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Original Article

Reliability, validity, and sensitivity testing of the expanded prostate index composite—Filipino version

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ABSTRACT

Objectives: The expanded prostate index composite (EPIC) is a widely used and well-validated quality of life (QOL) tool for prostate cancer patients. We developed a filipino version (EPIC-F) and tested its psychometric properties.

Material and Methods: The EPIC-F and validated filipino versions of the international prostate symptoms score (IPSS), international index of erectile function-5 (IIEF-5), and european organisation for research and treatment of cancer (EORTC) prostate cancer module (PR-25) were administered to patients with nonmetastatic prostate cancer at baseline, 10–14 days later and after ≥15 radiotherapy (RT) sessions. Cronbach's α, pearson correlation, and linear regression were used for reliability, validity, and sensitivity analyses. Alpha was set at $p < 0.05$.

Results: The validation cohort comprised 52 patients aged 54–86 years (70.10 ± 6.9), with stage I (21%), II (27%), III (33%), or IVA (19%) disease. At enrolment, 38% had prior surgery; 19% had prior RT and 81% were to undergo RT; and 31% were on hormonotherapy. Internal consistency was good to very good for all domains (*Cronbach's* α, 0.783–0.866). Test-retest reliability was moderate for all domains (Pearson's r, 0.509–0.688), except for the hormonal domain (low r, 0.369). Interscale correlation was moderate to high between each domain and its corresponding reference scale (*r*, 0.551–0.834), except between the bowel domain and the PR-25 bowel (low r, 0.457). Sensitivity testing showed a strong r^2 (0.311) for the bowel domain, but weak for the rest.

Conclusion: The EPIC-F is a reliable, valid, and sensitive tool for assessing the QOL of filipino prostate cancer patients.

Keywords: Prostate cancer, Quality of life, Validity, Reliability, Sensitivity

INTRODUCTION

Quality of life (QOL) preservation is paramount in decision-making in prostate cancer management, whether it is about local or systemic therapies.[1,2] QOL among prostate cancer patients encompasses sexual and hormonal domains, which patients may find too intimate a subject during routine follow-up visits.[3] A QOL questionnaire may facilitate screening and serial evaluation while limiting patient burden.

Among the QOL tools developed and validated for prostate cancer, the expanded prostate index composite (EPIC) is the most used. The original tool consists of 50 items (EPIC-50) that assessed function and bother in the urinary, bowel, sexual, and hormonal domains.[4] The urinary domain comprised incontinence and irritation/obstruction subscales. The tool has good reliability (Cronbach's $\alpha \geq 0.82$), test-retest reliability ($r \geq 0.80$ for every domain), convergent and divergent validity, and sensitivity to change. The most recent, shorter version consists of 32 items (EPIC-32) that evaluates the same domains and include one question on overall satisfaction with treatment received.[5]

We had previously developed a filipino version of the EPIC-32[6] and described its linguistic validation and usability among a pilot cohort of filipino prostate cancer patients with diverse demographic and clinical profiles.[7] We now report its psychometric properties based on testing among filipino prostate cancer patients seen at a radiotherapy (RT) center.

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MATERIAL AND METHODS

Ethics approval and informed consent

This study was reviewed and approved by the university of santo tomas hospital—research ethics committee (REC-2021-06-085-MD). Informed consent was obtained from all individual participants included in the study.

Subject eligibility and recruitment

From march 2022 to october 2023, we consecutively recruited filipino prostate cancer patients through the urology and radiation oncology departments of the university of santo tomas hospital. Eligible patients had a clinical or histologic diagnosis of prostate cancer, had nonmetastatic disease (regional nodal metastasis or Stage IVA was allowed), and were able to read and understand grade 6-level filipino and english.

For ethical reasons, given the content of the instruments and the burden of accomplishing the questionnaires, only patients with karnofsky performance status ≥60 and a life expectancy of ≥1 year were recruited. Patients with cognitive or mood disturbances due to a psychiatric or medical condition were precluded from either giving valid consent or responding validly to the QOL questionnaires.

For the sensitivity to change testing, patients who were referred for and proceeded to undergo definitive or adjuvant RT at the center were included. Per institutional protocol, definitive RT would be given as a moderately hypofractionated regimen (70 Gray over 28 fractions), while adjuvant RT as a normofractionated regimen (64–66 Gray over 32–33 fractions), both given using intensity-modulated techniques. Patients who would undergo brachytherapy boost before external RT were excluded from the sensitivity testing.

Baseline demographic and clinical data collection

Each consenting participant completed a demographic and disease information sheet. The following demographic information was collected: age, marital status, educational attainment, religion, and employment. The following disease information was collected: stage of disease, date of diagnosis, previous treatment, concomitant medications, smoking history, and medical comorbidities.

Quality of life assessment

The clinician determined the karnofsky performance status (KPS) based on the clinical interview and examination at baseline or on follow-up.

Participants accomplished the filipino version of the expanded prostate cancer index composite (EPIC-F) along with validated filipino version of the following QOL instruments:

1. *International Prostate Symptom Score* (IPSS).[8] This seven-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, with a lower score indicating better functioning.
2. *International Index of Erectile Function-5* (IIEF-5).[3,9] This questionnaire is an abbreviated five-item version of the 15-item international index of erectile function. It assesses erectile function and intercourse satisfaction. Scores range from 1 to 5, with a total score ranging from 5 to 25. Higher values indicate better sexual functioning.
3. *European Organization for Research and Treatment of Cancer Quality of Life Questionnaire—Prostate Cancer-Specific Module* (PR-25).[10] This 25-item questionnaire assesses health-related QOL (HRQOL) of prostate cancer patients over the past week (20 items) or the last four weeks (five items). It comprises two functional scales (sexual activity and sexual functioning) and four symptom scales (urinary, bowel, hormonal treatment-related, and 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) QOL.

The above instruments were administered during the initial encounter (baseline) and 10–14 days later (retest); no exposure or intervention that was expected to significantly impact QOL was to be given or started during this interval. Participants that were eligible for the sensitivity testing were asked to accomplish the above for a third time, after ≥15 sessions of RT.

Sample size calculation

In determining the sample size for the study, we considered the reliability and validity testing of the 32-item EPIC-F. Previous EPIC assessments have shown internal consistency in the range of 0.70–0.90.[4,11] To evaluate the internal consistency of the 32-item EPIC-F, we set null (CA0) and expected (CA1) Cronbach's α values at 0.60 (indicating poor internal consistency) and 0.80 (indicating expected internal consistency), respectively, while maintaining an alpha value of 0.05. To achieve a statistical power of 80%, a minimum sample size of 36 was needed.[12]

Psychometric testing

The following parameters were evaluated using jamovi (Version 2.3.28.0): internal consistency, test-retest reliability, construct validity, convergent and divergent validity, and sensitivity to change. Missing data, outliers, and distributions were examined using standard procedures.[13] No data imputation was performed, and the alpha level was set at 5%, two-tailed.

1. *Internal Consistency*. Using the full sample, Cronbach's α coefficient was calculated for each EPIC-F domain. An α > 0.70 would indicate acceptable internal consistency.[14]
2. *Test-retest reliability*. Correlations were computed between EPIC-F scores obtained on each domain on two different occasions, separated by 10–14-day intervals. In addition, scores between the two administrations were compared using linear mixed models with a one-time factor (two levels). A large significant correlation between the two time points (r > 0.5024) would indicate temporal stability.
3. *Convergent validity*. The convergent validity of each domain of the EPIC-26 was evaluated by assessing its relationship with other measures of similar constructs: IPSS for the urinary irritation/obstruction domain; IIEF for the sexual domain; and PR-25 for the other three domains (urinary incontinence, bowel, and vitality/hormonal domains).
4. *Divergent validity*. 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 EPIC and IIEF, which assesses sexual symptoms). Lower (or nonsignificant) Pearson correlations were expected compared to convergent validity correlations.
5. *Sensitivity to change*. To assess the capacity of the EPIC to detect changes in symptoms following treatment, the baseline, and after ≥15 sessions of RT were compared using a linear mixed model analysis with repeated measures to detect the presence of significant differences in each domain.

Table 1: Baseline characteristics of the validation cohort (n = 52).

	n (%)
Demographic variables	
Age (mean ± SD)	70.10 ± 6.91
Marital Status	
• Married	45 (86.54)
• Widower or with a partner	6 (11.54)
• Cohabitation	1 (1.92)
Religion	
• Roman Catholic	48 (92.31)
• Born-Again Christian	3 (57.69)
• Iglesia ni Cristo	1 (1.92)
Educational Attainment	
• No Formal Schooling	5 (9.62)
• Primary School	4 (7.69)
• Secondary School	5 (9.62)
• Tertiary School	38 (73.08)
Occupation	
• Unemployed or Retired	44 (84.62)
• Employed or Self-Employed	8 (15.38)
Clinical Variables	
Karnofsky Performance Scale (median, IQR)	90, 80–100
Disease Stage (AJCC 8)	
• I	11 (21.15)
• II	14 (26.92)
• III	17 (32.69)
• IVA	10 (19.23)
Radical Prostatectomy (Open)	20 (38.46)
Radiotherapy	
• Never	42 (80.77)
• Completed	10 (19.23)
Hormonal Therapy	
• Never	35 (67.31)
• Ongoing	16 (30.77)
• Completed	1 (1.92)
Smoking	
• Never	25 (48.08)
• Previous Smoker (Stopped >1 year)	20 (38.46)
• Current Smoker	7 (13.46)

SD: Standard deviation, IQR: Inter-quartile range, AJCC: American joint committee on cancer

RESULTS

Baseline demographic and clinical characteristics

The validation cohort comprised 52 patients aged between 54 and 86 (mean age 70.1 ± 6.9 years). Table 1 provides a comprehensive overview of participants' baseline demographic and clinical profile.

The majority were married (86.54%), Catholic (92.31%), retired or unemployed (84.62%), or had secondary or tertiary schooling (82.70%). The median KPS was 90 with an interquartile range of 80–100, reflecting a relatively high functional cohort.

The disease stage distribution (per the american joint committee on cancer (AJCC) eighth edition) was as follows: I (21.15%), II (26.92%), III (32.69%), and IVA (19.23%). Of these, ten patients (19.23%) had no evidence of disease (NED) following previous RT (five had postoperative RT; 5 had definitive RT), while 42 (80.77%) were referred for possible RT (15 for postoperative RT and 27 for definitive RT). All postoperative cases had open radical prostatectomy. Finally, 16 patients (30.77%) were currently on hormonotherapy.

Psychometric testing

The reliability, validity, and sensitivity testing results are detailed in Tables 2 and 3.

Reliability

The EPIC-F showed very good internal consistency in the urinary (Cronbach's α = 0.866), bowel (α = 0.815), and sexual (α = 0.844) domains, and good internal consistency in the hormonal (α = 0.783) domain. It showed excellent internal consistency in the sexual function (α = 0.946) and bother (α = 0.971) subdomains, but poor internal consistency in the bowel (α = 0.573) and hormonal (α = 0.589) function subdomains.

It showed moderate test-retest reliability in the urinary (Pearson's r = 0.688), bowel (r = 0.527), and sexual (r = 0.509) domains, but low test-retest reliability in the hormonal (r = 0.369) domain.

Validity

Regarding convergent validity, the EPIC-F urinary domain showed high convergent validity with both the IPSS (r = 0.834) and the PR-25 urinary scale (r = 0.756). The EPIC-F sexual and hormonal domains showed moderate convergent validity with the IIED (r = 0.551) and the PR-25 hormonal scale (r = 0.554), respectively. However, the EPIC-F bowel domain showed low correlation with the PR-25 bowel scale (r = 0.457).

Regarding divergent validity, the EPIC-F urinary domain showed low correlation with the IIEF (r = 0.358) and the EPIC-F bowel, sexual, and hormonal domains showed negligible correlation with the IIEF (r = 0.176), and the IPSS (r = 0.166 and r = 0.294), respectively.

Table 2: Reliability properties.

Internal Consistency (n = 52)			
Domain	**Subdomain**	**Cronbach's alpha**	**Interpretation**
Urinary	Overall	0.866	Very good
	Function	0.656	Good
	Bother	0.860	Very good
	Incontinence	0.768	Good
	Irritative/ Obstructive	0.807	Very good
Bowel	Overall	0.815	Very good
	Function	0.573	Poor
	Bother	0.856	Very good
Sexual	Overall	0.844	Very good
	Function	0.946	Excellent
	Bother	0.971	Excellent
Hormonal	Overall	0.783	Good
	Function	0.589	Poor
	Bother	0.882	Very good
Test-Retest Reliability (n = 49)			
Domain		**Pearson's r (p-value)**	**Interpretation**
Urinary		0.688 (<0.001)	Moderate
Bowel		0.527 (<0.011)	Moderate
Sexual		0.509 (<0.001)	Moderate
Hormonal		0.369 (<0.001)	Low

Table 3: Validity and sensitivity properties.

Convergent Validity (n = 52)			
Domain	**Comparison**	**Pearson's r (p-value)**	**Interpretation**
Urinary	IPSS	0.834 (<0.001)	High
	PR-25 Urinary	0.756 (<0.001)	High
Bowel	PR-25 Bowel	0.457 (<0.001)	Low
Sexual	IIEF	0.551 (<0.001)	Moderate
Hormonal	PR-25 Hormonal	0.554 (<0.001)	Moderate
Divergent Validity (n = 52)			
Domain	**Comparison**	**Pearson's r (p-value)**	**Interpretation**
Urinary	IIEF	0.358	Low
Bowel	IIEF	0.176	Negligible
Sexual	IPSS	0.166	Negligible
Hormonal	IPSS	0.294	Negligible
Sensitivity to Change Analysis (n = 20)			
Domain		**r^2 (p-value)**	**Interpretation**
Urinary		0.007 (<0.001)	Weak
Bowel		0.311 (<0.001)	Strong
Sexual		0.006 (<0.001)	Weak
Hormonal		0.011 (<0.001)	Weak

IPSS: International prostate symptom score, PR-25: Prostate cancer module, IIEF: International index of erectile function

Sensitivity

The sensitivity testing included data from 20 patients between the ages of 56 and 81 (with an average age of 70.3 ± 6.50), who had stage II (30%), III (50%), and IVA (20%) cancer. Of these, 60% received definitive RT and 40% postoperative RT; 50% were receiving hormone therapy.

The analysis revealed that EPIC-F was sensitive in detecting RT-related changes in all domains. The r^2 coefficient was strong (0.311) for the bowel domain and weak for the urinary, sexual, and hormonal domains (0.006–0.011).

DISCUSSION

We previously reported the development and the usability of the EPIC-F.[7] A determination of its psychometric properties

would support its use in the clinical assessment of filipino prostate cancer patients and in research toward the evaluation and improvement of treatment options.

Our validation cohort, which consisted of patients with high KPS and nonmetastatic disease who are undergoing curative RT, aside from ethical considerations, allowed us to limit the confounding effects of the complications of metastatic disease on the reliability and stability of the measurements and minimize nonresponse in the sexual domain items of the EPIC-F and the other instruments. The relatively predictable incremental side effects during fractionated external RT allowed us to test for sensitivity to change.[15]

Overall, our results indicate that the internal consistency of the original EPIC (α = 0.70-0.90) (4,11) was conserved in each of the domain in the EPIC-F (α = 0.78-0.87). However, there was poor internal consistency for the function scales of the bowel and hormonal domains. In the validation of the original EPIC, there was a noted lower α (0.74) among nonwhites, which nevertheless indicated good internal consistency.

In the EPIC-F, the test-retest reliability for each of the domains was lower (r = 0.37-0.69) than that reported for the original (r = 0.80). This could be due to our small sample size (calculated based on hypothesis on internal consistency) and sample selection. With a small sample, the effects of repeated testing and statistical regression (or regression to the mean)[16] may be more apparent. Further, most of the participants were referred for adjuvant RT and had just been started on hormonotherapy for intermediate or high risk disease. The low test-retest reliability may reflect the evolving recovery from surgery or the beginning effects of hormonotherapy. Other psychometric studies used prostate cancer survivor cohorts,[4,10] for whom the effects of treatment may have mostly stabilized.

The convergent validity of each of the domains with related, validated scales was moderate to high (r = 0.55–0.83), except for the bowel domain which correlated poorly with the PR-25 (r = 0.47). In the original EPIC, low to moderate interscale correlations were found between each domain and nondisease-specific scales.[4] Conversely, the PR-25 bowel subscale has been shown to have poor reliability and divergent validity.[10]

The divergent validity of each domain with unrelated scales was supported by negligible to low correlation coefficients.

Finally, testing for sensitivity to change showed that the EPIC-F could detect changes during RT. The r^2 value is strong (≥0.26) for the bowel domain,[14] but those for the urinary, sexual, and hormonal domains are negligible, indicating that the related changes could not be attributed to RT. Indeed, these changes also reflect the evolving effects of the surgery or hormonotherapy and the disease symptomatology. Overall, these support the utility of EPIC-F in monitoring acute side effects of RT, and probably other treatments, in clinical trials or in clinics. The EPIC-32 bowel and urinary domains were used in the NRG radiation therapy oncology group (RTOG) 1203 study on pelvic RT in endometrial or cervical cancer;[17] the EPIC-F could be used for similar research among filipino patients.[18]

Our validation cohort was limited to patients who had undergone or were to undergo RT. While, in general, the psychometric properties of EPIC-F are satisfactory to very satisfactory, and indicate conservation of the properties of the original, some domains or subdomains showed poor internal consistency (bowel and hormonal function subdomains), low test-retest reliability (hormonal domain), or low convergent validity (bowel domain). While the latter two may reflect limitations due to testing design or choice of reference instrument, respectively, the former or all three may reflect cultural differences regarding constructs of QOL.

We therefore suggest that future studies explore additional forms of validity and reliability. A confirmatory or exploratory factor analysis, which would require a larger sample, would provide a more thorough evaluation of construct validity.

CONCLUSION

The psychometric properties of the original EPIC are conserved in the filipino version, which is therefore a reliable, valid, and sensitive tool for assessing the HRQOL among filipino prostate cancer patients. With its transcultural equivalence, the EPIC-F can be effectively utilized for clinical studies, treatment, and patient monitoring.

Ethical approval

The research/study approved by the institutional review board at university of santo tomas hospital—research ethics committee, number REC-2021-06-085-MD, dated September 13, 2021.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

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Conflicts of interest

There are no conflicts of interest.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of AI-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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