Validation of the Brazilian version of the Expanded Prostate Cancer Index Composite (EPIC) for patients submitted to radical prostatectomy

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ABSTRACT

Objectives: Validation of the Expanded Prostate Cancer Index Composite (EPIC) questionnaire translated to Portuguese. This is an evaluation tool of the effects of treatment on quality of life of patients with prostate cancer.

Materials and Methods: In order to translate and validate, several recommended methodological techniques in the literature were included: initial translation, synthesis of translation, board committee review and back translation. Sample included 40 patients with localized prostate cancer submitted to surgical retropubic radical prostatectomy from 2008 to 2010.

Results: The internal consistency analysis of the scales of the questionnaire resulted in alpha Cronbach coefficients "very good" (> 0.9) and "good" (> 0.8) to 8 of 14 domains. The higher coefficients (0.94) were assigned to sexual score, subscales incontinence and sexual function. Post-operatory follow-up ranged from 3 to 35 months, median 18.7 months.

Conclusions: The Brazilian version of EPIC is reliable and valid, and is a useful tool to evaluate the impact of retropubic radical prostatectomy on quality of life of Brazilian patients with localized prostate cancer, in national and internationals studies.

INTRODUCTION

Prostate cancer is the sixth most common cancer in the World, representing 10% of all tumors. In Brazil, it is the second most common cancer among men (behind non-melanoma skin cancer), and it is 52.350 new cases are estimated in 2010, or an estimated risk of 54 new cases per 100.000 men. The rise of incidence is due to the diagnosis of asymptomatic patients, the rise of life expectancy and the improvement of the information systems of the country. The incidence raised mainly in areas of the country whe-re surveillance is common (1). The diagnosis of prostate cancer is made through rectal exam and prostate specific antigen essay (PSA) and confirmation with ultrasound-guided prostate biopsy. According to the recommendations of the Brazilian Society of Urology, the preventive exam must be done after 45 years of age, and for those with family history of prostate cancer after 40 years of age (2,3).

Prostate cancer treatment depends of the staging of the disease, histological grade, patient age and general status of the patient. To localized tumors, surgery is an option (radical pros-

tatectomy), as well as external radiotherapy or brachytherapy. To localized advanced tumors, it has been used surgery or radiotherapy combined with hormone therapy, and to metastatic disease, the treatment of choice is hormone therapy (4).

However, all therapeutic options have collateral effects (radical prostatectomy, brachytherapy and external radiotherapy), such as urinary incontinence, erectile dysfunction and intestinal alterations. The evaluation of the treatment must address not only the survival but the negative impact on quality of life of patients (5,6).

Quality of life evaluation related to health includes all aspects of patient evaluation and can verify the impact of the disease, health and treatment (7). The used questionnaires to evaluate quality of life are useful to transform subjective measures in objectives evaluations in order to quantify and analyze specific and global aspects (8,9).

World Health Organization (WHO) defines quality of life as the individual perception of his role in life, in relation to his (her) objectives, expectations, patterns and worries, in culture and values contexts. It is a broad and complex concept that encompass physical health, psychological status, independence level, social relations, personal beliefs, and relation to environment (10,11).

MATERIALS AND METHODS

EPIC questionnaire is a self-administered tool and is intended to evaluate the impact of treatment on quality of life of patients with prostate cancer. It includes 50 questions, of four domains: urinary, intestinal, sexual and hormonal; it evaluates the last four weeks and includes a Likert scale of answers of 5 options. Each domain contains two subscales (function and nuisance). The urinary domain still has two additional subscales: incontinence and irritative/obstructive symptoms (12).

Procedures for translation and validation

The translation and validation of the questionnaire was performed in four steps: initial translation, translation synthesis, board committee of specialists review and back translation, according to the criteria described by Guillemin et al (13).

Initial translation

Question translation was performed by two independent translators, fluent in English and aware of the study objectives.

Translation Synthesis

Production of a synthesis of the two translated versions carried out by the researcher and leader, maintaining the same fundamental characteristics of the original questionnaire.

Review by a Board of Specialists Committee

A committee of specialists included five urologists fluent in English that evaluated for each question the semantic, idiomatic, cultural and conceptual equivalents between the original and the translated version.

Semantic equivalence refers to the meaning of the words (grammar and vocabulary), while idiomatic equivalence refers to colloquial expressions that are equivalent to the original idiom. Cultural equivalence refers to the lived experiences in the cultural context of society. The conceptual equivalence refers to the words with different cultural meaning (14).

A first final version in Portuguese was proposed during the meeting of the panel of specialists, the leader and the researcher, after joint evaluation of instructions, questions and format.

Back Translation

During back translation, the questionnaire was translated again, but this time from Portuguese to English, by two native English translators with domain of the Portuguese language, who did not know the objectives of the study or the original questionnaire. Afterwards, they compared the translation with the original and did not find any discrepancy.

Population and Sampling

The sample included 40 male patients randomly selected in the ambulatory of Urology of Hospital São Paulo, with the following inclusion criteria: a) diagnosis of localized prostate cancer; b) clinical stage T1 or T2; c) did not receive any previous treatment for prostate cancer; d) therapeutic indication of retropubic radical prostatectomy.

Ethical Aspects

Initially, an e-mail authorization was referred to the authors of EPIC in order to translate and validate the original to Portuguese. After that authorization, the research was approved by the Ethical Committee of Research of the Federal University of São Paulo. All patients signed an Informed Consent.

Statistical analysis

In this phase, the same procedure adopted by the original EPIC study was performed, allowing the evaluation of a total sample of heterogeneous patients regarding the impact of treatment on the domains: urinary, intestinal, sexual and hormonal. The tests were performed using the quality of life scores obtained after treatment.

To internal consistency analysis, in order to verify the reliability of the instrument (15), it was used the statistical alpha test of Cronbach (16). This index varies from 0 to 1. The closest to 1, the higher the reliability of the instrument. Intern consistency was considered: very good, if superior to 0.9; good, between 0.8 and 0.9; reasonable, between 0.7 and 0.8; weak, between 0.7 and 0.8; and poor, between 0.6 and 0.7; it was considered inadmissible if inferior to 0.6. It there is no variance between the individual items, the alpha score is 1: all items of the instrument are totally homogeneous, producing exactly the same variance (17,18).

The significance level for the statistical tests was 5%, or p < 0.05. Data analysis was made using the software SPSS - Statistical Package for Social Science.

RESULTS

Socio-demographic characteristics of the 40 patients are described in Table-1. Median age was 63.8 ± 8.6 years, varying from 46 to 78 years, and 70% of patients were married or had a fixed partner.

Table-2 depicts the results of intern consistency, median and standard deviation for the 14 domains (4 summaries and 10 subscales) of the Brazilian version of EPIC. The internal consistency analysis of the scales of the questionnaire resulted in Cronbach alpha coefficients "very good" above 0.9 and "good" above 0.8 to 8 of them, and the higher

scores were obtained for the sexual score, subscales incontinence and sexual function. When we compared these data with the original version and the Spanish version (Table-3), it is observed that they are similar, without significant differences.

Table-4 shows the data for patients older than 65 or with less than 65 years and EPIC scores. It is observed that as the age rises, there is a decline of the scores "sexual domain", 'sexual function', "incontinence" and "urinary distress".

Table 1 - Socio-demographic profile.

Age	
Median	63.8%
Standard Deviation	8.6
Minimum	46
Maximum	78
Colour / Race	
White	42.5%
Black	42.5%
Brown	15.0%
Marital Status	
Married/fixed partner	70.0%
Single	12.5%
Widow	15.0%
Divorced	2.5%
Schooling	
Illiterate / Incomplete basic school	35.0%
Complete basic school/Incomplete high school	35.0%
Complete high school /Incomplete higher education	20.0%
Complete higher education	10.0%

Table 2 - Descriptive measures of EPIC.

HRQOL Domain	Number of itens	Mean Score (sd)	Internal consistency reliability
HRQOL Domain Summary Scores			
Urinary	12	82.2 (12.1)	0.87
Bowel	14	96.7 (2.1)	0.81
Sexual	13	35.2 (16.3)	0.94
Hormonal	11	94.0 (9.2)	0.74
Domain-Specific HRQOL Subscales			
Urinary Subscales			
Function	5	82.9 (14.9)	0.69
Bother	7	81.7 (11.0)	0.84
Incontinence	4	73.0 (8.7)	0.94
Irritative/Obstructive	7	89.3 (9.5)	0.78
Bowel Subscales			
Function	7	96.2 (2.5)	0.53
Bother	7	97.1 (1.6)	0.87
Sexual Subscales			
Function	9	29.1 (14.0)	0.94
Bother	4	48.9 (13.1)	0.93
Hormonal Subscales			
Function	5	89.7 (12.8)	0.57
Bother	6	97.6 (2.0)	0.66

Post-operatory follow-up varied from 3 to 35 months, median 18.7 months, with minimal significant correlations of the following EPIC scores: "domain and urinary function", "irritative/obstructive", "domain, function and intestinal distress" and "hormonal distress"). It is observed that as the time passes, the scores tend to decrease (Table-5).

DISCUSSION

The literature highly recommends the adaptation of scales and questionnaires previously validated, due to reduction of costs, a standardization of measure for investigation in different cultures, allowing international studies to compare the same phenomena in several cultures (19).

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Table 3- Comparision of EPIC data of original, spanish and brazilian versions.

HRQOL Domain	Number of items	Original Version		Spanish Version		Brazilian Version	
		Mean Score (sd)	Internal consistency reliability	Mean Score (sd)	Internal consistency reliability	Mean Score (sd)	Internal consistency reliability
HRQOL Domain Summary Scores							
Urinary	12	80.2 (17.5)	0.88	74.8 (21.1)	0.73	82.2 (12.1)	0.87
Bowel	14	86.6 (15.7)	0.92	92.2 (9.7)	0.75	96.7 (2.1)	0.81
Sexual	13	33.1 (23.6)	0.93	36.5 (22.0)	0.89	35.2 (16.3)	0.94
Hormonal	11	86.6 (13.8)	0.82	90.0 (11.4)	0.66	94.0 (9.2)	0.74
Domain-Specific HRQOL Subscales							
Urinary Subscales							
Function	5	86.5 (16.7)	0.69	72.3 (24.5)	0.68	82.9 (14.9)	0.69
Bother	7	75.8 (20.4)	0.85	76.5 (22.7)	0.74	81.7 (11.0)	0.84
Incontinence	4	83.2 (22.9)	0.89	72.2 (35.7)	0.85	73.0 (8.7)	0.94
Irritative/Obstructive	7	79.7 (18.5)	0.81	77.5 (19.2)	0.64	89.3 (9.5)	0.78
Bowel Subscales							
Function	7	87.9 (13.6)	0.75	89.2 (10.7)	0.43	96.2 (2.5)	0.53
Bother	7	85.3 (18.8)	0.9	95.2 (10.7)	0.75	97.1 (1.6)	0.87
Sexual Subscales							
Function	9	29.5 (24.0)	0.92	24.2 (19.4)	0.88	29.1 (14.0)	0.94
Bother	4	41.1 (30.1)	0.84	64.0 (43.0)	0.98	48.9 (13.1)	0.93
Hormonal Subscales							
Function	5	84.0 (15.3)	0.51	84.9 (14.2)	0.25	89.7 (12.8)	0.57
Bother	6	88.7 (13.6)	0.73	94.3 (11.1)	0.59	97.6 (2.0)	0.66

Table 4 - Correlation of EPIC score and age.

HRQOL Domain	< 65 years (a) (n = 23)		≥ 65 years (b) (n = 17)		p value between (a) and (b)
	Mean	Sd	Mean	Sd	
HRQOL Domain Summary Scores					
Urinary	81.2	7.5	75.2	13.5	0.08
Bowel	95.7	3.1	96.2	1.7	0.55
Sexual	40.4	15.7	28.1	17.7	< 0.03
Hormonal	90.9	11.3	90.7	9.1	0.95
Domain-Specific HRQOL Subscales					
Urinary Subscales					
Function	81.4	10.5	75.0	17.4	0.16
Bother	81.2	5.9	75.2	12.1	< 0.04
Incontinence	77.6	8.1	66.9	9.4	< 0.00
Irritative/Obstructive	85.9	4.2	86.5	12.9	0.84
Bowel Subscales					
Function	94.0	3.5	96.3	2.5	< 0.03
Bother	97.0	2.0	96.2	0.8	0.13
Sexual Subscales					
Function	35.3	14.1	20.7	14.5	< 0.00
Bother	51.9	14.0	44.9	12.1	0.11
Hormonal Subscales					
Function	86.1	15.5	84.8	9.8	0.76
Bother	95.7	0.9	94.9	1.0	< 0.01

After careful review of literature, in order to identify all available instruments for the evaluation of the impact of treatment of prostate cancer in quality of life, EPIC questionnaire was chosen, since it was the one that best approached our goals and was highly accepted in the international scientific community, and easy to use. Since EPIC was developed to the American population, it was necessary to translate it and adapt it to Brazilian context and to test its measure proprieties.

Final version of translated EPIC (Appendix) maintained the English original title, since it is internationally recognized. It was added "Brazilian Version" to the title to facilitate the search in data bases.

Tabela 5 - Correlation between the score and the EPIC segment postoperatively.

HRQOL Domain	< 12 months (a) n = 14		≥ 12 months (b) n = 26		p value between (a) and (b)
	Mean	Sd	Mean	Sd	
HRQOL Domain Summary Scores					
Urinary	73.9	9.5	81.6	10.7	< 0.03
Bowel	99.2	1.6	95.0	3.0	< 0.00
Sexual	35.1	14.9	35.2	17.3	0.99
Hormonal	91.5	11.1	92.8	9.5	0.70
Domain-Specific HRQOL Subscales					
Urinary Subscales					
Function	70.6	7.3	83.2	14.4	< 0.00
Bother	75.6	10.7	80.3	7.6	0.11
Incontinence	69.5	6.4	74.9	10.2	0.08
Irritative/Obstructive	79.5	11.3	88.1	7.0	< 0.01
Bowel Subscales					
Function	98.2	2.5	94.4	3.6	< 0.00
Bother	99.9	0.0	95.6	2.5	0.00
Sexual Subscales					
Function	29.9	13.6	28.7	14.7	0.80
Bother	46.9	11.6	50.0	14.2	0.49
Hormonal Subscales					
Function	88.4	16.1	89.2	11.9	0.86
Bother	94.6	1.5	97.4	1.4	< 0.00

The patients that answered the questionnaire were invited to answer open question regarding each item in order to identify questions with difficult understanding. In general, the instrument was easy to apply and well accepted by the patients, with good efficacy.

The results obtained in the current study are consistent with the original and indica-

te equivalency with the Brazilian version, with adequate reliability, high sensitivity to alterations. However, it is important to state that the questionnaire was used only for patients submitted to retropubic radical prostatectomy. In the present, another study comparing "open" to robotic-assisted laparoscopic radical prostatectomy is been carried out.

This questionnaire, after comparision of treatments, will be a resourceful tool for clinicals and researchers, to evaluate the impact of different treatmens on quality of life of pacients with prostate cancer.

CONCLUSIONS

Brazilian version of EPIC is valid and reliable as a new tool for the evaluation of the impact of retropubic radical prostatectomy in quality of life of Brazilian patients with localized prostate cancer, for national and international studies.

APPENDIX

The Expanded Prostate Cancer Index Composite (EPIC) – Brazilian version – Available at:
http://www.uroepm.com.br/setores/robotica.html

CONFLICT OF INTEREST

None declared.

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