



ONCOLOGY/RECONSTRUCTION

ORIGINAL ARTICLE

Validation of the Arabic version of the Functional Assessment of Cancer Therapy-Bladder questionnaire in Egyptian patients with bladder cancer



Mohamed H. Zahran^{a,*}, Khaled Sheir^a, Essam M. Zidan^b, Bedeir Ali-El-Dein^a

^a Urology Department, Urology and Nephrology Center, Mansoura University, Mansoura, Egypt

^b Mental Health Department, Faculty of Education, Mansoura University, Mansoura, Egypt

Received 9 September 2016, Received in revised form 26 November 2016, Accepted 8 January 2017

Available online 25 April 2017

KEYWORDS

Arabic version;
FACT-BI validation;
Quality of life;
Orthotopic neobladder;
Radical cystectomy

ABBREVIATIONS

BICS, bladder cancer subscale;
EWB, emotional well-being;
FACT-(BI)(G), Functional Assessment of Cancer Therapy-(Bladder) (General);

Abstract Objectives: To validate the Arabic version of the Functional Assessment of Cancer Therapy-Bladder (FACT-BI) questionnaire in Egyptian patients who underwent radical cystectomy (RC) and orthotopic neobladder (ONB) construction.

Patients, subjects and methods: The English version of the FACT-BI was translated into the Arabic language using multi-step process by two urologist and two independent translators. The Arabic version was validated by inviting 90 patients who underwent RC and ONB and 72 normal individuals to complete the questionnaire. The reliability of the questionnaire was tested for internal consistency using the Cronbach's α test. Inter-domain association was tested by Spearman's correlation coefficient. The discrimination validity was measured by comparing the scores in RC patients and in normal individuals using the Mann-Whitney U -test and independent sample t -test.

Results: Internal consistency was high for all domains. There was high correlation between all domains. This high internal consistency and good correlation was maintained when assessment included patients with <7.5 and those with ≥ 7.5 years follow-up. Discrimination validation was confirmed by the statistically significant lower scores of all domains in the studied patients in comparison to the controls.

* Corresponding author. Fax: +20 50226371.

E-mail addresses: zahranmha@yahoo.com, zahranmha@mans.edu.eg (M.H. Zahran).

Peer review under responsibility of Arab Association of Urology.



Production and hosting by Elsevier

FWB, functional well-being;
 HRQoL, health-related quality of life;
 PWB, physical well-being;
 ONB, orthotopic neobladder;
 RC, radical cystectomy;
 SWB, social well-being

Conclusion: The Arabic version of the FACT-BI is a reliable and validated instrument that can be used to evaluate health-related quality of life in patients after RC and ONB.

© 2017 Arab Association of Urology. Production and hosting by Elsevier B.V. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

Introduction

Radical cystectomy (RC) and urinary diversion remains the 'gold standard' treatment for organ-confined muscle-invasive bladder cancer [1]. However, it is a traumatic procedure that adversely affects various aspect of patients' health-related quality of life (HRQoL). Over the past three decades, there have been many advances in RC techniques and the types of urinary diversion, seeking to improve patients' satisfaction and HRQoL. Assessment of HRQoL after RC and urinary diversion has been the focus of much research over the last decade. Many tools have been used to objectively assess different aspects of patients' HRQoL; some being generic instruments that can be used for assessing HRQoL in different conditions and others specific for patients with cancer [2].

One of the commonly used instruments is the Functional Assessment of Cancer Therapy-Bladder (FACT-BI) questionnaire. It is a bladder cancer-specific module of the Functional Assessment of Cancer Therapy-General (FACT-G) [3]. It objectively assesses the four subscales of the FACT-G, physical, social, emotional and functional well-being, plus a bladder cancer subscale that assess urinary tract, intestinal and sexual symptoms [3]. Validated versions of the FACT-BI have been published in the Japanese, Chinese, Hungarian, and Italian languages [4–7].

In Egypt, bladder cancer is the most common cancer of the urinary tract in males and the fourth most common in females. Also, Arabic is the native language in Egypt and one of the most common languages in the world, being one of the six official languages in the United Nations [8]. This explains the ultimate need for the availability of a validated Arabic version of the FACT-BI questionnaire to allow for its use in future research in Arab-speaking countries. In the present study, we provide a reliable validation of the Arabic-translated version of the FACT-BI questionnaire for use in patients with bladder cancer.

Patients, subjects and methods

According to the guidelines for cross-cultural adaptation of HRQoL measures, a multi-step process was used

to produce the Arabic version of the FACT-BI questionnaire. The process included forward translation to Arabic by both urologists and independent, native Arabic-speaking professional translators who had English as the first foreign language. Then back translation to English by a native English-speaking urologist who had Arabic as the first foreign language. The two forms of the questionnaire (original and translated) were compared and differences were resolved in a consensus meeting. The revised version was used in the study (Appendix A) [9].

Cognitive and pilot testing

Cognitive and pilot testing of the FACT-BI questionnaire was performed initially on patients who underwent RC and urinary diversion. Data were collected by face-to-face interview by a third party not involved in the study. The pilot test results indicated that all items were not confusing, upsetting and difficult to understand nor associated with difficulty in response [9]. So, no further modifications were made.

Participant and data collection

Data for evaluation and validation of the Arabic version of the FACT-BI were collected between August 2011 and June 2015. The study included 90 patients who underwent RC and orthotopic neobladder (ONB) construction for muscle-invasive bladder cancer and attended for routine follow-up at our outpatient clinic. The included patients had all had their surgery at ≥ 12 months beforehand and had no evidence of oncological failure. All patients were adult and able to provide informed consent to participate in the study. Patients at < 12 months after the operation or with evidence of local recurrence or distant metastasis were excluded from the study. All patients were asked to respond to the FACT-BI questionnaire by face-to-face interview by a third party not included in the study. The available data were tested for reliability and validity. To perform a discrimination validity of the questionnaire, a control group of age-matched healthy individuals were included after accepting to participate in the study.

Statistical analysis

The reliability of the Arabic version of the FACT-BI questionnaire (Appendix A) was evaluated for internal consistency using Cronbach's α coefficient for each scale. The structure of the domains was examined by inter-domain association using Spearman's correlation coefficient (ρ). The discrimination validity was evaluated by comparing the scores of the questionnaire between the study and control groups using the Mann–Whitney *U*-test. All statistical tests were done using the Statistical Package for the Social Sciences (SPSS® version 16.0 for Microsoft; SPSS, Inc., Chicago, IL, USA), with a $P < 0.05$ considered to indicate statistical significance.

Results

The study included 90 patients (52 females and 38 males) who underwent RC and ONB and 72 age-matched healthy individuals. The demographic criteria of the study population are shown in Table 1.

The internal consistency was high for all scales except for the bladder cancer subscale (BICS), which was intermediate as shown in the Cronbach's α coefficient test (Table 2). There were good correlations between physical well-being (PWB) and social well-being (SWB) ($\rho = 0.68$), emotional well-being (EWB) ($\rho = 0.63$) and functional well-being (FWB) ($\rho = 0.67$). Also, there was a good correlation between SWB and EWB ($\rho = 0.51$) and FWB ($\rho = 0.74$). Another good correlation was detected between EWB and FWB ($\rho = 0.53$) (Table 2).

We divided the patients into two groups according to follow-up duration. Group 1 included 44 patients with a follow-up period of < 7.5 years and Group 2 included 46 patients with a follow-up period of ≥ 7.5 years. The internal consistency of the scales and inter-scales corre-

lation was measured in each group. In Group 1, the internal consistency was high for PWB, SWB and FWB, intermediate for EWB and low for BICS (Table 3). There were persistent good correlations between PWB and SWB, EWB and FWB and between SWB and FWB (Table 3). In Group 2, the internal consistency between scales was high for all scales except BICS, where it was intermediate (Table 4). Also, there was good correlation between PWB and SWB, EWB and FWB and between SWB and FWB (Table 4).

In comparison to the control group, the study group showed statistically significant lower scores for all the sub-scales and the total FACT-BI score (Table 5).

Discussion

After RC and ONB, patients wish to gain and maintain good health status, improve their functional abilities as much as possible, and achieve a satisfactory HRQoL [2]. HRQoL is a dynamic multidimensional construct that changes over time and can be modified by age and experience. It means different things to different people. Simply put, it can be defined as a patient's evaluation of the impact of a health condition and its treatment on relevant aspects of their life [10]. Assessment of HRQoL is important to judge overall treatment efficacy, determine whether the goals of treatment have been met, educate patients and clinicians about the full spectrum of treatment outcomes, and to facilitate medical decision-making [11].

There are numerous HRQoL instruments that have been validated and used in urological diseases. Some are generic and others are cancer specific.

The FACT is usually applied as a two part instrument that includes a general item set pertaining to all patients with cancer (FACT-G) and one of several item sets containing special questions for patients with specific tumours [3]. The FACT-BI was designed as a validated HRQoL tool consisting of the 27-item FACT-G (four subscales: PWB, SWB, EWB and FWB) plus an additional 12-item bladder cancer subscale that assesses urinary tract, intestinal and sexual symptoms. The score of all items ranges from 1 to 4. The score is reversed for certain items. To calculate the subscales score, the sum of the item scores is multiplied by the number of items in the subscale and then divided by the number of items answered. The five scales were scored separately and the scores ranged 0–28, 0–28, 0–24, 0–28 and 0–48 for PWB, SWB, EWB, FWB and BICS scales, respectively. Then the sum of the scales is calculated giving a score of 0–156 with a higher score indicating a better outcome [3]. Since the introduction of FACT-BI questionnaire, it has been widely used in the evaluation of HRQoL after RC and urinary diversion. Many linguistic translations have been done and validated versions in the Japanese, Chinese, Hungarian, Italian and Swedish

Table 1 Demographic data of the studied (RC + ONB) and control groups.

Variable	Study group	Control group	<i>P</i>
<i>N</i>	90	72	
Age, years, median (range)	51 (37–71)	53 (33–71)	0.6
Postoperative duration, years, median (range)	7.5 (1–20)	–	
Medical comorbidities, <i>n</i> (%)			0.7
Diabetes mellitus	8 (8.9)	11 (15.2)	
Hypertension	4 (4.4)	13 (18)	
Liver cirrhosis	2 (2.2)	2 (2.8)	
Heart disease	2 (2.2)	1 (1.4)	
Marital status, <i>n</i> (%)			0.09
Married	46 (51.1)	42 (58.3)	
Widow	44 (48.9)	30 (41.7)	

Table 2 Internal consistency (Cronbach's α) and inter-domain association by Spearman's correlation coefficient of FACT-BI.

Domain	Cronbach's α	PWB ρ (<i>P</i>)	SWB ρ (<i>P</i>)	EWB ρ (<i>P</i>)	FWB ρ (<i>P</i>)	BICS ρ (<i>P</i>)
PWB	0.83		0.68 (<0.001)	0.63 (<0.001)	0.67 (<0.001)	0.44 (<0.001)
SWB	0.94			0.51 (<0.001)	0.74 (<0.001)	0.27 (0.01)
EWB	0.8				0.53 (<0.001)	0.37 (<0.001)
FWB	0.89					0.21 (0.04)
BICS	0.67					

Table 3 Internal consistency (Cronbach's α) and inter-domain association by Spearman's correlation coefficient in Group 1 (<7.5 years follow up).

Domain	Cronbach's α	PWB ρ (<i>P</i>)	SWB ρ (<i>P</i>)	EWB ρ (<i>P</i>)	FWB ρ (<i>P</i>)	BICS ρ (<i>P</i>)
PWB	0.83		0.71 (<0.001)	0.83 (<0.001)	0.74 (<0.001)	0.43 (0.003)
SWB	0.92			0.63 (<0.001)	0.74 (<0.001)	0.42 (0.05)
EWB	0.75				0.58 (<0.001)	0.50 (<0.001)
FWB	0.87					0.48 (0.06)
BICS	0.5					

Table 4 Internal consistency (Cronbach's α) and inter-domain association by Spearman's correlation coefficient in Group 2 (>7.5 years follow up).

Domain	Cronbach's α	PWB ρ (<i>P</i>)	SWB ρ (<i>P</i>)	EWB ρ (<i>P</i>)	FWB ρ (<i>P</i>)	BICS ρ (<i>P</i>)
PWB	0.84		0.63 (<0.001)	0.65 (0.001)	0.61 (<0.001)	0.49 (0.001)
SWB	0.95			0.52 (0.003)	0.75 (<0.001)	0.42 (0.003)
EWB	0.84				0.55 (<0.001)	0.42 (0.003)
FWB	0.9					0.32 (0.02)
BICS	0.66					

Table 5 Comparison of domain scores between the control and study groups.

Domain	Study group	Control group	<i>P</i>
PWB, median (range)#	13 (0–22)	22 (16–28)	<0.001
SWB, median (range)#	17.7 (0–28)	24 (14–28)	<0.001
EWB, median (range)#	11 (0–22)	20 (14–24)	<0.001
FWB, median (range)#	13 (3–28)	22.5 (12.8–28)	<0.001
BICS, mean (SD)*	21.4 (6.7)	23.1 (4.1)	<0.001

* Independent sample *t*-test; # Mann–Whitney *U*-test.

languages are now available [4–7,12]. In the present study, the reliability of the Arabic version is confirmed by the high internal consistency for PWB, SWB, EWB and FWB scales and intermediate consistency for BICS, and the good inter-domain correlation. The lower internal consistency for the BICS scale may be due to the absence of response to the last two items, which assess presence of appliance and its effect on HRQoL and this is not applicable to patients with ONB. Also, the inclusion of patients with ileal conduits in this cohort would affect the results of the Cronbach's α coefficient test, as complete response data would not be available. This required re-validation of the questionnaire in ileal con-

duit patients in a separate study. The discrimination validity of the questionnaire is confirmed by the statistically significant lower scores in the RC patients with ONB compared to the controls.

Test–retest validation was not performed, as it requires repeated assessment of the same study group at different intervals, which was not available currently. Yet, we assessed the reliability in patients with <7.5 years follow-up and repeated this for patients with ≥ 7.5 years follow-up. The reliability of the Arabic version was maintained. This may be a confirmation of the validity of the instrument's use in patients after the procedure at different intervals with reliable results and confirms its responsiveness and how sensitive the scales are to changes over time. Comparison with different bladder cancer-specific HRQoL questionnaires was not done, which may be a limitation of the present study.

Conclusion

The results of the present study show that the Arabic version of the FACT-BI is a valid and reliable method for assessing HRQoL in Arabic-speaking patients after RC and ONB.

Conflict of interest

No conflicts of interest to declare.

Funding

No funding to declare.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <http://dx.doi.org/10.1016/j.aju.2017.01.008>.

References

- [1] Ali-EL-Dein B, Shaaban AA, Abu-Eideh RH, el-Azab M, Ashamallah A, Ghoneim MA. Surgical complications following radical cystectomy and orthotopic neobladder in women. *J Urol* 2008;**180**:206–10.
- [2] Zahran MH, El-Hefnawy AS, Zidan EM, El-Bilsha MA, Taha B, Ali-El-Dein B. Health-related quality of life after radical cystectomy and neobladder reconstruction in women: impact of voiding and continence status. *Int J Urol* 2014;**21**:887–92.
- [3] Cella DF, Tulsky DS, Gray G, Sarafian B, Linn E, Bonomi A, et al. The Functional Assessment of Cancer Therapy scale: development and validation of the general measure. *J Clin Oncol* 1993;**11**:570–9.
- [4] Kikuchi E, Horiguchi Y, Nakashima J, Ohigashi T, Oya M, Nakagawa K, et al. Assessment of long-term quality of life using the FACT-BL questionnaire in patients with an ileal conduit, continent reservoir, or orthotopic neobladder. *Jpn J Clin Oncol* 2006;**36**:712–6.
- [5] Hevér NV, Péntek M, Balló A, Gulácsi L, Baji P, Brodszky V, et al. Health related quality of life in patients with bladder cancer: a cross-sectional survey and validation study of the Hungarian version of the Bladder Cancer Index. *Pathol Oncol Res* 2015;**21**:619–27.
- [6] Li MY, Yang YL, Liu L, Wang L. Effects of social support, hope and resilience on quality of life among Chinese bladder cancer patients: a cross-sectional study. *Health Qual Life Outcomes* 2016;**14**:73.
- [7] Gacci M, Saleh O, Cai T, Gore JL, D'Elia C, Minervini A, et al. Quality of life in women undergoing urinary diversion for bladder cancer: results of a multicenter study among long-term disease-free survivors. *Health Qual Life Outcomes* 2013;**11**:43.
- [8] El-Nahas AR, Elsaadany MM, Tharwat M, Mosbah A, Metwally A, Hawary A, et al. Validation of the Arabic linguistic version of the Ureteral Stent Symptoms Questionnaire. *Arab J Urol* 2014;**12**:290–3.
- [9] Zahran MH, Zidan EM. Arabic translation and cognitive testing of EORTC-QLQ-C30 and FACT-BL questionnaires for assessment of quality of life after radical cystectomy. *Egypt J Urol* 2015;**21**:75–82.
- [10] Porter MP, Penson DF. Health related quality of life after radical cystectomy and urinary diversion for bladder cancer: a systematic review and critical analysis of literature. *J Urol* 2005;**173**:1318–22.
- [11] Frytak JR. Assessment of quality of life in older adult. In: Kane RA, Kane RA, editors. *Assessing older people: measures, meaning and practical applications*. Oxford: Oxford University Press; 2000. p. 200–36.
- [12] Mansson A, Davidsson T, Hunt S, Mansson W. The quality of life in men after radical cystectomy with a continent cutaneous diversion or orthotopic bladder substitution: is there a difference? *BJU Int* 2002;**90**:386–90.