



# Reliability and Validity of the Taiwan Chinese Version of the EORTC QLQ-PR25 in Assessing Quality of Life of Prostate Cancer Patients

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**Background/Purpose:** This study examined the psychometric properties and clinical validity of the EORTC QLQ-PR25, a questionnaire for assessing the quality of life of patients with prostate cancer.

**Methods:** The Taiwan Chinese version of the prostate cancer module (EORTC QLQ-PR25) and the core questionnaires (EORTC QLQ-C30) were administered to 81 patients with prostate cancer after they had been treated with surgery or hormone therapy or both. The QLQ-PR25 module assesses urinary symptoms, bowel symptoms, hormonal treatment-related symptoms, sexual activity and sexual functioning.

**Results:** The questionnaires were well accepted by the patients and very few of the items had missing data. Only the urinary symptom scale showed satisfactory internal consistency. Scales were able to differentiate clinical groups of patients with corresponding symptoms, but the differences were smaller than that of major functioning scales in the core questionnaire.

**Conclusion:** The Taiwan Chinese version of the EORTC QLQ-PR25 is acceptable in patients with prostate cancer in Taiwan, able to differentiate corresponding symptoms, but the scale structure needs further improvement.

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## 1. Introduction

Prostate cancer is one of the most common cancers in men in Western countries and developed Asian countries.<sup>1,2</sup> Along with a rapidly aging population and westernized dietary habits, the incidence and mortality of prostate cancer in Taiwan have increased rapidly in the last few decades. The age-adjusted incidence (adjusted by the 1976 world population) has risen from 1.86 per 100,000 men in 1979 to 18.40 per 100,000 men in 2006.<sup>3</sup> The age-adjusted mortality rate of prostate cancer has

risen from 2.3 per 100,000 men in 1986 to 6.7 per 100,000 men in 2007. This cancer is now the seventh leading cause of cancer death in men in Taiwan.<sup>3,4</sup>

Prostate cancer has relatively good prognosis among cancers. The 5-year survival rate can reach 70%.<sup>1,5</sup> The long survival means that quality of life (QoL) is an important indicator of treatment success in survivors. Among the various treatment modalities of surgery, radiotherapy, hormone therapy and chemotherapy, survival rates do not differ too much, but the adverse effects do.<sup>5–8</sup> Surgery affects sexual function and may cause stress urinary incontinence. Radiotherapy may induce irritative

voiding symptoms and gastrointestinal symptoms.<sup>9</sup> Therefore, QoL may differ after different treatments. It is necessary to develop a disease-specific instrument to measure these problems in patients with prostate cancer who undergo different treatments.

Among the randomized controlled trials of QoL of patients with prostate cancer between 1980 and 2001, the EORTC QLQ-C30 developed by the European Organisation for Research and Treatment of Cancer (EORTC) was the most commonly used instrument.<sup>10</sup> However, the specific problems of patients with prostate cancer are not covered. The EORTC established guidelines for supplementary module development in 1993.<sup>11</sup> For assessing the issues of QoL of patients with prostate cancer, the EORTC developed a supplementary module, the EORTC QLQ-PR25<sup>12</sup> according to the guidelines, which is comprised of 25 questions that cover 6 scales: PR URI (urinary symptoms, 8 items); PR AID (incontinence aid, 1 item); PR BOW (bowel symptoms, 4 items); PR HTR (hormonal treatment-related symptoms, 6 items); PR SAC (sexual active, 2 items); and PR SFU (sexual function, 4 items). Five items are conditional questions, conditioned on the need of incontinence aid (Q37, PR7), and the status of being sexually active (Q52–55, PR22–25). The results of international field validation published in 2008<sup>13</sup> and validation studies of the EORTC QLQ-C30 and PR25 in Spain published in 2008<sup>14</sup> and 2009<sup>15</sup> showed that the new instrument had acceptable psychometric properties, reliability and validity.

We obtained permission to translate and use the questionnaire from the EORTC and questionnaire developer with the agreement that we submit our results after the main international results have been published and that we follow EORTC guidelines for translation and pilot testing.<sup>16</sup> In the past few years, we have published local validation results for the EORTC QLQ-C30 for head and neck, breast and lung cancers, and briefly reported the part of the C30 in stomach cancer.<sup>17–20</sup> The aim of this study was to test the psychometric properties and clinical validity of the Taiwan Chinese version of the EORTC QLQ-PR25 in a medical center in Taipei.

## 2. Patients and Methods

### 2.1. Patients

Patients with histologically confirmed prostate cancer, who were cared for and followed-up by one of the authors (HJY) at the Department of Urology, National Taiwan University Hospital, between September 2004 and September 2005, who were able to understand and answer the questions in the questionnaires, and willing to sign informed consent forms, were invited to participate in the study. Patients who had other malignancies, whose life expectancies were less than 3 months, or who were participating in other QoL studies that may affect

the results of this study, were excluded. There was no limitation in age and performance status, or special preference in the recruitment process. The study was approved by the ethics committee of the study hospital.

### 2.2. Questionnaires and data collection

All patients were invited to complete the Taiwan Chinese version of the EORTC QLQ-C30 (version 3.0) and the EORTC QLQ-PR25. We also collected patients' comments regarding the time needed to complete the questionnaires, any help required during completion, and any questions that were confusing, difficult to answer or upsetting. Patients' demographic characteristics were collected during the interview. Patients' clinical information was collected by medical record review.

### 2.3. Statistical analyses

We described the distribution of demographic and clinical characteristics and answers of each question. The scores for each scale of the EORTC QLQ-C30 were calculated according to the scoring manual<sup>21</sup> and the developer's instructions. Cronbach's  $\alpha$  coefficient was used to evaluate the internal consistency of each scale. Multi-trait scaling analyses were used to evaluate convergent validity and the item discriminant validity of each item in each scale. We also assessed the convergent and discriminant validity of the EORTC QLQ-PR25 and the EORTC QLQ-C30 by examining the correlation coefficients of the scales of the two questionnaires. The clinical validity of each scale was examined by known-groups comparison among different groups of patients with different disease progression and treatments. Non-parametric methods, including Wilcoxon's rank sum test and Kruskal-Wallis test, were used because of the non-normality of most scales. SAS version 9.1 (SAS Institute, Cary, NC, USA) was used. A *p* value of less than 0.05 was considered statistically significant.

## 3. Results

We successfully recruited 81 patients; 59 (72.8%) were in the early stages (I or II) of the disease. Age, educational level, employment status, marital status and living arrangements did not differ between early- and advanced-stage patients, but patients with advanced disease had higher Gleason scores, more combined therapies, and partial prostatectomy (Table 1).

All patients completed the two questionnaires. The acceptability of the questionnaires was high. Most patients could complete the questionnaires in 15–30 minutes without help or only with help with reading the questions. There were no comments about wording and very few missing answers except on the conditional questions. There were no missing answers in the EORTC

**Table 1** Sociodemographic and clinical characteristics of the 81 patients\*

	Early disease stages (I, II) (n=59)	Advanced disease stages (III, IV) (n=22)
Age (yr)		
< 60	0 (0.0)	1 (4.6)
60–70	17 (28.8)	3 (13.6)
70–80	27 (45.8)	12 (54.6)
> 80	15 (25.4)	6 (27.3)
Education		
Below primary	2 (3.4)	1 (4.6)
Primary	5 (8.5)	7 (31.8)
Junior high	5 (8.5)	3 (13.6)
Senior high	10 (17.0)	2 (9.1)
College (below university)	21 (35.6)	4 (18.2)
University	8 (13.6)	4 (18.2)
Graduate	4 (6.8)	1 (4.6)
Missing data	4 (6.8)	0 (0.0)
Occupation		
Full-time	15 (25.4)	6 (27.3)
Retired	20 (33.9)	7 (31.8)
Unemployed	20 (33.9)	9 (40.9)
Missing data	4 (6.8)	0 (0.0)
Marital status		
Married/cohabiting	52 (88.1)	18 (81.8)
Single	0 (0.0)	1 (4.6)
Widowed	3 (5.1)	3 (13.6)
Missing data	4 (6.8)	0 (0.0)
Habitation		
With family	52 (88.1)	19 (86.4)
Alone	3 (5.1)	3 (13.6)
Missing data	4 (6.8)	0 (0.0)
Gleason score		
2	1 (1.7)	0 (0.0)
3	3 (5.1)	0 (0.0)
4	3 (5.1)	1 (4.6)
5	9 (15.3)	0 (0.0)
6	10 (17.0)	0 (0.0)
7	24 (40.7)	8 (40.0)
8	2 (3.4)	3 (13.6)
9	4 (6.8)	7 (31.8)
10	0 (0.0)	2 (9.1)
Missing data	3 (1.7)	1 (4.6)
Treatment		
Observation	1 (1.7)	0 (0.0)
Surgery	27 (45.8)	2 (9.1)
Hormonal	10 (17.0)	2 (9.1)
Surgery and hormonal	21 (35.6)	18 (81.8)
Prostatectomy		
No	10 (17.0)	2 (9.1)
Radical	39 (66.1)	11 (50.0)
Partial	10 (17.0)	9 (40.9)

(Contd)

Hormonal therapy		
No	28 (47.5)	2 (9.1)
Yes	31 (52.5)	20 (90.9)
Active treatment		
No	23 (39.0)	3 (13.6)
Yes	36 (61.0)	19 (86.4)

\*Data presented as n (%).

QLQ-C30. In contrast, only 10 of the 20 unconditional questions on the EORTC QLQ-PR25 had no missing answers. Most patients could understand the language of the questionnaire and complete the questionnaire by themselves. One Japanese patient needed some help with answering the questions.

Descriptive statistics of the answers to each question are shown in Table 2. Floor effects were seen for most questions, especially for Q37 (PR7, pain when urinating), Q41 (PR11, stool incontinence) and Q47 (PR17, weight loss).

In the analysis of internal consistency, only the Cronbach's  $\alpha$  coefficient of urinary symptoms reached a satisfactory level (0.80). The Cronbach's  $\alpha$  coefficients of bowel symptoms, hormonal treatment-related symptoms, and sexual activity were 0.41, 0.45, and 0.64, respectively (Table 3). The internal consistency for sexual functioning was not examined because of the high number of missing answers to conditional questions. The result of multi-trait scaling analysis of each scale corresponded well with internal consistency. Items whose item-to-own scale correlation was less than 0.40 included PR3 (Q33) urinary urgency, PR6 (Q36) incontinence, and PR7 (Q37) pain of urinary symptoms, all items of bowel symptoms (PR10–13, Q40–43), and all items of hormonal treatment-related symptoms (PR14–19, Q44–49). All these items did not have any significantly higher correlation with other scales.

Most correlation coefficients between scales of the EORTC QLQ-PR25 and the EORTC QLQ-C30 were between 0.40 and 0.70 (moderately correlated), while some were even less than 0.40 (weakly correlated). Only the correlation for bowel symptoms and emotional functioning was greater than 0.70 (highly correlated) (Table 4).

In the known-groups comparison for clinical validity, we compared the QoL scores of patients with different clinical conditions. The scales in the core questionnaire (C30) were more discriminative than those in the PR25. Patients with advanced disease had poorer physical, role and social functioning, more fatigue, pain, nausea/vomiting, appetite loss and financial difficulty (the EORTC QLQ-C30), and more hormonal treatment-related symptoms and lower sexual activity (the EORTC QLQ-PR25) than those with early-stage disease. Only the differences in physical functioning, fatigue and pain were highly significant ( $p < 0.01$ ) (Table 5). Patients who had hormonal therapy had poorer physical functioning, more constipation

**Table 2** Mean, standard deviation, prevalence and missing data of each item of the EORTC QLQ-PR25

Item	N	Mean	Standard deviation	Prevalence (%)	Missing data (%)
PR1: frequency/day	80	1.93	0.79	68.8	1.2
PR2: frequency/night	81	2.01	0.73	76.5	0.0
PR3: urgency	81	1.95	0.71	75.3	0.0
PR4: inadequate sleep	81	1.84	0.80	63.0	0.0
PR5: difficulty going out	81	1.56	0.79	39.5	0.0
PR6: urinary incontinence	81	1.64	0.66	55.6	0.0
PR7: pain when urinating	81	1.09	0.32	7.4	0.0
PR8: incontinence aid	21	1.71	0.96	47.6	74.7*
PR9: activity limited urinary	80	1.39	0.70	28.8	1.2
PR10: activity limited bowel	80	1.25	0.58	19.8	1.2
PR11: stool incontinence	80	1.05	0.22	5.0	1.2
PR12: blood in stools	79	1.13	0.43	10.1	2.5
PR13: bloated	80	1.29	0.60	22.5	1.2
PR14: hot flush	79	1.13	0.40	10.1	2.5
PR15: sore/enlarged nipples	80	1.24	0.56	18.8	1.2
PR16: leg/ankle swelling	80	1.23	0.48	20.0	1.2
PR17: weight loss	81	1.10	0.30	9.9	0.0
PR18: weight gain	81	1.22	0.45	21.0	0.0
PR19: less masculine	81	1.65	0.87	44.4	0.0
PR20: interest in sex	81	1.53	0.63	46.9	0.0
PR21: sexually active	80	1.19	0.45	16.3	1.2
PR22: sex enjoyable	14	1.93	0.62	78.6	82.7*
PR23: erection difficulty	14	2.07	0.83	78.6	82.7*
PR24: ejaculation difficulty	14	2.00	0.96	64.3	82.7*
PR25: uncomfortable	14	1.14	0.36	14.3	82.7*

\*Conditional questions.

**Table 3** Internal consistency, multi-item multi-method results of each scale of the EORTC QLQ-PR25

	Cronbach's $\alpha$	Item-own scale correlation	Item-other scale correlation*	Scaling success	Scaling success rate
Urinary symptoms PR1–PR9	0.80	0.20–0.73	0.02–0.50	15/27	55.6
Bowel symptoms PR10–PR13	0.41	0.17–0.37	0.01–0.51	1/12	8.3
HT-related symptoms PR14–PR19	0.45	0.01–0.39	0.01–0.44	4/18	22.2
Sexual activity PR20–PR21	0.64	0.48	0.02–0.23	6/6	100.0

\*The opposite value is displayed for negative correlations. HT = hormonal treatment.

and more hormonal-related symptoms than other groups; while those who underwent surgery had better physical and sexual activity than other groups ( $p < 0.01$ ) (Table 6). For patients who had surgery, the extent of surgery was also related to QoL scores. Patients who underwent radical prostatectomy had better physical, role, cognitive and sexual functioning, better global health and fewer fatigue symptoms; while patients who had no surgery had more constipation than other groups ( $p < 0.01$ ) (Table 7). Patients who were off-treatment had better physical and role functioning, better global health, less fatigue, and fewer urinary and hormonal treatment-related symptoms. Only the differences in physical functioning and hormonal treatment-related symptoms were significant ( $p < 0.01$ ) (Table 8).

#### 4. Discussion

In this study, we examined the internal consistency, multi-trait scaling, and known-groups comparison of the Taiwan Chinese version of the EORTC QLQ-C30 and QLQ-PR25 on 81 patients with prostate cancer cared for at the Department of Urology of National Taiwan University Hospital in Taipei. The acceptability of the questionnaires was high. The ages and educational levels of our patients were higher than that of the patients in the EORTC<sup>13</sup> and Spanish<sup>14,15</sup> studies.

The descriptive results of answers to the EORTC QLQ-PR25 questions were as expected<sup>5</sup> and correlated well to those of previous studies (in scales).<sup>13,15</sup> The results of satisfactory internal consistency of urinary symptoms,

**Table 4** Correlations between scales of the EORTC QLQ-C30 and QLQ-PR25

QLQ-C30 scales	QLQ-PR25 scales			
	Urinary symptoms	Bowel symptoms	Hormonal treatment-related symptoms	Sexual activity
<b>Functioning scales</b>				
Physical functioning	-0.48*	-0.46*	-0.30 <sup>†</sup>	0.18 <sup>†</sup>
Role functioning	-0.43*	-0.50*	-0.24 <sup>†</sup>	0.26 <sup>†</sup>
Emotional functioning	-0.51*	-0.72 <sup>‡</sup>	-0.39 <sup>†</sup>	0.14 <sup>†</sup>
Cognitive functioning	-0.47*	-0.41*	-0.31 <sup>†</sup>	0.25 <sup>†</sup>
Social functioning	-0.58*	-0.54*	-0.42*	0.13 <sup>†</sup>
Global health/QoL	-0.50*	-0.63*	-0.32 <sup>†</sup>	0.21 <sup>†</sup>
<b>Symptom scales</b>				
Fatigue	0.44*	0.46*	0.30 <sup>†</sup>	-0.23 <sup>†</sup>
Nausea and vomiting	0.08 <sup>†</sup>	0.29 <sup>†</sup>	0.41*	-0.03 <sup>†</sup>
Pain	0.44*	0.47*	0.38 <sup>†</sup>	-0.04 <sup>†</sup>
<b>Single item scales</b>				
Dyspnea	0.40*	0.62*	0.45*	-0.15 <sup>†</sup>
Insomnia	0.32 <sup>†</sup>	0.42*	0.08 <sup>†</sup>	-0.13 <sup>†</sup>
Appetite loss	0.23 <sup>†</sup>	0.33 <sup>†</sup>	0.36 <sup>†</sup>	-0.17 <sup>†</sup>
Constipation	0.41*	0.35 <sup>†</sup>	0.13 <sup>†</sup>	-0.24 <sup>†</sup>
Diarrhea	0.10 <sup>†</sup>	0.37 <sup>†</sup>	0.38 <sup>†</sup>	0.03 <sup>†</sup>
Financial difficulty	0.37 <sup>†</sup>	0.54*	0.37 <sup>†</sup>	-0.12 <sup>†</sup>

\*0.40–0.70 (moderate correlation); <sup>†</sup><0.40 (weak correlation); <sup>‡</sup>>0.70 (high correlation). QoL=quality of life.

**Table 5** Quality of life scores of patients with different stages of disease

Scale	Early disease stages (I, II) (n=59)	Advanced disease stages (III, IV) (n=22)	Wilcoxon two-sample test
Physical functioning	86.8 (16.7)	76.7 (23.0)	0.0057*
Role functioning	90.7 (19.6)	75.8 (33.2)	0.0380 <sup>†</sup>
Emotional functioning	88.6 (13.2)	81.1 (26.0)	0.5515
Cognitive functioning	82.2 (16.6)	74.2 (26.1)	0.3168
Social functioning	87.0 (17.3)	68.9 (31.0)	0.0214 <sup>†</sup>
Global health status	72.5 (18.9)	59.9 (25.5)	0.0612
Fatigue	16.6 (19.2)	37.9 (24.4)	0.0005*
Nausea and vomiting	0.3 (2.2)	3.0 (8.4)	0.0331 <sup>†</sup>
Pain	8.2 (14.6)	21.2 (24.8)	0.0078*
Dyspnea	9.6 (15.2)	18.2 (28.6)	0.3540
Sleep	20.3 (22.3)	27.3 (33.6)	0.6672
Appetite	2.3 (8.5)	13.6 (26.6)	0.0142 <sup>†</sup>
Constipation	13.0 (21.5)	19.7 (28.5)	0.3276
Diarrhea	10.2 (17.8)	12.1 (19.4)	0.7083
Financial difficulty	6.8 (14.9)	21.2 (28.3)	0.0133 <sup>†</sup>
Urinary symptoms	20.9 (14.9)	26.2 (18.2)	0.2060
Bowel symptoms	4.7 (7.5)	9.5 (13.8)	0.2568
HT-related symptoms	7.3 (8.4)	12.6 (10.9)	0.0364 <sup>†</sup>
Sexual activity	14.7 (17.0)	4.6 (7.6)	0.0111 <sup>†</sup>

\* $p < 0.01$ ; <sup>†</sup> $p < 0.05$ . HT=hormonal treatment.

and unsatisfactory results in bowel symptoms and hormonal treatment-related symptoms were consistent with previous studies, and that of near-satisfactory sexual activity was close to that of previous studies.<sup>13,15</sup> The low

scaling success rate of urinary symptoms may be due to clinically plausible correlation between urinary symptoms and other symptoms. Our sexually active patients were too few to examine the properties of the last scale

**Table 6** Quality of life scores among patients undergoing different treatments

Scale	Surgery only (n=29)	Surgery and HT (n=39)	HT only (n=12)	Kruskal-Wallis test
Physical functioning	91.5 (18.7)	82.2 (17.9)	73.4 (17.9)	0.0004*
Role functioning	93.1 (20.2)	82.5 (27.8)	84.7 (24.1)	0.1354
Emotional functioning	81.1 (21.4)	86.8 (15.0)	84.7 (18.4)	0.6796
Cognitive functioning	79.3 (22.1)	82.1 (18.9)	75.0 (18.1)	0.4128
Social functioning	87.4 (23.4)	78.6 (22.3)	79.2 (24.8)	0.1268
Global health status	75.6 (21.5)	65.6 (19.8)	63.9 (25.5)	0.1238
Fatigue	16.1 (21.5)	24.5 (21.5)	32.4 (26.2)	0.0600
Nausea and vomiting	0.6 (3.1)	0.9 (3.7)	2.8 (9.6)	0.7846
Pain	9.8 (19.7)	11.5 (13.9)	18.1 (28.8)	0.5922
Dyspnea	9.2 (21.6)	12.0 (17.9)	19.4 (22.3)	0.1787
Sleep	26.4 (27.3)	19.7 (26.2)	22.2 (21.7)	0.4896
Appetite	6.9 (20.7)	4.3 (11.3)	5.6 (19.3)	0.9137
Constipation	10.3 (15.7)	11.1 (22.1)	36.1 (33.2)	0.0098*
Diarrhea	11.5 (20.5)	8.6 (14.8)	16.7 (22.5)	0.4997
Financial difficulty	9.2 (21.6)	10.3 (17.4)	16.7 (26.6)	0.5968
Urinary symptoms	18.1 (13.3)	22.6 (16.6)	31.6 (17.5)	0.0791
Bowel symptoms	4.3 (8.2)	6.1 (10.6)	9.0 (10.3)	0.2335
HT-related symptoms	5.0 (7.3)	10.4 (8.7)	13.4 (12.6)	0.0077*
Sexual activity	19.0 (18.8)	9.0 (12.6)	5.6 (10.9)	0.0147 <sup>†</sup>

\* $p < 0.01$ ; <sup>†</sup> $p < 0.05$ . HT=hormonal treatment.

**Table 7** Quality of life scores among patients undergoing different degrees of surgery

Scale	Radical prostatectomy (n=50)	No surgery (n=12)	Partial prostatectomy (n=19)	Kruskal-Wallis test
Physical functioning	90.9 (10.8)	73.3 (18.6)	73.3 (27.2)	0.0003*
Role functioning	94.3 (12.4)	83.3 (24.7)	68.4 (38.0)	0.0054*
Emotional functioning	89.0 (13.9)	83.3 (18.6)	82.0 (25.2)	0.3766
Cognitive functioning	84.7 (17.1)	74.2 (18.8)	71.1 (25.1)	0.023 <sup>†</sup>
Social functioning	85.7 (18.8)	72.3 (25.0)	74.6 (30.6)	0.4009
Global health status	74.8 (18.0)	63.6 (26.7)	56.6 (22.3)	0.0075*
Fatigue	14.7 (16.4)	32.3 (27.4)	38.0 (24.9)	0.0006*
Nausea and vomiting	1.0 (4.0)	3.0 (10.1)	0.0 (0.0)	0.4909
Pain	7.7 (10.8)	19.7 (29.6)	18.4 (24.8)	0.2071
Dyspnea	8.7 (14.8)	21.2 (22.5)	15.8 (28.0)	0.2252
Sleep	19.3 (22.4)	21.2 (22.5)	37.6 (34.2)	0.4434
Appetite	3.3 (10.1)	6.1 (20.1)	10.5 (25.0)	0.4077
Constipation	8.0 (15.9)	36.4 (34.8)	19.3 (25.6)	0.0020*
Diarrhea	9.3 (17.9)	15.2 (22.9)	12.3 (16.5)	0.5822
Financial difficulty	6.0 (12.9)	18.2 (27.3)	19.3 (27.9)	0.0694
Urinary symptoms	19.0 (13.0)	32.9 (17.7)	25.0 (19.5)	0.0552
Bowel symptoms	4.4 (7.6)	9.9 (10.4)	7.5 (13.3)	0.1019
HT-related symptoms	8.4 (9.2)	13.6 (13.2)	7.3 (6.2)	0.6024
Sexual activity	16.0 (16.8)	6.1 (11.2)	5.3 (11.2)	0.0048*

\* $p < 0.01$ ; <sup>†</sup> $p < 0.05$ . HT=hormonal treatment.

of sexual functioning. This is consistent with our study of breast cancer<sup>18</sup> and the cultural characteristic that our patients avoid sex after having serious diseases such as cancer and focus much more on survival than sexual functioning.<sup>22</sup> According to these findings, the scales of

bowel symptoms and hormonal treatment-related symptoms may not be able to reflect the expected symptoms of patients and should be used with care. Most scales of the PR25 showed moderate to low correlation with that of the C30. But there were some scales that had high

**Table 8** Quality of life scores between patients on- and off-treatment\*

Scale	No active treatment within 6 mo (n=26)	Active treatment within 6 mo (n=55)	Wilcoxon two-sample test t-approximation, two-sided p
Physical functioning	92.3 (10.1)	80.1 (21.0)	0.0024 <sup>†</sup>
Role functioning	95.5 (10.1)	82.4 (28.4)	0.0403 <sup>‡</sup>
Emotional functioning	89.7 (14.2)	85.0 (19.1)	0.1899
Cognitive functioning	82.7 (16.0)	78.8 (21.4)	0.5967
Social functioning	89.7 (17.1)	78.5 (24.8)	0.0612
Global health status	76.9 (17.7)	65.3 (22.3)	0.0481 <sup>‡</sup>
Fatigue	12.8 (13.6)	26.9 (24.7)	0.0243 <sup>‡</sup>
Nausea and vomiting	0.6 (3.3)	12.2 (5.4)	0.7841
Pain	6.4 (9.5)	14.2 (21.4)	0.1952
Dyspnea	6.4 (13.4)	14.6 (22.0)	0.1292
Sleep	20.5 (23.2)	23.0 (27.1)	0.9547
Appetite	2.6 (9.1)	6.7 (18.6)	0.4027
Constipation	10.2 (15.7)	17.0 (26.4)	0.3331
Diarrhea	9.0 (20.1)	11.5 (17.2)	0.3498
Financial difficulty	7.7 (14.3)	12.1 (22.6)	0.6470
Urinary symptoms	16.0 (11.2)	25.3 (17.0)	0.0185 <sup>‡</sup>
Bowel symptoms	3.5 (6.3)	7.1 (10.8)	0.1853
HT-related symptoms	4.7 (7.3)	10.7 (9.6)	0.0056 <sup>‡</sup>
Sexual activity	9.4 (13.1)	7.9 (15.3)	0.0511

\*Reproduced from Reference 4; <sup>†</sup>p<0.01; <sup>‡</sup>p<0.05. HT=hormonal treatment.

correlation with scales of the core questionnaire. This is different from the results of the validation study of the EORTC<sup>13</sup> but close to the Spanish study.<sup>15</sup>

The results of known-groups comparison showed a better performance of the core questionnaire (C30) than the newly developed PR25. The performance of the C30 was consistent with the result of group comparison in the Spanish study.<sup>14</sup> Regarding the PR25, the scale of urinary symptoms could differentiate between on- and off-treatment; the scale of hormonal treatment-related symptoms could differentiate among stages, treatment methods, and on- and off-treatment; and the scale of sexual activity could differentiate among stages, treatments, and extent of surgery. Bowel symptoms did not differ in any of the four clinical conditions. These results were less good than those of previous validation studies using treatment intention and Karnofsky performance score.<sup>13,15</sup>

This study had some limitations. The sample size was small, but the problem could be resolved with non-parametric statistical methods. We did not collect Karnofsky performance scores. But data of clinical conditions were enough for known-groups comparison. We only collected data at one time-point and did not conduct test-retest and change over time comparison. The number of sexually active patients was too small to do any tests for the specific scale of sexual functioning. These issues may be included in future studies. Prostate cancer is increasing rapidly in Taiwan,<sup>3,4</sup> and the instrument will be useful in the assessment of treatment effectiveness through patients' QoL.

In conclusion, the Taiwan Chinese version of the EORTC QLQ-PR25 is acceptable to Taiwanese patients with prostate cancer. However, the scale structure of this module and the differential ability of the scale of bowel symptoms were not very satisfactory. The clinical validity of scales for different clinical conditions was acceptable but less so than those of the EORTC QLQ-C30. Some questions may need to be modified to reflect Taiwanese patients' problems more accurately.

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