

Korean Version of the Functional Assessment of Cancer Therapy (FACT)-Vanderbilt Cystectomy Index (VCI): Translation and Linguistic Validation

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Purpose: To develop a Korean version of the Functional Assessment of Cancer Therapy (FACT)-Vanderbilt Cystectomy Index (VCI) from the original English version, with subsequent linguistic validation in Korean patients who underwent radical cystectomy with urinary diversion.

Materials and Methods: Translation and linguistic validation were carried out between January and May of 2013, which consisted of the following stages: (1) permission for translation; (2) forward translation; (3) reconciliation; (4) backward translation; (5) cognitive debriefing and (6) final proof-reading.

Results: During the forward translation phases, words such as “bother”, “spend time”, “support”, “coping” and “concern” were adjusted to be more comprehensible to the target population. The conciled Korean version was accepted without certain objections because the original version and the backward translation were almost congruent except for minor differences in a subset of questions. The translation was tested using 5 Korean-speaking subjects. The subjects took an average of 8.2 minutes to complete the questionnaire, without difficulty and found the questionnaire clear and easy to understand. The panel discussed each of the issues raised by subjects and most terms were judged by the panel as to not require further changes because the overall comprehension levels were relatively high and because the translated terms were accurately rendered in the target languages.

Conclusion: This report has demonstrated that despite translation difficulties, the linguistic validation of the FACT-VCI in the Korean language was successful. The next step is to assess the psychometric properties of the Korean version of FACT-VCI.

Keywords: cystectomy; psychometrics; quality of life; questionnaires; reproducibility of results; urinary bladder neoplasms; linguistics.

INTRODUCTION

Current awareness of the psychological and social sequelae of cancer is evident from the intensified clinical research on these problems. Because of its impact on sexual function and body image, radical cystectomy for bladder cancer is probably more traumatic than many other cancer operations.⁽¹⁾ Bladder cancer is the ninth most common malignancy in South Korea, and annual incidence rate is reaching 6.8 cases per 100,000 people. The 5-year relative survival of bladder cancer was 78.3% in South Korea, however about one thirds of whole patients eventually receive radical cystectomy.⁽²⁾ However, the true impact of radical cystectomy with urinary diversion on distressing symptoms, quality of life and general well-being in survivors of bladder cancer remains controversial and

requires further clinical investigation.

Quality of life instruments assess general health perceptions, sense of overall well-being, and physical, emotional and social functions. Tools used to assess the quality of life in patients with bladder cancer include general instruments, cancer-specific instruments and instruments specific to bladder cancer. Although modules specific to bladder cancer have recently become available, they have not been tested as extensively as other general cancer instruments that are more applicable to a variety of cancer types. In addition, almost all clinical studies of the quality of life in patients with bladder cancer have used ad hoc questionnaires of untested validity and reliability.⁽³⁻⁷⁾

In 2003, Cookson and colleagues⁽⁸⁾ developed a new

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Table 1. Reconciliation after two forward translations.

US / English Items	First Forward Korean Translation	Second Forward Korean Translation	Reconciled Korean Version
I have nausea	나는메스꺼움을느낀다	나는구역질이나어지럽증이있다	나는메스꺼움을느낀다
Because of my physical condition, I have trouble meeting the needs of my family	내신체적상태때문에내가족의필요를채우는데어려움이있다	나의육체적상태때문에가정의필요에충족하지못하고있다	내신체적상태때문에내가족이필요로하는것들을충족시키는데어려움이있다
I am bothered by side effects of treatment	나는이치료의부작용때문에괴로움을느낀다	나는치료의부작용이신경쓰인다	나는치료부작용때문에불편하다
I am forced to spend time in bed	나는어쩔수없이침대에서시간을보내야만한다	나는침대에누워있는상태로시간을보낼수밖에없다	나는어쩔수없이침대에서지내야만한다
I get support from my friends	나는내친구들로부터지지를받는다	친구들이나를지지해준다	나는친구들로부터지지를받는다
I am satisfied with family communication about my illness	나는내가족과내병에대해서이야기하는것에만족한다	나의병에대하여가족들과의사소통하는것에만족한다	나는가족과내병에대해서이야기하는것에만족한다
I feel close to my partner (or the person who is my main support)	나는내배우자 (또는나에게가장많은지지가되는사람) 에게가깝게느낀다	나는내동반자가 (혹은주로부양하는사람) 가깝게느껴진다	나는내동반자가 (혹은주로지지는사람) 가깝게느낀다
Regardless of your current level of sexual activity, please answer the following question.	귀하의현재성생활과무관하게다음질문에답해주세요.	현재성생활의정도에무관하여다음질문에답변해주시시오.	귀하의현재성생활정도와무관하게다음의질문에답해주세요.
I am satisfied with how I am coping with my illness	나는내가내병을견디고있는것에만족한다	나의투병방식에대해서만족감을느낀다	나는내병에대처하고있는방식에만족한다
I am able to work (include work at home)	나는일을할수있다. (집에서하는일포함)	나는일할수있다 (채택근무포함)	나는일 (집에서하는일포함) 을할수있다.
I am able to enjoy life	나는내인생을즐길줄안다	나는인생을즐길수있다	나는삶을즐길수있다
Additional Concern	추가적인문제들	추가적인영향요소	추가적인문제들
I have to limit my sexual activity because of my condition	나는내건강상태때문에내성생활을제한해야만한다	나의성생활을건강상태에따라제한할수밖에없다	나는내건강상태때문에성생활을제한해야만한다

questionnaire for patients treated with radical cystectomy and urinary diversion, the Functional Assessment of Cancer Therapy (FACT)-Vanderbilt Cystectomy Index (VCI), on the basis of their clinical experiences. The questionnaire is a disease specific questionnaire that can objectively assess quality of life following radical cystectomy and urinary diversion, and has been shown to be clinically useful in validation studies.^(9,10) A recent study has demonstrated that a simple 15-item summary score of FACT-VCI (VCI-15) is a gender-neutral, reliable and valid measure of condition-specific quality of life in patients who undergo radical cystectomy and urinary diversion.⁽¹¹⁾ However, it is not simple to translate a questionnaire written in one language into a version in another language; translated versions must reflect differences in the culture and custom of subjects who use a given language. The linguistic validation is the first step of the cultural adaptation of a questionnaire.⁽¹²⁾ The objective of the present study was to develop a Korean version of the FACT-VCI from the original version, with subsequent linguistic validation among Korean patients who underwent radical cystectomy with urinary diversion. To our best knowledge, the current study is the first translation and linguistic validation of the FACT-VCI.

MATERIALS AND METHODS

Original FACT-VCI Questionnaire

The questionnaire developed by Cookson and col-

leagues⁽⁸⁾ was selected for this study. The original English version of the FACT-VCI consists of the 27-items FACT-G, divided into 4 subscales for physical, social/family, emotional and functional well-being in addition to 17 radical cystectomy specific questions, which specifically relates to urinary, bowel and sexual function.⁽⁸⁾ Each item is scored in a 5-point Likert scale (from 0 for ‘not at all’ to 4 for ‘very much’), with higher scores indicating better quality of life.

Methodology

This study was approved by the institutional review board at Seoul National University Hospital (Seoul, Korea; IRB No. H-1305-033-487). The purpose of translating this instrument was to obtain a translated version in the Korean language that is conceptually equivalent to the original, consistent across either of the two languages, and is easily understood by the subjects responding to the translated version, according to the standardized cultural adaptation process.⁽¹³⁾ The previous Korean validation studies in urologic field were also consulted.^(14,15) The linguistic validation process took place under the guidance of a project leader of the panel. The following individuals were involved at various steps of this process:

- A panel of six Korean experts
- Two forward translators
- One backward translator
- One interviewer

Translation and linguistic validation were carried out between January and May of 2013 and consisted of

Table 2. Backward translation.

Original Items	Forward Translation (reconciled)	Backward Translation
I have nausea	나는메스꺼움을느낀다	I feel nauseous
I feel close to my partner (or the person who is my main support)	나는내동반자가 (혹은주로지지하는사람) 가깝게느껴진다	I feel close to my companion (or my primary supporter)
I am forced to spend time in bed	나는어쩔수없이침대에서지내야만한다	I cannot help but stay in bed
I feel nervous	나는불안감을느낀다	I feel a sense of uneasiness

seven stages. A schematic overview of a typical linguistic validation process is illustrated in **Figure**. In brief, one corresponding author (JHK) contacted the author of the original version (MSC) to obtain permission for the translation of the English version of the FACT-VCI by e-mail. All three translators (two forward and one backward) were bilingual but did not own the medical license of the Korean Medical Association. Two translations of the original version into the Korean language were performed independently by two different translators according to the instructions for forward translation supplied by the corresponding author (Korean versions 1.0a and 1.0b, respectively). The two translations were compared and reconciled into the Korean language version after two meetings of a panel consisting of the aforementioned translators and the authors (Korean version 1.1).

To ensure that the Korean language version is faithful to the original version, particularly at the conceptual level, the version 1.1 was given to a third translator who was versed in the two languages (English and Korean) to formulate the questionnaire back into English. This backward-translated English version was subsequently compared to the original questionnaire by the panel. The discrepancies between the original English questionnaire and back-translated version led to subsequent changes to the reconciled translated version in the Korean language. This resulted in the production of a second Korean version and a report explaining the translation decisions (Korean version 1.2).

Standardized interviews were conducted by a trained interviewer and completion of patient-reported outcome. The Korean version 1.2 questionnaire was presented to five Korean-speaking subjects who had been treated with radical cystectomy and urinary diversion, to

test the clarity, cultural adequacy, and the linguistic understanding of each item and the appropriateness of the translated questions. The debriefing interviews consisted of subjects paraphrasing each item and indicating any difficult or confusing terms to the interviewer. This feedback from the five subjects was analyzed, and the panel agreed on resolutions for each issue raised (Korean version 1.3). The third version was proofread to check for spelling, grammar, and formatting, which corresponds with changes made for the final version (Korean version 1.4) (**Appendix**).

RESULTS

Some of the terms in the original English version were replaced with Korean expressions, which include ‘bother’, ‘spend time’, ‘support’, ‘coping’ and ‘concern’. During the forward translation phases, some of the words and phrases were adjusted to be more comprehensible to the target population (**Table 1**). The problems that arose during the translation of questionnaire can be divided into the three categories:

- Semantic equivalence: There were multiple meanings to a given word or a phrase. This included changing the term ‘my condition’ as this expression connote broader interpretations in the Korean language. Thus, ‘my condition’ was replaced with ‘my health condition’. Similarly, the word, ‘partner’ has many meanings in Korean, in which the word can refer to ‘party’, ‘couple’, ‘friend’, ‘member’, and ‘spouse’. Therefore, the word ‘partner’ was replaced by ‘spouse’ in order to convey the original meaning in the English version.
- Idiomatic equivalence: Often the English word did

Table 3. Resolution of subject comprehension problems during cognitive debriefing interviews.

Original Items	Translation (reconciled)	Comprehension Issue of Subjects	Resolution
I have a lack of energy.	나는에너지가부족하다	Energy (1)	Translated term is identical to original English term. No change necessary.
I have nausea.	나는메스꺼움을느낀다	Nausea (1)	Translated term is conceptually equivalent to original English term. No change necessary.
Because of my physical condition, I have trouble meeting the needs of my family.	내신체상태때문에내가족이필요로하는것들을충족시키는데어려움이있다	Trouble meeting the needs of my family (1)	Translated terms are conceptually equivalent to original English terms. No change necessary.
I am forced to spend time in bed.	나는어쩔수없이침대에서지내야만한다	In bed (2)	Change made from ‘침대에서’ to ‘누워서’.
I have control of my bowels.	나는배변활동을조절할수있다	Bowels (1)	Conceptual issue in original English. No change necessary.
I have trouble controlling my urine.	나는소변을조절하는데문제가있다	Controlling my urine (1)	Translated term is identical to original English term. No change necessary.

Appendix. Korean version of the Functional Assessment of Cancer Therapy-Vanderbilt Cystectomy Index.

아래내용은귀하와같은병을앓았던다른환자들이중요하다고이야기한목록입니다.지난 7일동안각각의내용들이귀하에게얼마나적합하였는지를각운항마다동그라미를한개만쳐주세요.

	신체적건강	전혀아님	아님	어느정도	꽤많이	아주많이
GP1	나는에너지가부족하다.	0	1	2	3	4
GP2	나는메스꺼움을느낀다.	0	1	2	3	4
GP3	내신체상태때문에내가족이필요로하는 것들을충족시키는데어려움이있다	0	1	2	3	4
GP4	나는중증이있다.	0	1	2	3	4
GP5	나는치료부작용때문에불편하다.	0	1	2	3	4
GP6	나는아프다고느낀다.	0	1	2	3	4
GP7	나는어쩔수없이누워서지내야만한다.	0	1	2	3	4
	사회적/가족적건강	전혀아님	약간	어느정도	꽤많이	아주많이
GS1	나는친구들과가깝게느낀다.	0	1	2	3	4
GS1	나는가족으로부터정서적인지 지를받는다.	0	1	2	3	4
GS3	나는친구들로부터지지를받는다.	0	1	2	3	4
GS4	가족은나의병을받아들였다.	0	1	2	3	4
GS5	나는가족과내병에대해서이야기 하는것에만족한다.	0	1	2	3	4
GS6	나는내동반자가(혹은주로지지 하는사람)가깝게느낀다.	0	1	2	3	4
Q1	귀하의현재생활동정도와의무관하게다음 의질문에답해주세요. 만약답하고싶지 않다면, 이네모(□)에표시해주시고다음 부분으로넘어가주세요.					
GS7	나는나의성생활에만족한다.	0	1	2	3	4
지난 7일동안각각의내용들이귀하에게얼마나적합하였는지를각운항마다동그라미를한개만쳐주세요.						
	정서적건강	전혀아님	약간	어느정도	꽤많이	아주많이
GE1	나는슬픔을느낀다.	0	1	2	3	4
GE2	나는내병에대처하고있는방식에만 족한다.	0	1	2	3	4
GE3	나는내병과싸우면서희망을 잃어가고있다.	0	1	2	3	4
GE4	나는불안감을느낀다.	0	1	2	3	4
GE5	나는죽는것이걱정된다.	0	1	2	3	4
GE6	나의상태가악화될까걱정된다.	0	1	2	3	4
	기능적건강	전혀아님	약간	어느정도	꽤많이	아주많이
GF1	나는일(집에서하는일포함) 을할수있다.	0	1	2	3	4
GF2	내일(집에서하는일포함)에성취감을 느낀다.	0	1	2	3	4
GF3	나는삶을즐길수있다.	0	1	2	3	4
GF4	나는내병을받아들였다.	0	1	2	3	4
GF5	나는잘잔다.	0	1	2	3	4
GF6	나는즐거움을위해주로하는활동들을 즐기고있다.	0	1	2	3	4
GF7	나는현재내삶의질에만족한다.	0	1	2	3	4
지난 7일동안각각의내용들이귀하에게얼마나적합하였는지를각운항마다동그라미를한개만쳐주세요.						
	추가적인문제들	전혀아님	약간	어느정도	꽤많이	아주많이
C2	나의체중이줄고있다.	0	1	2	3	4
C3	나는배변활동을조절할수있다.	0	1	2	3	4
C3	나는설사를한다.	0	1	2	3	4
C6	나는식욕이줄다.	0	1	2	3	4
C7	나는내외모에만족한다.	0	1	2	3	4
BL1	나는소변을조절하는데문제가있다.	0	1	2	3	4
ITU7	내건강상태때문에밤에잠을깨다.	0	1	2	3	4
ITU6	나는내건강상태때문에당혹스럽다.	0	1	2	3	4
C9	내소변상태를관리하는것이어렵다.	0	1	2	3	4
ITU3	나는내건강상태때문에사회적활동을 제한해야만한다.	0	1	2	3	4
ITU4	나는내건강상태때문에신체적활동을 제한해야만한다.	0	1	2	3	4
ITU5	나는내건강상태때문에성생활을 제한해야만한다.	0	1	2	3	4
ITU1	나는친구들과나의건강상태에대해 의논하는것이편하다.	0	1	2	3	4
VC1	나는나의소변상태에만족한다.	0	1	2	3	4
ITU2	나는화장실과멀리떨어져있는것이두렵다.	0	1	2	3	4
BL4	나는섹스에관심이있다.	0	1	2	3	4
BL3	(남성만해당) 나는발기가되고그상태를 유지할수있다.	0	1	2	3	4

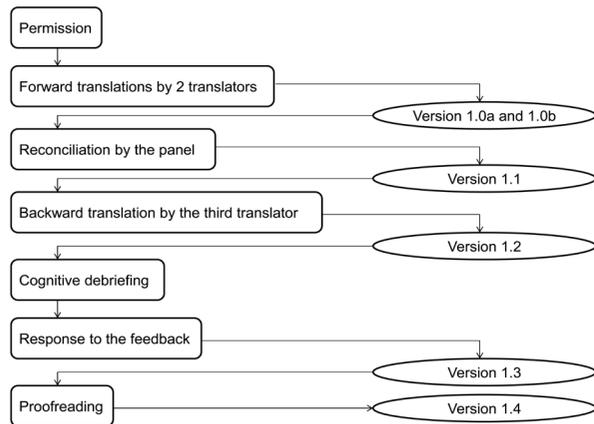


Figure. The standard linguistic validation algorithm.

not have quite the same conceptual meaning in the Korean language. For example, the question, 'I have control of my bowels' was translated into 'I have control of my defecation'. The question, 'I have to limit my sexual activity because of my condition' was translated to 'I have to limit my sex life because of my health condition' for a more natural expression. The item, 'Caring for my urinary condition is difficult', was translated into 'Managing my urinary condition is difficult', because of the possibility of difficulty in understanding of the expression 'caring for' in the Korean language.

•**Conceptual equivalence:** Some words hold different conceptual meaning between cultures. For instance, the meaning of 'Because of my physical condition, I have trouble meeting the needs of my family' would differ between cultures because the word 'family' could potentially mean 'immediate family' or 'family including extended relatives'.

The reconciled Korean version (version 1.1) was accepted without strong objections because the original version and the backward translation were almost congruent except for the questions listed in **Table 2**. Despite these differences, the meanings of respective items between both versions were judged to be almost identical.

The translation was tested using 5 subjects. The mean age was 67 years (range 55 to 73), and all subjects were male. The length of education ranged from 6 to 14 years, with a mean of 9.2 years. Four subjects had fewer than 12 years of education. The respondents completed the questionnaire within the average of 8.2 minutes, without difficulty, and reported the questionnaire to be clear and easy to understand. The panel discussed each of the issues raised by subjects to decide whether changes to the translation were needed. Items that were subsequently changes by the panel were considered resolved issues (**Table 3**). However, most terms were judged by the panel as not requiring changes because overall comprehension levels were relatively high and because the translated terms were accurately rendered in the target language.

DISCUSSION

The concept of quality of life can be defined as the extent to which the usual or expected physical, emotional, and social well-being is affected by a medical condition or its treatment.⁽¹⁶⁾ Having accurate baseline and post-treatment data is essential in evaluating the quality of life of patients and subsequently determining the effectiveness of management.⁽¹⁷⁾ Measuring quality of life might be challenging for physicians as it may take a long time during the overall assessment of their patients. Validated quality of life questionnaires are important tools to assess outcomes after surgery and help overcome this obstacle. In addition, the use of validated and standardized tools will allow comparison of outcomes across different studies and in meta-analyses.⁽¹⁸⁾

Radical cystectomy with urinary diversion is considered to be the most effective local treatment for invasive bladder cancer. Quality of life after radical cystectomy may be affected by diversion type, body image, urinary function, and sexual function. Although generic quality of life measures provide valuable information, they may not be sufficiently sensitive to detect cystectomy- or diversion-specific changes. The development of bladder cancer-specific instruments has been essential in detecting differences in urinary, bowel, sexual, and body image outcomes in bladder cancer survivors. Some condition-specific measures have been used to measure health-related quality of life in bladder cancer patients.⁽¹⁹⁻²¹⁾ However, only FACT-VCI and the Bladder Cancer Index (BCI) are reliable and validated disease-specific measures with known psychometric properties.^(8,22) Between the two, the FACT-VCI has been found to have adequate internal consistency (Cronbach's $\alpha > 0.7$).⁽⁸⁾ Interclass correlation for the first and second administration of the FACT-VCI was 0.79, which verifies the stability of the score derived from serial administrations of this questionnaire by the same respondent.⁽⁸⁾ Convergent validity was investigated by correlating the FACT-VCI with the generic RAND 36-Item Health Survey (SF-36) ($r = 0.81$).⁽⁸⁾

Differences in quality of life cannot simply be attributed to the disease process, when comparing culturally diverse populations.⁽²³⁾ Cultural adaptation is the first step when validating instrument in new language. In general, translation of a questionnaire into a version in another language is not straightforward, and differences in cultures and customs associated with each language have to be considered during the translation process. Therefore, the availability of high-quality translation is of vital importance to guarantee a successful implementation in the target language and to assure the international comparability of the data.⁽²⁴⁾ Consequently, detailed guidelines and appropriate documentation of each step of translation processes have been proposed.^(25,26)

In this study, we have presented the Korean version of the FACT-VCI by gaining permission of use from the original authors and verifying the appropriateness and reliability of the questionnaire in order for it to be officially used for patients in South Korea. We found that Korean subjects understood the translated questionnaire,

although a number of minor changes were made in an effort to improve the clarity and cultural appropriateness. This overall high comprehension rate and lack of significant unresolved comprehension issues demonstrated a high level of linguistic validity.

Potential limitations of the study included the small sample size and an imperfectly stratified subject pool in terms of level of education. Psychometric validation of the translation produced may be a useful next step for verifying the cross-cultural validity of the translated questionnaire.^(27,28)

CONCLUSION

This report has demonstrated that despite the translation difficulties, the linguistic validation of the FACT-VCI in Korean language was successful. We found that the translation was understood well by Korean-speaking subjects. The Korean version of the FACT-VCI questionnaire can be used as a tool for evaluating quality of life in patients who underwent radical cystectomy with urinary diversion and is expected to be useful in clinical research. The next step is to assess the psychometric properties of the Korean version of FACT-VCI.

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CONFLICT OF INTEREST

None declared.

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