

Research Report

Comparison of Health-Related Quality of Life Between Japanese and American Patients with Bladder Cancer as Measured by A Newly Developed Japanese Version of the Bladder Cancer Index

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Received 17 July 2020

Accepted 11 November 2020

Pre-press 1 December 2020

Abstract.

INTRODUCTION: The aim of this study is to characterize health related quality of life (HRQOL) in Japanese patients after bladder cancer surgery and to perform cross-cultural comparison between Japanese and American patients.

METHODS: Firstly, we cross-sectionally assessed HRQOL of 371 patients in Japan using the Bladder Cancer Index (BCI-Japanese). HRQOL of the four groups of patients (native bladder without intravesical therapy, native bladder with intravesical

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therapy, cystectomy with ileal conduit, and cystectomy with neobladder) were assessed. Secondly, we compared the Japanese with the American cohort ($n=315$) from the original BCI paper. After adjusting for age and gender, the differences in each BCI subdomain score was analyzed.

RESULTS: Among Japanese patients, the urinary domain function score was significantly lower among the cystectomy with neobladder group, compared to the cystectomy with ileal conduit group ($p<0.01$). Despite this, the urinary bother was comparable between the two groups. Although there were apparent differences between Japanese and American patients, there were few differences in Urinary and Bowel HRQOL. In three of the four treatment groups (other than native bladder with intravesical therapy), Japanese patients were more likely than Americans to report poor sexual function ($p<0.05$). However, Japanese patients were less likely than Americans to be bothered by their lower sexual function, regardless of treatment ($p<0.05$).

CONCLUSIONS: HRQOL outcomes following treatment of bladder cancer in Japan are comparable to those in the USA, except for sexual functioning and sexual bother. The BCI can be used for cross-cultural assessments of HRQOL in bladder cancer patients.

Keywords: Bladder cancer, quality of life, bladder cancer index, cancer survivor

INTRODUCTION

Recently, there has been a great deal of progress in the treatment of bladder cancer, including the introduction of new surgical techniques. Many patients who undergo bladder cancer surgery will experience urinary symptoms, bowel symptoms, and sexual dysfunction. Evaluating health related quality of life (HRQOL) is an important key to understanding the degree to which patients' daily lives are impaired by post-operative side effects. Although several clinical studies have assessed the HRQOL of postoperative patients using a Japanese version of FACT-BL (which is the only Japanese disease specific HRQOL questionnaire designed for bladder cancer patients), this instrument is limited in application because it incorporates few items that measure urinary, bowel, and sexual symptoms. However, the bladder cancer index (BCI) questionnaire was developed and validated to assess the HRQOL of bladder cancer patients [1, 2]. The BCI was designed to be a gender- and diversion-neutral instrument for patients treated with radiation, transurethral resection with or without intravesical therapy, and cystectomy. It consists of 34 items in 3 primary domains (urinary, bowel, and sexual health), with 2 subdomains (function and bother) for each primary domain. It has been translated and validated into Arabic, Dutch, French, Hungarian, Japanese, and Spanish [3–8].

The present study was performed to assess Japanese patients with bladder cancer, who had been treated with various surgeries, using the newly developed Japanese version of the BCI (BCI-Japanese). This data was then used to assess and compare

function and bother scores for the urinary, bowel, and sexual health domains among bladder cancer patients in Japan and the United States. Although there is a big difference (e.g., health insurance, health care system) between the two countries, [9] we also to analyze how race affects the profiles of the HRQOL after controlling for age and gender between the two countries.

MATERIALS AND METHODS

This study consisted of two parts. The first was a characterization of bladder cancer HRQOL in Japanese patients, and the second was a comparison of HRQOL between Japanese and American patients.

Japanese bladder cancer HRQOL

A Japanese cross-sectional cohort was established that consisted of four bladder cancer treatment groups (native bladder without intravesical therapy, native bladder with intravesical therapy, cystectomy with ileal conduit, and cystectomy with neobladder). A total of 400 patients were enrolled in the study. Answers were obtained from 371 patients (92.8%). These patients were treated between 1999 and 2017 were enrolled from 7 institutions (Hokkaido University, Keiyukai Hospital, Kushiro Rosai Hospital, Hokkaido Cancer Center, Sapporo City General Hospital, Kushiro City General Hospital, and Teine Keijinkai Hospital) in Japan. All recruitment and the study protocol were approved by each institutional review board. The approval number was 015–0504 for Hokkaido University Hospital. All

participants were at least 20 years old. To participate, patients were required to be ambulatory and active, with an Eastern Cooperative Oncology Group performance status of 0 or 1. Written informed consent was obtained from all participants. All participants were given the following questionnaires: BCI-Japanese, FACT-G (HRQOL related to physical, social, emotional and functional well-being in patients with cancer)[10], and FACT-BL (bladder cancer specific HRQOL). BCI-Japanese was developed and validated through the multi-step procedure, including forward-translation, back-translation and discussion with the original developers, as previously reported [8]. All questionnaires were self-administered and then either returned by mail or submitted to the outpatient clinic in a sealed envelope so the medical staff could not see the patient's responses. The questionnaires were scored centrally by trained staff. Comparison of HRQOL score difference (BCI-Japanese, FACT-G, and FACT-BL) among the four different treatment groups was analyzed using ANCOVA, after adjusting for age and gender. In addition, Tukey's range test (the Tukey HSD test) was performed to analyze the differences in each BCI subdomain score [11]. p -values of <0.05 were considered to indicate a statistically significant difference.

Cross-cultural comparison of BCI

The comparison group was 315 Americans with bladder cancer who had enrolled in a separate cross-sectional study at the University of Michigan between 1995 and 2004 and were treated with endoscopic treatment, intravesical therapy, or cystectomy with urinary diversion [1]. The study protocol was approved by the institutional review board at the University of Michigan. We used analysis of covariance (ANCOVA) and analyzed differences in the 6 subdomain scores of the BCI between Japanese and American patients in each of four treatment groups, after adjustment for age and sex. Statistical analyses were performed using JMP version 14 (SAS Institute Inc., Cary, NC, USA), and p -values of <0.05 were considered to indicate a statistically significant difference.

RESULTS

Table 1 shows the clinical characteristics of the cohort of 371 patients. The median age was 72 years (IQR 65–77), and most of the patients (75.7%)

Table 1
Clinical characteristics of 371 patients in Japanese cohort

Characteristic	No. Pts (%)
Primary intervention:	
Endoscopy, no intravesical therapy	118 (31.8)
Endoscopy+intravesical therapy	103 (27.8)
Cystectomy+ileal conduit diversion	101 (27.2)
Cystectomy+orthotopic continent diversion	49 (13.2)
Age: median (IQR)	72(65–77)
Gender:	
M	281 (75.7)
F	90 (24.3)
Disease stage:	
Nonmuscle invasive (Ta, Tis, T1)	284 (76.5)
Muscle invasive (T2–T4)	79 (21.3)
Unknown	8 (2.2)
Disease grade:	
Low	152 (41.0)
High	202 (54.4)
Unknown	17 (4.6)
Tumor histology:	
Urothelial Carcinoma	342 (92.2)
Other	29 (7.8)
Disease duration, month, median (IQR)	31(12–67)

were male. The median disease duration was 31 months (IQR 12–67). Noninvasive tumors (76.5%) were more common than muscle invasive disease (21.3%), and about half of cases (54.4%) consisted of high-grade cancer. Approximately 59.6% of patients enrolled in this study were treated endoscopically, including transurethral tumor resection and intravesical therapy. Of the remaining approximately 40.4% of patients who were treated with cystectomy, 101 underwent continent diversion (67.3% of those with cystectomy, and 27.2% of the overall cohort), and 49 underwent ileal conduit diversion (32.7% and 13.2%, respectively).

Table 2 shows a comparison of the six BCI subdomain scores among the four treatment groups. The BCI subdomain scores for urinary, bowel, and sexual health were significantly different among the four treatment groups, except for the sexual bother subdomain score ($p=0.14$). Although the difference of FACT-G score across the four treatment groups was not significant, the bladder cancer specific FACT-BL score was significantly different among the four treatment groups. Regarding BCI subdomain scores, the urinary function and bowel function scores were significantly lower among the cystectomy with neobladder group compared to the cystectomy with ileal conduit group (Fig. 1). In addition, the urinary bother and bowel bother scores were significantly lower among the cystectomy group compared to the native bladder group. Regarding the sexual health

Table 2
Mean BCI scores by treatment group, adjusted for age and gender

	Mean±SE Native bladder without intravesical therapy	Mean±SE Native bladder with intravesical therapy	Mean ± SE Cystectomy ileal conduit	Mean ± SE Cystectomy neobladder	
Urinary function	93.7 ± 1.8	94.8 ± 2.0	89.2 ± 2.1	52.5 ± 2.8	<0.01
Urinary bother	96.2 ± 1.4	94.8 ± 1.4	87 ± 1.4	84.3 ± 2.1	<0.01
Bowel function	91.2 ± 1.7	90.5 ± 1.9	85.6 ± 1.9	76.6 ± 2.7	<0.01
Bowel bother	92.7 ± 1.1	92.5 ± 1.2	87.5 ± 1.2	84.3 ± 1.7	<0.01
Sexual function	16.9 ± 1.8	17.6 ± 1.9	5.1 ± 2.0	6.9 ± 2.8	<0.01
Sexual bother	94 ± 2.0	95.6 ± 2.0	92.5 ± 2.1	87.9 ± 3.0	0.14
FACT-G domain	77.9 ± 1.7	78.1 ± 1.8	80.7 ± 1.7	79.1 ± 2.6	0.59
FACT-BL domain	33.2 ± 0.6	32.7 ± 0.6	31.2 ± 0.6	29.9 ± 0.9	<0.01

SE: Standard error.

domain, the sexual function subdomain score was significantly lower among the cystectomy group compared to the native bladder group, although the sexual bother subdomain score was not significantly different among the four groups. The FACT-BL scores of the ileal neobladder group were significantly lower than that of the native bladder with or without intravesical therapy group.

A comparison of the clinical characteristics of Japanese patients ($n=371$) and American patients ($n=315$) is shown in Supplementary Table 1. The male to female ratio was similar between the two groups. However, there were a number of differences in baseline characteristics between the two groups, as the Japanese cohort tended to be older and had a higher disease stage, while the American cohort had more recorded high-grade disease and was more likely to have been treated with cystectomy, compared to the Japanese cohort (59.7% vs. 40.4%). Figure 2 and Table 3 show the six BCI subdomain scores stratified by the four treatment groups. Even after adjusting for age and gender, Japanese patients were more likely than American patients to report poor sexual function ($p<0.01$), except in the native bladder with intravesical therapy group. However, Japanese patients were less likely than American patients to be bothered by poor sexual function ($p<0.01$) in all four treatment groups. Tables 4 and 5 present the proportions of patients in each cohort who reported ‘poor’ for sexual function and ‘no problem’ for sexual bother, according to each question. The Japanese cohort reported significantly worse sexual function subdomain scores for four of the seven questions. However, both the Japanese and American cohorts similarly reported that they were able to be sexually aroused, to have intercourse, and to function sexually. However, the Japanese patients

were more likely to report ‘no problem’ regarding sexual bother. There were no significant differences in scores for the urinary and bowel domains between Japanese and American patients.

DISCUSSION

We translated the BCI into Japanese, providing for cultural adaptation while maintaining the intent of the original BCI. The Japanese version of the BCI comprehensively covered the symptoms of patients with bladder cancer with high reliability and good construct validity, as well as the original BCI did [8]. In addition, we found substantially different cultural profiles of sexual function between Japanese and American patients with bladder cancer. To the best of our knowledge, this is the first study to report a cross-cultural comparison between Japanese and American bladder cancer patients. These findings are important as they provide evidence that HRQOL results reported in Western countries may not be directly generalized to Japanese patients. A cross-cultural comparative study using an internationally approved and well validated HRQOL questionnaire would certainly be beneficial to the global improvement of patient reported outcome evaluation and would support the importance of assessing HRQOL for each group.

As reported elsewhere, we found that urinary function in the Japanese cohort was significantly lower in the cystectomy with neobladder group compared to the cystectomy with ileal conduit group [2, 12]. This result indicates that improvement in urinary incontinence after radical cystectomy with neobladder would be beneficial for patients and improve their HRQOL. This low score in the urinary function

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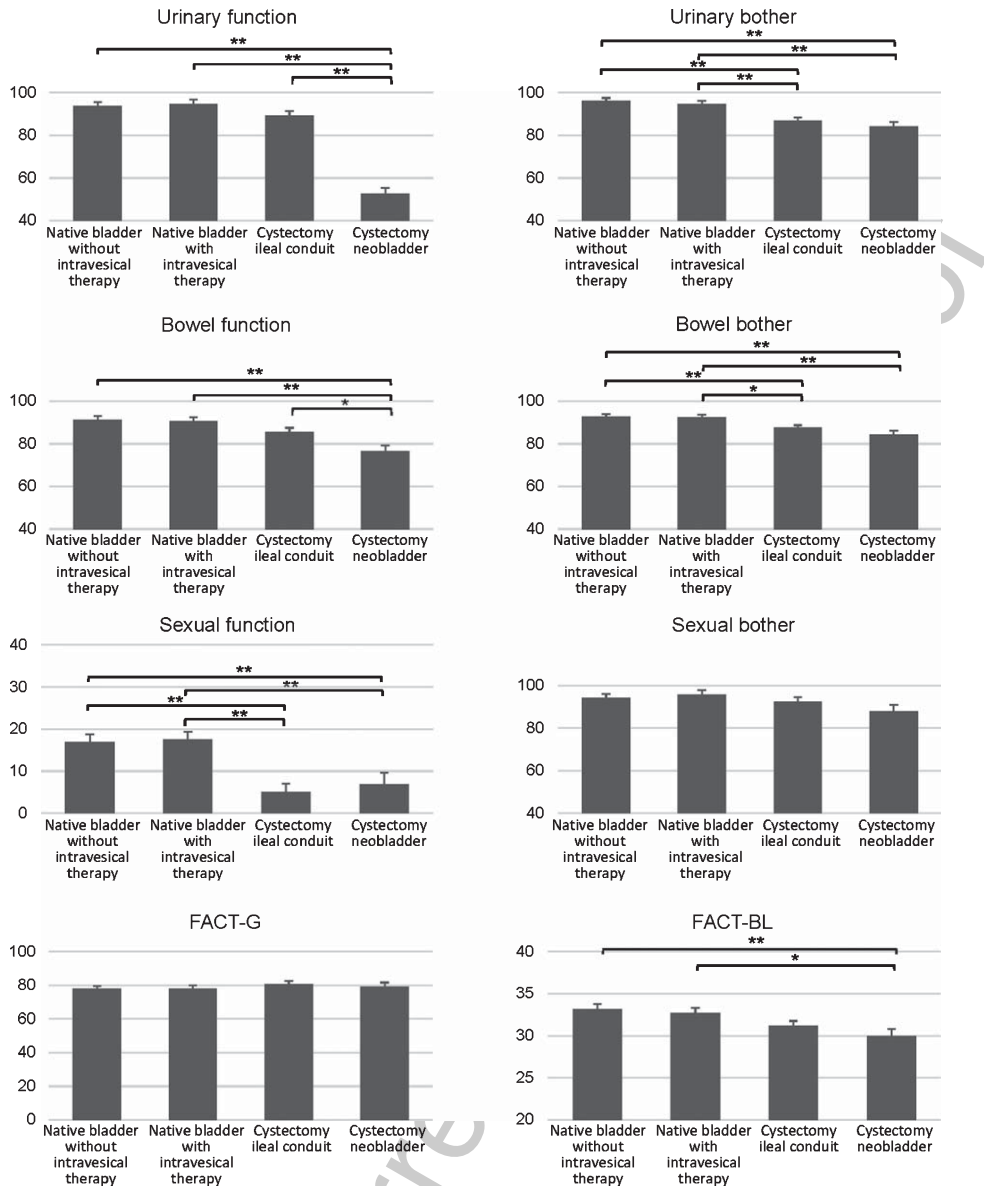


Fig. 1. Mean BCI subdomain scores and standard error by treatment group, adjusted for age and sex ($n=371$, Japanese cohort). Higher scores indicate better health status. (** indicates $p < 0.01$, and * indicates $p < 0.05$).

244 domain was thought to be due to more frequent incon-
 245 tinence and lack of urinary control in the cystectomy
 246 with neobladder group [2]. Despite this significant
 247 difference, the urinary bother subdomain scores did
 248 not significantly differ between the cystectomy with
 249 neobladder group and the cystectomy with ileal
 250 conduit group. In the Japanese cohort, the FACT-BL
 251 scores significantly differed among the four treatment
 252 groups, and the scores for the neobladder group were
 253 lower than in the other three treatment groups. FACT-
 254 BL scores measure HRQOL related to urinary, bowel,

sexual function, body image, appetite, and ostomy
 care (for patients with ostomy), and it also covers
 patients with a wide range of bladder cancer treat-
 ments [13]. However, it cannot identify the reasons
 for the difference. In other words, FACT-BL lacks the
 ability to discriminate which symptoms are most dis-
 turbing to the patient. In contrast, the BCI can help
 identify the reason for the difference of HRQOL,
 because it includes more question items and sepa-
 rately calculates subdomain scores for urinary, bowel,
 and sexual HRQOL.

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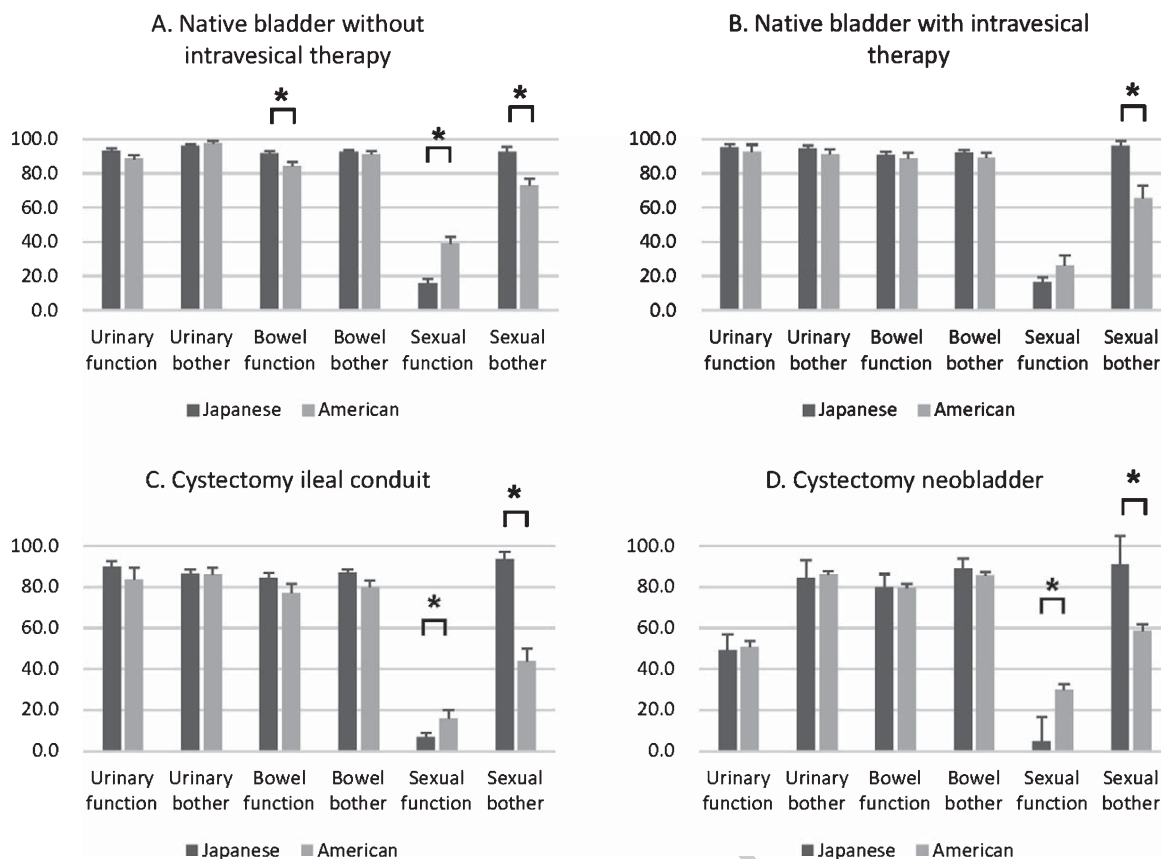


Fig. 2. Mean BCI subdomain scores and standard error by treatment group, adjusted for age and sex. The four groups are: A, native bladder without intravesical therapy; B, native bladder with intravesical therapy; C, cystectomy and ileal conduit urinary diversion; and D, cystectomy and ileal neobladder urinary diversion. Shaded areas show the mean scores across BCI domains within a treatment group. Higher scores indicate better health status. (* indicates $p < 0.05$).

266 Interestingly, Japanese patients reported lower sexual
 267 sexual function compared with American patients in
 268 three of the four treatment groups, even after adjust-
 269 ing for age and gender. This finding is consistent
 270 with findings for other urologic cancers. For example,
 271 assessment of sexual function among patients with
 272 localized prostate cancer also showed that Japanese
 273 men tended to report lower sexual functioning than
 274 American men [14]. Although the baseline differ-
 275 ences in sexual health between the two cohorts was
 276 unknown due to the design of this cross-sectional
 277 study, it is possible that the baseline sexual func-
 278 tion of the Japanese cohort may have been lower, as
 279 seen in men with prostate cancer [15]. Additionally, in
 280 one study of a multiethnic sample, Japanese women
 281 appeared to have less desire and less arousal than
 282 the white women in the study [16]. Although Amer-
 283 ican patients have been reported to greatly focus on
 284 their sexual function and feel bothered by sexual dys-
 285 function, [17, 18] Japanese patients did not perceive

266 this dysfunction as a bother and might more readily
 267 accept this as normal. This might be clarified by an
 268 earlier report, in which a satisfactory sexual life for
 269 Japanese women was not necessarily accomplished
 270 by more frequent intercourse, but that foreplay and
 271 orgasm were essential [19]. On the other hand, Amer-
 272 ican patients tend to perceive sexual impairment as
 273 a serious medical problem, especially when they are
 274 married or living with a partner.

275 As we reported previously, there were substantial
 276 differences between Japan and the US in periopera-
 277 tive management (e.g., length of hospital stay, type of
 278 postoperative complications) and health care system
 279 (e.g., hospital volume, medical cost) [9]. Regarding
 280 hospital volume, the median number of the radical
 281 cystectomy case per year in Japanese institutions and
 282 the US institution was 4 and 119, respectively [9]. The
 283 apparent differences such as more elderly patients and
 284 higher stage in Japanese patients were also observed
 285 here between the Japanese population and the

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Table 3

Mean BCI subscale score by treatment group, adjusted for age and sex

	Japanese	SE	American	SE	p-value
Native bladder without intravesical therapy					
Urinary function	93.1	1.5	88.3	2.2	0.08
Urinary bother	96.0	1.1	97.3	1.5	0.49
Bowel function	91.3	1.9	84.0	2.6	0.02
Bowel bother	92.5	1.2	91.2	1.6	0.50
Sexual function	15.7	2.7	39.1	3.7	<0.01
Sexual bother	92.6	3.0	73.0	3.8	<0.01
Native bladder with intravesical therapy					
Urinary function	94.8	2.0	92.5	4.2	0.63
Urinary bother	94.6	1.6	91.2	2.9	0.31
Bowel function	90.5	1.8	88.6	3.4	0.60
Bowel bother	91.9	1.6	89.0	3.1	0.40
Sexual function	16.2	3.2	26.2	5.9	0.14
Sexual bother	95.7	3.1	65.5	7.2	<0.01
Cystectomy ileal conduit					
Urinary function	89.9	2.8	83.5	6.0	0.41
Urinary bother	86.6	1.9	86.1	3.2	0.90
Bowel function	84.3	2.5	77.2	4.3	0.16
Bowel bother	86.7	2.0	79.8	3.3	0.08
Sexual function	6.6	2.2	15.9	4.0	0.04
Sexual bother	93.4	3.7	43.6	6.5	<0.01
Cystectomy neobladder					
Urinary function	49.1	8.0	50.6	3.1	0.86
Urinary bother	84.3	8.6	86.2	1.7	0.83
Bowel function	79.9	6.4	79.6	2.1	0.96
Bowel bother	89.0	4.9	85.8	1.6	0.54
Sexual function	4.6	12.0	29.8	2.8	0.04
Sexual bother	91.0	14.0	58.5	3.3	0.03

Higher scores indicate better health status. SE: standard error.

Table 4

The proportions of patients reporting 'poor' sexual function by ethnicity

Questions	Japanese n = 371 (%)	American n = 315 (%)	p-value
Poor level of sexual desire	236 (63.6)	143 (45.4)	<0.01
Poor ability to reach orgasm	227 (61.2)	159 (50.5)	<0.01
Poor level of sensation in the genital area	218 (58.8)	150 (47.6)	<0.01
Poor ability to be sexually aroused	210 (56.6)	163 (51.7)	0.20
Poor ability to have intercourse	244 (65.8)	199 (63.2)	0.48
Any poor recent sexual activity	339 (91.4)	246 (78.1)	<0.01
Poor ability to function sexually	236 (63.6)	199 (63.2)	0.91

American population in this study. Despite this difference, the BCI scores for each subdomain were largely comparable, other than the significant difference in the sexual subdomain scores between Japanese and American patients. For example, patients diagnosed

Table 5

The proportions of patients reporting 'no problem' regarding sexual bother by ethnicity

Questions	Japanese n = 371 (%)	American n = 315 (%)	p-value
pain related to intercourse	237 (63.9)	237 (75.2)	<0.01
level of sexual desire	242 (65.2)	112 (35.6)	<0.01
ability to have intercourse	222 (59.8)	81 (25.7)	<0.01
ability to reach orgasm	227 (61.2)	94 (29.8)	<0.01
lack of sexual function	235 (63.3)	95 (30.2)	<0.01

at initial stages of bladder cancer and cystectomy treated endoscopically showed good urinary function in both cohorts. Furthermore, urinary function in the / neobladder group was lower compared with cystectomy/ ileal conduit group in both cohorts.

This study has several potential limitations. First, it lacks longitudinal assessment, which would have allowed us to adjust for baseline assessment (e.g., baseline sexual function) and evaluate the HRQOL scores in different phases. Second, our study included a relatively small number of female patients. However, women less commonly have bladder cancer, and our Japanese cohort had approximately the same proportion of women as the American cohort did [1]. Third, the operative procedures used (such as robotic surgery and nerve-sparing technique), were not recorded for each case, due to our study's retrospective design; variation in surgical techniques might add other potential factors that could influence the postoperative sexual function between the two cohorts. Finally, the cohorts of these two countries were not a random sample, so selection bias may have been present. Moreover, the two cohorts were not well balanced in several baseline characteristics. Given the relatively short overlap between the two cohorts, this might introduce time dependent biases. These issues remain to be resolved by future cross-cultural study. Nevertheless, we believe that the current Japanese version of the BCI will contribute to the assessment of HRQOL in Japanese patients with bladder cancer and will provide useful information for comparison of different health services on both national and international levels.

An effective assessment of bladder cancer HRQOL among Japanese patients can be performed using the BCI-Japan questionnaire. Japanese patients with bladder cancer reported worse sexual function, but less sexual bother from the worse function, when compared with American patients. The Japanese version of the BCI can be used to evaluate the

351 HRQOL of patients who undergo new treatment
352 options for bladder cancer.

353 ACKNOWLEDGMENTS

354 The authors thank Dr. Yoshiyuki Kakehi and Dr.
355 Misa Takegami for their excellent support.

356 FUNDING

357 This work was supported by JSPS KAKENHI
358 Grant Number 18K09155.

359 AUTHOR CONTRIBUTIONS

360 OT: Conception, data collection, data analysis,
361 data interpretation, manuscript writing. WJ: Concep-
362 tion, data interpretation, manuscript writing. AT: Data
363 collection, data analysis, data interpretation. HM:
364 Data collection, data analysis, data interpretation.
365 RK: Review and editing. DR: Data collection. YS:
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367 FJ: Data collection, data analysis, data interpretation.
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372 data interpretation. TN: Data collection, data anal-
373 ysis, data interpretation. Minami K: Data collection,
374 data analysis, data interpretation. Morita K: Data col-
375 lection, data analysis, data interpretation. KA: Data
376 collection, data analysis, data interpretation. FS: Data
377 collection, data analysis, data interpretation. MS:
378 Data collection, data analysis, data interpretation. IY:
379 Data analysis and data interpretation. OK: Review
380 and editing. SN: Review and editing.

381 CONFLICT OF INTEREST

382 Dr. Yamada, Dr. Wei, Dr. Takada, Dr. Sato,
383 Dr. Shinohara, Dr. Ogasawara, Dr. Rew, Dr. Murai,
384 Dr. Matsumoto, Dr. Morita, Dr. Minami, Dr. Kiku-
385 chi, Dr. Kashiwagi, Dr. Ito, Dr. Harabayashi,
386 Dr. Fukuhara, Dr. Furumido, Dr. Dunn, Dr. Abe and
387 Dr. Honda have nothing to disclose.

388 SUPPLEMENTARY MATERIAL

389 The supplementary Table is available in the
390 electronic version of this article: [https://dx.doi.org/
391 10.3233/BLC-200359](https://dx.doi.org/10.3233/BLC-200359).

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