt. 2. Oncology Department, Tanta cancer Center, Ministry of Health, Tanta, Gharbiah, Egypt. Colorectal carcinoma in gharbiah district, Egypt: Comparison between the elderly and non-elderly *Journal of Solid Tumors*, June 2012, Vol. 2, No. 3.
3. Biondi A, Grosso G, Mistretta A, et al: Laparoscopic-assisted versus open surgery for colorectal cancer: short- and long-term outcomes comparison. *Journal of laparoendoscopic & advanced surgical techniques Part A* 2013, 23(1):1-7.
4. Biondi A, Tropea A, Basile F: Clinical rescue evaluation in laparoscopic surgery for hepatic metastases by colorectal cancer. *Surgical laparoscopy, endoscopy & percutaneous techniques* 2010, 20(2):69-72.

5. Verdecchia A, Francisci S, Brenner H, et al: Recent cancer survival in Europe: a 2000-02 period analysis of EURO CARE-4 data. *The lancet oncology* 2007, 8(9):784-796.
6. Baade PD, Youlten DR, Chambers SK: When do I know I am cured? Using conditional estimates to provide better information about cancer survival prospects. *Medical Journal of Australia* 2011, 194:373.
7. Donaldson GW, Moinpour CM: Individual differences in quality-of-life treatment response. *Medical care* 2002, 40(6 Suppl): III39-53.
8. Sprangers MA, Cull A., Bjordal K, et al: The European Organization for Research and Treatment of Cancer. Approach to quality of life assessment: guidelines for developing questionnaire modules. EORTC Study Group on Quality of Life. *Quality of life research: an international journal of quality of life aspects of treatment, care and rehabilitation* 1993, 2(4):287-295.
9. Cella DF, Tulsky DS: Quality of life in cancer: definition, purpose, and method of measurement. *Cancer investigation* 1993, 11(3):327-336.
10. Smith-Gagen J, Cress RD, Drake CM, et al: Quality-of-life and surgical treatments for rectal cancer--a longitudinal analysis using the California Cancer Registry. *Psycho-oncology* 2010, 19(8):870-878.
11. Wilson TR, Alexander DJ, Kind P: Measurement of health-related quality of life in the early follow-up of colon and rectal cancer. *Dis Colon Rectum* 2006, 49:1692-1702.
12. Ramsey SD, Berry K, Moinpour C, et al: Quality of life in long term survivors of colorectal cancer. *The American journal of gastroenterology* 2002, 97(5):1228-1234.
13. Whistance RN, Conroy T, Chie W, et al.: Clinical and psychometric validation of the EORTC QLQ-CR29 questionnaire module to assess health-related quality of life in patients with colorectal cancer. *Eur J Cancer* 2009, 45(17):3017-3026.
14. Ward WL, Hahn EA, Mo F, et al: Reliability and validity of the Functional Assessment of Cancer Therapy-Colorectal (FACTC) quality of life instrument. *Quality of life research: an international journal of quality of life aspects of treatment, care and rehabilitation* 1999, 8(3):181-195.
15. Cella D, Hernandez L, Bonomi AE, et al: Spanish language translation and initial validation of the functional assessment of cancer therapy quality-of-life instrument. *Medical care* 1998, 36(9):1407-1418.
16. Yoo HJ, Kim JC, Eremenco S, et al: Quality of life in colorectal cancer patients with colectomy and the validation of the Functional Assessment of Cancer Therapy-Colorectal (FACTC), Version 4. *Journal of pain and symptom management* 2005, 30(1):24-32.
17. Rotonda C, Conroy T, Mercier M, et al.: Validation of the French version of the colorectal-specific quality-of-life questionnaires EORTC QLQ-CR38 and FACT-C. *Quality of life research: an international journal of quality of life aspects of treatment, care and rehabilitation* 2008, 17(3):437-445.
18. Wong CK, Lam CL, Law WL, et al: Validity and reliability study on traditional Chinese FACT-C in Chinese patients with colorectal neoplasm. *Journal of evaluation in clinical practice* 2012, 18(6):1186-1195.
19. Cella DF, Tulsky DS, Gray G, et al.: The Functional Assessment of Cancer Therapy scale: development and validation of the general measure. *Journal of clinical oncology: official journal of the American Society of Clinical Oncology* 1993, 11(3):570-579.
20. Cull, A., et al: EORTC Quality of Life Study Group Translation Procedure. Brussels: European Organization for Research and Treatment of Cancer, 1994.
21. Lucas, C. P.: The order effect: Reflections on the validity of multiple test presentations. *Psychological Medicine*, 1992, 22, 197-202.
22. Zahran, M. H., et al: "Validation of the Arabic version of the Functional Assessment of Cancer Therapy-Bladder questionnaire in Egyptian patients with bladder cancer." *Arab Journal of Urology*, 2017, 15(2): 110-114.
23. Lionel Uwer, Christine Rotonda, Francis Guillemin, et al: Responsiveness of EORTC QLQ-C30, QLQ-CR38 and FACT-C quality of life questionnaires in patients with colorectal cancer, *Health and Quality of Life Outcomes*, 2011, 9:70.
24. Christine Rotonda, T. Conroy, M. Mercier, et al: Validation of the French version of the colorectal-specific quality-of-life questionnaires EORTC QLQ-CR38 and FACT-C, *Quality of Life Research*, 2008, Volume 17, Issue 3, 437-445.
25. Costet, N., et al.: Reliability and validity of the Functional Assessment of Cancer Therapy General (FACT-G) in French cancer patients. *Quality of Life Research*, 14, 2005, 1427-1432.
26. Yost, K. J., et al.: Minimally important differences were estimated for the Functional Assessment of Cancer Therapy-Colorectal (FACT-C) instrument using a combination of distribution- and anchor-based approaches. *Journal of Clinical Epidemiology*, 58, 2005, 1241-1251.