Validation of the French-Canadian version of the Expanded Prostate Cancer Index Composite (EPIC) in a French-Canadian population

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Abstract

Introduction: This study aims to empirically validate the French-Canadian version of the Expanded Prostate Cancer Index Composite (EPIC), a measure of health-related quality of life for prostate cancer patients.

Methods: 251 participants completed a battery of self-report scales including the French-Canadian version of the EPIC, after having received radiation therapy or radical prostatectomy for prostate cancer.

Results: The internal consistency for the urinary incontinence, bowel, and sexual domains of the EPIC-26 was high (Cronbach's alpha coefficients from .80 to .92), while coefficients for the urinary irritation/obstruction (.59) and hormonal (.67) domains were lower. Item-total correlations (rs=.15 to .85), and temporal stability (rs=.72 to .93) generally supported the reliability of the instrument. The 5-factor structure of the EPIC-26 was confirmed for the most part. The construct validity of the instrument was also supported by high correlations obtained between each domain and measures assessing similar constructs (rs=-.56 to .83). The EPIC also showed an excellent sensitivity to change with significant differences obtained on EPIC scores (all ps<.05) between pre- and post-prostate cancer treatment.

Conclusions: The psychometric qualities of the French-Canadian version of the EPIC are well supported, thus providing a valid tool to assess HRQOL in prostate cancer patients.

Introduction

Prostate cancer is the most common cancer in North-American men. Approximately 180,890 cases will be diagnosed in 2016 in the USA.[1] While some low-risk patients may be put on active surveillance programs, intermediate and high-risk prostate cancer usually requires treatment. Several options are available including radical prostatectomy, external beam radiation therapy and brachytherapy. While these treatment modalities have demonstrated their efficacy in treating prostate cancer, they are associated with some toxicity and long-term side-effects.[2-4] Health-related quality of life (HRQOL) is an important parameter of treatment success and is now typically assessed in standard practices.[5] It is also an important aspect to take into account when helping patients choose the most appropriate treatment option for their condition.

The *Expanded Prostate Cancer Index Composite* (EPIC), a self-report scale, was designed to measure HRQOL specifically among prostate cancer patients.[6] The original English version is composed of 50 questions encompassing 4 domains (urinary, bowel, sexual, and hormonal). Function and bother are assessed with different items within each domain, and the urinary domain comprises two additional subscales: incontinence and irritation/obstruction. Domain-specific standardized scores range from 0 to 100, a higher score indicating a better perceived quality of life. High Cronbach's alpha coefficients (>.82, a measure of internal consistency ranging from 0 to 1) and a very good test-retest reliability (rs>.80) were found for all domains. The EPIC-50 also has demonstrated an adequate validity with instruments assessing similar content (convergent validity) and other instruments assessing physical symptoms that are not specific to prostate cancer (divergent validity).[6] In addition, this evaluation tool has been found to be sensitive to change following prostate cancer treatment.[7]

A shorter 26-item version (EPIC-26) was developed to facilitate its use in a wide range of prostate cancer research and practice settings. The EPIC-26 is highly correlated with the full questionnaire (rs>.96 for all domains).[8] This abbreviated version comprises five domains rather than four: urinary incontinence, urinary irritation/obstruction, bowel, sexual, and vitality/hormonal. The EPIC-26 has shown high internal consistency (Cronbach's alpha=.70-.90) and test-retest reliability at 2-4 week intervals (rs=.69-.90 for all 5 domains). Moderate to strong correlations were found between the sexual domain and the Sexual Health Inventory for Men and between the urinary domain and the Incontinence Symptom Index, thus supporting its convergent validity.[9]

Two systematic comparisons of available instruments supported the use of the EPIC for the assessment of prostate-cancer specific HRQOL.[10,11] The EPIC has been validated in several languages (i.e., Norwegian, Spanish, Korean).[12-14] A French version is available, but only the EPIC-50 was validated.[15] Validating the short version is critical as this is the version most likely to be used in clinical contexts, as well as in randomized controlled trials. Also, given significant cross-cultural language differences between French people and French-Canadians, a French-Canadian validation of the EPIC was needed.

This study aimed to translate the EPIC into French, as well as to assess its psychometric properties among a clinical sample of French-Canadian prostate cancer patients. For purposes of

parsimony, only the results pertaining to the EPIC-26 will be described as this is the format typically used in clinics, although validation analyses were performed for both formats (see Appendix for results pertaining to the EPIC-50).

Methods

Language equivalence

An initial in-house French version of the EPIC-26 was developed and used for many years in the radiation oncology department of CHU de Québec-Université Laval. To verify its quality, this version was sent to two professional English–French translators whose native language is French, following recommendations by Haccoun.[16] Both translators assessed whether each of the items and response choices was correctly translated, and suggested an alternative wording when needed. Based on the translators' suggestions, these items were then reformulated by our research team (JS, EV, MHS). Translators were also asked to translate into French the 24 additional items of the EPIC-50. One of the two proposed French versions of each item or a version combining the two proposed formulations was retained.

Next, English and French versions of all items were sent to two different English-French translators whose native language is French (Canadian) to assess to what extent each item was correctly translated. The same strategy as described above was used to reach a single translation.

Pilot study

This preliminary French version of the EPIC-50 was tested among a sample of 10 prostate cancer patients. Participants were recruited during a medical appointment at the radiation oncology department of CHU de Québec-Université Laval by a research assistant. Patients were eligible when they were scheduled to receive or were currently receiving radiation therapy. Patients provided informed consent prior to their participation. They were asked to complete the EPIC while verbalizing out loud any comment about the clarity of the items or the response choices to the research assistant who was noted down their comments.

Only the French translation of "dribbling/dripping", used in one question and two response choices, was noted as lacking clarity by three participants, and was therefore slightly modified to yield the final version.

Empirical validation

Participants

French-Canadian prostate cancer patients were recruited at the radiation oncology and the uro-oncology departments of CHU de Québec-Université Laval from March 2014 to January 2015. Patients were solicited in person by a research nurse during a medical appointment at the clinic.

Inclusion criteria: (a) having received radiation treatments (external beam radiation therapy or brachytherapy) and/or a radical prostatectomy (RP) for prostate cancer in the past OR to be scheduled to receive radiation treatments (for sensitivity to change analyses only); (b) having a life expectancy > 1 year; and (c) to be readily able to read and understand French. This study was

approved by the research ethics board of the CHU de Québec-Université Laval and patients provided informed consent prior to their participation.

Measures

All of the following measures were validated in French or official French versions were used.

International Prostate Symptom Score (IPSS).[17,18] This 7-item questionnaire assesses irritative/obstructive urinary prostate symptoms. Items are scored on a scale ranging from 0 ("never") to 5 ("almost always"). The total score ranges from 0 to 35, a lower score indicating a better functioning.

Sexual Health Inventory for Men (SHIM).[19] This questionnaire is an abbreviated 5-item version of the 15-item International Index of Erectile Function.[20] It assesses erectile function and intercourse satisfaction. Scores range from 1 to 5 (item 1) or from 0 to 5 (items 2-5), with a total score ranging from 1 to 25. Higher values indicate a better sexual functioning.

European Organization for Research and Treatment of Cancer Quality of Life Questionnaire – Prostate Cancer-Specific Module (PR25).[21] This 25-item questionnaire assesses HRQOL of prostate cancer patients over the past week (20 items) or the last 4 weeks (5 items). It comprises two functional scales (sexual activity and sexual functioning) and four symptom scales (urinary, bowel, hormonal treatment-related, incontinence aid). Items are scored on a Likert scale ranging from 1 ("not at all") to 4 ("very much"). Standardized scores range from 0 to 100, a higher score indicating a better (functioning scales) or worse (symptom scales) quality of life.

Procedure

Participants taking part in the sensitivity to change study (*n*=51) were asked by the research nurse to complete the EPIC-50 along with the other self-report scales at their initial consultation, prior to receiving radiation therapy, and to fill out the EPIC-50 a second time during a follow-up visit at the hospital, approximately 3 months after their treatment ended (*M*=98.2 days; range=59–163 days).

The remaining participants (*n*=200) completed the same battery of questionnaires at a follow-up appointment with their radiation oncologist or surgical urologist. A subgroup of these participants (*n*=75) was randomly selected to fill out the EPIC-50 on a second occasion, 2 weeks later, for test-retest reliability analyses. The randomization sequence was prepared by a biostatistician and the allocation sequence was concealed in opaque, sealed envelopes, numbered in advance and opened sequentially. All research personnel were blind to the group allocation sequence. These randomly selected participants were given a copy of the EPIC-50 to take home and were instructed to complete it 2 weeks later and to return it by mail. Participants who did not return the questionnaire within 4 weeks were contacted by phone to remind them to complete and return it as soon as possible. A total of 68 participants returned the second questionnaire (median interval=21 days; range=7-41).

Statistical analyses

All data were double-entered and missing data, outliers, and distributions were examined using standard procedures.[22] No data imputation was performed and the alpha level was set at 5%, two-tailed. All analyses were conducted on both the full (EPIC-50) and the abbreviated (EPIC-26) scales using the SAS 9.3 software (2012, SAS Institute, Cary, NC, USA). EPIC-26 items were extracted from the 50-item version as the items are the same. All results pertaining to the EPIC-26, the version most likely to be used in clinical and research settings, are discussed in this article. Detailed results about the 50-item version can be found in the Appendix.

    Reliability (internal consistency). The Cronbach alpha coefficient[23] and item-total correlations were calculated for each EPIC domain using the full sample (*N*=251). An alpha > .80 and item-total correlations > .30 (moderate association[24]) were used to indicate an acceptable internal consistency.

    Test-retest reliability. Correlations were computed between EPIC scores obtained on each domain on two different occasions, separated by a 2-4 week interval. In addition, scores between the two administrations were compared using linear mixed models with one time factor (two levels). A large correlation between the two time points (r>.50[24]) and a non-significant *F* test were the criteria used to support the EPIC temporal stability.

    Construct validity (factor analysis). A confirmatory factor analysis using SAS PROC CALIS (structural equation modeling) was performed using the full sample (*N*=251) in order to verify the reproducibility of the factor structure of the EPIC-26 (5 domains: urinary incontinence, urinary irritation/obstruction, bowel, sexual, and vitality/hormonal symptoms) and the EPIC-50 (4 domains: urinary, bowel, sexual, hormonal). Various indices were examined to ensure an acceptable goodness of fit with the factorial structure of the original English version.

    Convergent and divergent validity. The convergent validity of each domain of the EPIC-26 and EPIC-50 was evaluated by assessing its relationship with other measures of similar constructs: the IPSS for the urinary irritation/obstruction domain; the SHIM for the sexual domain; and the PR25 for the other three domains (urinary incontinence, bowel, and vitality/hormonal domains). The divergent validity was evaluated by examining associations with different constructs, using the same questionnaires as for the convergent validity assessment (cross-correlations; e.g., between the urinary incontinence domain of the EPIC and the SHIM which assesses sexual symptoms). Lower (or non-significant) Pearson correlations were expected as compared to convergent validity correlations.

    Sensitivity to change. In order to assess the capacity of the EPIC to detect changes in symptoms following treatment, 51 patients were asked to complete the EPIC-50 prior to the initiation of radiotherapy and approximately 12 weeks following its termination. A linear mixed model analysis with repeated measures was conducted. The presence of significant differences between pre- and post-treatment assessments on each domain was expected.

Results

Participant characteristics
A total of 251 prostate cancer patients were included. Of these, 51 participated in the sensitivity to change study, whereas 68 other men were randomly selected to participate in the study's test-retest component.

Participants were between 46 and 89 years old (*M*=68.7; *SD*=7.39). The majority were married/cohabiting (73.3%) and retired from work (73.4%). Forty percent of the sample had a personal annual income lower than $40,000 CAN. Thirty-four percent (*n*=86) of the total sample were treated with a combination of external beam radiotherapy and brachytherapy, 18% (*n*=46) with radiotherapy only, 16% (*n*=39) with brachytherapy only, while 21% (*n*=53) received a combination of RP and radiotherapy, and the remaining 11% (*n*=27) had RP only. Similar proportions were found in the sample that participated in the test-retest substudy (36.0% radiotherapy and brachytherapy; 13.3% radiotherapy only; 18.7% brachytherapy only; 18.7% RP and radiotherapy; 13.3% RP only). Among the total sample, 46.2% of participants (n=116) received hormone therapy (current use: 21.6%). The median time since the initial cancer diagnosis was 34.6 months (range=0.3 to 320 months), and median time since the end of treatment was 35 months (range=1 to 233 months). Fifteen percent of the participants had had a prostate cancer recurrence before their study participation.

Descriptive statistics
Table 1 shows the descriptive statistics for each EPIC-26 domain. Mean scores ranged from 34.9 for the sexual function subscale to 92.4 for the bowel bother subscale, a higher score indicating a better functioning (see Table S1 for EPIC-50).
Reliability
Internal consistency. Table 1 also shows the Cronbach's alpha coefficients and item-total correlations obtained for each EPIC-26 domain (see Table S1 for EPIC-50). Coefficients obtained for the urinary incontinence, bowel, and sexual domains were high (from .84 to .92), while coefficients for the urinary irritation/obstruction (.59) and hormonal (.67) domains were lower. Items with the lowest item-total correlations were #4c (hematuria; r=.15), #6d (bloody stools; r=.33), #12 (overall sexuality problem; r=.31), and #13b (breast problems; r=.11).

Test-retest reliability. Large correlations were found between EPIC-26 mean scores obtained at the first assessment and 2-4 weeks later (rs ranging from .72 to .93) and no significant differences were found between the two administrations (all ps>.40; see Table 2 [and Table S2 for EPIC-50]).

Construct validity
Confirmatory factor analysis. A structural equation model with five latent variables (the five postulated factors of the original EPIC-26) and all 10 pairwise covariances between the five latent variables was estimated using the maximum likelihood method. An adequate fit with the empirical variance-covariance matrix of the 26 items was found, X^2(*N*=251, *df*=284)=560.03,

p<.001, chi-square/df ratio=1.97, Standardized Root Mean Square Residuals (SRMSR)=0.069, Bentler Comparative Fit Index (CFI)=0.919, Normed Fit Index=0.850. Correlations obtained between latent factors ranged from .23 to .48, with stronger correlations found between urinary incontinence and urinary irritation/obstruction scales, r=.69, and between bowel and hormonal scales, r=.51 (see standardized loadings in Table 3). Only two items were weakly associated (B<.30) with their postulated factor: item #4c of the urinary irritation/obstruction scale (hematuria), B=0.201, and item #13b of the hormonal scale (breast problems), B=0.155.

For the EPIC-50, a structural equation model with four latent variables and all 6 pairwise covariances between the latent variables was estimated. A poor fit with the empirical variance-covariance matrix of the 50 items was found, X^2(*N*=251, *df*=1165)=4538.6, p<.001, chi-square/df ratio=3.90, Standardized Root Mean Square Residuals (SRMSR)=0.099, Bentler Comparative Fit Index (CFI)=0.582, Normed Fit Index=0.512. Seven items were weakly associated with their postulated factor: items #2 (B=.26), #3 (B=.27), and #8 (B=.28) of the urinary scales, item #18 (.23) of the bowel scale, and items #41 (B=.24), #44 (B=.25) and #46 (B=.20) of the hormonal scale (see Table S3).

Convergent and divergent validity. As seen in Table 4 (Table S4 for EPIC-50), the correlations obtained between scores on EPIC-26 domains and those found on questionnaires measuring similar constructs were high (*r*s between .56 and .83, all *p*s<.05). In contrast, the correlations obtained with questionnaires/subscales measuring different constructs were consistently weaker. For instance, the correlation obtained between the EPIC-26 sexual domain and the urinary, bowel, and hormonal subscales of the IPSS or the PR25 were lower (*r*s between -.19 and .36) than with the SHIM or the PR25 sexual subscales (*r*s between .63 and .83).
Sensitivity to Change

As shown in Table 2 (Table S2 for EPIC-50), scores obtained on each EPIC-26 domain significantly decreased after radiotherapy treatment (all *p*s<.01), suggesting a worsening of HRQOL.

Discussion

The objective of this study was to validate empirically the French-Canadian version of the EPIC. Overall, the psychometric properties found in this study are similar to those of the original English version.[6,8] Hence, results suggest that this French version is a reliable and valid instrument for assessing prostate cancer-related symptoms.

Test-retest correlations at an interval of 2 to 4 weeks were high across all domains, suggesting an excellent reliability. Cronbach's alpha coefficients for the urinary incontinence, bowel, and sexual domains were high, whereas they were lower for the urinary irritation/obstruction and hormonal domains, suggesting weaker internal consistency for these two scales. These lower coefficients seem to be due to two more problematic items, that is hematuria (urinary – irritation/obstruction) and breast problems (hormonal) which seem to assess different constructs than their respective domain. They were also not frequently reported in our sample.

The 5-factor structure of the original EPIC-26 was in large part confirmed,[8] with the same two items being weakly correlated with their postulated factor (hematuria and breast problems). The 4-factor structure of the EPIC-50 was less sound with poor fit indices and seven items that loaded less strongly with their respective factor. These include three items in the urinary domain (two hematuria items and one dysuria item), one in the intestinal domain (bowel movements frequency) and three in the hormonal domain, the latest being the least strongly loaded with their postulated factor. It is interesting to note that these findings are consistent with those of Anota et al.[15] who, although they did not perform a confirmatory factor analysis, found that the hormonal domain of their French version presented a poor construct validity overall. Similarly, the authors of the Korean version of the EPIC-50 also observed some disparity in the factorial structure of this subscale.[14] Together, these findings question the composition of the hormonal subscale.

The convergent validity of the EPIC was also well supported. Indeed, for each of the five domains of the EPIC-26, the highest correlations (all>.55) were found with instruments measuring similar constructs, whereas lower correlations (all<.55) were consistently found with instruments measuring different constructs. Clearly, the French version of the EPIC accurately measures distinct domains that are relevant to prostate cancer-related quality of life.

Moreover, the French-Canadian version of the EPIC proved to be sensitive to clinical changes associated with prostate cancer treatment. All domain scores significantly decreased following radiotherapy, which is consistent with the bulk of evidence published on this instrument showing its good sensitivity.[25] Also, the magnitude of the differences observed between pre- and post-treatment data were all above the thresholds for a clinically relevant change (Minimally Important Difference) proposed by Skolarus et al. for this instrument.[26] This indicates that the French-Canadian version of the EPIC can be routinely used in clinics to track changes in patient-reported HRQOL associated with prostate cancer treatment.

The large sample size is a strength of this study, as well as the assessment of the translation quality and of various psychometric properties using rigorous and recognized procedures. On the other hand, no information was available on the number of patients who were approached in each clinic to document the participation rate, thus questioning the representativeness of the sample. Our sample, which received a variety of treatments alone and in combination, was fairly representative of the population of prostate cancer patients although recruiting a fully representative sample is a challenge in the context of this cancer. However, a representative sample is not critical to study the psychometric properties of an instrument, since correlations between items, and thus the internal structure of the instrument, are not expected to vary according to medical treatment options. Besides, the fact that EPIC scores significantly deteriorated after radiation therapy, a treatment usually associated with less sudden side effects than RP, provides convincing evidence of its sensitivity to clinical change.

Conclusion

The French-Canadian version of the EPIC, particularly its short-form (EPIC-26), is a reliable and valid measure of HRQOL in prostate cancer patients and can be used for both clinical and research purposes. The availability of this instrument in French will facilitate the

assessment and management of patient-reported outcomes in francophone clinics and research settings.

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Figures and Tables

Table 1. Descriptive statistics obtained on the EPIC-26 and results of internal consistency analyses (n=251)							
Domains	n	Mean score (T1)	SD	Median	Range	Cronbach's alpha	Range $r_{(tot)}$
Urinary incontinence	241	86.39	21.84	100.00	0–100	0.889	0.74–0.84
Urinary irritation/ obstruction	241	87.42	13.97	93.75	12.5–100	0.594	0.15–0.51
Urinary overall problem	250	78.60	27.02	87.50	0–100	NA	NA
Bowel	245	92.38	12.86	100.00	0–100	0.837	0.33–0.77
Sexual	246	34.87	28.77	25.00	20.83–100	0.887	0.31–0.85
Hormonal	246	89.92	14.10	95.00	0–100	0.670	0.11–0.74

EPIC: Expanded Prostate Cancer Index Composite; $r_{(tot)}$: item-total correlations; NA: not applicable (only one item).

Table 2. Results of test-retest and sensitivity to change analyses				
Domains	Mean score (T1)	Mean score (T2)	F-test	r (T1 vs. T2)
Test/re-test analyses (n=68)				
Urinary incontinence	84.42	84.63	0.04, p=0.83	0.93
Urinary irritation/obstruction	87.31	86.47	0.69, p=0.41	0.78
Urinary overall problem	77.76	78.55	0.11, p=0.74	0.72
Bowel	92.02	92.61	0.50, p=0.48	0.86
Sexual	30.76	30.46	0.06, p=0.81	0.92
Hormonal	89.63	89.70	0.00, p=0.95	0.75
Sensitivity to change analyses (n=51)				
Urinary incontinence	95.10	88.19	6.77, p=0.010	0.46
Urinary irritation/obstruction	87.93	81.59	8.21, p=0.006	0.45
Urinary overall problem	81.86	69.61	9.46, p=0.003	0.46
Bowel	94.00	86.54	11.48, p=0.001	0.33
Sexual	50.58	29.92	25.59, p<0.001	0.47
Hormonal	91.20	82.29	19.70, p<0.001	0.52

Table 3. Confirmatory factor structure of EPIC-26			
Item	**#item EPIC-50**	**#item EPIC-26**	**Standard loading**
URINARY – incontinence			
Leaking >1 time per day	1	1	0.855
Frequent dribbling	4	2	0.825
Any pad use	5	3	0.764
Leaking problem	6	4a	0.938
URINARY – irritation/obstruction			
Dysuria	7	4b	0.491
Hematuria	8	4c	0.201
Weak stream	9	4d	0.559
Frequency	11	4e	0.717
OVERALL urinary problem	12	5	0.928
BOWEL			
Urgency	20	6a	0.864
Frequency	21	6b	0.760
Fecal incontinence	23	6c	0.697
Bloody stools	24	6d	0.357
Rectal pain	25	6e	0.558
Overall bowel problem	26	7	0.810
SEXUAL			
Poor erections	28	8a	0.912
Difficulty with orgasm	29	8b	0.847
Erections not firm	30	9	0.838
Erections not reliable	31	10	0.908
Poor sexual function	35	11	0.818
Overall sexuality problem	39	12	0.326
HORMONAL			
Hot flashes	45	13a	0.479
Breast problems	46	13b	0.155
Depression	48	13c	0.685
Lack of energy	49	13d	0.938
Weight change	50	13e	0.448

All loadings were significant at $p < 0.05$.

Table 4. Correlations between domains of EPIC-26, IPSS, SHIM, and PR25									
Domain	**IPSS total (n=206)**	**IPSS QoL (n=203)**	**SHIM (n=203)**	**PR25-SAC[f] (n=199)**	**PR25-SFU[f] (n=117)**	**PR25-URI[s] (n=204)**	**PR25-BOW[s] (n=200)**	**PR25-HTR[s] (n=204)**	**PR25-AID[s] (n=40)**
Urinary incontinence	-0.44	-0.39	0.27	0.16	0.27	**-0.65**	-0.34	-0.28	**-0.70**
Urinary irritation/ obstruction	**-0.76**	**-0.56**	0.21	0.17	0.25	**-0.71**	-0.38	-0.31	-0.31 NS
Urinary overall problem	**-0.68**	**-0.61**	0.24	0.19	0.30	**-0.78**	-0.26	-0.25	**-0.71**
Bowel	-0.52	-0.35	0.18	0.14	0.26	-0.49	**-0.65**	-0.37	-0.30 NS
Sexual	-0.21	-0.34	**0.83**	**0.63**	**0.72**	-0.34	-0.25	-0.36	-0.19 NS
Hormonal	-0.47	-0.34	0.24	0.19	0.35	-0.45	-0.56	**-0.62**	-0.37

EPIC: Expanded Prostate Cancer Index Composite; IPSS: International Prostate Symptom Score; SHIM: Sexual Health Inventory for Men; PR25: Prostate cancer-specific module of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire; SAC[f]: sexual activity (functioning scale); SFU[f]: sexual functioning (functioning scale); URI[s]: urinary (symptom scale); BOW[s]: bowel (symptom scale); HTR[s]: hormonal treatment-related (symptom scale); AID[s]: incontinence aid (symptom scale). Correlations used for convergent validity are in bold. All correlations are significant at p<0.05 unless otherwise specified.