BRIEF COMMUNICATION

Adaptation and validation of the Spanish version of the Patient-Oriented Prostate Utility Scale (PORPUS)

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Abstract

Objective The Patient-Oriented Prostate Utility Scale (PORPUS) is a combined profile and utility-based quality of life measure for prostate cancer patients. Our objectives were to adapt the PORPUS into Spanish and to assess its acceptability, reliability, and validity.

Methods The PORPUS was adapted into Spanish using forward and back translations and cognitive debriefing. PORPUS was administered jointly with the SF-36 and the Expanded Prostate Index Composite (EPIC) to 480 Spanish prostate cancer patients treated with radical prostatectomy or radiotherapy. The Spanish PORPUS scores' distribution and reliability were examined and compared with the original instrument. To evaluate construct validity, relationships were assessed between PORPUS and other instruments (testing hypotheses of the original PORPUS study), and among known groups defined by side effect severity.

Results Reliability coefficient was 0.76 (similar to the original PORPUS' 0.81). Spanish PORPUS items presented correlations ranging 0.57–0.88 with the corresponding EPIC domains, as in the original PORPUS study (0.60–0.83). Both PORPUS-P and PORPUS-U showed significant differences and large effect sizes (0.94–1.90) when comparing severe versus no problem groups on urinary, bowel, sexual and hormonal side effects defined by EPIC.

Conclusions A conceptually equivalent Spanish version was obtained, with high reliability and good construct validity, similar to the original Canadian PORPUS version. It can therefore be used to measure health-related quality of life and utilities in Spanish prostate cancer patients.

Keywords Prostate cancer · Patient-reported outcomes · Utility · Metric properties · Cross-cultural validity

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Introduction

Generic multi-attribute utility instruments, such as the Health Utilities Index or the EQ-5D, have been frequently used in patients with prostate cancer. However, generic

instruments may not assess clinically relevant health differences for prostate cancer because they do not cover the main treatment side effects (sexual, urinary, and bowel problems). A recent systematic review identified 29 prostate cancer-specific questionnaires [1], although only the Patient-Oriented Prostate Utility Scale (PORPUS) provided a utility index.

The PORPUS is a combined profile and utility-based quality of life measure developed in Canada. It showed good validity [2, 3] and acceptable test–retest reliability [2]. The objectives of this study were to develop a Spanish version, to prove its conceptual equivalence with the original, and to assess its acceptability, reliability, and validity.

Methods

Instruments

The PORPUS is a health status classification system with 10 items, covering five broad Health-Related Quality of Life (HRQoL) domains (pain, energy, social support, communication with doctor, and emotional well-being) and five prostate cancer-specific domains (urinary frequency, urinary leakage, sexual function, sexual interest, and bowel function) [2]. The items have Likert-scale format with four to six levels each, resulting in a total of 6,000,000 potential health states [4]. The PORPUS generates direct and indirect utilities (PORPUS-U) and describes HRQoL as a psychometric instrument (PORPUS-P).

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The PORPUS-P is scored with each item contributing from 0 to 10 points, irrespective of the number of response categories. A minimum of eight completed items is required, and the scoring formula allows for prorating of the observed score to a full score ranging from 0 (worst) to 100 (best). The PORPUS-U is scored as an indirect multi-attribute index with the utility weights elicited by Tomlinson et al. [3].

A forward and back translations standard method with cognitive debriefing was used to develop the Spanish PORPUS. Two native Spanish speakers independently translated the original. An expert panel, formed by an epidemiologist, psychologist, urologist, and radiation oncologist, reviewed translations and discussed the clarity and cultural equivalence until consensus. Cognitive debriefing interviews were carried out in a convenience sample of 11 prostate cancer patients aged 57–78 years, 63 % retired, stage T2 or T3, and heterogeneous levels of education. Finally, the Spanish version was translated back into English by a native American English speaker. Only one major change on the urinary frequency item was recommended by the original PORPUS authors.

Study design and patient recruitment

This was a cross-sectional study of prostate cancer patients enrolled in two similar prospective cohorts. The first cohort, named 'Spanish Multicentric Study of Clinically Localized Prostate Cancer,' included men diagnosed with localized prostate cancer in 2003–2005. Details of the study are described elsewhere [5]. Briefly, the patients had stage T1 or T2 disease and were treated with radical prostatectomy, external radiotherapy, or interstitial radiotherapy at 10 hospitals. The second cohort (not previously published) included patients with localized or locally advanced prostate cancer (stage T2 or T3), treated with external radiotherapy with or without interstitial radiotherapy, and recruited in 2003–2006 at 6 hospitals. Both studies included similar clinical and HRQoL evaluations

Clinical characteristics were obtained at baseline. Annual computer-assisted telephone interviews were performed in both studies, including the SF-36v2 [6], the Functional Assessment of Cancer Therapy (FACTv4) [7], the Expanded Prostate Index Composite (EPIC) [8], and a list of self-reported comorbidities. The PORPUS was introduced in 2012, and analyses reported here were performed with a subsample of this annual follow-up. The protocol was approved by the institutional review board before patient enrollment.

The SF-36v2 measures eight dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). The FACTv4 is a 27-item instrument measuring

Table 1 Descriptive of sample characteristics

	N (%)[a]
Participants (*n*)	480
Age in years, mean (SD)	66.8 (6.4)
<65	168 (37.6 %)
65–70	119 (26.6 %)
≥70	160 (35.8 %)
PSA (ng/mL), mean (SD)	10.8 (15.3)
Gleason score, mean (SD)	6.0 (1.1)
Clinical stage (T)	
T1	265 (55.2 %)
T2	164 (34.2 %)
T3	50 (10.4 %)
Tx	1 (0.2 %)
Prostate volume (cc), mean (SD)	41.6 (20.3)
Treatment	
Radical prostatectomy	98 (20.4 %)
External radiotherapy	128 (26.7 %)
Brachytherapy	160 (33.3 %)
Combined radiotherapy	94 (19.6 %)
Number of comorbidities	
0	49 (12.3 %)
1	87 (21.8 %)
2	83 (20.8 %)
3 or more	180 (45.1 %)

[a] Absolute number and percentage, except where otherwise indicated

four well-being dimensions (FACT-General), with a prostate module (FACT-P) comprising 12 additional items about pain, urinary symptoms, bowel, and sexual function [7]. The EPIC contains 50 items from four domains (urinary, bowel, sexual, and hormonal) [8]. Higher scores represent better HRQoL in these instruments.

Data analyses

The distribution of PORPUS scores was examined, and reliability was estimated with the Cronbach's alpha coefficient. Two approaches were applied to evaluate construct validity. First, the relationship of the PORPUS items to other instruments was assessed, using the same hypotheses as the original study [2]: substantial correlations of prostate cancer-specific PORPUS domains with the EPIC and FACT-P, but moderate with the SF-36v2; substantial correlations of broad HRQoL PORPUS domains with the FACT-G and FACT-P, moderate with the SF-36v2, and insignificant with the EPIC. Secondly, patients were divided into known groups based on severity of side effects as defined by the EPIC items [9] ('no relevant problem,' 'small problem,' and 'severe problem'). PORPUS mean scores were compared among groups with ANOVA, and the magnitude of the difference was measured by effect size (ES) coefficient (difference in mean scores between groups/pooled standard deviation). Analyses were conducted using the statistical package SPSS 12.

Table 2 Distributions of generic and prostate cancer-specific questionnaires scores

Dimensions	Mean (SD)	Missing items[a] (%)	Theoretical range	Observed range	Floor effect[b] (%)	Ceiling effect[b] (%)
PORPUS-P	69.6 (14.1)	0	0–100	22–100	0	0.2
PORPUS-U	0.92 (0.09)	0	0–1	0.18–10	0	0
SF-36 physical function	64.0 (29.3)	0	0–100	0–100	2.7	1.9
SF-36 role physical	76.4 (29.8)	0	0–100	0–100	4	53.8
SF-36 bodily pain	68.7 (22.2)	0	0–100	0–100	0.2	21.5
SF-36 general health	58.0 (12.9)	0.2	0–100	20–95	0	0
SF-36 vitality	52.8 (22.7)	0	0–100	0–93.75	3.1	0
SF-36 social function	83.3 (28.9)	0	0–100	0–100	4.4	67.3
SF-36 role emotional	82.1 (27.3)	0	0–100	0–100	3.1	63.3
SF-36 mental health	75.4 (18.7)	0	0–100	0–100	0.2	0.2
FACT-P	35.2 (5.3)	7.7	0–48	13.1–45	0	0
FACT-G	71.2 (13.1)	11	0–108	26.2–93	0	0
EPIC urinary	83.9 (18.8)	0	0–100	6.25–100	0	40.2
EPIC bowel	95.5 (9.7)	0	0–100	28.6–100	0	68.3
EPIC sexual	38.8 (16.5)	0	0–100	5.8–90.4	0	0
EPIC hormonal	86.0 (16.0)	0	0–100	18.2–100	0	31.3

For all questionnaires and scales, a higher score indicates a better outcome

[a] Percentage of patients with any item missing on the scale

[b] Floor and ceiling effects were calculated as the percentages of patients with the worst and the best possible scores, respectively

Results

The 480 patients had a mean age of 66.8 years (SD = 6.4), 33.3 % were treated with brachytherapy, 26.7 % external radiotherapy, 20.4 % radical prostatectomy, and 19.6 % combined radiotherapy, as seen in Table 1. Table 2 shows the questionnaires' mean scores (69.6 for PORPUS-P and 0.92 for PORPUS-U), the score ranges, the percentages of floor/ceiling effects, and missing items, which were zero for the PORPUS scores. Cronbach's alpha of PORPUS-P was 0.76.

Correlations of Spanish PORPUS with other HRQoL instruments confirmed the hypotheses of the original Canadian study (Table 3) PORPUS prostate cancer-specific domains presented high correlations (>0.60) with the corresponding EPIC domains; and PORPUS broad HRQoL domains showed insignificant correlations (<0.30) with the

Fig. 1 Comparison between groups defined by severity according to ▶ items EPIC.One-way analysis of variance of QoL scores among the groups by severity according to items EPIC. Tukey studentized range post hoc comparisons with $p < 0.001$: *no relevant problem versus small to moderate problem and †small to moderate problem versus severe problem

EPIC, but substantial or high (>0.45) with some SF-36v2 and FACT-G scores. For example, PORPUS energy presented correlations ≥0.85 with SF-36 role physical and vitality, and FACT-G physical well-being.

Figure 1 shows mean scores of the PORPUS-P and PORPUS-U in each severity group defined by EPIC items. Effect sizes were ≥0.8 for both PORPUS scales when comparing the severe group with problem-free patients. Effect sizes were lower when comparing the small-problem group with the problem-free one, ranging 0.43–0.86 in PORPUS-P and 0.14–0.53 in PORPUS-U.

Table 3 Pearson coefficients of psychometric PORPUS item responses with subscales of other Instruments

SUBSCALES	PORPUS DOMAINS									
	BROAD QUALITY OF LIFE					PROSTATE CANCER SPECIFIC				
	Pain	Energy	Social support	Communication with MD	Emotional well being	Urinary leaking	Urinary frequency	Erectile dysfunction	Sexual interest	Bowel Problem
Prostate related dimensions										
EPIC urinary	0.28	0.29	<u>0.01</u>	<u>0.16</u>	0.37	**0.76**	**0.82**	0.21	0.17	0.20
EPIC bowel	0.19	0.23	<u>0.21</u>	<u>0.03</u>	0.28	0.23	0.10	0.01	0.08	**0.62**
EPIC sexual	0.21	0.33	<u>0.09</u>	<u>0.10</u>	0.32	0.24	0.19	**0.88**	**0.57**	0.12
EPIC hormonal	0.43	0.75	<u>0.10</u>	<u>0.05</u>	0.75	0.34	0.25	0.32	0.36	0.31
FACT-P	**0.68**	**0.64**	0.04	0.17	**0.64**	0.72	0.49	0.46	0.43	0.41
Physical well-being										
SF-36 Role Physical	**0.56**	**0.88**	0.04	0.12	0.74	*0.33*	*0.21*	*0.36*	*0.44*	*0.30*
SF-36 Bodily Pain	**0.93**	0.49	0.11	0.11	0.47	*0.27*	*0.19*	*0.23*	*0.29*	*0.24*
SF-36 Vitality	0.50	**0.85**	0.03	0.13	0.68	0.33	0.22	0.44	0.51	0.31
FACT-G physical well being	**0.64**	**0.86**	0.05	0.15	**0.78**	0.50	0.38	0.37	0.41	0.42
Social Support										
SF-36 Social Functioning	0.48	0.83	0.08	0.15	0.74	0.30	0.20	0.29	0.37	0.33
FACT-G social well being	0.26	0.42	0.28	0.18	0.46	0.19	0.13	0.40	0.34	0.20
Emotional well being										
SF-36 Role Emotional	0.43	0.78	0.14	0.14	**0.83**	0.34	0.23	0.26	0.33	0.35
SF-36 Mental Health	0.45	0.69	0.18	0.13	**0.87**	*0.36*	*0.28*	*0.23*	*0.28*	*-0.35*
FACT-G emotional wellbeing	0.40	0.48	0.11	0.10	**0.70**	0.36	0.29	0.23	0.24	0.30
Function										
SF-36 Physical Function	0.57	**0.82**	0.01	0.12	**0.65**	0.35	0.19	0.40	0.46	0.30
FACT-G functional well being	0.53	**0.86**	0.07	0.18	**0.84**	0.45	0.33	0.39	0.44	0.37

Strength of the expected correlations are marked according to hypotheses of the original PORPUS study with [2]: *gray cells* (substantial to high), **bold and italic** (moderate), and <u>underlined text</u> (insignificant). Cutoff applied [14] was insignificant (<0.30), moderate (0.30–0.45), substantial (0.45–0.60), and high (>0.60)
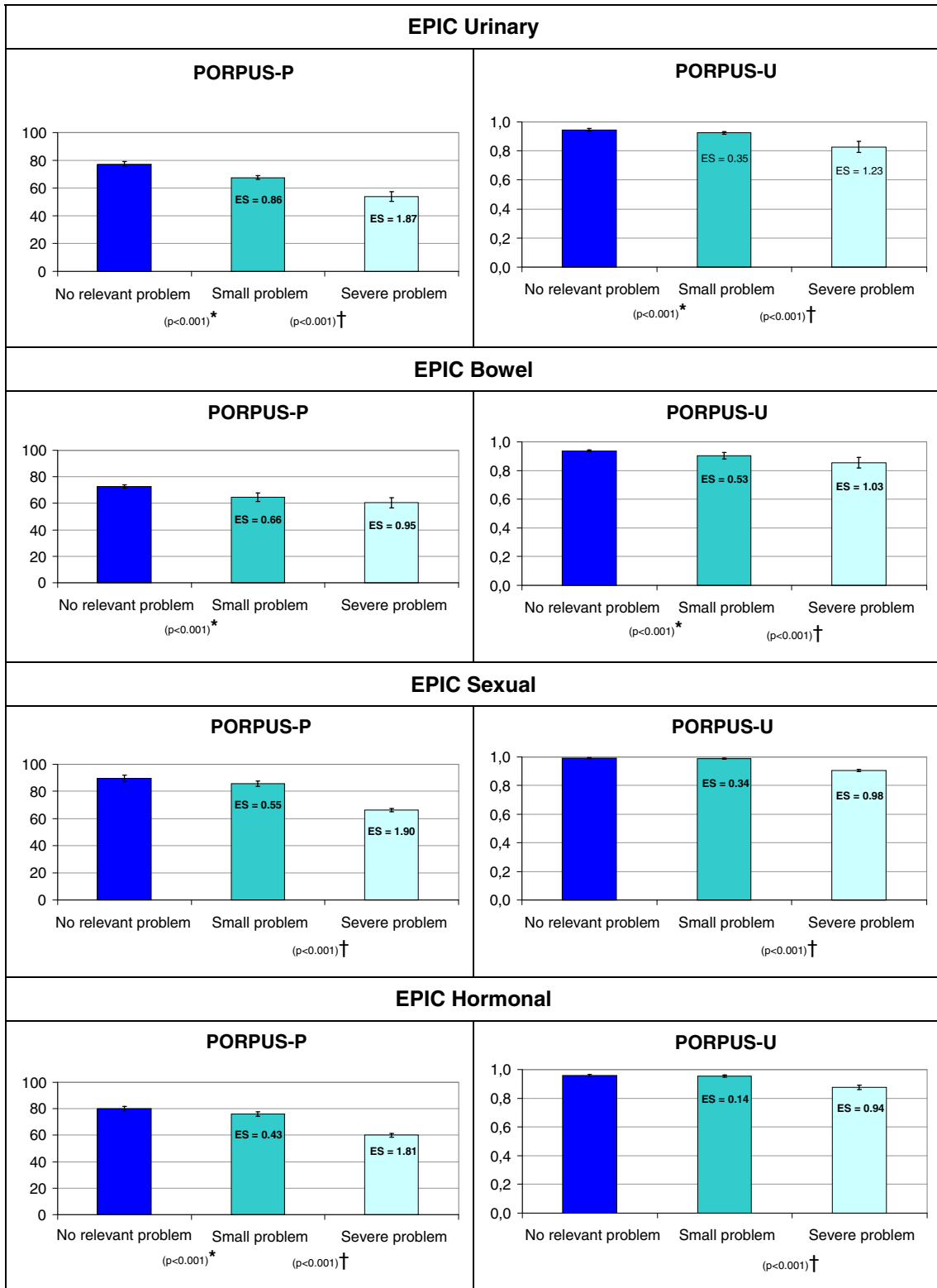
Discussion

The Spanish PORPUS demonstrated good acceptability and ease of administration by phone interview. Cross-cultural adaptation did not present any major difficulty, allowing a conceptually equivalent Spanish version, with a good reliability and construct validity. Overall, these results suggest that PORPUS-P and PORPUS-U may be used to evaluate HRQoL and estimate utilities in Spanish prostate cancer patients.

Unlike the widely used EQ-5D's considerable ceiling effect in prostate cancer patients (42 %) [10], the absence of floor and ceiling effects in PORPUS scores illustrates their ability to measure the full spectrum of HRQoL due to their covering both generic and disease-specific domains and, therefore, their potential ability to show improvement or deterioration in all patients. Otherwise, the high proportion of patients with the best possible score in some SF-36 dimensions (such as role physical and emotional and social function) suggests that aspects covered by them may not be totally relevant for patients with non-advanced prostate cancer; while the high proportions of patient subgroups with the best possible scores in the EPIC domains reflect the distinct adverse effect profile of treatments (e.g., the absence of bowel problems among patients treated with surgery or brachytherapy).

Similar to the 0.81 intraclass correlation coefficient of the original instrument [2], Cronbach's alpha coefficient of the Spanish version (0.76) was above the required standard of 0.7 for comparing groups, indicating good reliability [11]. We also found strong evidence of construct validity for the Spanish PORPUS. The items related to prostate cancer-specific domains were highly correlated with the EPIC (0.57–0.88), in the same way that the original version of the PORPUS correlated with UCLA Prostate Cancer Index scales [2] (0.60–0.83). The insignificant correlations between social support or communication with doctor and other instruments were similar to the original study and remarked PORPUS' singularity of covering domains not related to symptoms.

The ability of the PORPUS to detect differences between patient groups based on severity of urinary, bowel, sexual, and hormonal side effects is important considering the previously highlighted poor sensitivity and responsiveness of generic utility indexes to detect changes in prostate cancer-specific symptoms [12]. However, the magnitudes of the differences between severity groups were generally larger for the PORPUS-P than for the PORPUS-U. For example, the difference between no problem and small to moderate problem was fairly large for the PORPUS-P (effect size 0.43–0.86), but much smaller for the PORPUS-U (effect size 0.14–0.53). This reflects a true distinction between the simple descriptive profile and utilities which incorporate preferences.

Limitations of our study include its cross-sectional nature, which prevented assessing test–retest reliability and sensitivity to change over time. However, the high internal consistency of PORPUS-P demonstrates adequate reliability, and the large differences observed between problem-free patients and those with severe side effects support its responsiveness. Secondly, we used the original POR-PUS preference weights obtained from 234 Canadian patients [3] rather than obtaining preference weights from Spanish patients. However, Spain's EQ-5D health states value assignation patterns were generally similar to UK's [13]. Thirdly, we administered the PORPUS by phone and the generalizability of our results to other administration methods is uncertain.

Despite these limitations, the results provide considerable support for the appropriate metric properties of the Spanish PORPUS. At the same time, comparison with the original Canadian version shows that it is similarly reliable and valid, suggesting that the adaptation method followed has yielded an equivalent Spanish version. In conclusion, the PORPUS-P and PORPUS-U are appropriate and valuable tools for assessing HRQoL in Spanish prostate cancer patients and estimating utilities for cost-utility analysis [14].

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