

## Observational Study

# Validation of the chinese version of the EORTC QLQ-CR29 in patients with colorectal cancer

Jin-Bo Lin, Lei Zhang, Dong-Wen Wu, Zhou-Huan Xi, Xue-Jun Wang, Yun-Shou Lin, Wakana Fujiwara, Jing-Ru Tian, Min Wang, Peng Peng, Ai Guo, Zhen Yang, Le Luo, Ling-Ya Jiang, Qia-Qia Li, Xue-Ying Zhang, Yun-Feng Zhang, Hou-Wei Xu, Bing Yang, Xun-Lin Li, Yi-Xiong Lei

Jin-Bo Lin, Yi-Xiong Lei, School of Public Health, Guangzhou Medical University, Guangzhou 511436, Guangdong Province, China

Jin-Bo Lin, Bing Yang, Longgang Central Hospital of Shenzhen, Shenzhen 518116, Guangdong Province, China

Lei Zhang, Department of Thoracic Surgery, Tianjin Medical University Cancer Institute and Hospital, National Clinical Research Center for Cancer, Key Laboratory of Cancer Prevention and Therapy, Tianjin Lung Cancer Center, Tianjin 300060, China

Dong-Wen Wu, Zhou-Huan Xi, Jing-Ru Tian, Zhen Yang, Ling-Ya Jiang, Qia-Qia Li, Xue-Ying Zhang, Xiangya School of Medicine, Central South University, Changsha 410013, Hunan Province, China

Xue-Jun Wang, Department of Gastrointestinal Surgery, Tianjin Medical University Cancer Institute and Hospital, National Clinical Research Center for Cancer, Key Laboratory of Cancer Prevention and Therapy, Tianjin Lung Cancer Center, Tianjin 300060, China

Yun-Shou Lin, Min Wang, Peng Peng, Ai Guo, Xun-Lin Li, Tianjin Medical University, Tianjin 300060, China

Wakana Fujiwara, School of Medicine, Georgetown University, N.W., Washington D.C. 20057, United States

Le Luo, Department of Radiation Oncology, Tumor Hospital, Xiangya School of Medicine of Central South University, Changsha 410013, Hunan Province, China

Yun-Feng Zhang, Longgang District Peoples Hospital of Shenzhen, Shenzhen 518172, Guangdong Province, China

Hou-Wei Xu, Cancer Center of Guangzhou Medical University, Guangzhou 510182, Guangdong Province, China

**Author contributions:** Lin JB, Zhang L, Wu DW and Xi ZH designed the research; Wang XJ, Lin YS, Tian JR and Guo A

performed data analysis and interpretation; Wang M and Peng P wrote the paper; Yang Z, Luo L, Jiang LY, Li QQ, Zhang XY, Zhang YF, Xu HW, Yang B and Li XL collected the data; Fujiwara W and Lei YX revised the article; all authors have approved the final version to be published.

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Correspondence to: Yi-Xiong Lei, PhD, School of Public Health, Guangzhou Medical University, Xinzao, Panyu District, Guangzhou 511436, Guangdong Province, China. colorectum@163.com  
Telephone: +86-755-84802448  
Fax: +86-755-84816979

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## Abstract

### AIM

To assess the validity and reliability of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Colorectal Cancer 29 (EORTC QLQ-CR29) in Chinese patients with colorectal cancer (CRC).

### METHODS

From March 2014 to January 2015, 356 patients with CRC from four different hospitals in China were enrolled in the study, and all patients self-administered the EORTC QLQ-CR29 and the quality of life core questionnaire (EORTC QLQ-C30). Evaluation of the scores was based on the Karnofsky Performance Scale (KPS). The reliability and validity of the questionnaires were assessed by Cronbach's  $\alpha$  coefficient, the Spearman correlation test and Wilcoxon rank sum test.

### RESULTS

The EORTC QLQ-CR29 showed satisfactory reliability ( $\alpha > 0.7$ ), although the urinary frequency and blood and mucus in stool dimensions had only moderate reliability ( $\alpha = 0.608$ ). The multitrait scaling analyses showed good convergent ( $r > 0.4$ ) and discriminant validity. Significant differences were obtained for each item in the different KPS subgroups ( $KPS \leq 80$ ;  $KPS > 80$ ). Body image and most single-item dimensions showed statistically significant differences in patients with a stoma compared with the rest of the patients.

### CONCLUSION

The EORTC QLQ-CR29 exhibits high validity and reliability in Chinese patients with CRC, and can therefore be recommended as a valuable tool for the assessment of quality of life in these patients.

**Key words:** Colorectal cancer; Health-related quality of life; EORTC QLQ-CR29; Mainland China

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**Core tip:** This is the first study to examine the reliability and validity of the Chinese version of the EORTC QLQ-CR29 in patients with colorectal cancer in mainland China. The EORTC QLQ-CR29 exhibits high validity and reliability in Chinese patients with CRC, and can therefore be recommended as a valuable tool for the assessment of quality of life in these patients.

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## INTRODUCTION

Colorectal cancer (CRC) is the third most common cancer and the fourth leading cause of cancer death worldwide. According to the latest data, almost 1.4 million people were diagnosed with CRC and 700000 people died of CRC worldwide in 2012<sup>[1]</sup>. Moreover, the number of newly diagnosed CRC patients in China in 2012 was estimated to be 331 300, which accounted for approximately 24% of all cases in the world<sup>[2]</sup>. Therefore, it is important to prolong the lives of CRC patients and improve their quality of life.

The EORTC QLQ-CR29 questionnaire was developed by the European Organization for Research and Treatment of Cancer (EORTC) to evaluate the quality of life in CRC patients. It has already been validated in Holland, Spain, Poland and several other countries<sup>[3-8]</sup>. However, the dietary and cultural differences between China and Western countries may lead to different interpretations of quality of life. Therefore, it is essential to test the reliability and validity of the Chinese version of the EORTC QLQ-CR29 in patients with CRC, which has never been done in mainland China.

## MATERIALS AND METHODS

### Patients

A total of 356 patients with CRC in the Third Xiangya Hospital of Central South University, the Affiliated Tumor Hospital of Central South University, the Longgang Central Hospital of Shenzhen, and the Affiliated Tumor Hospital of Guangzhou Medical University were recruited between March 2014 and January 2015. Patients were included in the study if they were older than 18 years and had histological confirmation of colon or rectal cancer. Patients who had complications or who had been diagnosed with a cognitive disorder or psychoneurosis were excluded.

All participants completed the Chinese version of the EORTC QLQ-C30 and EORTC QLQ-CR29 during the 11-mo recruitment period.

### Instruments

**EORTC QLQ-C30:** The EORTC QLQ-C30 is the core questionnaire designed by the European Organization for Research and Treatment of Cancer, and has five functional dimensions: physical functioning (PF), role functioning (RF), cognitive functioning (CF), emotional functioning (EF) and social functioning (SF); three symptom scales: fatigue (FA), pain (PA), and nausea/vomiting (NV); six single items addressing various symptoms and perceived financial impact, and a global health-related quality of life (HRQOL) subscale. Among the 30 items, 29 have seven possible responses and are awarded a score of 1 to 7 points according to the answer; the other has a four-point answer scale: 1, Not at all; 2, A little; 3, Quite a bit; 4, Very much<sup>[9,10]</sup>. The reliability and validity of C30 have already been verified in China<sup>[11]</sup>.

**EORTC QLQ-CR29:** The EORTC QLQ-CR29 was specifically designed by the EORTC QL Group (The European Organization for Research and Treatment of Cancer Quality of Life Group) as the QLQ-C30 supplement for the evaluation of HRQOL in CRC patients. This combination has already been widely used in both clinical and basic research<sup>[12-14]</sup>.

The QLQ-CR29 includes 29 items that evaluate symptoms (gastrointestinal, urinary, pain and others) and functional areas (sexual, body image and others) that are associated with CRC and its treatments. There are separate items for patients with and without a stoma (items 49 to 54, with item 55 only for patients with a stoma) and separate items to evaluate the sexual function of men and women. The questionnaires ask for all items in the past week except those pertaining to sexuality, which request the patients to evaluate the items in the past four weeks. Similar to the EORTC QLQ-C30, the QLQ-CR29 has a Likert scale of four response categories (item 48 requires a yes or no answer)<sup>[5,8,9]</sup>. All patient-rated scores are linearly converted into a scale from 0 to 100 for both the QLQ-C30 and QLQ-CR29<sup>[7,15]</sup>.

According to the EORTC guidelines<sup>[16]</sup>, two translators first translated EORTC QLQ-CR29 into Chinese (Simplified Chinese), then another two translators translated the Chinese version of the EORTC QLQ-CR29 into English and compared it with the original questionnaire to verify whether it fully reflected the contents of the original questionnaire. After several amendments, we then selected 20 female and 20 male patients (both male and female patients included 3 stoma patients) to determine if the questionnaire was easy to understand. According to the feedback, we finally developed the Chinese version of the EORTC QLQ-CR29.

### Karnofsky performance scale

The Karnofsky performance scale (KPS) was determined by physicians according to the condition of the patient with respect to illness, self-care ability and daily activities. The total score of 100 was graded by 10 and the higher the score, the better the patient's health<sup>[17,18]</sup>.

### Ethics

Approval for this study was obtained from the Ethics Committees of the four participating hospitals. Before the investigation, we asked patients to provide a signed informed consent, and confirmed their consent to participate in the study to protect their voluntary participation, right to know, and right of privacy.

### Statistical analysis

We selected nurses on duty in the relevant departments as investigators in this study. After training, the investigators explained and introduced the protocol to the participants, and obtained basic information and KPS scores. Each participant completed the EORTC QLQ-CR29 and EORTC QLQ-C30 independently. Each scale score was converted based on standard formula, and the points ranged from 0 points (the worst) to 100 points (best).

All data were analyzed using SPSS17.0 software. Numbers (percentages) were used to describe numerical data and the mean  $\pm$  SD was adopted to describe measured data.

The internal consistency of the questionnaire was assessed using Cronbach's  $\alpha$  coefficient ( $\alpha > 0.7$  was considered acceptable).

Multitrait scaling analysis was used to assess the module structure. The convergent validity of each item was determined by calculating the correlation between each item and its own dimension ( $r > 0.40$  was considered acceptable). For discriminant validity, we expected the correlation between each item and its own dimension to be greater than the correlation between the item and the other dimensions.

Correlations between all of the EORTC QLQ-CR29 and the EORTC QLQ-C30 areas were calculated based on the Spearman correlation coefficient ( $r > 0.4$  was considered strongly correlated).

Known-groups validity was assessed by making comparisons between subgroups based on the presence of a stoma and KPS score ( $KPS \leq 80$ ;  $KPS > 80$ ) using the Wilcoxon rank sum test.

The acceptability was evaluated by the completion ratio of the questionnaires and the miss rate of each item.

## RESULTS

### Patient characteristics and compliance

A total of 356 patients were enrolled in the study and no one declined the invitation to participate. The study

**Table 1 Sociodemographic and clinical characteristics of the patients (*n* = 356) *n* (%)**

| Characteristics   | No. of patients <sup>1</sup> |
|---|------------------------------|
| Age (yr, mean ± SD)   | 54.5 ± 13.5                  |
| Sex   | 341 <sup>2</sup>             |
| Male  | 213 (62.5)                   |
| Female  | 128 (37.5)                   |
| Educational status  | 341 <sup>2</sup>             |
| Junior high school  | 182 (53.4)                   |
| Senior high school  | 107 (31.4)                   |
| University  | 47 (13.8)                    |
| Postgraduate and above                                      | 5 (1.5)                      |
| Marital status  | 340 <sup>2</sup>             |
| Single  | 5 (1.5)                      |
| Married   | 334 (98.2)                   |
| Divorced  | 1 (0.3)                      |
| Employment  | 343 <sup>2</sup>             |
| Yes   | 268 (78.1)                   |
| No  | 75 (21.9)                    |
| Location of tumor   | 342 <sup>2</sup>             |
| Colon   | 193 (56.4)                   |
| Rectum  | 147 (43.0)                   |
| Both  | 2 (0.6)                      |
| Metastasis  | 343 <sup>2</sup>             |
| Yes   | 102 (29.7)                   |
| No  | 215 (62.7)                   |
| Unknown   | 26 (7.6)                     |
| Time from first diagnosis (wk) Median (interquartile range) | 16.0 (33.8)                  |

<sup>1</sup>All percentages are valid; <sup>2</sup>There are missing data.

group included 213 men and 128 women with an average age of 54.5 (±13.5) years. Of the participants, 193 patients had colon cancer, 147 patients had rectal cancer and three had both colon and rectal cancer, and 102 patients had metastasis (Table 1).

### Reliability

**Internal consistency:** Reliability was assessed using Cronbach's  $\alpha$  coefficient. The correlations between the items showed that the body image and stool frequency dimensions had high reliability ( $\alpha > 0.7$ ), while the urinary frequency and blood and mucus in the stool dimensions had lower, but still moderate reliability (0.608 and 0.641). Except for the urinary frequency dimension (0.608 with vs 0.363 without), the reliability of other dimensions in patients without a stoma was higher than that in patients with a stoma (Table 2).

### Validity

**Multitrait scaling analyses:** The correlations between all dimensions and their sub-items were higher than 0.4. In addition to the finding that the correlation between item 28 for the patients with a stoma and blood and mucus in stool dimension was 1, the correlations between other dimensions and their sub-items were all greater than their correlations with other items (Table 2).

**Correlations with the EORTC QLQ-C30:** The

dimensions and the single items included in the CR29 had correlations of 0.004-0.648 with the C30. Abdominal pain and pain showed a good correlation ( $r = 0.648$ ), while the correlation between abdominal pain and fatigue was 0.411. The correlations between the anxiety dimension and the four dimensions of the C30 (role functioning, emotional functioning, social functioning and financial problems) were all greater than 0.4. The correlations between the blood and mucus in the stool dimension and three dimensions of the C30 (quality of life, pain and diarrhea) were all greater than 0.4. Seven dimensions (body image, buttock pain, hair loss, bloating, fecal incontinence, sore skin and dyspareunia) had correlation coefficients with nausea/vomiting that were higher than 0.4, and the correlations between the stool frequency and diarrhea as well as taste and appetite loss were also greater than 0.4 (Table 3).

**Known-groups validity:** The differences between the CR29 and C30 scores are shown in Table 4, where the data are grouped based on the clinical parameters. In addition to items such as abdominal pain, dry mouth and stoma care problems (0.059, 0.170, and 0.941) and dimensions such as urinary frequency and body image (0.098 and 0.589), other areas in subgroups divided by the KPS scores (KPS  $\leq 80$ ; KPS  $> 80$ ) also showed statistical significance ( $P < 0.05$ ). As for patients with or without a stoma, body image and most single-item dimensions from the CR29 and only role, social as well as nausea and vomiting dimensions from the C30 showed statistically significant differences.

### Acceptability

In the survey, 285 of 356 patients (80.1%) completed the EORTC (C30 and CR29) questionnaires, and a total of 265 patients (74.4%) completed the basic status questionnaire and the measurement questionnaires. The lowest response rates were associated with sexual problems, with a miss rate of 3.4% (12 cases). Overall, the questionnaire completion rate was higher than 90%, which shows that over 90% of the items were answered.

## DISCUSSION

Due to improvements in curative therapy, doctors have started to pay more attention to HRQOL in CRC patients<sup>[13,19-23]</sup>. In this study, we selected the EORTC QLQ-CR29 and EORTC QLQ-C30, and examined their reliability, validity, and acceptability in terms of assessing the quality of life in patients with CRC in mainland China. The overall goal of the study was to determine the feasibility of these instruments in the clinical setting in China.

The analysis of internal consistency showed that, regardless of whether a stoma was present, Cronbach's



**Table 2** Item convergent and discriminant validity for the EORTC QLQ-CR29 scales, and for patients with and without a stoma

| QLQ-CR29 scales          | Total sample ( <i>n</i> = 354) <sup>1</sup> |              |          | Without a stoma ( <i>n</i> = 298) |              |          | With a stoma ( <i>n</i> = 56) |              |          |
|--------------------------|---|--------------|----------|-----------------------------------|--------------|----------|-------------------------------|--------------|----------|
|                          | Convergent                                  | Discriminant | $\alpha$ | Convergent                        | Discriminant | $\alpha$ | Convergent                    | Discriminant | $\alpha$ |
| Urinary frequency        | 0.589-0.923                                 | 0.004-0.306  | 0.406    | 0.588-0.924                       | 0.002-0.321  | 0.363    | 0.587-0.919                   | 0.017-0.333  | 0.608    |
| Blood or mucus in stools | 0.794-0.886                                 | 0.004-0.712  | 0.641    | 0.790-0.891                       | 0.002-0.738  | 0.638    | 0.815-0.829                   | 0.037-1.000  | 0.632    |
| Stool frequency          | 0.689-0.965                                 | 0.003-0.641  | 0.679    | 0.696-0.967                       | 0.001-0.669  | 0.716    | 0.645-0.957                   | 0.003-0.389  | 0.423    |
| Body image               | 0.628-0.826                                 | 0.060-0.405  | 0.715    | 0.614-0.839                       | 0.039-0.422  | 0.718    | 0.703-0.792                   | 0.004-0.504  | 0.676    |

<sup>1</sup>Two are missing.**Table 3** Correlations between the EORTC QLQ-CR29 and the QLQ-C30

|                          | EORTC-QLQ-C30       |                     |                     |                     |                     |                     |                     |                     |                     |                     |                     |                     |                     |                     |                     |
|--------------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|
|                          | QOL                 | PF                  | RF                  | EF                  | CF                  | SF                  | FA                  | NV                  | PA                  | DY                  | SL                  | AP                  | CO                  | DI                  | FI                  |
| CR29 scales              |                     |                     |                     |                     |                     |                     |                     |                     |                     |                     |                     |                     |                     |                     |                     |
| Urinary frequency        | 0.004               | -0.071              | -0.111 <sup>a</sup> | -0.083              | -0.163 <sup>b</sup> | -0.159 <sup>b</sup> | 0.107 <sup>a</sup>  | -0.130 <sup>a</sup> | -0.033              | -0.046              | 0.061               | 0.023               | -0.131 <sup>a</sup> | -0.022              | 0.063               |
| Blood and mucus in stool | -0.412 <sup>b</sup> | -0.320 <sup>b</sup> | -0.074              | -0.091              | -0.166 <sup>b</sup> | 0.077               | 0.296 <sup>b</sup>  | 0.383 <sup>b</sup>  | 0.451 <sup>b</sup>  | 0.166 <sup>b</sup>  | 0.190 <sup>b</sup>  | 0.120 <sup>a</sup>  | 0.321 <sup>b</sup>  | 0.526 <sup>b</sup>  | -0.141 <sup>a</sup> |
| Stool frequency          | -0.322 <sup>b</sup> | -0.236 <sup>b</sup> | -0.075              | -0.132 <sup>a</sup> | -0.115 <sup>a</sup> | -0.026              | 0.268 <sup>b</sup>  | 0.340 <sup>b</sup>  | 0.349 <sup>b</sup>  | 0.212 <sup>b</sup>  | 0.188 <sup>b</sup>  | 0.120 <sup>a</sup>  | 0.247 <sup>b</sup>  | 0.492 <sup>b</sup>  | -0.113 <sup>a</sup> |
| Body image               | 0.254 <sup>b</sup>  | 0.179 <sup>b</sup>  | -0.052              | 0.051               | 0.100               | -0.172 <sup>b</sup> | -0.303 <sup>b</sup> | -0.485 <sup>b</sup> | -0.363 <sup>b</sup> | -0.251 <sup>b</sup> | -0.185 <sup>b</sup> | -0.279 <sup>b</sup> | -0.240 <sup>b</sup> | -0.224 <sup>b</sup> | 0.132 <sup>a</sup>  |
| CR29 single items        |                     |                     |                     |                     |                     |                     |                     |                     |                     |                     |                     |                     |                     |                     |                     |
| Urinary incontinence     | 0.084               | 0.040               | 0.237 <sup>b</sup>  | 0.203 <sup>b</sup>  | -0.071              | 0.171 <sup>b</sup>  | -0.038              | 0.270 <sup>b</sup>  | 0.125 <sup>a</sup>  | 0.311 <sup>b</sup>  | 0.080               | 0.040               | 0.135 <sup>a</sup>  | 0.139 <sup>b</sup>  | -0.291 <sup>b</sup> |
| Dysuria                  | 0.032               | 0.101               | 0.223 <sup>b</sup>  | 0.210 <sup>b</sup>  | -0.185 <sup>b</sup> | 0.288 <sup>b</sup>  | 0.053               | 0.330 <sup>b</sup>  | 0.272 <sup>b</sup>  | 0.296 <sup>b</sup>  | 0.133 <sup>a</sup>  | 0.003               | 0.279 <sup>b</sup>  | 0.158 <sup>b</sup>  | -0.294 <sup>b</sup> |
| Abdominal pain           | -0.357 <sup>b</sup> | -0.399 <sup>b</sup> | -0.149 <sup>b</sup> | -0.086              | -0.245 <sup>b</sup> | 0.097               | 0.411 <sup>b</sup>  | 0.342 <sup>b</sup>  | 0.648 <sup>b</sup>  | 0.321 <sup>b</sup>  | 0.307 <sup>b</sup>  | 0.241 <sup>b</sup>  | 0.375 <sup>b</sup>  | 0.381 <sup>b</sup>  | -0.118 <sup>a</sup> |
| Buttock pain             | -0.114 <sup>a</sup> | -0.105              | 0.129 <sup>a</sup>  | 0.056               | -0.138 <sup>a</sup> | 0.271 <sup>b</sup>  | 0.131 <sup>a</sup>  | 0.487 <sup>b</sup>  | 0.343 <sup>b</sup>  | 0.224 <sup>b</sup>  | 0.178 <sup>b</sup>  | 0.139 <sup>b</sup>  | 0.278 <sup>b</sup>  | 0.160 <sup>b</sup>  | -0.273 <sup>b</sup> |
| Bloating                 | -0.261 <sup>b</sup> | -0.233 <sup>b</sup> | -0.277 <sup>b</sup> | -0.302 <sup>b</sup> | -0.129 <sup>a</sup> | -0.206 <sup>b</sup> | 0.213 <sup>b</sup>  | 0.080               | 0.240 <sup>b</sup>  | 0.130 <sup>a</sup>  | 0.221 <sup>b</sup>  | 0.183 <sup>b</sup>  | 0.207 <sup>b</sup>  | 0.252 <sup>b</sup>  | 0.125 <sup>a</sup>  |
| Dry mouth                | -0.117 <sup>a</sup> | -0.074              | 0.181 <sup>b</sup>  | 0.120 <sup>a</sup>  | -0.104              | 0.216 <sup>b</sup>  | 0.152 <sup>b</sup>  | 0.321 <sup>b</sup>  | 0.262 <sup>b</sup>  | 0.358 <sup>b</sup>  | 0.134 <sup>a</sup>  | 0.110 <sup>a</sup>  | 0.218 <sup>b</sup>  | 0.122 <sup>a</sup>  | -0.163 <sup>b</sup> |
| Hair loss                | -0.112 <sup>a</sup> | -0.085              | 0.167 <sup>b</sup>  | 0.037               | -0.131 <sup>a</sup> | 0.222 <sup>b</sup>  | 0.184 <sup>b</sup>  | 0.486 <sup>b</sup>  | 0.286 <sup>b</sup>  | 0.276 <sup>b</sup>  | 0.108 <sup>a</sup>  | 0.127 <sup>a</sup>  | 0.232 <sup>b</sup>  | 0.155 <sup>b</sup>  | -0.200 <sup>b</sup> |
| Taste                    | -0.218 <sup>b</sup> | -0.238 <sup>b</sup> | -0.214 <sup>b</sup> | -0.278 <sup>b</sup> | -0.222 <sup>b</sup> | -0.107 <sup>a</sup> | 0.266 <sup>b</sup>  | 0.137 <sup>a</sup>  | 0.102               | 0.088               | 0.294 <sup>b</sup>  | 0.459 <sup>b</sup>  | 0.013               | 0.163 <sup>b</sup>  | 0.083               |
| Anxiety                  | -0.233 <sup>b</sup> | -0.147 <sup>b</sup> | -0.425 <sup>b</sup> | -0.547 <sup>b</sup> | -0.033              | -0.412 <sup>b</sup> | 0.150 <sup>b</sup>  | -0.272 <sup>b</sup> | -0.103              | -0.095              | 0.011               | 0.134 <sup>a</sup>  | -0.089              | 0.066               | 0.449 <sup>b</sup>  |
| Weight                   | -0.217 <sup>b</sup> | -0.266 <sup>b</sup> | -0.346 <sup>b</sup> | -0.371 <sup>b</sup> | -0.175 <sup>b</sup> | -0.244 <sup>b</sup> | 0.287 <sup>b</sup>  | 0.042               | 0.103               | 0.026               | 0.202 <sup>b</sup>  | 0.287 <sup>b</sup>  | 0.005               | 0.184 <sup>b</sup>  | 0.306 <sup>b</sup>  |
| Flatulence               | -0.057              | -0.094              | 0.170 <sup>b</sup>  | 0.039               | -0.115 <sup>a</sup> | 0.159 <sup>b</sup>  | 0.092               | 0.433 <sup>b</sup>  | 0.206 <sup>b</sup>  | 0.180 <sup>b</sup>  | 0.106 <sup>a</sup>  | 0.180 <sup>b</sup>  | 0.200 <sup>b</sup>  | 0.236 <sup>b</sup>  | -0.166 <sup>b</sup> |
| Fecal incontinence       | -0.017              | -0.032              | 0.275 <sup>b</sup>  | 0.218 <sup>b</sup>  | -0.129 <sup>a</sup> | 0.320 <sup>b</sup>  | 0.049               | 0.447 <sup>b</sup>  | 0.284 <sup>b</sup>  | 0.252 <sup>b</sup>  | 0.163 <sup>b</sup>  | 0.055               | 0.229 <sup>b</sup>  | 0.257 <sup>b</sup>  | -0.350 <sup>b</sup> |
| Sore skin                | -0.052              | -0.132 <sup>a</sup> | 0.208 <sup>b</sup>  | 0.170 <sup>b</sup>  | -0.094              | 0.296 <sup>b</sup>  | 0.081               | 0.497 <sup>b</sup>  | 0.205 <sup>b</sup>  | 0.130 <sup>a</sup>  | 0.160 <sup>b</sup>  | 0.123 <sup>a</sup>  | 0.106 <sup>a</sup>  | 0.194 <sup>b</sup>  | -0.271 <sup>b</sup> |
| Embarrassment            | -0.049              | -0.041              | 0.200 <sup>b</sup>  | 0.085               | -0.019              | 0.209 <sup>b</sup>  | 0.036               | 0.317 <sup>b</sup>  | 0.167 <sup>b</sup>  | -0.006              | 0.027               | 0.059               | 0.070               | 0.088               | -0.209 <sup>b</sup> |
| Stoma care problems      | -0.184              | 0.210               | 0.224               | -0.254              | 0.044               | 0.064               | -0.025              | 0.019               | -0.033              | -0.265              | -0.059              | 0.007               | -0.161              | 0.073               | 0.175               |
| Sexual interest (men)    | -0.108              | -0.177 <sup>a</sup> | -0.051              | 0.041               | -0.276 <sup>b</sup> | -0.184 <sup>b</sup> | 0.142 <sup>a</sup>  | -0.089              | 0.051               | 0.119               | 0.112               | 0.004               | -0.010              | 0.039               | 0.092               |
| Impotence                | -0.026              | -0.102              | 0.189 <sup>b</sup>  | 0.177 <sup>a</sup>  | -0.212 <sup>b</sup> | 0.243 <sup>b</sup>  | 0.105               | 0.242 <sup>b</sup>  | 0.082               | 0.155 <sup>a</sup>  | 0.175 <sup>a</sup>  | 0.157 <sup>a</sup>  | 0.069               | 0.093               | -0.256 <sup>b</sup> |
| Sexual interest (women)  | -0.319 <sup>b</sup> | -0.213 <sup>a</sup> | -0.092              | 0.030               | -0.386 <sup>b</sup> | -0.006              | 0.091               | -0.099              | 0.044               | 0.194               | 0.270 <sup>b</sup>  | 0.056               | 0.176               | -0.010              | 0.215 <sup>a</sup>  |
| Dyspareunia              | 0.026               | 0.003               | 0.213 <sup>b</sup>  | 0.322 <sup>b</sup>  | -0.129              | 0.258 <sup>b</sup>  | -0.094              | 0.423 <sup>b</sup>  | 0.185               | 0.227 <sup>a</sup>  | 0.005               | 0.090               | 0.312 <sup>b</sup>  | 0.117               | -0.193              |

<sup>a</sup> $P < 0.05$ , <sup>b</sup> $P < 0.01$ , EORTC QLQ-CR29 vs the QLQ-C30. QOL: Quality of life; PF: Physical functioning; RF: Role functioning; EF: Emotional functioning; CF: Cognitive functioning; SF: Social functioning; FA: Fatigue; NV: Nausea/vomiting; PA: Pain; DY: Dyspnea; SL: Insomnia; AP: Appetite loss; CO: Constipation; DI: Diarrhea; FI: Financial problems.

s  $\alpha$  coefficient in each dimension was satisfactory or near-satisfactory. In the original EORTC study, Cronbach's  $\alpha$  coefficients were greater than or almost equal to 0.7<sup>[9]</sup>. Our data mainly showed lower Cronbach's  $\alpha$  coefficients than those in a similar study by Nowak *et al*<sup>[8]</sup>, particularly in the urinary frequency dimension (0.363-0.608). Of note, in the studies by Arraras *et al*<sup>[5]</sup>, Nowak *et al*<sup>[8]</sup> and Arraras Urdaniz *et al*<sup>[24]</sup>, Cronbach's  $\alpha$  coefficients below 0.7 were also obtained for the abdominal pain and blood and mucus in the stool dimensions. The differences

between our findings and those of previous studies may be due to differences in the perceptions of quality of life in patients from different regions; however, the differences were still in the acceptable range. In addition, the reliability of the dimensions related to body image and stool frequency in patients without a stoma was higher than that in patients with a stoma, which is different from the studies reported by Nowak *et al*<sup>[8]</sup> and Whistance *et al*<sup>[9]</sup>.

In agreement with the results reported by Whistance, the correlations between the EORTC

**Table 4** Known group comparisons: scales and items in the QLQ-C30 and CR29 for clinically distinct groups

|                          | Stoma ( <i>n</i> = 56) | No stoma ( <i>n</i> = 298) | <i>P</i> value <sup>1</sup> | KPS ≤ 80 ( <i>n</i> = 162) | KPS > 80 ( <i>n</i> = 177) | <i>P</i> value <sup>1</sup> |
|--------------------------|------------------------|----------------------------|-----------------------------|----------------------------|----------------------------|-----------------------------|
| CR29 scales              |                        |                            |                             |                            |                            |                             |
| Urinary frequency        | 6.5 ± 14.5             | 6.1 ± 13.5                 | 0.856                       | 6.7 ± 12.3                 | 5.8 ± 14.9                 | 0.098                       |
| Blood and mucus in stool | 18.9 ± 25.9            | 10.3 ± 16.3                | 0.160                       | 13.8 ± 19.7                | 7.3 ± 12.7                 | 0.019                       |
| Stool frequency          | 8.0 ± 13.2             | 8.4 ± 14.8                 | 0.960                       | 11.2 ± 18.2                | 5.1 ± 9.6                  | 0.017                       |
| Body image               | 81.7 ± 18.9            | 88.6 ± 14.7                | 0.004                       | 87.7 ± 17.7                | 89.0 ± 11.9                | 0.589                       |
| CR29 single items        |                        |                            |                             |                            |                            |                             |
| Urinary incontinence     | 7.7 ± 4.2              | 1.6 ± 7.1                  | < 0.001                     | 0.8 ± 0.7                  | 4.2 ± 11.1                 | 0.001                       |
| Dysuria                  | 7.7 ± 16.8             | 5.4 ± 12.3                 | 0.444                       | 3.2 ± 11.2                 | 8.0 ± 14.7                 | < 0.001                     |
| Abdominal pain           | 11.9 ± 21.5            | 12.0 ± 18.7                | 0.651                       | 13.5 ± 21.0                | 9.0 ± 16.1                 | 0.059                       |
| Buttock pain             | 10.7 ± 15.7            | 5.4 ± 13.2                 | 0.005                       | 2.5 ± 8.8                  | 9.0 ± 16.1                 | < 0.001                     |
| Bloating                 | 16.1 ± 16.8            | 20.9 ± 21.4                | 0.183                       | 25.2 ± 23.9                | 15.0 ± 16.6                | < 0.001                     |
| Dry mouth                | 11.9 ± 17.3            | 7.2 ± 15.1                 | 0.025                       | 6.0 ± 14.4                 | 8.0 ± 15.1                 | 0.170                       |
| Hair loss                | 14.3 ± 18.9            | 9.6 ± 16.6                 | 0.058                       | 7.7 ± 17.2                 | 11.1 ± 16.2                | 0.010                       |
| Taste                    | 15.5 ± 22.9            | 23.8 ± 21.7                | 0.002                       | 26.0 ± 25.0                | 18.8 ± 18.4                | 0.015                       |
| Anxiety                  | 31.0 ± 31.0            | 44.6 ± 23.7                | < 0.001                     | 52.1 ± 22.6                | 35.1 ± 24.1                | < 0.001                     |
| Weight                   | 22.6 ± 21.2            | 44.6 ± 23.7                | 0.032                       | 32.3 ± 19.9                | 21.6 ± 16.8                | < 0.001                     |
| Flatulence               | 14.3 ± 17.8            | 5.0 ± 13.4                 | < 0.001                     | 4.5 ± 14.6                 | 7.0 ± 13.6                 | 0.012                       |
| Fecal incontinence       | 15.5 ± 20.1            | 4.4 ± 11.9                 | < 0.001                     | 2.5 ± 10.2                 | 8.0 ± 15.1                 | < 0.001                     |
| Sore skin                | 26.2 ± 23.5            | 3.1 ± 10.1                 | < 0.001                     | 3.5 ± 12.7                 | 9.7 ± 17.5                 | < 0.001                     |
| Embarrassment            | 25.0 ± 20.4            | 2.3 ± 8.4                  | < 0.001                     | 4.1 ± 12.8                 | 7.1 ± 14.6                 | 0.019                       |
| Stoma care problems      | /                      | /                          | /                           | 18.8 ± 20.8                | 19.8 ± 25.2                | 0.941                       |
| Sexual interest (men)    | 74.4 ± 23.5            | 69.8 ± 25.5                | 0.333                       | 76.3 ± 22.8                | 66.0 ± 26.0                | 0.020                       |
| Impotence                | 9.4 ± 17.0             | 8.5 ± 20.2                 | 0.364                       | 6.5 ± 19.2                 | 10.7 ± 19.9                | 0.021                       |
| Sexual interest (women)  | 81.0 ± 17.8            | 77.1 ± 22.5                | 0.749                       | 83.7 ± 16.8                | 71.2 ± 25.0                | 0.005                       |
| Dyspareunia              | 9.5 ± 16.3             | 4.3 ± 14.1                 | 0.172                       | 2.7 ± 15.0                 | 6.5 ± 13.4                 | 0.012                       |
| QLQ-C30 scales           |                        |                            |                             |                            |                            |                             |
| Physical                 | 85.5 ± 12.4            | 82.9 ± 16.5                | 0.335                       | 77.6 ± 18.3                | 89.4 ± 10.7                | < 0.001                     |
| Role                     | 84.8 ± 17.2            | 69.4 ± 20.6                | < 0.001                     | 61.7 ± 20.6                | 81.2 ± 16.4                | < 0.001                     |
| Emotional                | 80.5 ± 17.7            | 74.4 ± 14.0                | 0.001                       | 69.3 ± 14.4                | 81.2 ± 11.9                | < 0.001                     |
| Cognitive                | 79.5 ± 20.5            | 80.7 ± 20.0                | 0.397                       | 75.4 ± 34.9                | 85.9 ± 14.6                | < 0.001                     |
| Social                   | 60.0 ± 22.4            | 45.7 ± 25.5                | < 0.001                     | 38.5 ± 24.9                | 55.7 ± 23.5                | < 0.001                     |
| Overall quality of life  | 67.9 ± 21.4            | 67.8 ± 17.4                | 0.636                       | 59.5 ± 16.5                | 76.4 ± 14.4                | < 0.001                     |
| Fatigue                  | 18.8 ± 18.2            | 22.8 ± 19.9                | 0.108                       | 30.5 ± 20.3                | 13.2 ± 13.8                | < 0.001                     |
| Nausea and vomiting      | 11.6 ± 13.8            | 6.1 ± 14.4                 | < 0.001                     | 4.7 ± 15.7                 | 8.1 ± 12.5                 | < 0.001                     |
| Pain                     | 13.0 ± 16.6            | 12.0 ± 17.3                | 0.427                       | 13.3 ± 19.1                | 9.4 ± 13.8                 | 0.211                       |

<sup>1</sup>Wilcoxon rank sum test.

QLQ-CR29 items and their dimensions were greater than the correlation coefficients of other dimensions, suggesting that the EORTC QLQ-CR29 has great convergent validity and discriminant validity<sup>[9]</sup>. Item 28 was examined only in females. In this subgroup, there were 10 women, five of whom answered one survey, while the other five answered two surveys. The correlation coefficient between item 28 in the stoma group and the presence of blood and mucus in the stool was 1, probably due to the small number of cases in the sample. A similar finding was noted in the study by Arraras *et al.*<sup>[5]</sup>.

The correlation coefficients between the EORTC QLQ-CR29 and EORTC QLQ-C30 scales showed that similar dimensions of QLQ had high correlations, while unrelated dimensions were only weakly correlated, demonstrating the validity of the QLQ-CR29 and indicating that the two questionnaires had different points of emphasis.

A comparison of the results showed that there were different QLQ-CR29 dimension scores among the groups divided by the KPS scores (KPS ≤ 80;

KPS > 80) and whether the patients had a stoma or not, which signified that the QLQ-CR29 had good clinical validity and can be used to measure different patients with different conditions. These results are consistent with those reported by Whistance and other foreign validity tests<sup>[5,8,9]</sup>. In addition, this study showed that patients with a KPS > 80 had higher scores in functional dimensions, but lower scores in the symptom dimensions, and those patients with a KPS ≤ 80 had a poorer quality of life. Statistically significant differences existed in numerous dimensions in groups divided by the KPS score (e.g., stool frequency, *P* = 0.017). Due to the impact of disease or treatment, sexual function in patients was significantly inhibited, similar to the findings in previous reports by other groups<sup>[5,6,24]</sup>. The studies by Song *et al.*<sup>[25]</sup> and Peng *et al.*<sup>[26]</sup> revealed that treatment of CRC may lead to impotence. However, this was not found in our study, probably because different countries perform different types of surgery, which result in different types of complications. In addition, compared with patients with a stoma, patients without a stoma had

lower scores in the symptom dimensions, and higher scores in the functional dimensions, which indicated better quality of life. Moreover, in our study, the scope of the scores was wide in each dimension of the questionnaire, indicating that the Chinese version of the CR29 had good clinical validity.

People of different cultures often have a different understanding of quality of life. After adequate translation, the EORTC QLQ-CR29 was also proved to be suitable for Chinese patients. When Arraras performed research on a Spanish version of the survey, 4.7% of patients considered some of the items in the questionnaire to be difficult to understand or answer, or unrelated to quality of life<sup>[5]</sup>. In our study, few patients had such problems and there was a high compliance rate (with a low miss rate), both of which indicate that the Chinese version of the EORTC QLQ-CR29 had great acceptability. Compared with the studies by Arraras *et al.*<sup>[5]</sup> and Whistance *et al.*<sup>[9]</sup>, the sexual dimension in our study had a higher miss rate (2.9% and 2.3% vs 3.4%). This may be due to the fact that Asians are more reticent when talking about sex than Western patients, and were not willing to tell the truth to doctors<sup>[26]</sup>. In order to address this problem and obtain a more accurate and comprehensive evaluation, a more detailed explanation from medical professionals is required when patients complete the questionnaire.

There are a few limitations in our study. Firstly, the subgroups were only segregated by the score on the Karnofsky Performance Scale, the presence of a stoma had more clinical significance than previously thought, and increased bias should not be ignored. In addition, the representativeness of our study should be treated cautiously due to the deficiency of larger cross-regional multicenter studies in mainland China. To obtain more rigorous results, we will pay more attention to these limitations in future studies.

In conclusion, the present study showed that the EORTC QLQ-CR29 (Chinese version) is a valid and reliable instrument for assessing the quality of life of patients with CRC in mainland China.

## COMMENTS

### Background

Colorectal cancer (CRC) is the third most common cancer and the fourth leading cause of cancer death. In 2012, almost 1.4 million people were diagnosed with CRC and 700 000 people died of CRC worldwide, of which China accounted for approximately 24%. Therefore, assessing and improving the quality of life of patients with CRC have become more important in these patients. The EORTC QLQ-CR29 questionnaire was developed by the European Organization for Research and Treatment of Cancer (EORTC) to evaluate quality of life in CRC patients.

### Research frontiers

The EORTC QLQ-CR29 questionnaire has already been validated in Spain, Poland and several other countries. However, the dietary and cultural differences between China and Western countries may lead to different interpretations of quality of life. Therefore, it is essential to test the reliability and validity of the Chinese version of the EORTC QLQ-CR29 in patients with CRC, which has never been done in mainland China.

## Innovations and breakthroughs

In the past few decades, advances in medical technology have made it possible for CRC patients to live longer. More attention has been paid to the quality of life of these patients; thus, questionnaires that can accurately assess quality of life have been developed, of which the series of EORTC questionnaires play very important roles. The EORTC developed sub-questionnaires, including the core questionnaire QLQ-C30 for all cancers, the BR-23 for breast cancer, the CX-24 for cervical cancer and the CR-29 for CRC.

## Applications

Due to improvements in curative therapy, doctors have started to pay more attention to health-related quality of life in CRC patients. In this study, the authors selected the EORTC QLQ-CR29 and EORTC QLQ-C30 and examined their reliability, validity, and acceptability in terms of assessing the quality of life in patients with CRC in mainland China. The overall goal of the study was to determine the feasibility of these instruments in the clinical setting in China.

## Terminology

The EORTC QLQ-C30 is the core questionnaire designed by the European Organization for Research and Treatment of Cancer, which can be used for all types of cancer. Based on the QLQ-C30, the EORTC QLQ-CR29 was specifically designed by the EORTC QL Group (The European Organization for Research and Treatment of Cancer Quality of Life Group) as a QLQ-C30 supplement for the evaluation of health-related quality of life in CRC patients.

## Peer-review

By now, available papers have shown the EORTC QLQ-C30 combined the EORTC QLQ-CR29 can assess the quality of life of patients with CRC in Spanish, Polish and Malaysia. And this combination has already been widely used in both clinical and basic research.

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