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## ONCOLOGY/RECONSTRUCTION ORIGINAL ARTICLE

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



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#### **KEYWORDS**

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

#### **ABBREVIATIONS**

BICS, bladder cancer subscale; EWB, emotional wellbeing; FACT-(Bl)(G), Functional Assessment of Cancer Therapy-(Bladder) (General); **Abstract** *Objectives:* To validate the Arabic version of the Functional Assessment of Cancer Therapy-Bladder (FACT-Bl) questionnaire in Egyptian patients who underwent radical cystectomy (RC) and orthotopic neobladder (ONB) construction.

**Patients, subjects and methods:** The English version of the FACT-Bl 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  $\alpha$  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  $\ge 7.5$  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.

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FWB, functional wellbeing; HRQoL, healthrelated quality of life; PWB, physical wellbeing; ONB, orthotopic neobladder; RC, radical cystectomy; SWB, social well-being **Conclusion:** The Arabic version of the FACT-Bl is a reliable and validated instrument that can be used to evaluate health-related quality of life in patients after RC and ONB.

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#### 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-Bl) 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-Bl 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-Bl 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-Bl 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-Bl questionnaire. The process included forward translation to Arabic by both urologists and independent, native Arabicspeaking 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-Bl questionnaire was performed initially on patients who underwent RC and urinary diversion. Data were collected by faceto-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-Bl 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  $\geq 12$  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-Bl 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.

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