ORIGINAL ARTICLE

Received: April 2017
Accepted: January 2018

Psychometric properties of the Iranian version of colorectal cancer specific quality of life questionnaire (EORTC QLQ-CR29)

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BCCR
2017; 9(3): 32-41
www.bccrjournal.com

ABSTRACT

Background: The authors selected European Organization for Research and Treatment (EORTC) C30 and EORTC QLQ CR29 to specify bowel, bladder, and sexual dysfunction of Iranian colorectal cancer patients. **Methods:** A sample of 100 patients with colorectal cancer attending Iran Cancer Institute from March 2012 to March 2013 at first-line chemotherapy in the adjuvant or palliative settings participated in the study. Patients responded to the study questionnaires at the beginning and after 3-4 cycles of chemotherapies. Responses to the core questionnaire (QLQ-C30) and the QLQ-CR29 were linearly converted into 0-100 scores, using the EORTC guidelines. Correlations between the QLQ-C30 and QLQ-CR29 were examined, using Pearson's product moment correlation in order to assess construct validity. Known groups' comparon examined the ability of EORCT-CR29 to dtinguh between subgroups of patients with and without a stoma. Sensitivity to changes over time was examined by the response to chemotherapy in palliative or neoadjuvant settings. Internal constency was measured using Cronbach's alpha coefficient with estimates of a magnitude of 0.7. **Results:** The mean age of patients was 53.6. Based on clinical and pathologic staging, 60% of the patients had presented while their cancer was in stage IV with dtant metastas at the time of referring to the clinic. Thirty-three percent of patients, almost all from rectal tumor group, had a permanent ostomy. In general, the correlation between the EORTC QLQ-C30 and QLQ-CR29 was in the expected directions, demonstrating that functional scales of both questionnaires had a positive correlation with each other while negative correlation was observed between functional and symptom subscales. In addition, the QLQ-CR29 differed considerably between patients with and without a stoma.The QLQ-CR29 results showed improved functioning scores after treatment and at the same time symptoms decreased. The Cronbach's alpha for the scales ranged from 0.48-0.77. **Conclusion:** In general, the Iranian version of the EORTC QLQ-CR29 worked well and now could be used in outcome studies in colorectal cancer.

Keywords: Quality of life, EORTC, questionnaire, colon cancer, Iranian

INTRODUCTION:

Colorectal cancer death the third commonest cancer-related one in Iran. The incidence of the disease 7 per 100000 men and 5 per 100000 women with mortality rates of 2 per 100000 people[1]. With changing lifestyles and food habits of Iranians toward those of western world, the prevalence of colorectal cancer has been increasing in recent years[1]. Although worldwide, surgical resection the best curative treatment and chemotherapy, radiation, and targeted therapy have increased survival of advanced colorectal cancer patients from less than six months to more than 20 months. In general, the patient's expectation desire and perspective of outcomes are not considered seriously in Iran. Since there are extensively validated core as well as specific modules in western countries for assessment of Health-Related Quality of Life (HRQOL) measures, the authors selected European Organization for Research and Treatment (EORTC) QLQ-C30 and EORTC QLQ-CR29 to evaluate bowel, bladder, and sexual dysfunction[2] of Iranian colorectal cancer patients.EORTC-C30, as a core questionnaire to find the quality of life of patients with cancer in general, has been already translated and validated in Persian[3]. At the beginning of the present study, and after a search in Medline, PubMed and Embase, the authors couldn't find the same research in Iran. Recently, one validity study on a specific module for colorectal cancer in Iran has been published[4]. The present study was conducted after approval of the proposal by Research Deputy of TUMS and there were different structures for the study the authors' based on comparing different groups of patients instead of very homogenous cases of our colleagues in Isfahan. So the research team decided to publish the present study on translation and validation of the Persian version of EORTC QLQ-CR29 for use in outcome studies and clinical trials in Iran.

METHODS:

The questionnaire

A sample of 100 patients with colorectal cancer attending Iran Cancer Institute from March 2012 to March 2013 at first-line chemotherapy in the adjuvant or palliative settings participated in the study. Patients responded to the study questionnaires at the beginning and after 3-4 cycles of chemotherapies. Responses to the core questionnaire (QLQ-C30) and the QLQ-CR29 were linearly converted into 0-100 scores, using the EORTC guidelines. Correlations between the QLQ-C30 and QLQ-CR29 were examined, using Pearson's product moment correlation to assess construct validity. Known groups' comparison examined the ability of EORCT-CR29 to dtinguh between subgroups of patients with and without a stoma. Sensitivity to changes over time was examined by the response to chemotherapy in palliative or neo-adjuvant settings. Internal consistency was measured using Cronbach's alpha coefficient with estimates of a magnitude of 0.7.

Translation

After getting permission from the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Group, the authors applied forward-backward translation procedure to translate the English version of the EORTC-CR29 into Persian (the Iranian language). Two general physicians not connected to the study prepared two forward translations. Then, a consolidated Persian version was provided. And two independent professional translators provided back translations. The study coordinator provided the consolidated backward version. Finally, the consolidated Persian version was checked against the consolidated English version. Overall, no significant differences were observed between the two versions. However, some minor editing was made to provide the provisional Persian version of the questionnaire.

Patients

A sample of 100 patients with colorectal cancer attending Iran Cancer Institute from March 2012 to March 2013 voluntarily participated in the study. Inclusion criteria were: written informed consent, age more than 18 years, histologically confirmed the diagnosis of colorectal adenocarcinoma, being at the beginning of first-line chemotherapy in the adjuvant or palliative settings, and with the time limit of more than one month from surgery or end of radiotherapy. Cases with concurrent malignancy or problems hampering completion of questionnaire were excluded. Patients responded to the study questionnaires at the beginning and after 3-4 cycles of chemotherapy. Response to treatment was assessed at that time based on REST criteria[5] in the neoadjuvant or palliative settings but adjuvant therapy.

Additional measure

Each patient also completed the core cancer questionnaire (EORTC QLQ-C30). The EORTC QLQ-C30 assessed functional and symptom aspects of HRQOL[6] and the questionnaire was validated in Persian language[7]. Responses to the core questionnaire and the QLQ-CR29 were linearly converted into 0-100 scores, using the EORTC guidelines[6].

Statistical analysis

Validity:

1. Construct validity: correlations between the scales and single items of both the QLQ-C30 and QLQ-CR29 were examined, using Pearson's product moment correlation. Pearson's values of greater than 0.40 were considered highly correlated. It was anticipated that similar scales in the new module would be related to generic questionnaire while similar scales would not be related to each other.

2. Clinical validity: Using known-groups comparison, the ability of EORCT QLQ-CR29 was examined to discriminate between subgroups of patients who differed in the stoma. T-test assessed differences.

Responsiveness to change:

Sensitivity to changes over time was examined by comparing baseline scores with scores before and after treatment response to chemotherapy in palliative or neoadjuvant settings.

Reliability:

Internal consistency was measured with Cronbach alpha coefficient with estimates of a magnitude of 0.7 or more for acceptable value.

Ethics

The ethics committee of Tehran University of Medical Sciences approved the study. We obtained written informed consent from all participants.

RESULTS:

Descriptive findings

The characteristics of patients are shown in **Table 1**. The mean age of patients was 53.6 (SD = 12.6) years ranging from 22 to 78. Based on clinical and pathologic staging, 60% of the patients presented with stage IV and showed distant metastasis. Thirty-three percent of the patients, almost all from the rectal tumor group had permanent ostomy.

Psychometric findings

1. Construct validity:

a. The correlation between the EOPRTC QLQ-C29 and functioning subscales of the EORTC QLQCR30 and between the EOPRTCQLQ-C29 and symptom subscales of the EORTCQLQ-C30 are shown in **Table 2** and **Table 3** Respectively. There were positive correlations between functioning scores while negative correlations observed for symptom scales as expected.

b. Known groups comparison

The QLQ-CR29 differentiated well between patients with

and without a stoma. The results are shown in **Table 4.**

2. Responsiveness to change

Both questionnaires were responsive to treatment. The findings are shown in **Table 5** and **6**.

3. Reliability

The internal consistency of functioning subscales as measured by Cronbach's alpha showed acceptable results. The findings are shown in **Table 7**.

DISCUSSION:

Colorectal specific questionnaires to assess bowel, urinary, rectal and sexual dysfunction after treatment of colorectal cancer has been developed in recent years, but even after 15 years, there are problems in using them internationally[7]. Th study presents the Persian version of CR29 Colon Cancer Quality of life Questionnaire to compare results with other presented translation of original one.

In order to preserve the original format of the MPQ and avoid the creation of a new kind, the authors practiced the translation-based method. It also brought the world health organization's guidelines and Melzak's guidelines into consideration regarding the process of translation and assessment tools compatibility[8]

The EORTC-CR29 contains 29 items. There are 18 items related to gastrointestinal symptoms, pain and

Table 1. The charactertics of study sample (n =100)

	No.	%
Age		
Mean (SD)	53.6 (12.6)	
Range	20-78	
Gender		
Male	47	47
Female	53	53
Stage (TNM)		
I	3	3
II	10	10
III	27	27
IV	60	60
Metastas		
No	40	40
Yes	60	60
Stoma		
No	67	67
Yes	33	33

SD: Standard deviation

Table 2. Correlation between the EORTC QLQ-CR29 and functioning subscales of the EORTC QLQ-C30

	PF	RF	EF	CF	SF	QOL
QLQ-CR29 functioning						
Body image	0.18	0.38**	0.24	0.08	0.16	0.36
Anxiety	0.45	0.83	0.38**	0.30*	0.22	0.17
Weight	0.14	0.14	0.32**	0.14	0.12	0.12
Sexual interest (men)	0.31	0.04	0.10	0.09	0.02	0.49**
Sexual interest (women)	0.31	0.04	0.10	0.09	0.02	0.49**
QLQ-CR29 Symptoms						
Urinary frequency	-0.01	-0.16	-0.15	-0.23	-0.07	-0.04
Blood and mucus in stool	-0.24	-0.33**	-0.26*	-0.21	-0.28*	-0.05
Stool frequency	-0.15	0.12	-0.02	-0.25	-0.00	-0.12
Urinary incontinence	-0.05	-0.11	-0.16	-0.15	-0.02	-0.09
Dysuria	-0.24*	-0.38**	-0.26*	-0.26*	-0.21	-0.018
Abdominal pain	-0.34**	-0.33**	-0.12	0.09	-0.27*	-0.23
Buttock pain	-0.37**	-0.28*	-0.16	-0.03	-0.15	-0.12
Bloating	-0.20	-0. 27*	-0.14	-0.04	-0.06	-0.05
Dry mouth	-0.23	-0.22*	-0.14	-0.07	-0.14	-0.11
Hair loss	-0.09	-0.01	-0.07	-0.03	-0.17	0.09
Taste	-0.05	-0.04	-0.06	-0.12	-0.07	-0.05
Flatulence	-0.04	-0.05	-0.04	-0.11	-0.02	-0.10
Fecal incontinence	-0.20	-0.03	-0.04	-0.24	-0.23	-0.06
Sore skin	-0.33*	-0.44**	-0.34*	-0.01	-0.08	-0.06
Embarrassment	-0.05	-0.04	-0.27	-0.05	-0.13	-0.04
Impotence	-0.19	-0.06	-0.05	-0.03	-0.07	-0.03
Dyspareunia	-0.19	-0.06	-0.05	-0.03	-0.07	-0.03

*p<0.05, ** p<0.001.
QOL= quality of life, PF= Physical functioning, RF= Role functioning, EF= Emotional functioning, CF= Cognitive functioning, SF= Social functioning.

Table 3. Correlation between the EORTC QLQ-CR29 and symptom subscales of the EORTC QLQ-C30

	FA	NV	PA	DY	SI	AP	CO	DI	FI
QLQ-CR29 functioning									
Body image	-0.36**	-0.29	-0.30*	-0.07	-0.01	-0.15	-0.17	-0.01	-0.15
Anxiety	-0.33**	-0.40**	-0.07	-0.06	-0.12	-0.07	-0.27*	-0.15	-0.27*
Weight	-0.35**	-0.37**	-0.21	-0.05	-0.10	-0.27*	-0.30*	-0.11	-0.19
Sexual interest (men)	-0.15	-0.12	-0.19	-0.01	-0.17	-0.30*	-0.16	-0.01	-0.15
Sexual interest (women)	-0.15	-0.12	-0.19	-0.01	-0.17	-0.30*	-0.16	-0.00	-0.15
QLQ-CR29 Symptoms									
Urinary frequency	0.07	0.42**	0.06	0.05	0.27*	0.16	0.04	0.16	0.05
Blood and mucus in stool	0.44**	0.32**	0.22	0.20	0.12	0.11	0.02	0.55**	0.03
Stool frequency	0.19	0.09	0.09	0.06	0.01	0.07	0.13	0.05	0.01
Urinary incontinence	0.23	0.25*	0.01	0.00	0.15	0.01	0.02	0.31*	0.09
Dysuria	0.33**	0.32**	0.38**	0.00	0.31*	0.11	0.08	0.31*	0.04
Abdominal pain	0.33**	0.18	0.44**	0.13	0.08	0.11	0.00	0.07	0.11
Buttock pain	0.32**	0.28*	0.35**	0.12	0.09	0.22	0.14	0.11	0.00
Bloating	0.27*	0.33**	0.17	0.06	0.01	0.13	0.13	0.01	0.17
Dry mouth	0.33**	0.31**	0.22	0.13	0.32**	0.33**	0.36**	0.01	0.07
Hair loss	0.24	-0.03	0.19	0.05	0.04	0.11	0.05	0.13	0.20
Taste	0.01	0.05	0.09	0.02	0.05	0.16	0.05	0.10	0.19
Flatulence	0.07	0.27	0.02	0.22	0.09	0.16	0.03	0.17	0.13
Fecal incontinence	0.08	-0.08	0.12	0.14	-0.00	0.01	0.01	0.20	0.21
Sore skin	0.37*	0.56**	0.40**	-0.09	0.34*	0.27	0.27	0.08	0.09
Embarrassment	0.16	0.02	0.19	0.15	0.15	0.00	0.07	0.12	0.11
Impotence	0.15	0.06	0.09	0.14	0.057	0.02	0.04	0.02	0.02
Dyspareunia	0.03	0.15	0.09	0.14	0.05	0.02	0.4	0.02	0.02

*p<0.05, ** p<0.001.
FA= Fatigue, NV= Nausea/vomiting, PA= Pain, DY= Dyspnea, SL= Insomnia, AP= Appetite loss, CO= Constipation, DI= Diarrhea, FI= Financial problems.

Table 4. Comparing QLQ-CR29 scores between patients with and without a stoma (known groups comaeson)

	With a stoma (n = 33)	Without a stoma (n = 67)	
	Mean (SD)	Mean (SD)	P
QLQ-CR29 functioning			
Body image	62.2 (21.9)	68.8 (24.1)	0.18
Anxiety	68.3 (27.5)	73.9 (29.5)	0.36
Weight	75.4 (22.5)	80.0 (24.3)	0.35
Sexual interest (men)	81.1 (16.2)	84.5 (16.8)	0.33
Sexual interest (women)	79.2 (13.9)	81.0 (14.1)	0.54
QLQ-CR29 Symptoms			
Urinary frequency	30.0 (7.5)	26.2 (8.5)	0.03
Blood and mucus in stool	24.5 (9.6)	12.1 (8.4)	< 0.001
Stool frequency	33.2 (15.2)	27.0 (15.8)	0.06
Urinary incontinence	27.2 (7.2)	14.6 (8.0)	< 0.001
Dysuria	20.5 (9.8)	18.3 (9.0)	0.26
Abdominal pain	42.2 (16.0)	18.0 (14.4)	< 0.001
Buttock pain	45.2 (17.2)	34.0 (17.4)	0.003
Bloating	39.3 (10.6)	30.1 (11.8)	< 0.001
Dry mouth	38.7 (17.3)	33.2 (15.1)	0.11
Hair loss	33.3 (15.9)	35.9 (16.5)	0.45
Taste	17.5 (6.9)	18.1 (7.5)	0.70
Flatulence	40.7 (9.8)	23.1 (10.2)	< 0.001
Fecal incontinence	30.1 (10.2)	15.3 (9.4)	< 0.001
Sore skin	28.5 (7.4)	13.1 (8.6)	< 0.001
Embarrassment	38.1 (8.4)	23.3 (7.4)	< 0.001
Impotence	40.2 (16.7)	35.2 (18.8)	0.19
Dyspareunia	48.1 (7.2)	24.3 (8.4)	< 0.001

*p<0.05, ** p<0.001.

FA= Fatigue, NV= Nausea/vomiting, PA= Pain, DY= Dyspnea, SL= Insomnia, AP= Appetite loss, CO= Constipation, DI= Diarrhea, FI= Financial problems.

problems of micturition and there are separate scales for those with or without osteoma and different items addressing sexual function in men and women[9, 10]. The present study showed acceptable internal consistency for functioning scales. However, there was lowest consistency for blood/mucous in stool in relation to urine incontinence and body image. Whence study had similar results about blood/mucous in stool[11]. However, there was good internal consistency for urinary incontinence in comparison to Whtance study[11].

There were better results for the patients in early stage II (fewer symptoms and better functional scales) than advanced stage patients (palliative group).These results are correlated with those of other studies[11, 12].

Table 5. Quality of life in patients with colorectal cancer before and after treatment as measured by the EORTC QLQ-C30 (n = 100)

	Before treatment Mean (SD)	After treatment Mean (SD)	P-value
Functioning scores*			
Physical functioning	67.8 (22.1)	70.4 (20.3)	0.37
Role functioning	77.5 (25.4)	84.7 (22.8)	0.04
Emotional functioning	66.2 (28.5)	66.0 (30.0)	0.97
Cognitive functioning	84.7 (23.4)	81.5 (24.9)	0.39
Social functioning	77.1 (31.1)	79.5 (29.5)	0.61
Global functioning	58.1 (27.3)	64.0 (25.1)	0.18
QLQ-CR29 Symptoms			
Fatigue	37.2 (26.8)	30.7 (29.7)	0.15
Nausea and vomiting	14.1 (20.4)	9.3 (18.1)	0.11
Pain	32.4 (29.5)	27.5 (27.8)	0.27
Dyspnoea	10.1 (18.8)	13.5 (23.2)	0.35
Insomnia	24.1 (28.4)	26.4 (32.2)	0.63
Appetite loss	34.4 (31.8)	28.8 (32.7)	0.27
Constipation	20.0 (33.8)	14.1 (29.8)	0.17
Diarrhea	16.6 (29.4)	18.3(31.3)	0.70
Financial difficulties	70.6 (31.6)	71.1 (33.0)	0.91

* Higher scores indicate better conditions

** Higher scores indicate worse conditions

Table 6. Quality of life in patients with colorectal cancer before and after treatment as measured by the EORTC QLQ-CR29 (n = 100)

	Before treatment Mean (SD)	After treatment Mean (SD)	P
QLQ-CR29 functioning			
Body image	65.5 (23.0)	67.4 (20.5)	0.25
Anxiety	71.1 (28.5)	72.2 (28.8)	0.91
Weight	77.7 (23.4)	79.4 (26.3)	0.24
Sexual interest (men)	80.1 (16.5)	85.4 (18.2)	0.33
Sexual interest (women)	82.8 (14.0)	87.3 (14.7)	0.63
Symptom scores*			
Urinary frequency	28.1 (8.0)	26.9 (10.1)	0.02
Blood and mucus in stool	18.3 (9.0)	15.1 (6.7)	0.003
Stool frequency	30.1 (15.5)	18.6 (9.6)	< 0.001
Urinary incontinence	20.9 (7.6)	11.6 (4.7)	< 0.001
Dysuria	19.4 (9.4)	16.0 (5.0)	< 0.001
Abdominal pain	30.1 (15.2)	29.2 (12.6)	0.06
Buttock pain	39.6 (17.3)	33.3 (10.9)	< 0.001
Bloating	34.7 (11.1)	32.2 (15.0)	0.003
Dry mouth	35.9 (16.2)	30.9 (14.5)	0.27
Hair loss	34.6 (16.7)	43.2 (14.3)	0.12
Taste	17.8 (5.7)	15.3 (7.4)	0.009
Flatulence	26.9 (10.1)	23.3 (12.1)	0.07
Fecal incontinence	22.7 (9.8)	20.8 (9.0)	0.39
Sore skin	20.8 (8.0)	16.1 (7.1)	0.23
Embarrassment	25.7 (7.7)	20.3 (6.6)	0.12
Impotence	37.6 (17.5)	37.0 (18.1)	0.73
Dyspareunia	36.2 (7.8)	35.2 (8.0)	0.80

* Higher scores indicate better conditions

** Higher scores indicate worse conditions

One of the limitations of the present study was limited sample size. The other one was cultural problems of patients with questions related to their private life, especially sexual relationships or disabilities. Even some patients were reluctant to speak about osteotomy. In Summary, an acceptable correlation between was found items and hypothesized sub-scales, lending to support to CR-29 questionnaire construct validity. In addition, the questionnaire well-dcriminated patients who differed in stage and metastasis. The Iranian version of the EORTC QLQ-CR29 worked well and now could be used in outcome studies in colorectal cancer.

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Table 7. Reliability and stability of the EORTC QLQ-CR29

	Number of items	Cronbach's alpha
Body image	3	0.75
Urinary frequency	2	0.86
Blood or mucus in stools	2	0.48
Stool frequency	2	0.77

* Higher scores indicate better conditions

** Higher scores indicate worse conditions