Original Article

Translation, Linguistic Validation, and Cultural Adaptation of the Bladder Cancer Index (BCI) Questionnaire Into the Persian (Farsi) Language and Comparing it With WHO Quality of Life Questionnaire: An Observational Study

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Received March 2023; Revised and accepted August 2023

Abstract

Objective: Whether ileal conduit diversion (ICD) or orthotopic neobladder (ONB) urinary diversion provides better quality of life (QoL) is still under debate. The Bladder Cancer Index (BCI) is a specific tool for bladder cancer (BCa) patients, providing reliable results in previous studies. A validated Farsi version of the BCI concerning cultural aspects could help Farsi-speaking clinicians gain more reliable feedback on QoL following urinary diversion.

Materials and methods: Based on WHO suggestions, we translated the BCI questionnaire into the Persian language. Then, we performed a cross-sectional study on BCa patients who underwent ICD or ONB urinary diversion. We compared their QoL via BCI and WHO questionnaires. Chi-square and independent t-tests were used where appropriate.

Results: The content validity ratio and the content validity indexes were 1 and 0.8-1.0, respectively. Of 57 participants, six patients (10.5%) were women. The ICD was performed for 38 (66.7%) and ONB diversion for 19 (33.3) participants. The mean age of ICD and ONB was 68.71 ± 7.40 and 64.28 ± 8.34 years, respectively (p-value: 0.055). In all sub-domains of BCI, except bowel habits, the mean scores were higher in the ICD group. A significant difference between ICD and ONB groups was found regarding urinary function (p-value<0.001). There was no significant difference between ICD and ONB groups in none of the domains of the WHO questionnaire.

Conclusion: The QoL of ICD and ONB patients did not differ significantly. Even ICD may be superior in ritual purification, while the psychological status of ONB patients was better.

Keywords: Bladder Cancer Index; Bladder Cancer; Questionnaire; Quality of Life; Persian; Bladder Neoplasms

Introduction

In 2021, bladder cancer (BCa) accounted for the sixth cause of new cancer diagnosis in the United States (1). The American Cancer Society estimated 81,180 new cases and 17,100 deaths in 2022 (2). BCa is more prevalent in men (1 in 27 men versus 1 in 89 women) and is considered the fourth most common cancer in males (2). BCa was among the top ten most incident cancers in Iran in 2020, with 5,065 new cases (3). The gold standard management of muscle-invasive non-metastatic bladder cancer is radical cystectomy with urinary diversion (4). Urinary diversion may be implemented via different approaches; the two most commonly used options are orthotopic neobladder (ONB) and ileal conduit diversion (ICD) (4). Such interventions affect patients' social, psychological, sexual, and occupational function, contributing to one's quality of life (QoL). Several questionnaires are designed to assess QoL in BCa patients; 12-item and 36-item Short-Form Health Survey score (SF-12 and SF-36), European Organization for Research and Treatment of Cancer Quality of Life Core-30 (EORTC QLQ-C30), the Functional Assessment of Cancer Therapy General and Bladder specific (FACT-G and FACT-Bl), and the World Health Organization Quality of Life (WHOQOL-BREF) are examples of tools to assess QoL in BCa patient population (5, 6). The Bladder Cancer Index (BCI) includes three major domains of urinary, bowel, and sexual health; each domain contains bother and function status (7). *Shi et al*. performed a meta-analysis on QoL of BCa patients managed with ICD or ONB; they found that the main differences reported previously between QoL after ICD and ONB arise from the type of questionnaire used in each study (5). Of note, results of meta-analyses after excluding articles that used BCI, the negative value of combined Hedges' g turned to a positive value. Thus, BCI gives a different point-of-view from other questionnaires and is specific to BCa patients' conditions.

The BCI had translated and validated in multiple languages to fit the specific cultural and religious status of non-English speaking patients (8-11). We failed to find a QoL assessment of BCa patients in Iran, partly because the questionnaires were not translated and validated in Persian. The present study aimed to translate and validate the BCI tool to the Persian language (Farsi) to be used in Farsi-speaking countries.

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Materials and methods

Gilbert and colleagues developed the BCI questionnaire at the University of Michigan in 2004 (8). We translated and validated this tool based on the World Health Organization (WHO) criteria for translation and adaptation of instruments (12). After standard translation, we assessed the QoL of BCa patients referred to our tertiary hospital via the Persian BCI and compared the findings with the Farsi version of the WHO Quality-of-Life (WHOQOL-BREF) questionnaire (6). We used the surgical technique of *Hautmann et al*. to perform ONB reconstruction (13), and the standard Bricker technique was used to implement ICD.

Forward-translation and expert panel: After granting permission from the authors (as the BCI tool is still protected by copyright), forward translation to Farsi was done by one native Persian physician and another native scientist, and discrepancies were resolved after consensus. Then we submitted the Farsi version to a committee of eight translators, including five bilingual experts (familiar with BCa management and instrument development and translation), to evaluate the concepts of expressions and their probable insufficiency, transparency, and essentiality. As ritual purification is a routine practice performed by Muslims in Iran and our patients with urinary diversion regularly complained of ritual purification issues, a related question was added to the questionnaire for cultural adaptation after extensive counseling with the committee.

Back-translation and Pre-testing: After approving the translated Farsi version and face validation by the committee in the second step, back-translation was performed by a native English translator with no previous familiarity with the BCI questionnaire. The discrepancies were resolved through discussions in the committee. The questionnaire was submitted to seven (five men, two women; as it is more prevalent among men) BCa patients heterogeneous in age and socioeconomic status to address their concerns about transparency and difficult-to-understand expressions. They were asked to repeat the questions in their own words and suggest alternatives for inappropriate words. Their comments were discussed without major changes in the Farsi version.

Validity and Reliability Assessment: We used the Content Validity Ratio and Index (CVR and CVI) to assess the validity of the translated questionnaire

quantitatively. To assess CVR, we submitted the final translated version to five urologists involved for at least seven years in managing BCa patients. They asked to address the essentiality of each statement by choosing from "Essential, Useful but not essential, and Not essential" options. Questions with CVR ≥ 0.99 were considered valid. CVI was assessed by a four-item questionnaire (relevant, somewhat relevant, quite relevant, very relevant) by dividing the number of experts chosen "quite" and "very relevant" answers by the number of all experts. The statements with CVI ≥ 0.79 considered acceptable, CVI < 0.70 considered rejected, and if 0.79 > CVI ≥ 0.70, the statement needs revision. For reliability assessment we calculated Cronbach's Alpha (Internal consistency > 0.7 considered good, and > 0.5 acceptable).

Observational Survey: We performed a cross-sectional study on BCa patients who underwent radical cystectomy with urinary diversion and were referred to our tertiary university hospital of Emam Reza from January 2020 to January 2022. Fifty-seven patients (6 women, 51 men) included in our study if they underwent a 1) radical cystectomy with urinary diversion (ICD or ONB) and 2) the surgery should implement at least six months before the entrance to this study. The exclusion criteria were 1) not consenting to participate, 2) death during the survey, 3) patients with suspected signs of metastasis in the last six months of study, and 4) patients who need adjuvant therapy following cystectomy and urinary diversion.

To assess the QoL, participants completed questionnaires while a physician explained the questions to them during two follow-up visits. We used two instruments for this assessment. WHOQOL-BREF questionnaire (26 items) is a general index of QoL, and the BCI questionnaire gives a specified estimate of QoL in patients with BCa. The BCI questions' classification and scoring (Supplementary Material 1) plus Farsi BCI (Supplementary Material 2) are also attached.

Statistical Analysis: We used SPSS 21.0 (IBM Corp. Released 2012. IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp) to analyze our findings. After assessing the normality of the data by the Kolmogorov-Smirnov test, statistical significance evaluated via Chi-Square and independent t-test were appropriate.

Results

The CVR of 1 and CVI of 0.8-1.0 were calculated based on the experts' assessment, and both were in the acceptable range. From 57 participants, 6 patients (10.5%) were women and 51 patients (89.5%) were men. The mean age of women, men, and overall participants were 71.67 ± 6.50, 66.59 ± 7.99, and 67.17 ± 7.95 years, respectively (overall range 48-86). No statistically significant difference was found between the age of women and men (p = 0.143). All women participants were in menopausal status and mothered at least one child through normal vaginal delivery but had no previous urinary or sexual problems. Similarly, none of the men reported sexual or urinary problems before surgery.

The ICD was performed for 38 (66.7%) and ONB diversion for 19 (33.3) participants. The mean age of ICD and ONB was 68.71 ± 7.40 and 64.28 ± 8.34 years, respectively, with no significant difference (p = 0.055).

The correlation between the main three aspects of the BCI (urinary, bowel, and sexual) and their sub-domains (bother and function) are presented in Supplementary Material 3. The correlation between the domains of BCI and WHOQOL-BREF is shown in Table 1.

Table 1: The correlation of the domains of BCI and WHOQOL-BREF

Domains		Physical health	Psychological health	Social relations	Environmental health	General health
		r p-value	r p-value	r p-value	r p-value	r p-value
Urinary	Function	0.197	0.225	0.384	0.298	0.391
		0.142	0.092	0.003	0.024	0.003
	Bother	0.451	0.445	0.361	0.315	0.509
		0.000	0.001	0.006	0.017	0.000
Bowel	Function	0.245	0.140	0.277	0.084	0.253
		0.066	0.300	0.037	0.532	0.057
	Bother	0.254	0.169	0.220	0.070	0.124
		0.057	0.210	0.100	0.603	0.356
Sexual	Function	0.216	0.191	0.276	0.116	0.080
		0.107	0.154	0.038	0.390	0.553
	Bother	0.490	0.407	0.435	0.300	0.388
		0.000	0.002	0.001	0.023	0.003

This correlation was low and insignificant in terms of bowel habits. A significant correlation was observed between the bother subdomains of urinary and sexual function of BCI and all aspects of the WHOQOL-BREF questionnaire.

All participants answered all questions of the BCI tool, and we had no missing items. The most scored sub-domain was bowel function, and the least scored domain was sexual function, as shown in Table 2. Except for the sexual function sub-domain (24.6% had a score of zero), none of the other domains had scored minimum points (percent of patients scored zero). Full scores were observed in all sub-domains except for the sexual function subdomain. 71.9% of patients had full scores in the function subdomain of bowel habits, and sexual bother had the least maximum scored items (percent of patients who had full scores), as low as 5.3%. Cronbach alpha was found to be acceptable for all domains and subdomains.

The table also shows the score distribution of BCI based on the type of urinary diversion (ICD versus ONB). The most scored sub-domain in both groups was bowel function, and the lowest was sexual function. Sexual function was the only sub-domain with the minimum scored items, and none of them scored maximum points. In all sub-domains except bowel habits, the mean scores were higher in the ICD group; however, this difference was statistically significant only in the urinary domain ($p = 0.028$). A significant difference between ICD and ONB groups was found regarding urinary function ($p < 0.001$). The Cronbach alpha of the bowel habit domain was lower in the ONB group, especially in the bowel bother subdomain. The sexual scores are generally lower than bowel and urinary problems, especially sexual bother sub-domain.

Table 3 shows scores of the WHOQOL questionnaire. There was no significant difference between ICD and ONB groups in none of the domains. Finally, Table 4 indicates that the ICD group showed slightly better outcomes for ritual purification.

Table 2: The mean participants' scores after assessment via the Persian BCI tool provided as an overall score (in bold) and the scores of each sub-domain

Domains		Diversion type	Items	Mean (SD)	Range	Scored maximum	Scored minimum	Cronbachs alpha
Urinary	Total	Overall	14	84.45(12.71)	56.92-100	0	15.8	0.821
		ICD	14	87.05(12.01)	58.33-100	0	23.7	0.850
		ONB	14	79.25(12.79)	56.92-94.50	0	0	0.792
	Function	Overall	6	76.92(24.45)	16.5-100	0	42.1	0.869
		ICD	6	84.67(20.53)	50-100	0	57.9	0.891
		ONB	6	61.42(24.77)	16.50-100	0	10.5	0.801
	Bother	Overall	8	88.21(10.09)	62.5-100	0	28.1	0.719
		ICD	8	88.24(9.84)	62.50-100	0	26.3	0.709
		ONB	8	88.16(10.85)	68.75-100	0	31.6	0.761
Bowel	Total	Overall	10	91.30(10.97)	35-100	0	29.8	0.788
		ICD	10	90.62(12.22)	35-100	0	26.3	0.842
		ONB	10	92.67(8.05)	75.8-100	0	36.8	0.529
	Function	Overall	4	95.47(10.51)	37.50-100	0	71.9	0.767
		ICD	4	94.64(11.83)	37.50-100	0	68.4	0.784
		ONB	4	97.14(7.21)	70.75-100	0	78.9	0.661
	Bother	Overall	6	88.52(12.73)	33.33-100	0	29.8	0.634
		ICD	6	87.93(13.55)	33.33-100	0	26.3	0.712
		ONB	6	89.69(11.14)	62.50-100	0	36.8	0.402
Sexual	Total	Overall	12	29.24(12.88)	8.33-68.08	0	0	0.703
		ICD	12	30.21(12.36)	8.33-57.67	0	0	0.673
		ONB	12	27.29(13.99)	8.33-100	0	0	0.750
	Function	Overall	7	16.03(15.67)	0-73.86	24.6	0	0.851
		ICD	7	16.16(15.08)	0-52.43	26.3	0	0.847
		ONB	7	15.77(17.21)	0-73.86	21.1	0	0.865
	Bother	Overall	5	47.72(21.09)	20-100	0	5.3	0.660
		ICD	5	49.87(21.45)	20-100	0	5.3	0.665
		ONB	5	43.42(20.21)	20-100	0	5.3	0.632

SD: Standard deviation; ICD: Ileal conduit diversion; ONB: Orthotopic neobladder

Table 3: The scores of the WHOQOL questionnaire

Domains	Physical health		Psychological health		Social relations		Environmental health		General health	
Type of diversion	ICD	ONB	ICD	ONB	ICD	ONB	ICD	ONB	ICD	ONB
Mean (SD)	67.95(14.32)	71.05(11.54)	69.63(15.47)	75.66(15.10)	55.92(14.36)	54.38(13.14)	67.76(18.18)	72.69(13.50)	71.38(15.89)	69.08(20.98)
Median (IQR)	71.43(22.32)	75(14.28)	66.67(26.05)	79.17(25)	58.33(25)	50(16.67)	64.06(32.13)	71.87(25)	75(12.5)	75(12.5)
Min.	32.14	46.43	29.17	45.83	25.00	33.33	31.25	50.00	50.00	12.50
Max.	96.43	89.29	100.00	95.83	83.33	75.00	96.88	90.63	100.00	100.00
p-value	0.320		0.188		0.712		0.300		0.811	

SD: Standard deviation; ICD: Ileal conduit diversion; ONB: Orthotopic neobladder

Table 4: Responses to the added ritual purification question

Type of Urinary Diversion	Answers	Number (%)
ICD	1	32(84.2)
	2	5(13.2)
	3	1(2.6)
	4	0(0)
ONB	1	15(78.9)
	2	4(21.1)
	3	0(0)
	4	0(0)

ICD: Ileal conduit diversion; ONB: Orthotopic neobladder

Discussion

The present study translated and validated a useful tool for assessing QoL in Farsi-speaking BCa patients. Then, we used this instrument and WHOQOL questionnaire for 57 participants who underwent radical cystectomy with urinary diversion (ICD or ONB). Our participants experienced no pre-operative sexual, urinary, or bowel discomfort. Correlation of the urinary and bowel parts of the BCI tool showed a good relation ($r = 0.3$, $p = 0.03$), but these domains showed a weak correlation with the sexual domain; *Hever et al*. also reported such low correlation between the sexual domain and two other domains (10). Resection of internal urinary organs and regional possible neurovascular damage during the surgery are two probable causes of this weak correlation between the sexual domain and other domains.

While evaluating the correlation between bother and function of each domain, we found a correlation in the bowel and urinary domains ($r_{Bowel} = 0.521$, $r_{Urinary} = 0.45$); again, there was a weak correlation between sexual bother and function ($r = 0.09$). Such low correlation can be attributed to our small sample size or general low scores of patients in the sexual domain. *Schmidt et al*. found that sexual bother and function had the lowest correlation among the three domains (14). Interestingly, a negative correlation was observed between sexual sub-domains in the study of *T. Osawa* and colleagues (15).

The urinary domain included 14 questions (function: 6; bother: 8) with a mean score of 84.45 ± 12.71 (range: 56.92-100) and an acceptable Cronbach alpha of 0.82. Cronbach alpha was also favorable for the bother, and the function was 0.71 and 0.86, respectively. The mean scores for ICD and ONB were 87 (function: 84.6; bother 88.24) and 79.25 (function: 61.4; bother: 88.16), respectively, affirming the better urinary function in ICD participants with no major difference in urinary bother. Osawa et al. reported similar results that the mean urinary function score was higher in ICD (89.2 ± 2.1) compared to ONB (52.5 ±2.8) patients (11).

The bowel domain included ten items (function: 4; bother: 6) with a mean score of 91.3 ± 10.9 (range: 35-100) and an acceptable Cronbach alpha of 0.78. The bother and the function sub-domains had Cronbach alpha of 0.63 and 0.76, respectively. Both ICD (overall: 90.6; function: 94.6; bother: 87.93) and ONB (overall: 92.67; function: 97.14; bother: 89.69) patients had high and relatively equal scores in bother and function sub-domains. *Gilbert et al.* reported generally lower scores but without a significant difference between ICD and ONB in bowel sub-domains (7).

The sexual domain included 12 questions (function: 7; bother: 5) with the lowest score among the main domains, with a mean score of 29.24 ± 12.88 (range: 8.3-68) and an acceptable Cronbach alpha of 0.7. Cronbach alpha for bother and function were 0.66 and 0.85, respectively. Both ICD (overall: 32.20; function: 16.16; bother: 49.87) and ONB (overall: 27.9; function: 15.77; bother: 43.42) groups had low and relatively equal scores in bother and function sub-domains. *Osawa et al*. found no difference in sexual function between ICD and ONB. Of note, sexual bother did not differ significantly between ICD, ONB, native bladder without intravesical therapy, and native bladder with intravesical therapy (11). Japanese patients also had higher scores than our patients and the American study they used in their analyses regarding the sexual bother sub-domain (16). The different results in the sexual function (significantly higher scores in sexual bother and lower scores in sexual function) were attributed to cultural priorities. Namely, sexual relation, in an American view, constitutes a bigger share of QoL, while this issue has a smaller effect on the Japanese based on their culture. Such results indicate that QoL assessment tools still failed to address a culture-centered point-of-view.

WHOQOL questionnaire domains showed no statistically significant difference between ICD and ONB. The most correlation of social relations, environmental health, and general health domains was observed with urinary function and bother sub-domains of the BCI, and the least correlation of WHOQOL domains was found with the bowel domain of BCI. ICD and ONB groups had the lowest scores in social relationships. The highest scores in the ICD and ONB patients were found in the "general health" and "psychological health" domains, respectively. Although the ONB group had better scores in "physical health," "psychological health," and "environmental health" and lower scores in "social relations" compared to ICD, these differences were not statistically significant. Philip et al. claimed that although no significant difference exists in most indexes of QoL between ICD and ONB, the psychological burden of body image is higher in the ICD group. *Shi et al*. concluded from their meta-analysis that global health status, physical functioning, role functioning, emotional wellbeing, and sexual

function were better in the ONB group, and only urinary function was more favorable than ONB (5).

Our additional question regarding ritual purification showed that 21% of ONB and 13% of ICD patients had problems staying clean based on religious criteria (body fluids of the genitourinary system are mostly considered unclean in Islam). This difference is mostly because of a urinary leak in the ONB group. Most patients had no problems with ritual purification (84% of ICD and 78% of ONB). No statistically significant difference was observed regarding this issue.

Proper patient selection for each type of urinary diversion is of the utmost importance concerning patient's economic status (ICD needs frequent bag changes), patients' baseline psychological status before surgery, and judicious counseling pros and cons of each urinary-diversion type play a major role in patient satisfaction (17). Previous studies showed that patients adapt better to the intervention when chosen by themselves (18). Moreover, some studies claimed that the QoL improves for 12 months following the surgery and plateaus after that (19).

Our study was not without limitations. Apart from its cross-sectional design and lack of prospective follow-up, some patients were lost-to-follow-up, especially those who were living in neighboring cities; the COVID-19 pandemic worsened this situation, and some patients died without firm documents regarding the exact cause of death. We also failed to perform matching of ICD and ONB participants.

Conclusion

In conclusion, The QoL of ICD and ONB patients did not differ significantly. Even ICD may be superior in terms of ritual purification, while the psychological status of ONB patients was better. Appropriate patient selection for each type of diversion is of utmost importance. Both groups had low scores in the sexual domain, which should be considered in patients' counseling.

Conflict of Interests

Authors declare no conflict of interests.

Acknowledgments

We would like to thank our patients for their patience through this study. We also thank the Clinical Research Development Unit of Imam-Reza Hospital for contributing to this study.

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Citation: Ghorbani H, AfzalAghai M, Soltani S, Mottaghi M, Tavakkoli M, Lotfi A. **Translation, Linguistic Validation, and Cultural Adaptation of the Bladder Cancer Index (BCI) Questionnaire Into the Persian (Farsi) Language and Comparing it With WHO Quality of Life Questionnaire: An Observational Study.** J Family Reprod Health 2023; 17(3): 128-35.