

Urological note

Development of the Japanese version of the health-related quality of life questionnaire for bladder cancer patients using bladder cancer index: a pilot study

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Patient-reported outcomes (PRO) represent an important aspect of a patient's health status assessment that come without bias of the health care 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 may include both general and disease specific quality of life. **This is the author manuscript accepted for publication and has undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the [Version of Record](#). Please cite this article as [doi: 10.1111/iju.14073](https://doi.org/10.1111/iju.14073)**

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Although several bladder cancer specific health related quality of life (HRQOL) instruments exist, there is only one with a Japanese translation - Functional Assessment of Cancer Therapy-Bladder Cancer (FACT-BI) - previously validated by Hinotsu et al. (1). However, assessment with FACT-BI is limited to systemic symptoms since it lacks items specific to urinary, bowel, sexual function, which are important components for assessing bladder cancer patients. In the previous report, the Japanese version of the Expanded Prostate Cancer Index Composite (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 performed. That's because EPIC was designed for male prostate cancer patients. The Bladder Cancer Index (BCI) was developed and validated in the United States to assess the severity of symptoms for urinary, bowel, and sexual domains (Appendix S1) (3). The BCI was intended to be a gender 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). Moreover, 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 (6), we performed a multi-stage procedure to develop a preliminary Japanese version after permission from the original developer (Dr. J. T. Wei) to translate and use the BCI. Two Japanese translations of the BCI were carried out independently by two native Japanese physicians who had English as the 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 are overlapped with the EPIC, and therefore, the Japanese version of EPIC are applied with the permission of Dr. J. T. Wei and Dr. 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 Dr. J. T. Wei, resulting in the draft Japanese BCI version. This draft version was then reviewed by lay persons fluent in Japanese to develop a linguistically-valid, easy-to-understand Japanese version (Appendix S2, Figure 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 done using the JMP® software (SAS Institute, Cary, NC). After obtaining approval from the institutional review board (015-0504), cognitive interviews and pilot testing of the BCI were performed in 14 patients (9 females and 5 males) with a mean age was 69.5 (47-93) years and disease duration was 31.5 (11-272) months. Of these patients, 8 patients after transurethral resection of bladder tumor (TURBT) and 6 patients underwent radical cystectomy (among them 2 patients had ileal conduit, 2 had neobladder, 1 had cutaneous ureterostomy, and 1 had continent catheterizable pouch). The Cronbach's alpha coefficient were 0.86, 0.72, and 0.92 for 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 time of the interview was 30 minutes. Most patients completed the questionnaire without difficulty, and further modifications was unnecessary. In a final consensus review that included urologists and clinical psychologists, the final Japanese version was finalized (Appendix S1). This Japanese version of the BCI has demonstrable face validity and reliability. It may be used for evaluating HRQOL among Japanese patients with bladder cancer and for cross cultural comparisons. The copyright of the Bladder Cancer Index resides strictly with The University of Michigan. The University of Michigan has granted the right to usage of the Japanese version of the Bladder Cancer Index to healthcare providers who doesn't obtain profit by using this.

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Conflict of interest

None declared.

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List of supporting information

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Appendix S1: The original English version of the Bladder Cancer Index.

Appendix S2: The Japanese version of the Bladder Cancer Index.

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Figure S1: Multistep procedures to develop the Japanese version of the Bladder Cancer Index

Figure/ Table legend

Table 1: Domain specific characteristics of the Japanese version of the Bladder Cancer Index

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BCI domain		Number of 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

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