UROLOGY

The Romanian translation and validation of the Extended Prostate Cancer Index Composite in patients undergoing radical prostatectomy

Ioan-Bogdan Juravle[1,2], Elisabeta Ioana Hiriscau[3,4], Tudor Coroi[5], Bogdan-Ovidiu Feciche[6,7], Nicolae Crisan[1,8], Ioan Coman[1], Cristian-Doru Pop[9]

1) Urology Department, Iuliu Hatieganu University of Medicine and Pharmacy, Cluj-Napoca, Romania

2) Urology Department, Emergency County Hospital, Zalau, Romania

3) Nursing Department, Iuliu Hatieganu University of Medicine and Pharmacy, Cluj-Napoca, Romania

4) Intensive Care Unit, University Clinical Municipal Hospital, Cluj-Napoca, Romania

5) Urology Department, CH de Valence, Valence, France

6) Surgery Department, University of Medicine and Pharmacy, Oradea, Romania

7) Urology Department, Clinical Emergency County Hospital Bihor, Oradea, Romania

8) Urology Department, University Clinical Municipal Hospital, Cluj-Napoca, Romania

9) Clinique de Villeneuve-Saint-Georges, Villeneuve-Saint-Georges, France

Abstract

Background and aims. To evaluate the quality of life in patients treated for prostate cancer in detail, an accessible, extensive, and easy-to-administer questionnaire is needed. The self-administered 50-item "Expanded Prostate Cancer Index Composite" (EPIC) is an instrument used for this purpose, but it is not officially translated into Romanian. The aim of the study was to translate and validate the Romanian version of the EPIC.

Methods. We translated and culturally adapted the EPIC into Romanian. For validation, we included a retrospective analysis of 112 patients who underwent robotic radical prostatectomy and a prospective study including 120 consecutive patients hospitalized before surgical treatment. Baseline and follow-up assessments took place before and at six months, two, and five years post-surgery, between January 2014 and December 2015. We performed cross-sectional correlations between the EPIC, AUASI, and SF-12 at baseline, factor analysis, and calculated the internal consistency.

Results. For most EPIC domains and subscales, our a priori-defined criteria for reliability were fulfilled (Cronbach's alpha 0.7–0.9). Cross-sectional correlations between EPIC scales and AUASI domain ranged from 0.23-0.69, and SF-12 domains ranged from 0.21–0.53 and 0.22–0.61, respectively. The retrospective analysis showed a medium acceptability and understanding of the EPIC questionnaire. In the prospective study, the revised EPIC draft showed an overall higher acceptability with a responding rate of 66% at a 5-year follow-up. All domains exhibited good internal consistency except for the hormonal section (Cronbach's $\alpha = 0.67$) at the 6-month follow-up.

Conclusion. The Romanian version of the EPIC is reliable, responsive and valid for measuring HRQL in prostate cancer patients. The EPIC questionnaire proved to be an exhaustive and reproducible instrument for evaluating the quality of life in Romanian prostate cancer patients.

Keywords: quality of life, prostate cancer, radical prostatectomy, translation, validation

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Address for correspondence:
Elisabeta Ioana Hiriscau
ioanahiriscau@gmail.com

Backgrounds and aims

Prostate cancer (PC) is the second most common neoplasm in men in Europe and, in terms of incidence, the fourth most commonly diagnosed cancer in Romania in 2020 [1,2]. Predictive factors such as staging and grading, as assessed by clinical examination, medical imaging, and Gleason score, influence treatment choice [1]. In addition, the role of patient preference in the treatment decision-making process is becoming increasingly important. Despite this, there is evidence to suggest that men with prostate cancer (PC) are not adequately informed about the adverse effects, relative benefits, and harms of the treatments available for PC [3]. Clinicians have a professional duty to cure cancer and ensure their patients have the best possible quality of life after treatment.

Given the rising prevalence of long-term survival rates [4], it is of paramount importance to prioritize the maintenance of health-related quality of life (HRQL) among prostate cancer patients. This should be a primary consideration when developing tailored treatment approaches. Health-related quality of life (HRQoL) is an important concept used to assess the impact of disease and treatment outcomes on an individual's personal and social functioning in the short and long term. This assessment can provide a comprehensive bio-psycho-social understanding of the patient, expressed in terms of disease state and physical symptoms, functional autonomy, and psychological, emotional, and social functioning [5,6]. The results allow the medical team to tailor further, improve treatment, and develop appropriate solutions if necessary.

Regarding prostate cancer patients, data on the effects and side effects of the various treatment modalities on HRQL (surgery, brachytherapy, external beam radiation, androgen deprivation) are of great value in guiding physicians in formulating treatment advice and helping patients make informed decisions about their treatment [7]. Consequently, patient-reported outcome measures are essential for the reliable, valid, and sensitive assessment of relevant aspects of health-related quality of life (HRQL) over time, with the capacity to detect patient-important changes in HRQL. Such information is critical for clinicians, enabling them to adapt and improve treatment regimens and devise effective solutions when necessary.

To ensure an appropriate evaluation of health-related quality of life (HRQoL), the assessment instrument employed must be accessible, user-friendly, and comprehensive without being intrusive. Using a self-administered questionnaire may enhance the response rate, offering respondents a sense of greater privacy. One of the most widely established and frequently utilized instruments specifically designed to assess disease-specific aspects related to prostate cancer and associated treatments is the 50-item Expanded Prostate Cancer Index Composite (EPIC) [8].

The EPIC is a standardized, self-administered questionnaire developed to measure HRQoL in PC patients who underwent radical prostatectomy or were treated with brachytherapy, external beam radiation, or hormonal therapy. The EPIC was initially developed in English by the Michigan School of Medicine in the United States and subsequently translated and validated into several other languages, including German [9], Japanese [10], Brazilian in the Portuguese language [11], Spanish [12], and French [13].

Wei et al. developed the EPIC, composed of 20 items, as an extension of the original UCLA-PCI [8]. Both instruments scored highest in the Evaluating Measures of Patient-Reported Outcomes (EMPRO) study, which compared several HRQoL instruments in PC patients [14]. The complete EPIC questionnaire contains 50 items that evaluate the HRQoL on urinary, bowel, sexual, and hormonal scales and general treatment satisfaction. It can be used alone or in combination with other instruments. Most commonly used along with the EPIC, the Medical Outcomes Short Form 12 (SF-12) is a 12-item index evaluating physical (Physical Composite Scale) and mental well-being (Mental Health Composite Scale), a down-sized version of the Short Form 36 [15]. Another addition is the American Urological Association Symptom Index (AUASI), which is similar to the International Prostate Symptom Score (IPSS), which uses only symptom items covering frequency, nocturia, weak urinary stream, hesitancy, intermittence, incomplete emptying, and urgency, without considering general QoL question [16]. A demographic module can be added to collect social, familial, and medical-related information. The EPIC was validated on 252 patients treated by radical prostatectomy, external beam radiation, or brachytherapy. Test-retest reliability was evaluated, and internal consistency was assessed by calculating Cronbach's alpha coefficient [8].

Furthermore, two abbreviated versions have been developed: a 26-item (EPIC26) and a 16-item (EPIC-CP) version. [17,18] Although brief versions of questionnaires are typically beneficial in clinical practice, a reduction in precision in the assessment occurs when utilizing these versions compared to their comprehensive counterparts. Consequently, the extensive original EPIC version comprising 50 items remains a valuable instrument for detailed assessment. In comparison to the European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire–Prostate 25 (EORTC QLQ-PR25) tool, the EPIC appears to offer a more balanced approach to the assessment of various side effects, irrespective of the treatment modality ultimately selected [19].

To the best of our knowledge, there is not yet a validated EPIC Romanian version. One of the key strengths of EPIC is its robust psychometric properties. Studies have demonstrated its high reliability and validity, making it

a trusted tool in clinical practice and research settings. The questionnaire's sensitivity to changes over time also allows clinicians to monitor symptoms' progression and treatments' effectiveness, thus facilitating more personalized patient care. Furthermore, EPIC has been translated into multiple languages and culturally adapted, broadening its applicability across diverse patient populations.

We considered the EPIC suitable for assessing the impact of PC and its therapeutic approach on a sample of Romanian patients, as it is the most widely used instrument for assessing HRQoL in prostate cancer patients. The aim of this study was to translate and validate the EPIC questionnaire for the Romanian population as a tool for assessing HRQoL in prostate cancer patients. We assessed the Romanian patients using the complete EPIC questionnaire, including the SF-12, the AUASI, and the demographic add-on. No translation was required for the SF-12 questionnaire, which has been validated for the Romanian-speaking population. Also available in Romanian were the AUASI form items used in the IPSS. A translation was required for the EPIC and the demographic add-on.

Methods

The EPIC consists of 50 items with Likert-type response options covering four domains: Urinary, Bowel, Sexual, and Hormonal. Each domain is divided into two subscales, Functional and Bother, which assess the severity of symptoms and the extent of symptom-related HRQL impairment, respectively. The urinary domain is further divided into two subscales: Incontinence and Irritation/Obstruction. The domains and subscales are presented on scales ranging from 0 to 100, with higher scores representing better HRQL.

Translation and cultural adaptation

The translation and cultural adaptation process was based on the recommendations of the international ISPOR Task Force [20] and followed a sequence of forward and reverse translation.

The first Romanian translation of the EPIC was produced after combining the independent translation drafts performed by two urologists with good expertise in medical English. This version was used to assess HRQoL retrospectively in a sample of prostate cancer patients who underwent robotic-assisted radical prostatectomy. Debriefing within the EPIC translation and validation team resolved disagreements over outstanding issues from the first translation. Based on the retrospective analysis, the multidisciplinary medical team, including a clinical psychologist and five senior researchers from different surgical specialties (urology, general surgery, oncology, and gynecology), agreed on a second version that was checked for clarity and consistency for further use.

The second revised EPIC translation was used prospectively to assess HRQoL in a sample of prostate cancer patients hospitalized before surgical treatment.

The analysis of the second data series led to the third revision of the Romanian translation, which was further verified by reversion by a certified translator for medical English at an authorized translation office. After review, the multidisciplinary medical team approved the Romanian translation of the EPIC.

The stages of the EPIC translation process in Romanian are depicted in figure 1.

Study population and study design

For the retrospective analysis, we recruited a subsample of 112 consecutive patients who underwent robotic-assisted radical prostatectomy in our center from January 2011 to December 2013. The EPIC, the SF-12, the AUASI, and the demographic add-on were mailed to all patients. An information sheet, an informed consent form, and a self-addressed stamped envelope were included for easy return. The completion rate of returned questionnaires was used to indicate the level of understanding of the content.

The second revised EPIC translation was applied prospectively to evaluate 120 consecutive PC patients hospitalized before surgical treatment from January 2014 to December 2015. Seven patients were excluded after the pre-treatment assessment in accordance with the study protocol. After explaining the assessment process and obtaining written consent, the researchers administered the EPIC, SF-12, AUASI, and a demographic add-on to each patient. Baseline assessments took place before radical prostatectomy and included the EPIC assessment (internal consistency and cross-sectional construct validity). The investigators collected the completed questionnaires, extracted data, and discussed each patient's specifics and potential difficulties.

The sample sizes for the retrospective and prospective studies were adequate, as determined by Cochran's formula and the variability/standard deviation from previous studies.

Follow-up assessments were conducted six months, two years, and five years postoperatively. As with the retrospective survey, questionnaires were sent by post. Fifteen patients were lost to follow-up before the final evaluation (five years after surgery). One patient died of disease progression. The completion rate was measured at each time point as the percentage of completed forms returned by patients. The comparative data allowed the questionnaire to be validated for reproducibility.

Approval of using the EPIC questionnaire

The written approval (while not mandatory) to translate and use the EPIC questionnaire was obtained from Professor J. Wei, MD, co-author of the original EPIC, at the University of Michigan on July 21st, 2017.

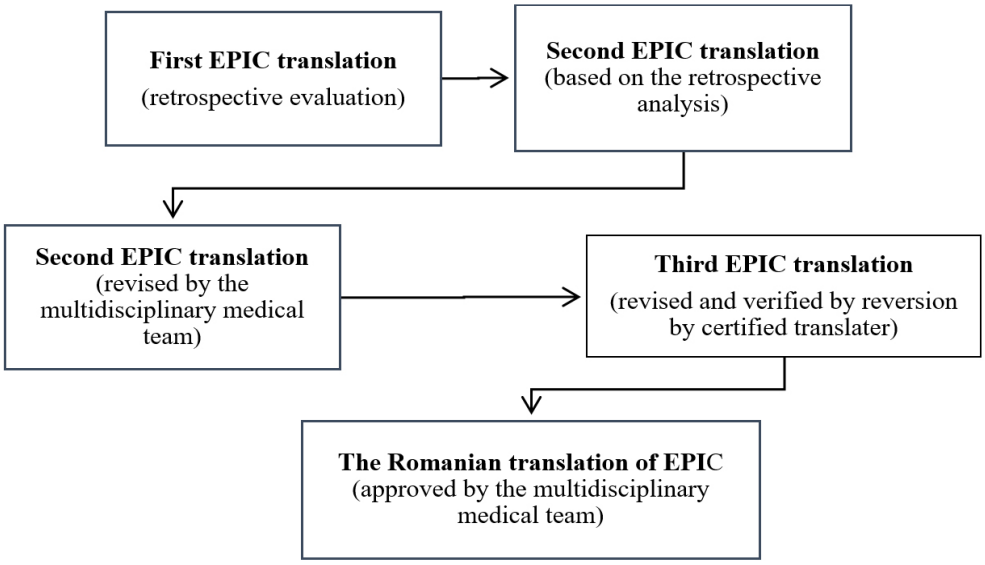

Figure 1. The EPIC translation process in Romanian.

Ethical consideration

The study was conducted according to the ethical principles of medical research stated in the Declaration of Helsinki. The patients were informed about the study's aim and were guaranteed/ensured confidentiality and anonymity. Completing the questionnaire was considered consent to participate. The Ethics Committee of the Iuliu Hatieganu University of Medicine and Pharmacy, Cluj-Napoca, Romania (reference protocol no. 307/29.06.2016) approved the study protocol.

Statistical analysis

For demographic data, we used median and percentages. We assessed the internal consistency of the EPIC scores by Cronbach's alpha (adequate internal consistency a priori defined: 0.7–0.9). We performed an exploratory factor analysis to check the factor loadings. We used Pearson or Spearman's rank correlation coefficients at baseline to assess cross-sectional validity.

We reassessed internal consistency by measuring Cronbach's alpha coefficient at each testing point during the follow-up (6 months, 2 years, and 5 years).

The data analysis was conducted using the IBM SPSS Statistics software package for Windows, version 22.0 (IBM Corp., Armonk, NY, USA).

Results

The retrospective evaluation had a response rate of 48.21%, corresponding to 54 returned forms out of 112 sent out. Of these, 52 questionnaires had enough items answered per section to remain interpretable. Two forms had more than one section unanswered and were invalidated.

The in-hospital administration of the second revised translation was unanimously accepted. Table I shows the demographics of the patients prospectively assessed in the hospital. Table II shows the mean scores of the EPIC summary domains and subscales, and the validation instruments at baseline and 6 months, 2 and 5 years follow-up after robotic-assisted radical prostatectomy.

Table I. Socio-demographic profile of the patients included in the prospective study.

Age	Median	63.0 (58.0 – 68)
	Standard deviation	6.3
	Minimum	46
	Maximum	76
Race	White/Caucasian (not Latino/ Spanic)	80%
	Latino/Spanic/Mexican-American	20%
Marital status	Married	93%
	Separated	1%
	Divorced	3%
	Widowed	3%
Education	Grade school or less/	4%
	Some high school	3%
	High school or technical school graduate	28%
	Some college	2%
	College graduate	44%
	Graduate or professional school after college	19%

Table II. Mean scores of the EPIC summary domains and subscales and the validation instruments at baseline and follow-up after robotic-assisted radical prostatectomy.

	Baseline (n=120)	Follow-up 6 months (n=89)	Follow-up 2 years (n=79)	Follow-up 5 years (n=64)
EPIC domain-specific summary scores				
Urinary	81.82(13.2)	73.40(18.5)	77.64(18.6)	77.12(19.2)
Bowel	91.25(10.2)	93.21(7.8)	92.31(9.2)	90.78(10.6)
Sexual	43.65(23.4)	24.37(18.7)	29.40(20.9)	31.12(21.4)
Hormonal	85.92(13.6)	87.13(11.3)	86.94(15.7)	89.20(13.3)
Urinary subscales				
Function	93.97(9.9)	76.38(18.9)	80.28(18.7)	80.17(18.1)
Bother	73.22(18.7)	70.72(21.3)	75.67(20.4)	74.47(23.4)
Incontinence	92.62(15.0)	62.47(30.2)	67.56(30.8)	68.54(29.0)
Irritation/Obstruction	82.45(4.9)	81.94(13.0)	85.16(13.4)	83.71(15.6)
Bowel subscales				
Function	92.38(9.7)	93.82(7.6)	92.81(9.2)	91.74(10.1)
Bother	90.04(11.9)	92.56(9.9)	91.25(12.7)	89.67(13.2)
Sexual subscales				
Function	38.14(27.3)	13.57(19.7)	18.90(23.2)	18.28(24.8)
Bother	56.21(30.5)	48.97(35.9)	53.89(35.3)	60.25(36.3)
Hormonal subscales				
Function	83.30(17.3)	85.51(13.4)	86.10(17.1)	86.63(14.6)
Bother	88.21(12.7)	88.40(11.0)	87.43(16.0)	89.39(13.8)
AUASI[1]	9.03(6.1)			
Medical Outcomes SF[2]-12				
SF-12 PCS[3]	72.19(22.7)			
SF-12 MHCS[4]	66.02(24.9)			

Notes: [1]American Urological Association Symptom Index; [2]Short Form; [3]Physical Composite Scale; [4]Mental Health Composite Scale.

Table III. Recurrent items not unanswered at pre-treatment evaluation.

Item	Section	
#62	Sexual	During the last 4 weeks, how often did you have any sexual activity?
#69	Hormonal	Over the last 4 weeks, how often have you experienced hot flashes?
#70	Hormonal	How often have you had breast tenderness during the last 4 weeks?
#74	Hormonal	How big a problem (…) Hot flashes
#75	Hormonal	How big a problem (…) Breast tenderness/enlargement
#76	Hormonal	How big a problem (…) Loss of Body Hair
#80	Overall Satisfaction	Overall, how satisfied are you with the treatment you received for your prostate cancer?

The completion rate improved, with 108 forms out of 120 administered. One patient left an entire section blank. Seven items requiring revision or clarification were identified in the Sexual and Hormonal domains and overall satisfaction (see Table III).

The cross-sectional correlations between EPIC scales and AUASI ranged from 0.23-0.69; between SF-12 PCS they ranged from 0.21–0.53 and SF-12 MHCS from 0.22–0.61.

A factor analysis on the EPIC main scales was performed based on the correlations between the EPIC variables. As a condition for multi-collinearity, all correlations above 0.8 were excluded from the analysis. For the Urinary scale, four components explained 71% of the variance; for the Bowel scale, three components explained 61% of the variance; for the Sexual scale, two components explained 72% of the variance; and for the Hormonal scale, four components explained 72% of the variance.

The third revision was employed during follow-up with a return rate of 78.76%, 69.91%, and 65.97%, respectively. The completion rate was 92.13% at six months, 89.87% at two years, and 81.25% at five years. An entire domain section was left unanswered at six months, four at two years, and one at five years, respectively. Five of the six unanswered sections assessed sexuality. One item (#70 - *How often have you had breast tenderness during the last 4 weeks?*) posed recurrent acceptability issues and needed further clarification.

Table IV. Cronbach's alpha coefficient variation for the section scales and subscales of the questionnaire.

EPIC domains	No. of items	Cronbach's alpha reliability coefficient			
		Baseline (n = 120)	Follow-up 6 months	Follow-up 2 years	Follow-up 5 years
Domain Summary Scores					
Urinary	12	0.77	0.88	0.89	0.90
Bowel	14	0.82	0.78	0.82	0.85
Sexual	13	0.92	0.89	0.90	0.90
Hormonal	11	0.79	0.67	0.84	0.81
Urinary subscales					
Function	5	0.70	0.72	0.71	0.70
Bother	7	0.79	0.84	0.86	0.88
Incontinence	4	0.70	0.91	0.91	0.91
Irritation/Obstruction	7	0.71	0.69	0.74	0.79
Bowel subscales					
Function	7	0.72	0.64	0.70	0.77
Bother	7	0.73	0.75	0.84	0.81
Sexual subscales					
Function	9	0.95	0.95	0.95	0.97
Bother	4	0.90	0.94	0.94	0.96
Hormonal subscales					
Function	5	0.71	0.64	0.72	0.72
Bother	6	0.70	0.76	0.75	0.76

Starting with its second revision, Cronbach's alpha coefficient was computed for the questionnaire's section scales and subscales (urinary, digestive, sexual, and hormonal). The results are shown in Table IV.

Discussion

The EPIC is a comprehensive instrument designed to evaluate the functional outcomes in patients with prostate cancer treated by surgical or other therapies (brachytherapy, external beam radiation, hormonal), which was translated, culturally adapted, and validated in different languages. In the process of EPIC translation and validation, the German research team included a consecutive subsample of 92 patients with localized prostate cancer undergoing radical prostatectomy, with a baseline assessment before surgery and a follow-up at six weeks after prostatectomy. Most EPIC domains and subscales obtained a Cronbach's alpha coefficient of 0.7–0.9 and an intraclass-correlation coefficient≥0.7 [9]. Similar results were also obtained by the Brazilian team within the EPIC validation process in a sample that included 40 patients with localized prostate cancer who underwent surgical retropubic radical prostatectomy, with a post-operatory follow-up ranging from 3 to 35 months. Alpha Cronbach coefficients were > 0.9) and > 0.8 to 8 of 14 EPIC domains [11]. The EPIC translation in French and its validation were performed in two groups of patients: 125 receiving treatment for localized prostate cancer and 90 cured of prostate cancer. In the treatment group, two assessments were performed before and at the end of the treatment to assess sensitivity to change, and at 2-weeks interval in the cured group for assessing test-retest reliability. All domains exhibited good internal consistency except the bowel domain (Cronbach's $\alpha = 0.61$) [13].

Our results are similar to those presented above. Two of the authors of the present paper translated the first draft of the EPIC questionnaire into Romanian, corresponding to the transcultural adaptation of the original English version of the EPIC, according to the back translation technique. The draft resulting from the back translation technique went through a continuous improvement process, being applied to patients included in two studies. The first study was a retrospective evaluation of the HRQoL of a series of 112 consecutive prostate cancer patients undergoing robotic-assisted radical prostatectomy [14]. The second study assessed the HRQoL and treatment outcomes of a series of 120 consecutive PC patients up to 5 years after radical prostatectomy.

During the retrospective study, the EPIC questionnaire with an information sheet and consent form was mailed to a series of 112 consecutive patients who underwent surgical treatment for PC. Neither a direct interaction with the investigators nor any discussion occurred before sending the EPIC questionnaire, which might partially explain the relatively low return rate of 48.21%. However, other factors might be involved, such as treatment satisfaction, comprehension level, privacy concerns, or address changes. The high completion rate

among the returned forms might suggest a selection bias related to education or intellectual level. Two invalidated questionnaire forms had at least two scale sections left unanswered and multiple other items randomly.

All 120 patients accepted the in-hospital, pre-treatment administration of the second revised version of EPIC. The completion rate was improved compared to the retrospective study, and the inpatient setting also allowed for direct feedback and clarification. The discussion with the investigators led to more items being answered before returning the form, further increasing the overall response rate. One patient left the hormonal section due to the initial belief that it was specifically female-oriented.

Several items that posed recurrent answerability issues, shown in Table II, were identified and discussed with the patients. Item #62 had a translation error where the term "sexual" was lost; therefore, its meaning changed. Certain items in the "Hormonal" section needed clarification because patients believed the questions addressed female-oriented issues. Further explanations in the information sheet were proposed as a solution. Item #80, concerning overall treatment satisfaction, was frequently answered at the pre-treatment moment because some patients did not make the distinction between prostate cancer treatment and other treatments, such as antibiotics for urinary tract infections.

The 6-month, 2- and 5-year follow-up assessment presented an acceptable return rate. However, this is not to be confused with the acceptability rate, which, due to unmeasurable factors, as stated before, is non-evaluable. The completion rate slightly decreased with time, with the lowest value of 81.25% registered at the 5-year evaluation point, which we considered optimal. During the follow-up, the items in the "Hormonal" section posed fewer problems than in previous questionnaire versions, as only one patient left this section unanswered. Item #70 required further clarification, which materialized as a translator note explaining that "breast tenderness" may appear in men because of prostate cancer treatment. The "Sexuality" section was left entirely on five forms, with one or more items unanswered in others. This was probably due to the decreased importance of the sexual aspect, as explained in writing by several patients during follow-up.

The internal consistency of the various revisions of the translated questionnaire was assessed by measuring Cronbach's alpha coefficient for the symptom scales; the closer the coefficient is to 1, the higher the consistency of the items on a scale. Analyzing data obtained before surgery, we found acceptable reliability for the urinary and hormonal symptom scales ($\alpha > 0.7$), suitable for bowel symptoms ($\alpha > 0.8$), and excellent for the sexual section ($\alpha > 0.9$), respectively, as shown in Table IV. For Hormonal The Cronbach's alpha coefficient evolved with the text's revisions, and the translated questionnaire's final version showed excellent consistency for the urinary and sexual scales. Slightly lower but acceptable alpha values were observed in the digestive and hormonal scales. This can be explained by the particularity of the prospective study, which included patients with localized prostate cancer treated by surgery, as well as a low frequency of biochemical recurrence requiring hormonal deprivation therapy among the respondents in the follow-up.

The comparison of the pre-treatment data with that collected during the 5-year follow-up showed optimal consistency and good reproducibility with variation of the functional results after treatment in a way comparable to previous studies [21,22]. The in-depth analysis of these results, however, is beyond the purpose of this paper.

Conclusions

In conclusion, the EPIC is an essential tool in the arsenal of prostate cancer management. It not only aids in the holistic assessment of treatment impacts, but also empowers patients by involving them in evaluating their health outcomes. The Romanian translation of the EPIC was successfully used to evaluate the HRQoL, posing neither understanding nor completion difficulties. The Romanian EPIC questionnaire seems to have adequate psychometric properties, comparable to those exhibited by the original English-language version. It has proved to be an exhaustive and reliable instrument for evaluating HRQoL in Romanian-speaking prostate cancer patients.

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