RESEARCH ARTICLE

Editorial Process: Submission:09/07/2023 Acceptance:06/11/2024

Cultural Adaptation and Validation of the Punjabi Version of EPIC

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Abstract

Background: With earlier prostate cancer (PCa) diagnosis and increased survivorship, post-treatment quality of life (QoL) has become increasingly important. The Expanded Prostate Cancer Index Composite (EPIC) is a widely adopted QoL instrument for PCa. We aimed to create a Punjabi version of EPIC to further research in the Punjabi-speaking population. **Methods:** A prototype of the Punjabi version of EPIC was created by forward-backward translations and revision. After concluding the cultural adaptation phase by interviewing 15 participants, a pilot version was created. Validation of the pilot version was performed by having 72 participants complete the Punjabi EPIC and another commonly used QoL instrument, the EORTC QLQ-c30, twice within a 4-week period. Test retest reliability (Pearson's correlations and difference distribution) and internal consistency (Cronbach's alpha) were measured using SAS version 9.4. **Results:** Modifications were needed for the prototype Punjabi version after forward-backward translations. Cultural adaptation has highlighted a few issues including syntax and terminology. Test-retest reliability of the Urinary, Bowel, Sexual and Hormone domains were 0.88, 0.91, 0.91, and 0.95, respectively, and subscale correlations ranged from 0.75 to 0.93. Internal consistency for domains and subscales was good except for Sexual Domain. Performance of EPIC is comparable, and in some cases, slightly better than validated Punjabi version of EORTC QLQ-C30. **Conclusions:** The EPIC questionnaire was successfully translated into Punjabi and was culturally adapted. The resultant Punjabi version has high reliability and validity and will be an important tool for QoL research in the Punjabi population. EPIC was successfully translated, culturally adapted, and validated with high reliability and validity into Punjabi. It will be a valuable QoL tool for physicians in clinical and research settings, and for patients in decision-making.

Keywords: EPIC- Prostate cancer- Quality of life- Survivorship- Validation studies

Asian Pac J Cancer Prev, **25 (6)**, 1945-1951

Introduction

Prostate cancer (PCa) is often detected early with very favorable survival. According to Surveillance, Epidemiology, and End Results [1], the five-year survival rate for PCa is 97.5% in the United States. Therefore, post-treatment monitoring of side effects is relatively more important in PCa in comparison to other fast-progressing cancers such as lung cancer. CONSORT (CONsolidated Standards of Reporting Trials) guideline is a joint effort of Medical Research Council, Family Health International, Oxford University, and Ottawa Hospital Research Institute. In 2013, CONSORT has stated that QoL measurement is to be incorporated in all clinical trial outcome measurements and reports [2]. There is a clear role for a validated QoL questionnaire for the PCa population.

There are many different validated quality of life (QoL) questionnaires available for PCa assessment such as the Functional Assessment of Cancer Therapy-Prostate (FACT-P) and the EORTC Prostate Module [3, 4]. EPIC (Expanded Prostate Inventory Composite), developed by University of Michigan, is unique in several ways [5]. First, it systematically organizes post PCa treatments side effects in four domains that can be used synergistically or independently. Second, there is a comprehensive section on hormone therapy side effects, which are often neglected by other questionnaires. Third, it has separated the more objective functional aspects of side effects and the more subjective impacts, by introducing the more subjective concept of "Bother" in QoL assessment. Lastly, EPIC has both a long and short form that can be chosen, based on patients' capacity and willingness, as well as different goals in research and clinical settings.

EPIC is widely used because of its comprehensiveness and flexibility [6-9]. Initially available in English version only, multiple countries including Spain, Netherlands, Japan, and Korea have since successfully developed a validated version of EPIC into their own language [10-12]. Multiple prostate cancer studies have demonstrated racial disparity. In the North American context, differing ethnic minorities have been shown to have different treatment outcomes [13-15]. However, a validated EPIC for Punjabi

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version was not available. Without a Punjabi version of EPIC, it is difficult to compare PCa related QoL in the Punjabi speaking population, with other published studies that have utilized EPIC in English version. Reporting on QoL outcomes may also be limited for new clinical trials originating from Punjabi speaking countries.

In light of this limitation, we launched a multi-phase project to culturally adapt and validate EPIC for the Punjabi speaking population with PCa.

Materials and Methods

EPIC consists of 50 questions, divided into four domains: urinary, bowel, sexual, and hormonal. Each domain is subdivided into function components, which evaluates severity of side effects, and bother components, which evaluates the level of distress from the side effects. The Urinary domain has additional irritative and incontinence subscales. Each question is scored on a Likert scale. Final calculation is based on EPIC scoring guideline, with score ranging from the 0 to 100; the higher the score, the better is the QoL. Our research ethics broad has reviewed considered the project to be quality improvement and required no formal REB approval. Eligibility criteria included a history of biopsy proven PCa and the ability to understand the spoken and written Punjabi language. Ineligibility criteria included a history of chemotherapy, or a recent history of surgery, radiation, or initiation of androgen deprivation therapy within 4 weeks.

Prototype development of the Punjabi version of EPIC

Forward translation was completed by translating English version of EPIC into Punjabi by two professional translators (#1 and #2), independently. These two translations were combined with inputs from translator (#3) and one of the authors, the Research Assistant who was fluent in written and spoken Punjabi and English. This combined Punjabi version was back translated to English by translator (#4). In terms of process of achieving the most credible Punjabi version of a questionnaire, we also tested the translated version with two patients. We incorporated their suggestions before going into the validation process of the questionnaire. The prototype of the Punjabi version of EPIC was generated after a final round of discussion and adjustment (Appendix 1). This methodology of translation and back-translation is similar to the cultural adaptation and validation of the Chinese version and ensured accurate translation and appropriateness for language comprehension for Punjabi speaking and reading populations [16].

Cultural Adaptation

Fifteen eligible participants living in Canada were recruited for pilot testing. After informed consent was obtained, each participant completed the EPIC prototype in the presence of an interviewer who was fluent in both written and spoken Punjabi. After completion of each domain, the participant was asked a set of open ended questions, to seek feedback on whether each question was culturally acceptable, and whether any adjustment could be made to improve its clarity. Each interview was conducted in Punjabi and digitally recorded. Field notes were taken by the interviewer to document the facial expressions and body languages of participants. Interviews were transcribed verbatim, and checked for accuracy against the recording. Each transcript was then reviewed line-by-line independently by at least four investigators. The goal was to adjust word choices and sentence structures, incorporate feedback from investigators and participants, and to create a pilot Punjabi version of EPIC for validation.

Validation

Eligible participants (n = 72) living in Canada and India were recruited for validation. After informed consent was obtained, each participant completed the pilot Punjabi version of EPIC and EORTC QLQ-c30 in two sessions, each separated by 2-4 weeks.

EORTC QLQ-c30 is one of the earliest QoL instruments available to clinical trials for cancer patients [17]. It has nine multi-item scales, including five function scales (physical, role, cognitive, emotion, and social), three symptoms scales (fatigue, pain, and nausea and vomiting), and a global health and QoL scale. Similar to EPIC, it has been translated and adapted in multiple languages throughout the world. Because it has been translated and validated into Punjabi, we have chosen this instrument for convergent validity.

Each participant's response was entered and scoring was calculated according to EPIC and EORTC QLQ-c30 scoring guidelines. Each participant's demographic information was recorded along with tumor characteristics and treatment modalities.

Statistical Analysis

Reliability and validity testing were performed with SAS version 9.4. Test-retest reliability of subscale scores used Pearson's Product Moment Correlation coefficient (Pearson's r) as well as the Wilcoxson signed-rank test to examine differences in the distributions of test and retest scores. Internal consistency of subscales, which assesses congruency of the questions within each subscale, was assessed with Cronbach's alpha coefficient. Correlations between domains and scales and convergent validity between the EPIC and the EORTC QLQ-C30 subscales were assessed using Pearson's r. This reflects how domains relate or differ from each other, how each subscale relates to each domain, and how subscales relate to each other. In terms of convergent validity, we looked at which EPIC domains correlated with the EORTC QLQ-C30 subscales.

Results

Prototype Development of the Punjabi Version of EPIC

The translations were consistent in syntax, with slightly different vocabulary choices and spelling to clarify the meaning of certain words, especially when emphasis had to be placed on some syllable or the word to expand on the understanding of body parts or physiologically related words that did not exist in Punjabi. One example of this was "breast" for men.

At the beginning of the questionnaire, there were two

lines of instructions given for clarity of how to complete the demographic data section and further instructions to make it clearer as to the expectations of the participant for completing this survey correctly. In questions 1-3, the response 5 was changed from "rarely or never" to "no leakage or never happens" under two lines to clarify a true response of this incidence. In the first section of "Urinary Function", for Question 4, the term "frequent dribbling" was first translated as "tupka, tupka", which can be interpreted as "a little bit at a time". We have switched the term, which elicits the meaning for frequent dribbling. In question number 5, since there is no specific word for pad or adult diapers in Punjabi, the suggestion was to add common brands of adult pads and diapers that people may be using so that the question can be understood better.

In Question 6, it was suggested the word "problem" has been used too many times, and can be a cause of confusion while reading for the elderly, along with clarifying some words in the responses. Questions 7-13 required rewording and rephrasing of the questions themselves to provide a better description of what the question was trying to elicit about the participant's experiences. For Question 14, the Punjabi words for "Pelvis" and "Rectum" were swapped to present a clearer understanding of the question to Punjabi men. In Question 15, the sentence was reworded to present a fuller meaning of the types of bowel movements, since there are not many words that truly describe these clearly. Question 24 required rewording and rephrasing of the questions and responses in order to elicit an appropriate response.

For Question 25, it was suggested that we ask for "ability to have sex" instead of "sexual ability" for better clarity. For "hot flashes" in question 26, instead of just using the term "hot flashes" as suggested by the translator, we provided an additional term "gharmi" with responses to clarify the meaning. Lastly, the term "breast" in question 27 was originally translated as "chaati" which can mean either "breast region" or "breast" as women have breasts and men do not. We have added in brackets "some men get breast enlargement. Depending on your treatment, this may/may not apply to you" to make it useful to add the explanation here, "that due to hormonal treatment" to facilitate comprehension. Questions 27 also needed rephrasing since it addressed "breast tenderness", therefore the suggestion was to rephrase it as "chest area, around the nipple it was so sore that it was painful to touch". In Question 29, the "lack of energy" maybe interpreted as sexual energy. So, the suggestion was: "feeling low in energy". Question 31 needed rewording and the responses needed rephrasing of words and terms in order to provide a fuller understanding of the meaning of the question in order to elicit accurate responses.

Cultural Adaptation

The Prototype was modified based on participants' feedback. The option "Rarely or never" in many of the question was initially translated to "Kade, kade hota hai" which means "Rarely happens or sometimes happens". After studying the participants' responses, the fourth author determined that "Rarely or never" should be given two options with descriptive syllables by including the subject in the answer choices. For example, in question 1 concerning urine leakage, the option was translated to "aapne aap nikal gaya, pishaab aapne aap kade vi nahin nikaleya jaan bahut ghat" which means "no leakage or never happens". Similar changes were made to the rest of EPIC with meanings directed towards the question content itself.

Some participants did not feel comfortable completing the Sexual Domain section, because they did not have any sexual activity and were uncomfortable completing this section. We have added an extra line: "Please try your best to answer the following questions even if you do not have any sexual activity", in the hope that it will increase completion rate. Most participants expressed great difficulty comprehending the terms "hot flashes" and "breast" within the Hormone Domain. "Hot flashes" was misinterpreted as a female phenomenon. "Breast" was regarded as a female-only body part, so it was changed to the general chest area around the nipple. We have also

Table 1. Distribution of Participants' Demographics, Prostate Cancer Characteristics, and Treatment Modalities

Characteristic	
Age at First Treatment, Mean ± SD	67.6 ± 7.91
Year after Treatment, Mean ± SD	2.85 ± 5.42
Initial PSA, Mean ± SD	120.97 ± 358.57
Clinical T-stage, n(%)	
Missing	1 (1%)
T1c	5 (6%)
T2a, T2b, or T2c	31 (39%)
T3a or T3b	35 (44%)
T4	7 (9%)
Clinical N-stage, n(%)	
Missing	1 (1%)
N0	64 (81%)
N1	14 (18%)
History of Orchiectomy, n(%)	
No	67 (85%)
Yes	12 (15%)
History of Hormone Therapy, n(%)	
No	36 (46%)
Yes	43 (54%)
Risk stratification, n(%)	
Missing	2 (3%)
Low	7 (9%)
Intermediate	14 (18%)
High	38 (48%)
Metastatic	18 (23%)
Treatment, n(%)	
Nil	8 (10%)
Surgery	22 (28%)
EBRT	37 (47%)
Surgery + EBRT	4 (5%)
ADT	8 (10%)

Table 2. Expanded Prostate Cancer Index Composite (EPIC) Test-Retest Reliability Measures on Domain and Subdomains

	Test			Retest			Difference (retest - test)				
	N	Median	IQR*	N	Median	IQR*	r#	N	Median	IQR*	p-value‡
Urinary Domain	61	84.75	(74.3 - 95.5)	65	88.92	(70.2 - 93.1)	0.86	56	0	(-2.1 - 2.1)	0.97
Function	69	93.4	(78.4 - 100)	70	91.7	(75 - 100)	0.74	67	0	(0 - 0)	0.28
Bother	61	83.33	(64.3 - 92.9)	65	85.71	(71.4 - 96.4)	0.85	56	0	(0 - 3.9)	0.1
Incontinence	62	85.5	(66.8 - 100)	66	85.5	(66.8 - 100)	0.87	58	0	(0 - 0)	0.74
Irritation	61	89.29	(75 - 96.4)	64	89.29	(76.8 - 98.2)	0.84	55	0	(0 - 3.6)	0.34
Bowel Domain	58	91.07	(82.1 - 100)	62	91.07	(83.9 - 98.2)	0.91	53	0	(-1.8- 3.6)	0.7
Function	71	89.29	(78.6 - 100)	70	91.07	(85.7 - 100)	0.78	69	0	(0 - 3.6)	0.12
Bother	58	94.64	(82.1 - 100)	60	92.86	(82.1 - 100)	0.9	53	0	(-3.6 - 3.6)	0.73
Sexual Domain	60	30.77	(16.8 - 32.7)	61	29.46	(13.5 - 30.8)	0.88	56	0	(-3.2 - 0)	0.08
Function	62	1.39	(0 - 12)	65	0	(0 - 17.6)	0.92	58	0	(-0.9 - 0)	0.3
Bother	61	75	(25 - 100)	59	75	(25 - 100)	0.75	56	0	(0 - 0)	0.72
Hormone Domain	62	84.09	(69.4 - 95.5)	64	86.36	(67 - 94.3)	0.93	58	0	(-2.3 - 2.3)	0.88
Function	70	80	(60 - 95)	69	80	(60 - 95)	0.91	67	0	(0 - 0)	0.71
Bother	63	91.67	(75 - 100)	65	91.67	(79.2 - 100)	0.86	60	0	(-2.9 - 4.2)	0.66

*, Interquartile range; #, Pearson's r, based on non-missing values. All correlations were significant with p < .0001; ǂ, p-value of the Wilcoxon Signed rank test. P <= 0.05 indicates the test and retest scores differ

Table 3. Internal Consistency (Cronbach's alpha*) of the Expanded Prostate Cancer Index Composite (EPIC)

		Test	Retest
Urinary Summary		0.79	0.81
	Urinary Function	0.59	0.54
	Urinary Bother	0.8	0.82
	Urinary Incontinence	0.76	0.7
	Urinary Irritation	0.63	0.61
Bowel Summary		0.89	0.87
	Bowel Function	0.65	0.56
	Bowel Bother	0.87	0.86
Sexual Summary		0.82	0.81
	Sexual Function	0.94	0.93
	Sexual Bother	0.9	0.92
Hormone Summary		0.82	0.81
	Hormone Function	0.63	0.67
	Hormone Bother	0.8	0.82

* Raw Cronbach Coefficient Alpha

added an explanation in the instruction section, describing the symptoms of "hot flashes" and "breast tenderness" as side effects from anti-androgen therapy. We further added in the question words that are more descriptive of how it feels to have hot flashes in question 26.

Validation

Participants were recruited from the Radiation Oncology Department of BC Cancer in Canada and in India. The average age of participants at treatment was 67.6 +/- 7.91 years. Prostate cancer characteristics and treatment modalities are summarized in Table 1. Most of the participants received their education in India so converting to North American equivalence was not possible.

Table 2 summarizes the test-retest reliability for the four domains and their subscales of EPIC. The Pearson's correlations between test and retest scores of the Urinary, Bowel, Sexual, and Hormonal Domains were 0.86, 0.91, 0.88, and 0.93 respectively. Subscale test-retest

Table 4. Pearson's (r) amongst EPIC's four Major Domains

		Urinary Domain r (p-value)	Bowel Domain r (p-value)	Sexual Domain r (p-value)	Hormonal Domain r (p-value)
Test					
	Urinary Domain	1			
	Bowel Domain	0.50 (<.0001)	1		
	Sexual Domain	0.31 (0.02)	0.14 (0.32)	1	
	Hormonal Domain	0.48 (<.001)	0.46 (<.001)	0.23 (0.09)	1
Retest					
	Urinary Domain	1			
	Bowel Domain	0.56 (<.0001)	1		
	Sexual Domain	0.16 (0.23)	0.05 (0.74)	1	
	Hormonal Domain	0.52 (<.0001)	0.46 (<.001)	0.24 (0.06)	1

Table 5. Pearson's (r) amongst EPIC's Domains and Sub-Scales

		Urinary Domain r (p-value)	Bowel Domain r (p-value)	Sexual Domain r (p-value)	Hormonal Domain r (p-value)
Test					
	Urinary Function	0.81 (<.0001)	0.28 (0.05)	0.18 (0.23)	0.37 (0.01)
	Urinary Bother	0.93 (<.0001)	0.57 (<.0001)	0.32 (0.03)	0.52 (<.001)
	Urinary Incontinence	0.79 (<.0001)	0.38 (0.01)	0.22 (0.14)	0.28 (0.05)
	Urinary Irritation	0.84 (<.0001)	0.46 (<.01)	0.3 (0.04)	0.61 (<.0001)
	Bowel Function	0.42 (<.01)	0.93 (<.0001)	0.16 (0.29)	0.35 (0.01)
	Bowel Bother	0.55 (<.0001)	0.96 (<.0001)	0.13 (0.36)	0.48 (<.001)
	Sexual Function	0.3 (0.04)	0.11 (0.45)	0.73 (<.0001)	0.23 (0.11)
	Sexual Bother	0.11 (0.46)	0.1 (0.52)	0.68 (<.0001)	0.14 (0.33)
	Hormonal Function	0.45 (<.01)	0.29 (0.04)	0.22 (0.14)	0.91 (<.0001)
	Hormonal Bother	0.5 (<.001)	0.52 (<.001)	0.28 (0.06)	0.9 (<.0001)
Retest					
	Urinary Function	0.86 (<.0001)	0.38 (0.01)	0.06 (0.68)	0.48 (<.001)
	Urinary Bother	0.93 (<.0001)	0.56 (<.0001)	0.27 (0.06)	0.5 (<.001)
	Urinary Incontinence	0.85 (<.0001)	0.38 (0.01)	0.04 (0.78)	0.3 (0.03)
	Urinary Irritation	0.87 (<.0001)	0.52 (<.001)	0.29 (0.04)	0.68 (<.0001)
	Bowel Function	0.46 (<.001)	0.93 (<.0001)	0.04 (0.81)	0.36 (0.01)
	Bowel Bother	0.55 (<.0001)	0.97 (<.0001)	0.05 (0.74)	0.5 (<.001)
	Sexual Function	0.24 (0.09)	0.13 (0.37)	0.69 (<.0001)	0.25 (0.08)
	Sexual Bother	0.05 (0.73)	-0.07 (0.64)	0.7 (<.0001)	0.06 (0.68)
	Hormonal Function	0.49 (<.001)	0.37 (0.01)	0.21 (0.15)	0.91 (<.0001)
	Hormonal Bother	0.5 (<.001)	0.47 (<.001)	0.19 (0.19)	0.89 (<.0001)

correlations, ranged from 0.74 to 0.92. The distribution of scores for domains and subscales were comparable in initial test and retest with no significant difference between test and retest distributions. EORTC QLQ-c30 Pearson r between test and retest scores ranged from 0.61 to 0.90, where the Emotional Functioning subscale test and retest values were significantly different.

Table 3 summarizes the Cronbach's alpha for domains and subscales for both test and retest measures. The range for all Domains and Subscales was between 0.54 and 0.94, with Urinary Function lowest and Sexual Function highest in both test and retest.

Pearson correlation coefficients (r) between EPIC's four domains and domains and subscales are summarized in Tables 4 and 5. The inter-domain correlations (Table 4) among different domains were highest between urinary and bowel domains (r = 0.56), and urinary and hormone domains (r = 0.52). Otherwise, all the other correlations were lower.

Individual subscales (Table 5) have high correlations with their own domain (r ranges from 0.68 to 0.97, $p < 0.0001$) and lower correlations with the other domains. Hormone domain correlated strongest with EORTC QLQ-c30 subscales Emotional Functioning with r =0.75 and $p < 0.001$, which demonstrate convergent validity.

Discussion

The initial translation in this current study was overall straightforward, although some changes were needed due to syntax and limitation and difference on vocabularies due to language differences.

Cultural adaptation has highlighted potential problems. Participants showed preference towards more descriptive and specific responses towards question. Similar to the Chinese population in our previous study, "hot flashes" and "breast" were unfamiliar terms for our participants. A description of "hot flashes" was interpreted as a female only phenomenon that should not happen to men. Describing "hot flashes" as a side effect for anti-androgen therapy was needed to help participants understand the terminology. Similarly, "breast" was regarded as a female-only body part and a less specific description as a general chest area was needed. In other words, unless patients have experienced hot flashes and gynecomastia from androgen deprivation therapy, they might not be able to comprehend questions 26 and 27 in the Hormonal Domain correctly.

Our validation phase has shown good test-retest reliability in all domains and subscale. The overall test-retest reliability of EPIC is also comparable if not better than the previously validated EORTC QLQ-c30.

Internal consistency was assessed by Cronbach's alpha with value higher than 0.7 considered to be very good. The individual domains and majority of the subscales have excellent internal consistencies except for Urinary Function, Urinary Irritation, Bowel Function, and Hormone Function. All of the domains and the majority of the subscales within the Punjabi version of EPIC

showed high correlations between each domain and its subscales and weaker correlations between subscales from other domains, both of which are relevant features. EORTC QLQ-c30 Emotional Function showed the strongest correlations with Hormone domain. Because hormone therapy has the widest range of side effects from cognitive function to overall well-being, this correlation pattern provides a good level of convergent validity. Therefore, this Punjabi Version of EPIC shows good level of validation (Appendix 1).

In conclusions, our current study has followed a strict methodology including forward and back translations, cultural adaptation, and validation. The resulting Punjabi version of EPIC can be used as a validated tool for clinical and research purposes.

Clinicians can use this tool in monitoring treatment side effects for Punjabi-speaking PCa patients, before and after their PCa treatment. Usage of the Punjabi version of EPIC should also be considered when developing new treatment techniques in Punjabi-speaking populations to monitor and report side effect profiles. Lastly, using EPIC as a baseline assessment may help patients understand potential treatment side effects and facilitate treatment decisions.

Author Contribution Statement

All authors contributed equally in this study.

Acknowledgements

This study was funded by AbbVie Canadian Association of Radiation Oncology Uro-Oncologic Radiation Award. The study protocol has been reviewed and approved by Research Ethics Board of University of British Columbia, Canada. All the listed authors were involved in the design, translation, recruitment, data analysis, and manuscript preparation. Ms. Gurpreet Oshan has helped with Punjabi version generation and communication with participant. There was no conflict of interest. Dr. Narendra Kumar has helped with recruitment.

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