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RESEARCH ARTICLES

The EORTC Quality of Life Questionnaire for patients with prostate cancer: EORTC QLQ-PR25. Validation study for Spanish patients

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Abstract
Objectives The EORTC Quality of Life (QL) Group has developed a questionnaire, the EORTC QLQ-PR25, for evaluating QL in prostate cancer. The aim of this study is to assess the psychometric properties of the EORTC QLQ-PR25 when applied to a sample of Spanish patients.
Materials and methods One hundred and thirty-seven prostate cancer patients with localised disease who started radiotherapy with radical intention combined with or without hormonotherapy prospectively completed the EORTC QLQ-C30 and EORTC QLQ-PR25 questionnaires three times: on the first and last day of radiotherapy and in the follow-up period. Psychometric evaluation of the questionnaires' structure, reliability and validity was conducted.
Results Multitrait scaling analysis showed that many of the item-scale correlation coefficients met the standards of convergent and discriminant validity. Exceptions appeared mainly in the scales for bowel symptoms and for hormonal-treatment-related symptoms. Cronbach's coefficients of the scales were good (0.72–0.86) for the urinary symptoms and sexual function scales but they were lower (<0.70) for the bowel and hormonal treatment scales. Most scales of the EORTC QLQ-PR25 had low to moderate intercorrelations. Correlations between the scales of the QLQ-C30 and the module were generally low. Group comparison analyses showed better QL in patients with higher Performance Status. Changes in QL appeared throughout the measurements. These were in line with the treatment process.
Conclusions The EORTC QLQ-PR25 was a reliable and valid instrument when applied to a sample of Spanish prostate cancer patients. These results are in line with those of the EORTC validation study.

Keywords Cancer · Prostate · Quality of life · Validation · Spanish · EORTC QLQ-PR25

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Introduction

Prostate cancer is one of the most frequent tumours in Western societies. Most patients with this tumour are elderly: in the USA, for example, the mean age of patients with prostate cancer is 66 at the time of diagnosis [1, 2]. Today quality of life (QL) assessment plays a key role in the evaluation and treatment of cancer patients. It is considered important to conduct QL studies for this tumour site that evaluate the effects of the treatments and orientate patients and professionals [3].

Treatments administered to prostate cancer patients produce secondary effects, mainly in the areas of sexual, urinary and bowel function. However, they also produce fatigue and hot flashes, which are related to hormonotherapy. In the case of prostate cancer with localised disease, it is important to evaluate QL because of the high prevalence rate, the long mean survival period, the fact that patients can receive different treatment modalities (on their own or combined), and because surgery and radiotherapy can have a similar curative effect [4].

The European Organization for Research and Treatment of Cancer (EORTC) has a working group on QL. One of the main tasks of this group is to develop questionnaires to assess QL in clinical trials. These instruments can also be used in clinical practice. The group uses a modular approach that includes a core questionnaire (QLQ-C30) designed to evaluate QL across a wide spectrum of patient populations and treatments and a range of supplementary modules designed to assess specific issues, according to the type of treatment or disease site, or dimensions such as fatigue. The EORTC questionnaires are widely used in Spain and other Spanish-speaking countries [5, 6].

This study group recently developed a module for prostate cancer – the EORTC QLQ-PR25. This instrument has been validated in a multicentre study with patients in localised and advanced disease stages from 13 countries but not including Spain [7]. The EORTC QL Study Group recommends the performance of validation studies of their instruments (like the QLQ-PR25) in individual countries. These studies are useful for professionals because, among other reasons, they estimate the expected QL values for each country and for different groups of patients and explore whether the questionnaires have a good psychometric functioning.

Other instruments have been developed to assess QL in prostate cancer: these include the Functional Assessment of Cancer Therapy – Prostate (FACT P) [8, 9]; the University of California Los Angeles (UCLA) Prostate Cancer Index (PCI) [10]; the Expanded Prostate Cancer Index Composite (EPIC) [11]; and the PCQOL [12]. Some questionnaires, such as the ESCAP-CDV [13] and the Hot Flashes Questionnaire [14], have been developed in Spain.

The aims of this study are to determine the psychometric properties of the QLQ-PR25 when applied to a sample of Spanish prostate cancer patients with localised disease and to compare the results of these analyses with those of the previous validation study conducted by the EORTC QL study group.

Materials and methods

Participants

A consecutive sample of prostate cancer patients was used. This sample consisted of patients with localised disease (T1-T3 N0 M0) who started radiotherapy with radical intention, combined or not with hormonotherapy, at the Radiotherapeutic Oncology Department of the Hospital of Navarre. Patients received the treatment protocols of the department depending on the risk group to which they belonged.

Patients with low-risk prostate cancer received radiotherapy alone with three-dimensional planning. Patients with intermediate-risk prostate cancer received radiotherapy combined with a six-month period of neoadjuvant and concomitant hormonal treatment that consisted of a combination of an antiandrogen (bicalutamide or flutamide) and an LHRH analogue (goserelin or leuprolide). Patients with high-risk prostate cancer received radiotherapy and the same combination of neoadjuvant and concomitant hormonal therapy as the intermediate-risk group, followed by two years of adjuvant treatment with the LHRH analogue. Radiotherapy dosages ranged between 72 GY in the low-risk group and 76 GY in the intermediate- and high-risk patients.

For sample size we followed the recommendation of Tabachnik and Fidel [15]: five patients per module item.

Measures

Patients completed the QLQ-C30 (version 3.0) [16], which our group had validated for use in our country [17, 18], and the EORTC QLQ-PR25 [7]. The structure of this second questionnaire is shown in Table 1. The questionnaire had been translated into Spanish following the translation procedure of the EORTC QL Study Group [19]. Sociodemographic and clinical data were taken from clinical records. Performance status (KPS) was assessed by the physician at various time-points using the Karnofsky scale [20]. Questionnaires with less than 70% of the items answered were excluded.

Data collection procedures

Patients completed the questionnaires on the first and last day of radiotherapy, and a month and a half after the end of this treatment.

Statistical analysis

Multitrait scaling analysis [21] was used to examine item convergent validity (item scale correlation >0.40; scale corrected for overlap) and item discriminant validity (item own scale correlation higher than with the other scales).

The internal consistence reliability of the scales was assessed with Cronbach's alpha coefficient [22] (≥0.70 criteria).

Validity was studied with four approaches. Interscale correlations of the *QLQ-PR25* were calculated, as were correlations between the *QLQ-PR25* and *QLQ-C30* scales, to study convergent and discriminant validity (Pearson's correlation coefficients; two-tail analysis). All of these

Table 1 Structure of the EORTC QLQ-PR25

Scales/single items–name	Number items	
Urinary symptoms (1)	8 (items 1–7 and 9)	
Incontinent aid (1)	1 (item 8)	Conditional on using an incontinence aid
Bowel symptoms (1)	4 (items 10–13)	
Hormonal-treatment-related symptoms (1)	6 (items 14–19)	
Sexual activity (2)	2 (items 20, 21)	
Sexual functioning (2)	4 (items 22–25)	Conditional on being sexually active

The scores range from 0 to 100, with a higher score representing more symptoms (1) or a higher level of functioning (2)

analyses were performed at the first and second assessments.

Known group comparison analysis was performed to determine the extent to which the questionnaire was able to discriminate between subgroups of patients differing in clinical status. Group differences were assessed using Mann–Whitney U-tests ($p<0.05$). We compared subgroups based on KPS levels: 70 to 90 and 100 in the first and third measurements and 70–80 and 90–100 in the second.

We also studied responsiveness to change over time using the differences among the three measurements (Friedman test $p<0.05$ and Bonferroni criteria to determine between which pairs of measurements the differences appeared).

Results

Patients' characteristics and compliance

Out of 141 patients that were addressed between October 2001 and November 2003, 137 completed the first questionnaire, 126 the second and 120 the third. At the second measurement the reasons for not completing the questionnaires were: administrative failure (8 cases), patient refusal (2 cases) and death (1 patient). At the third measurement the reasons were: administrative failure (13 cases), patient refusal (2 cases) and death (1 patient). In all questionnaires more than 70% of the items were answered. Sociodemographic and clinical characteristics of the patients are shown in Table 2 and their scores on the QLQ-PR25 are shown in Table 3.

Multitrait scaling analysis

Many of the items exceeded the 0.4 criterion for convergent validity. Exceptions were items 12–17 in both measurements, item 22 in the first, and items 18 and 19 in the second. Item discriminant validity was successful in most analyses except for items 12–15 and item 22 in the first measurement, and items 16–18 in the second measurement.

In both measurements, internal consistency reliability estimates of the QLQ-PR25 scales were above the

Table 2 Characteristics of the sample

	Number	Mean	S.D.	%
Age		70.9	5.2	
Level of studies				
Less than compulsory school education	44			32.1
Compulsory school education	75			54.7
Post-compulsory education below university	8			5.8
University level	10			7.4
Civil status				
Single	17			12.4
Married	116			84.7
Separated	1			0.7
Widower	3			2.2
Hormonotherapy				
Yes	117			85.4
No	20			14.6
Karnofsky 1		96.1	6.1	
Karnofsky 2		87.6	6.7	
Karnofsky 3		91.8	7.6	

Karnofsky 1, 2 and 3: performance status evaluated at the three QL assessment points (Karnofsky scale)

Table 3 Quality of life scores according to QLQ-PR25 in the three measurements

Areas	Measurement	Mean	S.D.	% floor	% ceiling
Urinary symptoms (1)	First	20.9	18.5	9.5	0.7
	Second	35.20	21.0	1.6	0
	Third	20.2	15.6	7.7	0
Incontinent aid (1)	First	18.5	37.7	77.8	11.1
	Second	20.3	27.9	60.9	0
	Third	19.4	22.3	50.0	0
Bowel symptoms (1)	First	3.5	7.6	72.8	0
	Second	9.2	12.2	44.4	0
	Third	3.5	6.6	72.3	0
Hormonal treatment related symptoms (1)	First	9.2	10.9	35.8	0
	Second	12.1	11.1	24.4	0
	Third	12.9	10.1	18.3	0
Sexual activity (2)	First	15.1	22.8	57.4	2.2
	Second	15.9	26.9	64.8	4.1
	Third	10.6	22.2	72.5	0
Sexual functioning (2)	First	62.1	27.6	9.7	3.2
	Second	55.2	21.6	3.4	0
	Third	50.9	30.4	15.8	5.3

Mean±SDs of the scores in the QLQ-PR25, at the three measurements
The scores range from 0 to 100, with a higher score representing more symptoms (1) or a higher level of functioning (2)
% floor, percentage of respondents at the lowest scale rating; % ceiling, percentage of respondents at the highest scale rating

0.70 criterion for three scales –urinary symptoms (0.83, 0.86), sexual activity (0.74, 0.72), sexual functioning (0.73, 0.77)– and below the 0.70 criterion for two scales – bowel symptoms (0.45, 0.53) and hormonal-treatment-related symptoms (0.45, 0.39).

Most scales of the QLQ-PR25 had low to moderate correlations with the other scales. The highest correlations were between sexual activity and sexual functioning in the second measurement (0.68). In both measurements, low correlations were found between sexual activity and urinary symptoms (0.07, 0.01) and between sexual activity and bowel symptoms (0.07, 0.03).

The correlations between the scales of the QL-C30 and the module were generally low, except for the urinary symptoms scale (0.47 in the first measurement and 0.45 in the second measurement with the pain scale of the QLQ-C30), bowel symptoms (0.48 with physical functioning and fatigue and 0.53 with role functioning and social functioning in the first measurement and 0.47 with fatigue in the second measurement) and sexual function (0.51 with physical functioning and 0.60 with fatigue in the first measurement and 0.46 with physical functioning and 0.51 with social functioning in the second measurement).

Group comparisons

In analyses performed with KPS as the grouping variable, there were significant differences in urinary symptoms, incontinence aid and sexual activity in the second measurement and in urinary symptoms in the third.

Responsiveness to change

There was a significant worsening of the condition between the first and second measurements in two areas (urinary symptoms and bowel symptoms), a significant improvement between the second and third measurements, and no significant differences between the first and third measurements. For the hormonal-treatment-related symptoms scale, there was a worsening between the first measurement and the second measurement that continued into the third measurement. In the sexual activity scale, there was a worsening in the third measurement with respect to the first and second measurements.

Discussion

In this paper we have presented the results of a validation study of the EORTC QLQ-PR25 questionnaire for Spain. Levels of compliance were high and missing data were few, which indicates that the instrument was well accepted. Except for the sexuality scales, where our patients had lower scores [7], the scores in the QLQ-PR25 (Table 3) were in line with those in the subsample of early-stage patients in the EORTC field study. Different QL studies carried out by our group on Spanish patients with other tumours have also shown low scores in the sexuality scales [23–25].

Multitrait scaling analyses confirmed the psychometric structure of three scales, though in two of these (bowel symptoms and hormonal-treatment-related symptoms) there were some limitations. These results, slightly worse

than those of the international field study, could be due to the fact that in our study these analyses were carried out with patients with localised disease, whereas in the field study they were carried out with patients with initial and advanced diseases [7].

Three scales satisfied the reliability criteria and two scales (bowel symptoms and hormonal-treatment-related symptoms) did not. These low alphas and the results of the multitrait scaling analyses are partly explained by the score distribution: the standard deviation for both scales in the two measurements was low and score variance was limited (0–50 and 0–66.7 for the bowel symptoms scale, and 0–55.6 for the hormonal-treatment-related symptoms).

QLQ-PR25 interscale correlations were satisfactory. These indicated that the areas were related but represented different QL dimensions. Scales with closer content (sexual activity and sexual functioning) had higher correlation coefficients in the expected direction. Scales with quite different content, on the other hand (for example, sexual activity and urinary or bowel symptoms), had lower correlation coefficients. Correlations with the QLQ-C30 scales were also satisfactory and indicated that the two questionnaires evaluate different QL dimensions. Scales whose content could have a mutual influence had higher correlation coefficients (e.g., bowel symptoms and fatigue).

Group comparison analyses were satisfactory since they were in line with the clinical data: patients with higher KPS had better QL. Comparisons between the different measurements were satisfactory as they had clinical significance. These results showed that the QLQ-PR25 is highly sensitive to changes. At the end of the treatment the urinary symptoms and the bowel symptoms tended to get worse. In the follow-up they improved, perhaps due to the low toxicity of the radiotherapy. The worsening of the hormonal-treatment-related symptoms and the sexual activity scales may be related to the cumulative effect of hormonotherapy.

The results for the reliability and validity analyses are in line with those of the EORTC international study [7].

Conclusions

In summary, the EORTC QLQ-PR25 demonstrated satisfactory psychometric properties when applied to a sample of Spanish patients with localised prostate cancer. Our results are in line with those of the validation study carried out by the EORTC QL study group. We consider that the EORTC QLQ-PR25 is a robust instrument for use with Spanish cancer patients. New studies with other disease stages could confirm these results.

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Conflict of interest The authors declare that they have no conflict of interest relating to the publication of this manuscript.

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