

Development of the Japanese version of the health-related quality of life questionnaire for bladder cancer patients using the Bladder Cancer Index: A pilot study

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Abbreviations & Acronyms

BCI = Bladder Cancer Index
EPIC = Expanded Prostate
Cancer Index Composite
FACT-BI = Functional
Assessment of Cancer
Therapy-Bladder Cancer
HRQOL = health-related
quality of life
PRO = patient-reported
outcome

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PROs represent an important aspect of a patient's health status assessment that come without bias of the healthcare provider. PROs allow clinicians to evaluate the effects of illness and medical treatments by quantifying symptoms that are by definition, subjective, and therefore, unmeasured by medical devices. PROs can include both general and disease-specific quality of life. Although several bladder cancer-specific HRQOL instruments exist, there is only one with a Japanese translation – FACT-BI – previously validated by Hinotsu *et al.*¹ However, assessment with FACT-BI is limited to systemic symptoms, as it lacks items specific to urinary, bowel and sexual function, which are important components for assessing bladder cancer patients. In the previous report, the Japanese version of the EPIC was used to evaluate HRQOL after bladder preservation therapy instead of FACT-BI.² Although reasonable and acceptable outcomes were obtained, further assessment needs to be carried out. That is because EPIC was designed for male prostate cancer patients. The BCI was developed and validated in the USA to assess the severity of symptoms for urinary, bowel and sexual domains (Appendix S1).³ The BCI was intended to be a sex- and diversion-neutral instrument for patients treated with cystectomy, transurethral resection with/without intravesical therapy and radiation. The BCI has been translated and validated into French, Spanish, Arabian and Hungarian languages.⁴ Furthermore, the BCI was recently used to evaluate function HRQOL among patients treated for bladder cancer in a comparative study.⁵

According to the previously reported method for cross-cultural translation of HRQOL, we carried out a multistage procedure to develop a preliminary Japanese version after permission from the original developer (JT Wei) to translate and use the BCI.⁶ Two Japanese translations of the BCI were carried out independently by two native Japanese physicians who had English as a second language. Subsequently, the reconciled translation was back-translated into English by a native English professional translator. Of 34 items in the BCI, 22 items overlapped with the EPIC, and therefore, the Japanese version of EPIC is applied with the permission of JT Wei and Y Kakehi.⁷ The two forms of the BCI (original and backward translation) were compared, and qualities lost in the translation due to cultural nuances were discussed and resolved in a consensus meeting with JT Wei, resulting in the draft Japanese BCI version. This draft version was then reviewed by laypersons fluent in Japanese to develop a linguistically valid, easy-to-understand Japanese version (Appendix S2; Fig. S1).

Statistical validation was undertaken. The reliability of the Japanese version of the BCI was evaluated for internal consistency using Cronbach's alpha coefficient for each domain of the BCI. All statistical tests were carried out using the JMP software (SAS Institute, Cary, NC, USA). After obtaining approval from the institutional review board (015-0504), cognitive interviews and pilot testing of the BCI were carried out with 14 patients (nine males and five females), with a mean age of 69.5 years (range 47–93 years) and disease duration of 31.5 months (range 11–272 months). Of these patients, eight patients underwent transurethral resection of bladder tumor and six patients underwent radical cystectomy (among them two patients had ileal conduit, two had neobladder, one had cutaneous ureterostomy and one had continent catheterizable pouch). The Cronbach's alpha coefficients were 0.86, 0.72 and 0.92 for the urinary domain, bowel domain and sexual domain, respectively. These were all in the range of 0.70–0.95, indicating high internal consistency (Table 1). The average length of the interview was 30 min. Most patients completed the questionnaire without difficulty, and further modifications were unnecessary. In a final consensus review that included urologists and clinical psychologists, the Japanese version was finalized (Appendix S1). This Japanese version of the BCI has demonstrable face validity and reliability. It can be used for evaluating HRQOL among Japanese patients with bladder cancer and for cross-cultural comparisons. The copyright of the BCI resides strictly with The University of Michigan. The University of Michigan has granted the right to use the Japanese version of the BCI to healthcare providers who do not obtain profit using this.

Table 1 Domain-specific characteristics of the Japanese version of the BCI

BCI domain	No. items	Chronbach's α
Urinary domain		
Function	4	0.86
Bother	8	
Bowel domain		
Function	4	0.72
Bother	6	
Sexual domain		
Function	7	0.92
Bother	5	

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Conflict of interest

None declared.

References

- Hinotsu A, Niimi M, Akaza H *et al.* Development of Japanese version of QOL questionnaire for bladder and prostate cancer patients using FACT-BI and P: pilot study. *Gan To Kagaku Ryoho* 1999; **26**: 657–66.
- Hashine K, Miura N, Numata K, Shirato A, Sumiyoshi Y, Kataoka M. Health-related quality of life after bladder preservation therapy for muscle invasive bladder cancer. *Int. J. Urol.* 2008; **15**: 403–6.
- Gilbert SM, Wood DP, Dunn RL *et al.* Measuring health-related quality of life outcomes in bladder cancer patients using the Bladder Cancer Index (BCI). *Cancer* 2007; **109**: 1756–62.
- Ziouziou I, Touzani MA, Karmouni T, El Khader K, Koutani A, Attya Andalousi AI. Arabic translation and linguistic validation of the questionnaire Bladder Cancer Index. *Afr. J. Urol.* 2018; **24**: 104.
- Moncrief TJ, Balaji P, Lindgren BB, Weight CJ, Konety BR. Comparative evaluation of bladder-specific health-related quality of life instruments for bladder cancer. *Urology* 2017; **108**: 76–81.
- Acquadro C, Jambon B, Ellis D, Marquis P. *Quality of Life and Pharmacoeconomics in Clinical Trials*. Lippincott-Raven Publishers, Philadelphia, 1996.
- Takegami M, Suzukamo Y, Sanda MG *et al.* The Japanese translation and cultural adaptation of Expanded Prostate Cancer Index Composite (EPIC). *Nihon Hinyokika Gakkai Zasshi* 2005; **96**: 657–69.

Supporting information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Figure S1. Multistep procedures to develop the Japanese version of the BCI.

Appendix S1. The original English version of the BCI.

Appendix S2. The Japanese version of the BCI. The copyright of the BCI resides strictly with The University of Michigan. The University of Michigan has granted the right to use the Japanese version of the BCI to healthcare providers who do not obtain profit by using this.