PUBLIC HEALTH RESEARCH

Internal Consistency Study of EORTC QLQ-C30 and QLQ-PR25 Questionnaires for Quality of Life Assessment among Prostate Cancer Patients in a University Hospital, Kuala Lumpur, Malaysia

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ABSTRACT

Received	30 May 2019
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Introduction	Prostate cancer is forth most common diagnosed tumors in Malaysian male. The use of a self-reported, quality of life assessment is important for clinical practice, care taker and researcher to evaluate the level of quality of life. The aim of this study was to measure the internal consistency of the translated Malay Language EORTC QLQ-C30 and EORTC PR-25 questionnaires among prostate cancer patient at National University of Malaysia hospital in Kuala Lumpur, Malaysia.
Methods	This was a cross sectional study conducted between July 2017 and Dec 2017. The respondent comprised of 110 Malaysian prostate cancer patients who were under follow up at Urology and Oncology Clinic. Sets of translated Malay language EORTC QLQ C30 and EORTC PR-25 consisted of functional, symptom and global health status domains were administered to assess their quality of life.
Results	The translated questionnaires were acceptable by 110 respondents. Cronbach`s α coefficient result were 0.913 (EORTC QLQ-C30) and 0.829 (EORTC PR-25) respectively suggested that this instrument had good internal consistency.
Conclusions	Our study confirmed that translated Malay language EORTC QLQ-C30 and QLQ-PR25 questionnaires are acceptable, reliable and valid instrument to be used among Malaysian prostate cancer patients.
Keywords	Quality of Life - EORTC QLQ C30 - EORTC PR-25 - Prostate Cancer - Malay Language.

INTRODUCTION

Prostate cancer is one of the most frequently diagnosed tumor in the Western and many Asian developed countries.[1] In Malaysia, prostate cancer reported as third most common type of cancer in male with 1,807 new cases in 2018 and accounts for 8.8% of all cancer cases after respiratory system and colorectal cancer.[2] The incidence of prostate cancer is low in men under 50 years of age. The rate increases sharply with increment of age and is highest in the oldest age group. With increasing life expectancy, westernized diet, improvement of medical technologies in screening and treatment the mortality among prostate cancer patients were decreased significantly.

As a one of the common malignancy in elderly male, prostate cancer contributed to the burden of health care which may include the cost of screening, treatment and follow up, hospital stay, psychological anxiety or depression and even palliative care.

Quality of life in cancer patient may be affected by physical function, emotional, role, social and also financial constrain.[4] It is defined as the ability to perform everyday activities that reflect physical, psychological, and social well-being; and patient satisfaction with levels of functioning and control of the disease. The use of self-reported, quality of life assessment has become a valuable tool in clinical practice and research to determine the status of the cancer patients according to their stage of disease and the treatment received. Besides that, the quality of life tool play significant role in guiding the clinician to offer treatment to the cancer patients. The European Organization for Research and treatment of Cancer (EORTC) had come out with the set of questionnaires to assess the quality of life among cancer patients in general and also for specific cancer types. As for prostate cancer, multiple center studies had used the tool to assess patients` quality of life.[5]

Generally, treatment offered to cancer patients were determined by their stage of malignancy. These treatment may lead to urinary, incontinence, bowel and sexual function changes. Although many studies had concluded that prostate cancer has better prognosis with good survival rates compared to other malignancies[1], the quality of life aspect such as their role, social and financial difficulties must also be focused, as different type of treatment may cause different adverse effect to patient.[6-8]

Many studies reported that quality of life differed among patients receiving different type of treatment such as radical prostatectomy, radiation therapy and brachytherapy. In a study of 580 patients with localized prostate cancer reported that urine incontinence and sexual function were better after external beam radiation therapy.[9] While another study among 212 prostate cancer patients who underwent brachytherapy reported low global health scores lower functional-scale and symptom scores in the brachytherapy group compared with those who underwent radical prostatectomy.[10]

In Malaysia, there was no study assessing quality of life among prostate cancer patients using EORTC questionnaires identified. The main objective of the study was to evaluate and measure the internal consistency of psychometric properties of the EORTC Quality of Life questionnaires QLQ-C30 and QLQ-PR25 in prostate cancer patients and to compare with validation studies done in other countries. This secondary objective was to measure the score of quality of life related to different stages and type of treatment in prostate cancer disease.

METHODS

Design and Sample Characteristics

This was a descriptive cross sectional study done in National University of Malaysia Hospital. The study was conducted between July 2017 and Dec 2017. The respondents consisted of prostate cancer patients who followed up at the Urology Clinic and Oncology Clinic. A universal sampling was done to get the prostate cancer patients during biweekly urology clinic follow-up every Monday and Friday. All prostate cancer diagnosed patients who came to follow up clinic were offered to participate in the study. The minimum numbers of respondent were calculated based on ratio of questions and respondent to one question to minimum three respondents per set of questionnaire[18] which require 90 respondents for EORTC QLQ C30 and 75 respondents for EORTC QLQ-PR25 questionnaires. The inclusion criteria were Malaysian citizen, able to read and understand the Malay language translated questionnaires and willing to sign consent form prior to study. Patient with multiple malignancies disease were excluded in this study. There were no limitations of the age, stage of disease and type of treatment among patients. The list of prostate cancer patients were first confirmed by tracking the result of Trans-Rectal Ultrasound guided (TRUS) biopsy from the medical record. This study was approved by ethics committee of the study hospital as it was part of thesis study (FF-249-2017) measuring survival and quality of life of the prostate cancer patients.

Instrument

All prostate cancer patients in the study were given two complete sets of Malay language translated of EORTC QLQ-C30 (version 3.0) and EORTC PR-25 questionnaires. The questionnaires were already translated to Malay Language as per protocol produced.[11] The EORTC QLQ-C30 set consist of 30 items with three main domains of Functionality, Symptom and Global Health Status while EORTC PR-25 consist of 25 questions with functionality and symptom domains (Table 1). The patients and the

relatives were first explained regarding the purpose of study, requirement and scale of the questionnaires used and given time from their registration at the follow up clinic till end of the clinic session. Any difficulty, confusion and help required during completion of the questionnaire were noted during session. In order to ensure the completion of answer, all patients were assisted to answer the missing answer questions and asked for their comment on understanding the questionnaires. Other patient related clinical information were collected during the interview and reviewing of patient`s medical record after clinic session been done.

Table 1 Domain structure of EORTC QLQ-30 and EORTC-PR 25 questionnaires

Domain	Number of Questions
EORTC QLQ-30	
Functional Scale	
Physical	5
Role	2
Emotional	4
Cognitive	2
Social	2
Symptom Scale	
Fatigue	3
Nausea & Vomiting	2
Pain	2
Dyspnoe	1
Insomnia	1
Appetite Loss	1
Constipation	1
Diarrhea	1
Financial Difficulties	1
Global Health Status	2
Functional Scale	
Sexual Activity	2
Sexual functioning	4
Symptom Scale	
Urinary Symptom	8
Bowel Symptom	4
Treatment-Related Symptom	6
Incontinence-Aid Symptom	1

Statistical analyses

All collected data were analysed using Statistical Package for Social Science (SPSS) version 21. All descriptive categorical data were presented in frequency and percentage while continuous data calculated in mean and standard deviation. Descriptive statistics were used to describe socio-demographics and clinical related information. The score for each domain in the EORTC QLQ-C30 and PR-25 were calculated and scaled according to the scoring manual.[12] Raw scores were transformed into a scale ranging from 0 to 100 with higher scores indicate better functioning on the functional subscales and the global quality of life scale, and more symptoms on the symptom subscales. Cronbach`s α coefficient was used to measure the internal consistency of each domain.[13] Cronbach`s α of 0.70 was set as an acceptable level of reliability[13-14]. Inter item correlation is performed to find out the relationship between items in each variable. If all the scales have statistically significant inter item correlations, it means the scales are reliable and measure the same variable in question. One–way Anova test method was used to measure the difference between stages and type of treatment received by prostate cancer patients. A *p*-value of less than 0.05 was considered as statistically significant.

RESULTS

Table 2 Sociodemographic and clinical characteristics of the 110 prostate cancer patients

	Stage I *n* = 8	Stage II *n* = 73	Stage III *n* = 24	Stage IV *n* = 5
Age (Years)				

< 60	0 (0.0)	2 (2.7)	1 (4.2)	0 (0.0)	
≥ 60 – 69	2 (25.0)	24 (32.9)	3 (12.5)	2 (40.0)	
≥ 70 – 79	2 (25.0)	26 (35.6)	13 (54.2)	1 (20.0)	
≥ 80 – 89	3 (37.5)	21 (28.8)	7 (29.1)	2 (40.0)	
≥ 90	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	
Mean (S.D)	78.6 (7.7)	73.6 (8.3)	75.0 (6.8)	75.4 (8.4)	
Race					
Malay	4 (50.0)	29 (39.8)	6 (25.0)	1 (20.0)	
Chinese	3 (37.5)	40 (54.8)	15 (52.5)	4 (80.0)	
Indian	1 (12.5)	4 (5.4)	3 (12.5)	0 (0.0)	
Marital Status					
Single	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)	
Married	6 (75.0)	60 (82.2)	18 (75.0)	5 (100.0)	
Widowed/Divorced	2 (25.0)	13 (17.8)	5 (20.8)	0 (0.0)	
Education Level					
Primary and Below	2 (25.0)	36 (49.3)	13 (54.2)	2 (40.0)	
Secondary	5 (62.5)	29 (39.7)	10 (41.7)	2 (40.0)	
Tertiary	1 (12.5)	8 (11.0)	1 (4.1)	1 (20.0)	
Income					
< RM 1 000	1 (12.5)	15 (20.5)	3 (12.5)	2 (40.0)	
≥ RM 1000 – RM 3000	4 (50.0)	27 (37.0)	13 (54.1)	1 (20.0)	
≥ RM 3000 – RM 5000	2 (25.0)	21 (28.8)	4 (16.7)	2 (40.0)	
≥ RM5000	1 (12.5)	10 (13.7)	4 (16.7)	0 (0.0)	
Gleason Score					
4	0 (0.0)	2 (2.7)	1 (4.1)	0 (0.0)	
5	0 (0.0)	1 (1.6)	1 (4.1)	0 (0.0)	
6	3 (37.5)	27 (37.0)	6 (25.0)	1 (20.0)	
7	1 (12.5)	20 (27.3)	7 (29.2)	2 (40.0)	
8	1 (12.5)	5 (6.8)	4 (16.7)	1 (20.0)	
9	3 (37.5)	17 (23.2)	4 (16.7)	1 (20.0)	
10	0 (0.0)	1 (1.4)	1 (4.2)	0 (0.0)	
Treatment					
Active Surveillance	3 (37.5)	3 (4.1)	0 (0.0)	0 (0.0)	6 (5.5)
Hormonal Therapy	2 (25.0)	29 (39.7)	5 (20.8)	0 (0.0)	36 (32.7)
Surgical Intervention	1 (12.5)	7 (9.6)	1 (4.2)	0 (0.0)	9 (8.2)
Combination Therapy	2 (25.0)	34 (46.6)	18 (75.0)	5 (100.0)	59 (53.6)

*data describe as *n* (%)

Description of sociodemographic and clinical information of the prostate cancer patients are displayed in Table 2. A total of 110 respondents with prostate cancer were willing to participate in the study. All patients were able to complete the questionnaires in the time frame given with only five patients required assistant on translated English to Malay language words of "*inkontinens*" (incontinence), "*buku lali*" (ankle), "*ereksi*" (erection) and "*ejakulasi*" (ejaculation). Most of the prostate cancer patients were in the Stage II (66.6%) followed by Stage III (21.8%), Stage I (7.3%) and Stage IV (4.5%). Level of education had showed that most prostate cancer patients had attended at least secondary education level (90%) and more than half of them earned less than RM 3000 monthly. Gleason score reported 33.6% prostate cancer patients with Gleason 6 and 27.2% with Gleason 7. In the distribution of treatment offered to patients showed that only 5.5% prostate cancers opted or selected for active surveillance and watchful waiting based on their condition, 32.7% on hormonal therapy, 8.2% for surgical intervention and more than half had undergone combination therapy (53.6%).

Questionnaires for Quality of Life Assessment among Prostate Cancer Patients

Group Comparisons

Table 3 EORTC QLQ-30 and EORTC-PR 25 questionnaires scoring of 110 prostate cancer patients based on stage

Domain	Stage I n=8 Mean (± S.D)	Stage II n=73 Mean (± S.D)	Stage III n=24 Mean (± S.D)	Stage IV n=5 Mean (± S.D)	ANOVA	*p-value**
EORTC QLQ-C30						
Functional Scale						
Physical	75.83 (17.43)	53.70 (25.07)	59.44 (25.17)	66.67 (20.00)	2.359	0.076
Role	81.25 (24.30)	54.57 (32.79)	61.81 (23.30)	53.33 (32.06)	2.032	0.114
Emotional	79.17 (17.25)	69.06 (25.85)	72.57 (24.01)	78.33 (22.51)	0.612	0.608
Cognitive	70.83 (19.42)	59.59 (26.05)	68.06 (24.53)	63.33 (21.73)	1.008	0.392
Social	72.92 (28.08)	61.19 (33.80)	68.06 (30.66)	70.00 (34.16)	0.554	0.647
Symptom Scale						
Fatigue	33.38 (20.57)	51.46 (26.68)	42.58 (25.52)	40.00 (30.02)	1.747	0.162
Nausea & Vomiting	6.25 (8.63)	20.09 (22.39)	12.50 (17.20)	3.33 (7.45)	2.453	0.067
Pain	27.08 (17.68)	42.24 (29.14)	34.03 (24.81)	26.67 (32.49)	1.401	0.247
Dyspnea	8.33 (15.43)	22.83 (26.57)	9.72 (15.48)	6.67 (14.91)	2.840	0.041
Insomnia	33.33 (39.84)	47.95 (34.24)	48.61 (34.02)	40.00 (27.89)	0.523	0.667
Appetite Loss	16.67 (17.82)	35.62 (27.40)	26.39 (29.45)	33.33 (47.14)	1.494	0.221
Constipation	4.17 (11.79)	26.48 (28.31)	20.83 (25.66)	40.00 (27.87)	3.086	0.030
Diarrhea	0.00 (0.00)	20.09 (25.90)	19.44 (27.66)	6.67 (14.91)	1.905	0.133
Financial Difficulties	37.5 (27.81)	45.25 (36.16)	37.50 (35.86)	46.67 (44.72)	0.358	0.783
Global Health Status	76.04 (13.68)	72.26 (13.03)	44.10 (11.39)	33.33 (19.54)	4.205	0.007
EORTC PR-25						
Functional Scale						
Sexual Activity	64.58 (30.13)	81.96 (18.58)	80.56 (21.79)	66.67 (26.35)	2.414	0.071
Sexual functioning	57.29 (24.57)	74.88 (19.10)	65.63 (23.86)	53.33 (32.06)	3.566	0.017
Symptom Scale						
Urinary Symptom	36.98 (26.95)	44.79 (19.20)	44.79 (19.20)	34.27 (10.79)	0.609	0.611
Bowel Symptom	9.37 (9.38)	16.32 (19.27)	16.32 (19.27)	3.33 (4.56)	1.607	0.192
Treatment-related Symptom	17.33 (10.04)	20.14 (17.86)	20.17 (17.86)	21.13 (19.80)	0.624	0.601

1. The score range from 0 – 100 with a higher score representing higher functioning level and more symptoms.
2. *significant value at the level *p < 0.05*

The results showed that there were significant differences in global health status, sexual function and in symptom of dyspnea and constipation in the different stages of cancer while scores based on type of treatment showed significant difference in constipation symptom. Incontinence symptom was excluded during analysis as the patients with incontinence aid were less than 10%. Global Health status or Quality of Life domain showed no significant difference in the different type of treatment received by the patients.

Table 4 EORTC QLQ-30 and EORTC-PR 25 questionnaires scoring of 110 prostate cancer patients based on type of treatment

Domain	Active Surveillance n=6 Mean (± S.D)	Hormonal Therapy n=36 Mean (± S.D)	Surgical Intervention n=9 Mean (± S.D)	Combination Therapy n=59 Mean (± S.D)	ANOVA	*p-value**
EORTC QLQ-C30						
Functional Scale						
Physical	76.67 (22.21)	56.85 (27.30)	60.00 (16.99)	68.08 (22.06)	1.441	0.235
Role	66.67 (29.81)	55.56 (23.99)	59.26 (29.00)	54.96 (24.30)	0.238	0.870
Emotional	81.94 (19.31)	75.00 (23.99)	59.26 (20.17)	58.47 (28.09)	1.506	0.217
Cognitive	69.44 (19.48)	61.57 (26.67)	57.41 (22.22)	69.21 (25.81)	0.292	0.831

Social	83.33 (27.88)	62.50 (33.42)	61.11 (32.27)	63.28 (37.22)	0.757	0.521
Symptom Scale						
Fatigue	57.17 (27.76)	45.37 (27.78)	53.08 (21.36)	47.27 (25.32)	0.484	0.694
Nausea & Vomiting	57.41 (38.76)	15.28 (21.22)	14.81 (15.47)	19.21 (21.62)	1.286	0.283
Pain	2.78 (6.80)	40.28 (27.42)	35.18 (24.22)	38.42 (28.07)	0.102	0.959
Dyspnea	36.11 (40.02)	14.81 (21.74)	25.93 (22.22)	18.08 (24.23)	0.854	0.468
Insomnia	22.22 (40.37)	47.22 (34.16)	55.56 (33.33)	47.46 (33.45)	1.250	0.295
Appetite Loss	27.78 (25.09)	35.19 (23.06)	29.63 (26.06)	31.07 (28.27)	0.229	0.876
Constipation	16.67 (18.26)	13.87 (23.06)	44.44 (37.28)	24.86 (26.67)	3.662	0.015
Diarrhea	5.56 (13.61)	14.81 (23.15)	22.22 (28.86)	20.34 (26.99)	0.915	0.437
Financial Difficulties	22.22 (27.22)	39.81 (36.36)	29.63 (35.14)	49.15 (35.21)	1.823	0.147
Global Health Status	73.61 (13.35)	63.89 (18.15)	62.96 (20.46)	68.08 (22.06)	0.649	0.585
EORTC PR-25						
Functional Scale						
Sexual Activity	69.44 (37.14)	77.77 (20.70)	85.18 (17.57)	81.07 (19.68)	0.865	0.462
Sexual functioning	54.17 (27.76)	71.99 (23.83)	74.07 (19.74)	70.83 (20.39)	1.252	0.295
Symptom Scale						
Urinary Symptom	40.27 (18.19)	36.81 (20.03)	42.59 (18.61)	45.76 (19.35)	1.600	0.194
Bowel Symptom	15.28 (16.17)	11.11 (15.81)	24.07 (19.29)	18.36 (17.49)	2.032	0.114
Treatment-related Symptom	27.78 (20.18)	19.29 (16.35)	22.84 (18.52)	24.39 (18.34)	0.778	0.509

1. The score range from 0 – 100 with a higher score representing higher functioning level and more symptoms.
2. *significant value at the level $p < 0.05$

Validity of EORTC QOL Instruments

Table 5 Reliability test of the EORTC QLQ-30 and PR-25

Questionnaires	No. of Item	Cronbach`s α	Inter-Item Correlation
EORTC QLQ-30	30	0.913	0.18-0.67
Functional scale	15	0.905	0.41-0.72
Symptom scale	13	0.878	0.47-0.68
Global Health status	2	0.937	0.891
EORTC PR-25	25	0.829	0.17-0.53
Functional scale	6	0.787	0.23-0.70
Symptom scale	19	0.869	0.22-0.62

The reliability test, Cronbach`s α coefficient result for all domains in both sets of questionnaires showed more than 0.70 (Table 5) with 0.913 (QLQ-C30) and 0.829 (EORTC-PR25) respectively. Inter-item in the general EORTC QLQ-C30 had showed moderate (0.40-0.60) and high correlation (0.891) while item in the EORTC PR-25 showed weak to moderate correlation (0.20-0.70).

DISCUSSION

In this study, we measured the internal consistency of Malay language translated version of EORTC QLQ-C30 and EORTC PR-25 questionnaires on prostate cancer among patients who undergone follow up at Urology and Oncology clinic of Malaysia National University hospital. The study showed that the acceptability and understanding of the translated Malay language questionnaires were very good although the respondent comprised of three different races.

The Cronbach`s α of more than 0.70 were good in both questionnaires showed that this set of questionnaire were acceptable to be used in Malaysia[14]. Cronbach`s α indicate that the item in this questionnaires fit together conceptually.

Although some author suggested that coefficient alpha should be more than 0.90, DeVellis had contended that the value of more than 0.90 showed redundancies and indicated that the tools should be shortened.[12-14] The patients were able to complete the sets of questionnaires without extensive help. Sociodemographic features showed that our patients age and level of education slightly difference from few study done in European countries and Taiwan.[5,15-17] The findings where both domain scales for EORTC-PR-25 showed low to moderate correlation comparing to the core EORTC-QLQ C30 was consistent with other studies.[16-17] The result of group comparison showed a higher score in the EORTC-QLQ-C30 functional group compared to the newly developed EORTC-PR-25 questionnaire. Similar findings were reported by studies done among Spanish and Taiwanese population.[16-17]

Comparing result of internal consistency of questionnaires, this study had similarity in the value of Cronbach`s α with other studies conducted in different countries such in a Polish population with 0.898 (EORTC QL-C30) and 0.870 (EORTC QLQ-PR25), Spanish population with 0.720 to 0.860 and Taiwanese population with 0.800 (EORTC QLQ-C30).[16-17]

As prostate cancer had been shown to have very good survival rate and prognosis, the difference in the score of functional and symptom between stages of disease were not significantly different.[1] There were no significant differences of scores in the functional domains of physical, role, emotional, cognitive and social function among prostate cancer either they were diagnosed in early or advanced stages. The study also showed that there were no significant differences between types of treatment with the functionality of the prostate cancer patients.

CONCLUSION
Our internal consistency study confirmed that translated Malay language EORTC QLQ-C30 and QLQ-PR25 questionnaires are reliable with Cronbach`s alpha 0.91 and 0.83 respectively, can be used to measure quality of life in Malaysian patients with prostate cancer. However, more comparison study should be conducted to ensure it could be used in a bigger scale study.

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DECLARATION
Authors declared that there were no conflicts of interest in this study

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