

Psychometric properties of the Functional Assessment of Cancer Therapy, prostate version (FACT-P), in Mexican patients

Propiedades psicométricas de la Escala de Evaluación Funcional para el Tratamiento del Cáncer, versión próstata (FACT-P), en pacientes mexicanos

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Abstract

Background: Prostate cancer is the most frequent neoplasm in Mexican men, the research literature contains few studies that address prostate cancer patients and quality of life in Mexico. **Objective:** The objective of the study was to validate the Functional Assessment Cancer therapy (FACT-P) scale. **Methods:** 201 males 49-90 years of age, at any clinical stage of prostate cancer, under treatment or follow-up participated. It is a non-experimental cross-sectional study. Patients were evaluated through the FACT-P jointly with the European Organization for Research and Treatment of Cancer Quality of Life and Hospital Anxiety and Depression Scale. Exploratory analysis examined the factorial structure, and confirmatory analysis to evaluate the adjustment of the exploratory model to the data. **Results:** A four-factor model that explained 64.65% of the variance, Cronbach's alpha 0.79, and correlations were statistically significant, Pearson's r of 0.146-0.716, $p < 0.01$ and $p < 0.05$. Analyses also distinguished metastatic patients from non-metastatic ones. The main indices of the confirmatory model were satisfactory for the adjustment of data and showed an estimate error close to zero. **Conclusions:** This Mexican version of FACT-P showed reliability and validity comparable to the original one.

Keywords: Quality of life. Prostate cancer. FACT-P. Mexico. Validation study.

Resumen

Antecedentes: El cáncer de próstata es la neoplasia más frecuente en los varones mexicanos, pero pocos estudios han abordado la calidad de vida en los pacientes con cáncer de próstata en México. **Objetivo:** Validar la Escala de Evaluación Funcional para el Tratamiento del Cáncer, versión próstata (FACT-P). **Métodos:** 201 pacientes de 49 a 90 años en cualquier etapa clínica, en tratamiento o seguimiento. Diseño de estudio: transversal no experimental. Se usaron el FACT-P, el Inventario de la Organización Europea para la Investigación y Tratamiento del cáncer y Calidad de Vida, y la Escala de Ansiedad y Depresión Hospitalaria. Se realizaron análisis factorial exploratorio y análisis factorial confirmatorio para evaluar el ajuste del modelo de los datos, mediante el método de máxima verosimilitud. **Resultados:** Se obtuvo un modelo de dos factores y dos indicadores que explicaron el 64.65% de la varianza, alfa de Cronbach 0.79, correlaciones estadísticamente significativas,

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r de Pearson de 0.146-0.716, $p < 0.01$ y $p < 0.05$. La escala discrimina los pacientes sin y con metástasis. Los principales índices del modelo confirmatorio sugieren un modelo estable y parsimonioso, con error próximo a cero, que se ajusta aceptablemente a los datos analizados. **Conclusiones:** La versión mexicana del FACT-P posee una confiabilidad y una validez adecuadas, similares a las de la original.

Palabras clave: Calidad de vida. Cáncer de próstata. FACT-P. México. Validación.

Introduction

According to the most recent data, overall incidence of prostate cancer is estimated to be 1,276,106 cases, with a mortality of 4.06 per 100,000 population and an estimated 5-year prevalence of 3,724,658 cases, which represent 96.73 per 100,000 population¹. In Mexico, the National Institute of Statistics and Geography reports that deaths caused by cancer have been on the rise; in 2008, there were 6.1 cases per 10,000 population, and by 2017, there were 6.8 cases per 10,000 population reported. Deaths caused by malignant tumors were 84,142 cases, out of which genitourinary organs accounted for 19,408 cases (23.1%). By age groups, the group most affected by this condition is that of men aged 65 years or older, with 41,088 deaths (54.6%)².

In Mexico, 25,049 cases of prostate cancer were identified, 13.1 per 100,000 population and, until that year, it was the most common type of neoplasm in the male population. The estimated number of deaths was 6,915 (8.3 per 100,000 population), which represents the leading cause of cancer death in Mexico. Finally, there is a 5-year prevalence of 55,565 people (85.34 per 100,000 population)³.

Quality of life can be defined as the degree at which physical, emotional, and social well-being is affected by a medical condition or its treatment⁴. In patients with prostate cancer, quality of life is affected by the disease and medical treatments in different dimensions, both physical and psychological. The following data have been described, for example, with regard to physical symptoms: urinary incontinence (20% only with active surveillance, 65% with radical prostatectomy, and 33% with radiotherapy), urinary urgency (52% with active surveillance, 43% with radical prostatectomy, and 75% with radiotherapy), diarrhea (13% with active surveillance, 9% with radical prostatectomy, and 20% with radiotherapy), fatigue (7% with active surveillance, 8% with radical prostatectomy, and 20% with radiotherapy), erectile dysfunction (23% with active surveillance, 76% with radical prostatectomy, and 55% with external beam radiotherapy), and pain

(12% with active surveillance, 18% with radical prostatectomy, and 22% with radiotherapy)⁵.

As for psychological symptoms, international findings report a feeling of decreased masculinity (16% only with active surveillance, 61% with radical prostatectomy, and 49% with external beam radiotherapy), emotional distress (16% with active surveillance, 9% with radical prostatectomy, and 12% with external beam radiotherapy)⁵, depression (17% at pretreatment, 15% during treatment, and 18% at post-treatment), and anxiety (27% at pretreatment, 15% during treatment, and 18% at post-treatment)⁶.

Given the above results, it is necessary to accurately assess the quality of life dimensions, especially considering that there is little research on the subject in the Mexican population with prostate cancer^{7,8}. So far, no scale designed or validated for this group of patients has been identified. The fact of not having a specific instrument limits accurate knowledge of the quality of life and the cultural differences that may be found in comparison with other populations.

In this context, the Functional Assessment of Cancer Therapy Scale-prostate (FACT-P) was validated⁹, which has shown its usefulness at different cultural settings^{10,11} and has revealed levels of internal consistency ranging from 0.687 in the case of the Chinese scale¹¹ to 0.880 for the Korean version¹⁰. The scale has also shown that it is able to discriminate patients with and without metastases⁹, all of which makes for its possible use in different countries to be relevant. FACT-P is a self-administered scale consisting of 39 items in its original version, which has an internal consistency of 0.87-0.89, and for the prostate cancer subscale, an alpha-value of 0.65-0.69⁹.

Methods

Participants

Two-hundred and one prostate cancer patients recruited at the National Institute of Cancerology (INCan – *Instituto Nacional de Cancerología*), Mexico City, did participate. The inclusion criteria were:

patients with prostate cancer diagnosis, who were undergoing cancer treatment (any type or combination thereof) or on follow-up period, at any clinical stage, and who knew how to read and write. The exclusion criteria were: patients with cognitive dysfunction, patients with hearing impairment and patients with visual deficit. The elimination criteria were: that the patient decided not to continue participating or did not complete the answers to the instruments. Mean age was 68.5 years (49-90) and table 1 shows the participants sociodemographic data. The present study was previously approved by INCAN Ethics and Research Committee.

Instruments

The FACT-P is a self-administered multidimensional scale made up of 39 items, out of which 12 are specific for prostate cancer, which measures pain, urinary function, sexual function, social and emotional aspects, with internal consistency coefficients of 0.65-0.69¹² and which is applied together with FACT-G, with an internal consistency alpha score of 0.87-0.89¹³.

The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30), validated in Mexico¹⁴, contains 30 items with scales for four domains (physical function, emotional role, social function, and cognitive function); two items evaluate overall quality of life, and, in addition, it has three symptom scales (fatigue, pain, and vomiting), with internal consistency coefficients of 0.60-0.70¹⁵.

The Hospital Anxiety and Depression Scale (HADS)¹⁶, already validated in Mexico¹⁷, is an instrument that measures anxiety and depressive symptoms, with 12 items in its Mexican version, with overall internal consistency ($\alpha = 0.86$) and coefficients for each subscale with a value of 0.79-0.80, and shows 48.04% of explained variance.

A participant identification card was added, which collected clinical and sociodemographic variables from the INCAN System, with all ethical and confidentiality criteria being preserved.

Cultural adaptation

A pilot test of the questionnaire was applied to 30 Mexican patients with the FACT-P Spanish language version in order to explore for possible expressions that could be confusing or interpretable in more than

one way and to ensure that patients understood the content of all items¹⁸. A case report form was used, which included a specific questionnaire to cover the comprehension of the instructions, of each item and of the answer options. The collected data indicated that 16.7% of participants had comprehension problems in one item, which was close to the 20% criterion considered for the item to be modified. Based on these data, a "judging" process was carried out to assess the items' structure, looking for information, certainty, judgment, or opinion for the Spanish language version of the item to be reviewed¹⁹. To the item in English "I am able to feel like a man" the word "un" could be added, and thus it would read in Spanish "*Soy capaz de sentir como un hombre.*" This observation was submitted to a group of qualified psychologists with at least a master's degree along with a template of instructions and there was no consensus regarding the change, and thus the item was used with the literal translation.

Analysis

Central tendency analyses were carried out using the Kolmogorov-Smirnov test, as well as descriptive analyses, with median and mode for FACT-P inferential statistics. The criteria used for analysis were the following: no minimum factor loads were assigned, no minimum number of items per factor was considered, and internal consistency coefficient was considered for each factor with Cronbach's $\alpha > 0.60$. For the relationship between FACT-P, EORTC QLQ-30 and HADS, Pearson's correlation was used by the interval level of variables with a $p < 0.05$. In addition, internal consistency analysis and exploratory factor analysis were carried out using varimax rotation, since low and medium correlations between items were identified²⁰. For the above analyses, version 24 of IBM SPSS® software was used.

In addition, a comparison of quality of life levels was carried out using the FACT-P subscales between patients without and with metastases. For this, Mann-Whitney's U-test was employed. Based on the results of the exploratory model, a confirmatory factor analysis was carried out with the maximum likelihood method using the AMOS statistical program (version 23.0) to estimate its fit to the data using the following indices: for global fit, the absolute Chi-square value and then the Chi-square/degrees of freedom ratio to confirm if there are errors in null variances and covariances, and

Table 1. Demographic data of participants for FACT-P validation

	f	%		f	%
N	201	100	Paternity		
			Yes	186	92.5
Age (Range)			No	15	7.5
49-90					
$\bar{x}$ = 68.53					
Marital status			Medical status		
Married	132	65.7	Hormonal therapy and radiotherapy	71	35.3
Single	27	13.4	Hormonal therapy	44	21.9
Cohabiting	17	8.5	No treatment	22	10.9
Widowed	14	7	Surgery	20	10
Divorced	6	3	Radiotherapy	15	7.5
			Hormonal therapy and chemotherapy	8	4
Schooling			Surgery and radiotherapy	8	4
Primary school	84	42	Hormonal therapy, radiotherapy and chemotherapy	9	4.5
Secondary school	35	17.5	Orchiectomy	4	2
College degree	34	17			
High school	26	13	Treatment period		
None	14	7	Active treatment	134	66.7
Postgraduate	8	4	Follow-up	52	25.9
			Diagnosis	10	5
Economic level			Treatment initiation	5	2.
Level I	24	11.9			
Level II	57	28.4	Comorbidity		
Level III	103	51.2	None	97	48.5
Level IV	6	3	High blood pressure	40	20
Level V	1	0.5	Diabetes	22	10.9
Level VI	10	5	Combination	16	8
			Other	24	11.9
Current occupation					
Self-employed	73	36.3	Clinical stage	68	33.8
Unemployed	69	34.3	IV	14	7
Employees	25	12.4	III	18	9
Retired	11	5.5	I		
Field worker	19	9.5		101	50.2
Other occupation	4	2	II		
ECOG scale			Weight (kg)		
0	101	50.2	45-65	35	17.9
1	93	46.3	66-85	123	61.2
2	6	3	86-105	38	18.9
3	1	.5	106-115	4	2

ECOG: Eastern Cooperative Oncology Group.

if it fits large samples ($n \geq 200$), as recommended by several experts^{21,22}.

Overall fit was estimated against a null model using the Comparative Fit Index (CFI) and Tucker-Lewis Index (TLI), which “penalizes” complexity and fit of the model to the data²³.

Parsimony and balance of the model were estimated using TLI, as well as goodness of fit with the Goodness of Fit Index (GFI), Adjusted Goodness of Fit Index (AGFI), and the root mean squared error of approximation (RMSEA). Finally, goodness of fit was confirmed by calculating the root mean square residual (RMR) index²³⁻²⁵.

Results

Factor structure

On Bartlett’s sphericity test, the FACT-P scale obtained a p-value of 0.001 and a KMO index of 0.774. Correlations between items ranged from 0.145 to 0.645. With all items, a Cronbach alpha value (internal consistency) of 0.79 was identified. An exploratory factor analysis yielded a two-factor model (pain alpha = 0.81 and urinary function alpha = 0.70) with two indicators (sexual function alpha = 0.48 and functionality alpha = 0.50) that explained 65.7% of

Table 2. Rotated factors for FACT-P, ordered according to their factor load

FACT-P subscale items	Component				12-item alpha ($\alpha = 0.79$)		
	1	2	3	4	Explained variance	Mean $\pm$ SD	Cronbach's alpha
					64.65%		
Pain subscale						11.68 $\pm$ 3.75	$\alpha = 0.81$
P1 <i>Tengo dolores que me molestan</i> (I have aches and pains that bother me)	0.913	0.128	0.062	0.046			
P2 <i>Tengo dolor en ciertas partes del cuerpo</i> (I have certain parts of my body where I experience pain)	0.904	0.154	0.125	-0.033			
P3 <i>El dolor me impide hacer las cosas que quiero hacer</i> (My pain keeps me from doing things I want to do)	0.751	0.246	0.145	0.133			
P6 <i>Tengo problemas con el estreñimiento</i> (I have trouble moving my bowels)	0.420	0.257	-0.092	0.141			
Urinary function subscale						12.03 $\pm$ 3.16	$\alpha = 0.70$
BL2 <i>Orino más frecuentemente de lo usual</i> (I urinate more frequently than usual)	0.133	0.788	0.113	-0.140			
P7 <i>Tengo dificultad al orinar</i> (I have difficulty urinating)	0.103	0.771	0.026	0.115			
P8 <i>Mis problemas con el orinar limitan mis actividades</i> (My problems with urinating limit my activities)	0.330	0.710	0.025	0.069			
C2 <i>Estoy bajando de peso</i> (I am losing weight)	0.327	0.391	-0.186	0.374			
Sexual function subscale						2.8 $\pm$ 1.8	$\alpha = 0.48$
BL5 <i>Soy capaz de tener y mantener una erección</i> (I am able to have and maintain an erection)	0.109	0.118	0.807	-0.124			
P5 <i>Soy capaz de sentir como un hombre</i> (I am able to feel like a man)	0.005	-0.008	0.722	0.426			
Functionality subscale						4.9 $\pm$ 1.7	$\alpha = 0.50$
C6 <i>Tengo buen apetito</i> (I have a good appetite)	0.005	0.063	0.042	0.830			
P4 <i>Estoy satisfecho con el alivio que tengo por el momento</i> (I am satisfied with my present comfort level)	0.402	-0.109	0.425	0.568			

SD: Standard deviation.

Four-factor factor analysis, Kaiser-Meyer-Olkin 0.774, Bartlett $P > 0.001$.

total variance, with total estimators of 31.44 ± 7.36 (mean and standard deviation); these factors and indicators are equivalent to those reported in other studies (Table 2).

Discrimination between patients with and without metastases

To assess the ability of the FACT-P scale to differentiate the quality of life of patients with and without metastases, once the analyses have been performed, there are statistically significant differences in the instrument total score ($p \leq 0.001$). The group with the poorest quality of life is that of patients with metastases in the following subscales: prostate cancer subscale ($p = 0.009$), trial outcome index ($p \leq 0.001$), general physical health status ($p \leq 0.001$), and personal functioning capacity ($p = 0.006$); however, there are no significant differences in the family and social

well-being ($p = 0.691$) and emotional well-being subscales ($p = 0.565$).

Confirmatory analysis

Figure 1 shows the model with the four-factor final structure, the estimators calculated for each factor and the correlations between them, as well as the explained variance for each item. At the bottom, the most relevant indices are indicated, such as the relative comparative fit indices (CFI, TLI, and AGFI), the values of which are ideal (> 0.90) and corroborate an acceptable and parsimonious model, compared against the null model²². Overall fit is observed to be excellent on Chi-square test adjusted to 48 degrees of freedom (Chi-square Mean Index/Degree of Freedom [CMIN]/df = 1.613), which confirms an excellent absolute fit of the model to the observed data²⁵.

The RMR index is very close to zero and is < 0.08 (RMR = 0.078), indicating an almost null difference

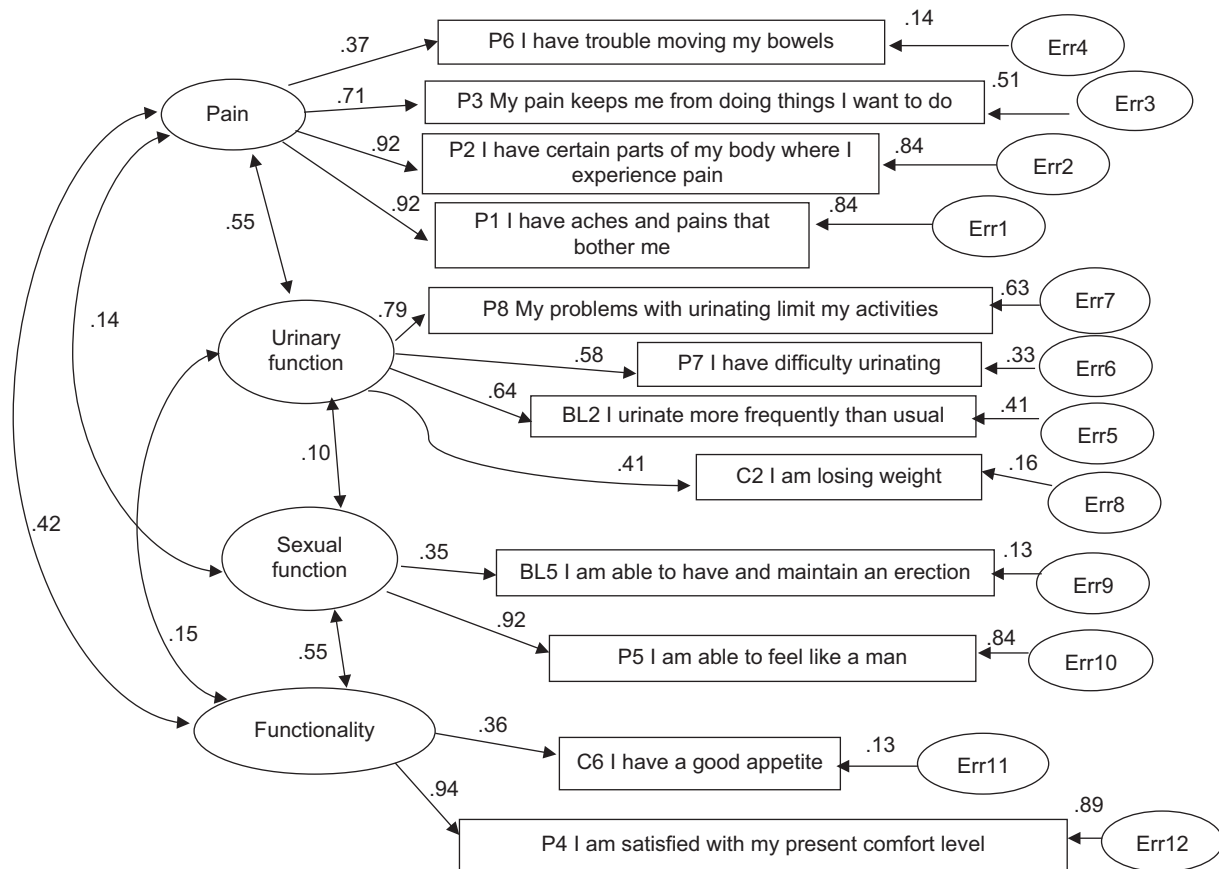


Figure 1. Four-factor confirmatory factor analysis model for FACT-P in patients with prostate cancer ($N = 201$). Chi-square test = 77.43, 48 degrees of freedom, $p = .005$, CMIN/df = 1.613, RMR = 0.078, GFI = 0.941, AGFI = 0.904, TLI = 0.944, CFI = 0.960, RMSEA = 0.055 (0.031-0.077), Hoelter index (sample size acceptability, $p = .01$, $n = 191$).

between the observed and predicted covariance matrix, and we can assume that the discrepancy between the proposed model and the actual data is almost null or very low^{21,24,25}.

The RMSEA index value (root mean square error of approximation, or mean square root of the ratio between the non-central parameter adjusted for degrees of freedom) is almost zero (RMSEA = 0.055; 0.031-0.077) and indicates almost nullity in model error²⁵.

On Hoelter's index test ($n = 191$, $p = 0.01$), the theoretical sample size does not exceed the one that was used, and we can, therefore, affirm that the model is correct and the hypothesis (probability of an alpha error of 0.01) that the sample is sufficient for the analyses is accepted^{24,25} (Fig. 1).

A FACT-P concurrent validation was carried out using the EORTC QLQ 30 and HADS instruments, with the correlations being positive and statistically significant (Pearson's r of 0.146-0.716, $p < 0.01$ and

$p < 0.05$) between the subscales, for example, global health, physical function, and functional, emotional, cognitive and social roles. On the other hand, negative correlations were identified between FACT-P, EORTC QLQ 30, and HADS, which indicate an inversely proportional relationship (Pearson's r from -0.206 to 0.0744, $p < 0.01$) in fatigue, nausea, pain, anxiety symptoms, depression, and HADS total score (Table 3).

Discussion

FACT-P is regarded as one of the best tools for measuring quality of life in patients with prostate cancer²⁶, and validations in other countries thus show it^{10,11}, as well as the satisfactory results it showed in Mexican patients in this study.

Quality of life evaluation in patients with prostate cancer is highly relevant, since it is possible to quickly and reliably document how the person perceives the

Table 3. FACT-P Mexican version correlation coefficients with EORTC QLQ-30 and HADS

Subscale/ Total scale	EORTC QLQ-30									HADS		
	Global health	Physical function	Functional role	Emotional	Cognitive	Social	Fatigue	Nausea	Pain	HADS anxiety	HADS depression	HADS total
PCS	0.581 [†]	0.716 [†]	0.641 [†]	0.440 [†]	0.384 [†]	0.484 [†]	-0.679 [†]	-0.498 [†]	-0.764 [†]	-0.445 [†]	-0.559 [†]	0.581 [†]
TOI	0.659 [†]	0.720 [†]	0.664 [†]	0.486 [†]	0.407 [†]	0.533 [†]	-0.699 [†]	-0.522 [†]	-0.744 [†]	-0.524 [†]	-0.634 [†]	0.659 [†]
PWB	0.612 [†]	0.706 [†]	0.658 [†]	0.512 [†]	0.377 [†]	0.546 [†]	-0.774 [†]	-0.622 [†]	-0.753 [†]	-0.509 [†]	-0.563 [†]	0.612 [†]
SWB	0.202 [†]					0.146 [*]						0.202 [†]
EWB	0.365 [†]	0.259 [†]	0.254 [†]	0.579 [†]	0.308 [†]	0.305 [†]	-0.342 [†]	-0.244 [†]	-0.268 [†]	-0.545 [†]	-0.389 [†]	0.365 [†]
FWB	0.496 [†]	0.406 [†]	0.391 [†]	0.288 [†]	0.275 [†]	0.330 [†]	-0.320 [†]	-0.206 [†]	-0.365 [†]	-0.388 [†]	-0.501 [†]	0.496 [†]

EWB: emotional well-being; FWB: functional well-being; PCS, prostate cancer subscale; PWB: physical well-being; SWB: social and family well-being; TOI: trial outcome index (in the sum, only physical well-being, personal well-being and prostate cancer subscale are used).

*The correlation is significant at a 0.05 level.

†The correlation is significant at a 0.01 level.

impact the disease and the received treatments have on his/her life. Due to the deterioration these patients often show in both physical and psychological variables, it is necessary to establish how these variables are affected with reasonable certainty²⁷.

The number of participants was appropriate for analysis. In addition, in the factor analysis, as confirmed by Bartlett's sphericity test and Kaiser-Meyer-Olkin test and the varimax rotation, the correlations between items were determined to be within the criteria for small or medium.

In addition, it should be pointed out that FACT-P also appropriately discriminates between patients with and without metastases, just as the original scale does, considering only physical aspects. In contrast, it does not discriminate the family and social well-being and physical well-being subscales, but it could be considered that, strictly speaking, these variables do not necessarily have a direct relationship with metastasis⁹.

The present results regarding FACT-P are consistent with reports in international research literature^{9,12}, with a structure whose subscales measure pain, urinary function, sexual function, and social and emotional aspects related to prostate cancer. However, the item "I am losing weight," due to its factor load, was associated with the urinary function (Table 2). In theory, this item would not have a direct relationship with the rest of urinary function questions, but the patients understood that losing weight and urinating problems might be closely related according to other previously reported data²⁸. It should be noted that the research

on said data was based on obese patients with urinary function problems, and the investigation indicated that fewer problems urinating would be related to a more appropriate weight. By virtue of the above, leaving this item on that position was decided, until future studies examine the behavior of said item to facilitate a decision in this regard, that is, whether it is moved to another factor or removed from the scale.

It is necessary for future investigations to evaluate the stability of the instrument over time; applying it to newly diagnosed patients and to patients on follow-up is also suggested for a timely multidisciplinary approach to quality of life, as well as to compare the results with different populations.

Conclusions

The FACT-P scale is a reliable and valid, stable and parsimonious instrument for measuring the quality of life of prostate cancer patients in Mexico.

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Conflicts of interest

The authors of this work declare that they have no conflicts of interest.

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Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this research.

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors have obtained informed consent from the patients and/or subjects referred to in the article. This document is in the possession of the corresponding author.

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