Original Article

Validation of EORTC QLQ-C30 and QLQ-BR23 questionnaires in the measurement of quality of life of breast cancer patients in Singapore

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Received: 02-18-2014, Accepted: 04-25-2014

ABSTRACT

Objective: To validate EORTC QLQ-C30 and EORTC QLQ-BR23 questionnaires and to measure the health-related quality of life (HRQOL) of women with breast cancer in Singapore during their first 4 years of post-diagnosis and treatments. **Methods:** A quantitative and cross-descriptive sectional study. All of 170 subjects were recruited in a Singapore tertiary cancer center. The European Organization for Research and Treatment-QOL questionnaire and breast cancer specific module (EORTC QLQ-C30 and QLQ-BR23) were used to measure the HRQOL among women with breast cancer. All statistical tests were performed using SPSS Version 18. The reliability of the EORTC QLQ-C30 and QLQ-BR23 questionnaires was examined using Cronbach's alpha test. EORTC QLQ-C30 was validated against EuroQol Group's 5-domain questionnaires (EQ5D) by examining its concurrent validity using Pearson Product Moment Correlation to calculate the total scores. **Results:** The Cronbach's alpha coefficient results for EORTC QLQ-C30 and QLQ BR-23 were 0.846 and 0.873 respectively which suggested relatively good internal consistency. The correlation between EORTC QLQ-C30 and EQ5D QOL instruments demonstrated a modest linear relationship (r=0.597; P<0.001) that indicated a moderately strong correlation between the two measures. The study showed that Singaporean women with breast cancer had enjoyed high levels of HRQOL during their first 4 years of survivorship but they had significant concern over the financial impact of breast cancer. One of the key findings was younger women had experienced more physical and psychosocial concerns than older women. **Conclusion:** The EORTC QLQ-C30 and QLQ-BR23 questionnaires are feasible and promising instruments to measure the levels of HRQOL in Singaporean women with breast cancer in future studies.

Key words: Breast cancer survivors, EORTC QLQ, quality of life

Access this article online

Quick Response Code:

Website: www.apjon.org

DOI: 10.4103/2347-5625.135817

Introduction

Breast cancer is a most common cancer being diagnosed worldwide. It accounts for about 1.38 million of newly diagnosed breast cancer cases in 2008.[1] In Singapore, breast cancer is the top leading cancer among women. There were about 1325 Singaporean women diagnosed with breast cancer on an annual basis, in which 1 in every 17 women might contract the illness.[2] Hence, there is a high prevalence of breast cancer incidences in Singapore.

Quality of life of breast cancer survivors

Many studies reported that women often experienced uncertainty, stress, anxiety and depression as well as a decline in their physical and social functioning following breast cancer diagnosis and treatments.[3,4] Other studies also indicated that women in their early years of survivorship often expressed concerns about the challenges to resume back to their family, social and work roles which affect their long-term adjustment and quality of life (QOL) outcomes.[5,6]

QOL is defined as the assessment of at least three domains of well-being which are physical, emotional and social.[7] Cella and Nowinski also described health-related QOL (HRQOL) as effects of a medical condition or its treatments on the individual.[8]

While many studies evaluated the HRQOL of women with breast cancer following cancer diagnosis and treatments or long-term survivals of 5 to 10 years,[9-12] few studied the impact of breast cancer diagnosis and interventions of acute survivorship among women between their first and fourth years of post-cancer interventions to assess their QOL which might change over time. Some studies have also reported that women who had completed their breast cancer treatments several months later have difficulties coping and adapting to being a breast cancer survivor.[13,14]

In Singapore, there is currently no study that evaluates patients' QOL during their first 4 years of breast cancer survivorship after intervention. This is an important acute survival to long-term survival transitional period that may affect women's QOL outcomes. Hence, there was a significant value to study the QOL of Singaporean women with breast cancer after their diagnosis and treatments in assessing their physical and psychosocial well-being. This could help to identify their specific physical and psychosocial concerns so as to develop appropriate strategies in meeting their needs.

The two well-known QOL instruments that have been validated overseas for breast cancer are the European Organization for Research and Treatment (EORTC) QLQ-C30 and QLQ-BR23 measures. The former is a general QOL tool while the latter is specific for breast cancer. Singapore is a multi-cultural Asian country that comprise of many ethnic groups that include the population of Chinese, Malay, Indian and Eurasians. Although the EORTC instruments have been validated in other countries, it would be necessary to evaluate the appropriateness of using these questionnaires in the Singapore local patient population as the cultural and social context may be very different from the socio-cultural setting of another country.

This study aims to validate EORTC QLQ-C30 and EORTC QLQ-BR23 questionnaires and to measure the levels of QOL in Singaporean women with breast cancer during their first 4 years of post-diagnosis and treatments. The specific objectives of this study are to:

1. Validate the selected measurement tools (EORTC QLQ-C30 and EORTC QLQ-BR23 Questionnaires) and evaluate their applicability in the local setting.
2. Examine the HRQOL of women with breast cancer in Singapore during their first 4 years of survivorship using the EORTC QLQ-C30 and QLQ-BR23 questionnaires.
3. Evaluate the relationship of QOL and the sociodemographic factors which consist of age, educational level and income.
4. Examine the relationship of QOL and the medical variables that include existing co-morbidities, stage of breast cancer and type of surgery.

Materials and methods

Research design and sample

This was a quantitative and cross-sectional descriptive study. It was conducted at a premier National Cancer Centre in Singapore. A total of 170 breast cancer patients in their first 4 years of post-interventions were recruited in the study. A minimum sample size of 175 would be required to achieve an effect size of 0.3 with a power of 80% and alpha at 5%.

A purposive sampling strategy was used to recruit participants for this study. Women more than 21 years old with breast cancer stage 0 to 3A and in the first 4 years of post-interventions were recruited. Post-interventions included breast surgery of wide excision or mastectomy with or without chemotherapy, radiotherapy and hormonal therapy. They must be residing in Singapore as citizens or permanent residents and able to understand any of the four major languages which are English, Mandarin, Malay and Tamil.

The exclusion criteria for this study included women who were diagnosed with breast cancer of lobular carcinoma *in situ*, metastatic disease, disease recurrence within 1 to 4 years post-treatments and had cognitively impaired or of unsound mind.

Instruments

The instruments used in this study included three sets of questionnaire, available in the languages of English, Mandarin, Malay and Tamil. The first set of questionnaire

consisted of general questions to obtain an understanding of the participants' sociodemographic characteristics. The variables included age, education and income levels of the participants as well as their medical variables of breast cancer stage, year(s) of post-interventions, types of surgery and existing co-morbidities.

The second and third sets of questionnaires were used to assess the QOL of women in their first 4 years of breast cancer survivorship. They consisted of the EORTC QLQ-C30 (version 3) together with the EORTC QLQ-BR23 and the EQ5D. Permission to use both sets of questionnaires prior to the study has been sought and approved.

EQ5D

The validity of the EORTC QLQ-C30 is assessed using concurrent validity with another QOL instrument which is the EQ5D. This is a well-validated generic QOL measure that is commonly used in Singapore to assess the QOL of cancer patients.[15,16] EQ5D has two main components of a health descriptive system and a visual analog scale. It assesses domains of mobility, self care, usual activities, pain or discomfort, anxiety or depression and provides a quantitative measurement of health outcome.

EORTC QLQ-C30 and QLQ-BR23

The EORTC QLQ-C30, version 3.0 is a cancer-specific measure of HRQOL.[17] It consists of 30 items to assess physical, role, emotional, cognitive and social functioning, global health status or QOL scales, fatigue, pain, nausea and vomiting, dyspnea, insomnia, appetite loss, constipation, diarrhea and financial difficulties. The EORTC QLQ-BR23 is a breast-specific module that comprises of 23 questions to assess body image, sexual functioning, sexual enjoyment, future perspective, systemic therapy side effects, breast symptoms, arm symptoms and upset by hair loss.

The scoring of the EORTC QLQ-C30 and QLQ-BR23 were performed according to the EORTC scoring manual.[18] All scores were linearly transformed to a 0 to 100 scale. A high or healthy level of functioning is represented by a high functional score. A high QOL is represented by a high score for global health status or QOL. More severe symptoms or problems are represented by high symptom scores or items. Internal reliability of EORTC QLQ-C30 and QLQ-BR23 would also be assessed using Cronbach's alpha scores.

Data collection procedures

This study was conducted after ethical approval was obtained from the institutional review board of the study centre. The study period was from 1 December 2011 until 5 January 2012 in National Cancer Centre Singapore. The team had attained approval and support from the various heads of department of physicians in the disciplines of breast surgical oncology, medical oncology and radiation oncology to refer potential participants for the study.

The participants were recruited when they came for follow-up consultations at the outpatient clinics. The case records of all women with a diagnosis of breast cancer were screened for eligibility on the day before they turned up for their appointments with their primary physicians. Prior to the study at the outpatient oncology clinics, the research team sought permission and obtained help from the physicians to recruit potential participants suitable for the study. The researchers then approached the eligible participants to explain the study and obtain their written consent. The participants would complete four sets of questionnaires (EORTC QLQ-C30, QLQ-BR23, EQ5D and sociodemographic data) in their appropriate languages of English, Chinese, Malay or Tamil. The participants were given the choice of a face-to-face interview with the researchers or to answer the questionnaires by themselves. The questionnaires took approximately 20 minutes to complete.

Statistical analysis

Data analysis was performed using Statistical Package for Social Science (SPSS)-Version 18. All categorical data were presented in frequency and percentage and continuous data were presented in mean, median and standard deviation. Descriptive statistics were used to describe the participants' demographics and cancer related information. Independent sample-*t*-test and ANOVA tests were used to assess the relationship between QOL, sociodemographic and medical variables. A statistical significant level was set at 0.05 for all tests. Reliability of the questionnaires was examined using Cronbach's alpha test. A Cronbach's alpha of 0.7 was set as an acceptable level for reliability. EORTC QLQ-C30 was validated against EQ5D questionnaire by examining its concurrent validity using Pearson Product Moment Correlation to calculate the total scores.

Results

Sample characteristics

Descriptions of the sociodemographic characteristics and medical profile of the participants are displayed in Tables 1-6. A total of 184 patients with breast carcinoma were invited to participate in the study. There were 170 patients who participated in the study and completed the sociodemographic data sheet and three sets of QOL

questionnaires (EORTC QLQ-C30; QLQ-BR23 and EQ5D) at the outpatient clinics. Fourteen patients declined to participate in the study. The mean age of the participants was 54 (±9) years. A majority of the participants were Chinese (82.4%) followed by Malay (11.8%), Indian (4%) and other ethnic groups (1.8%).

Most of the participants were married women (80%). About 39% of the participants had attended a secondary education and the least percentage (12.9%) had university education. There were about 51% of the participants employed with a gross monthly household income of $2000 (Singapore dollars) or less and 17% of the participants earned more than $5000 and above. Most of the breast carcinoma participants were 4 years (28.8%) post-interventions and least in participants who were 3 years (22.4%) post-interventions. Most of the participants had stage IIA (38.2%) breast carcinoma, followed by stage I (24.1%), stage IIB (16.5%), stage IIIA (12.4%) and stage 0 (8.8%) breast carcinoma upon diagnosis. A total of 98 participants had mastectomy and 72 participants had wide excision surgery.

Validity of the EORTC QOL instruments

In the reliability test, Cronbach's alpha coefficient results for EORTC QLQ-C30 and QLQ-BR23 were 0.846 and 0.873, respectively [Table 7]. This suggested that the items in EORTC QLQ-C30 and QLQ-BR23 questionnaires had relatively good internal consistency. The Pearson Product Moment Correlation was used to calculate the total scores for 170 participants using the two QOL instruments of EORTC QLQ-C30 and EQ5D to test for concurrent validity. The correlation between EORTC QLQ-C30 and EQ5D QOL instruments demonstrated a modest linear relationship (r=0.597; P<0.001) in Table 8. This indicated a moderately strong correlation between the two measures.

Relationship between EORTC QLQ-C30, QLQ-BR23 scores and other factors

Results of both EORTC QLQ-C30 and QLQ-BR23 questionnaires are reported and displayed in Tables 1-6 and 9-10. Participants with chronic disease of osteoarthritis had poorer QOL in terms of physical functioning (P<0.001), role functioning (P<0.001), fatigue (P<0.001), pain (P=0.004), dyspnea (P=0.014), insomnia (P<0.001), appetite loss (P<0.001), diarrhea (P<0.001), financial (P<0.001), future health function (P=0.006) and systemic therapy side effects (P=0.019) as compared to patients who had no osteoarthritis [Tables 5 and 6].

There were 14 participants with chronic disease of diabetes mellitus reported significantly lower QOL as

Table 1: EORTC QLQ-C30 scores by sociodemographic characteristics of participants

Characteristics	Physical functioning	Role functioning	Emotional functioning	Cognitive functioning	Social functioning
	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD
Age, yrs (n=170)					
30-39 (n=9)	90.12±14.11	97.78±06.67	67.68±25.35	72.22±30.05	85.19±15.47
40-49 (n=52)	85.26±17.43	87.31±24.10	82.52±17.16	82.69±20.34	91.67±17.31
50-59 (n=58)	86.21±21.36	93.45±18.50	82.29±24.82	85.06±22.88	91.09±20.52
60-69 (n=44)	86.62±13.03	97.73±07.74	78.31±24.58	82.95±17.05	93.18±14.52
≥70 (n=7)	87.30±17.48	85.71±29.92	92.21±09.72	90.48±16.27	100.0±00.00
F	0.16	2.32	1.52	0.95	0.80
P	0.959	0.059	0.199	0.435	0.525
Education level (n=169)					
Primary and below (n=43)	89.92±12.79	97.21±12.78	84.99±19.32	87.21±15.79	95.74±10.35
Secondary (n=66)	84.34±20.90	92.42±19.14	81.54±22.27	83.84±21.68	92.17±19.66
Post-secondary (n=38)	84.50±17.05	91.58±17.17	79.67±25.31	80.26±23.20	87.28±20.66
University (n=22)	87.37±15.82	85.45±28.41	73.97±23.19	79.55±23.53	90.91±14.30
F	1.03	1.95	1.23	1.01	1.63
P	0.379	0.123	0.299	0.388	0.185
Income level (SGD) (n=170)					
≤$2000 ($n$=86)	85.01±18.81	93.72±18.47	83.93±21.18	85.27±18.69	94.77±15.61
$2001-$5000 (n=56)	88.69±14.29	91.79±20.81	81.01±18.53	83.33±22.02	90.18±18.47
>$5000 ($n$=28)	85.32±19.84	90.71±16.76	71.75±30.24	77.38±24.52	86.31±19.27
F	0.79	0.34	3.20	1.51	2.95
P	0.457	0.714	0.043*	0.223	0.055

*Significant level at P<0.05, SD: Standard deviation, SGD: Singapore dollar

Table 2: EORTC QLQ-C30 scores by sociodemographic of participants

Characteristics	Fatigue	Nausea & vomiting	Pain	Dyspnea	Insomnia
	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD
Age, yrs					
30-39	24.69±19.07	16.67±35.36	25.93±26.50	27.78±26.35	33.33±33.33
40-49	19.66±19.51	00.00±00.00	14.74±17.67	08.65±21.51	15.38±24.22
50-59	18.77±20.94	04.31±19.39	15.23±24.24	12.93±25.75	17.82±30.08
60-69	11.87±14.85	03.41±12.75	14.77±17.32	05.68±19.34	14.39±19.55
≥70	06.35±12.60	00.00±00.00	11.90±12.60	21.43±39.34	04.76±12.60
F	2.17	2.48	0.67	2.25	1.48
P	0.075	0.046*	0.611	0.066	0.210
Education level					
Primary and below	09.56±12.96	03.49±12.89	09.69±13.23	10.47±25.72	06.98±13.72
Secondary	17.51±19.40	02.27±13.68	16.16±21.48	09.85±21.87	23.23±31.47
Post-secondary	21.93±21.22	03.95±17.94	20.61±25.24	10.53±26.40	17.54±25.39
University	22.73±19.84	04.55±21.32	15.15±17.75	15.91±23.84	13.64±19.68
F	3.93	0.16	2.02	0.36	3.75
P	0.010*	0.921	0.114	0.780	0.012*
Income level (SGD)					
≤$2000	14.86±18.48	02.91±14.05	15.70±19.86	09.30±22.38	17.05±26.93
$2001-$5000	18.06±18.78	00.89±06.68	13.39±19.95	11.61±23.34	13.69±21.81
>$5000	21.83±20.39	08.93±27.40	18.45±22.83	14.29±30.00	20.24±29.17
F	1.55	2.59	0.59	0.49	0.65
P	0.215	0.078	0.554	0.613	0.525

*Significant level at *P*<0.05, SD: Standard deviation, SGD: Singapore dollar

Table 3: EORTC QLQ-C30 scores by medical profile of participants

Characteristics	Physical functioning	Role functioning	Emotional functioning	Cognitive functioning	Social functioning
	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD
Breast carcinoma stage (*n*=170)					
0 (*n*=15)	84.44±25.13	93.33±25.82	79.39±29.85	84.44±14.73	93.33±12.28
I (*n*=41)	84.28±22.22	93.17±15.24	72.28±26.50	74.80±26.65	89.84±18.21
IIA (*n*=65)	89.40±13.09	95.38±12.63	86.01±16.39	87.18±17.87	94.36±14.21
IIB (*n*=28)	82.94±16.42	89.29±24.03	77.60±25.17	84.52±20.75	86.90±23.73
IIIA (*n*=21)	86.24±14.87	86.67±27.08	87.88±13.89	85.71±17.71	93.65±17.85
F	0.93	1.10	3.20	2.44	1.12
P	0.446	0.360	0.015*	0.049*	0.346
Year post-interventions (*n*=170)					
1 year (*n*=39)	86.61±16.16	94.36±12.20	77.62±25.78	78.21±25.69	87.18±19.67
2 years (*n*=44)	85.61±18.02	91.82±18.96	83.47±14.97	87.50±19.06	92.42±17.77
3 years (*n*=38)	85.96±22.17	91.05±22.15	75.12±26.03	79.39±20.29	90.35±20.37
4 years (*n*=49)	86.85±14.64	93.06±21.04	85.90±21.24	86.73±17.67	96.26±10.90
F	0.05	0.23	2.17	2.30	2.13
P	0.987	0.877	0.093	0.079	0.098
Type of treatment (*n*=170)					
Wide excision (*n*=72)	87.04±16.15	91.94±19.76	78.28±21.12	81.48±19.09	92.13±16.30
Mastectomy (n=98)	85.71±18.67	93.06±18.41	82.93±23.21	84.69±22.15	91.67±18.27
F	0.23	0.14	1.80	0.98	0.03
P	0.630	0.705	0.182	0.324	0.865

*Significant level at *P*<0.05, SD: Standard deviation

compared to patients with no diabetes mellitus, which were affected by physical functioning (*P*=0.002), role functioning (*P*=0.001), fatigue (*P*=0.025), pain (*P*=0.005), appetite loss (0.016), diarrhea (*P*<0.001) and financial (*P*=0.010) [Table 5]. Participants with hypertension also reported significant lower QOL as compared to those

Table 4: EORTC QLQ-C30 scores by medical profile of participants

Characteristics	Appetite loss	Constipation	Diarrhea	Financial	Global health status & quality of life
	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD
Breast carcinoma stage					
0	11.11±27.22	06.67±13.80	10.00±28.03	17.78±30.52	87.41±18.24
I	03.25±12.48	08.94±14.95	03.66±17.29	19.51±29.79	85.64±16.34
IIA	02.05±08.07	07.69±16.42	01.54±08.70	10.26±17.60	90.77±12.82
IIB	08.33±21.52	09.52±23.76	03.57±13.11	19.05±27.86	85.71±16.52
IIIA	06.35±17.06	00.00±00.00	00.00±00.00	12.70±19.70	87.30±15.02
F	1.67	1.29	1.39	1.27	0.97
P	0.159	0.274	0.241	0.285	0.424
Year post-interventions					
1 year	05.13±12.18	09.40±20.16	01.28±08.01	11.11±20.71	88.03±18.09
2 years	00.76±05.03	06.06±13.00	03.41±12.75	12.88±22.98	87.88±12.86
3 years	06.14±23.06	09.65±20.37	03.95±17.94	26.32±33.02	87.43±14.88
4 years	06.80±16.64	04.76±11.79	03.06±15.84	10.88±17.20	88.43±15.04
F	1.38	0.95	0.26	3.83	0.03
P	0.252	0.420	0.855	0.011*	0.992
Type of treatment					
Wide excision	04.17±12.43	08.33±14.54	02.78±14.26	13.43±23.51	87.65±14.27
Mastectomy	05.10±17.49	06.46±17.69	03.06±14.03	15.99±24.98	88.21±15.78
F	0.15	0.54	0.02	0.46	0.06
P	0.699	0.464	0.897	0.499	0.814

*Significant level at *P*<0.05, SD: Standard deviation

Table 5: EORTC QLQ-C30 scores by co-morbidities of participants

Co-morbidities	Osteoarthritis (*n*=6)		Diabetes (*n*=14)		Hypertension (*n*=35)		Hyperlipidemia (*n*=36)	
	Mean±SD	*P*	Mean±SD	*P*	Mean±SD	*P*	Mean±SD	*P*
Physical functioning	53.70±38.11	0.000*	81.75±31.61	0.002*	81.59±21.38	0.244	81.79±23.33	0.031*
Role functioning	70.00±41.47	0.000*	81.43±31.83	0.001*	94.28±17.20	0.275	92.78±21.46	0.913
Emotional functioning	45.45±27.57	0.152	72.08±27.50	0.204	83.90±19.61	0.377	81.06±24.81	0.163
Cognitive functioning	72.22±36.00	0.126	86.90±22.81	0.865	88.10±17.42	0.157	87.50±15.62	0.092
Social functioning	75.00±20.41	0.329	89.29±14.03	0.995	96.67±08.86	0.000*	92.13±17.13	0.954
Fatigue	38.89±41.43	0.000*	26.19±28.45	0.025*	16.51±16.47	0.510	19.75±22.24	0.232
Nausea & vomiting	08.33±20.41	0.174	00.00±00.00	0.092	00.00±00.00	0.004*	00.00±00.00	0.003*
Pain	55.56±32.77	0.004*	19.05±31.93	0.005*	13.33±16.07	0.141	16.67±22.54	0.994
Dyspnea	25.00±41.83	0.014*	10.71±21.29	0.842	07.14±21.50	0.046*	06.94±17.54	0.019*
Insomnia	44.44±50.18	0.000*	30.95±30.56	0.654	14.29±20.27	0.146	23.15±28.53	0.251
Appetite loss	22.22±40.37	0.000*	09.52±27.51	0.016*	01.90±07.85	0.015*	03.70±17.42	0.472
Constipation	05.56±13.61	0.583	04.76±12.10	0.218	03.81±10.76	0.004*	05.56±14.91	0.200
Diarrhea	16.67±40.82	0.000*	14.29±30.56	0.000*	02.86±11.78	0.911	02.78±16.67	0.916
Financial	44.44±50.18	0.000*	28.57±36.65	0.010*	12.38±22.99	0.282	14.81±26.96	0.773
Global health status & quality of life	74.07±16.73	0.754	87.30±11.41	0.266	87.62±16.34	0.428	87.96±15.57	0.758

*Significant level at *P*<0.05, SD: Standard deviation

without hypertension in social functioning (*P*<0.001), nausea and vomiting (*P*=0.004), dyspnea (*P*=0.046), appetite loss (*P*=0.015), constipation (*P*=0.004) and systemic therapy side effects (*P*=0.028) [Tables 5 and 6]. Similarly, participants with hyperlipidemia had significant lower QOL score for physical functioning (*P*=0.031), nausea and vomiting (*P*=0.003) and dyspnea (*P*=0.019) [Table 5].

Nausea and vomiting (*P*=0.046), body image (*P*=0.001), sexual function (*P*=0.014), future health function (*P*=0.001) were significantly associated with age [Tables 2 and 9]. Factors such as fatigue (*P*=0.010), insomnia (*P*=0.012), body image (*P*=0.008), future health function (*P*=0.001) were affected by the level of education [Tables 2 and 9]. Income level was also associated with emotional functioning (*P*=0.043), body image (*P*<0.001)

Table 6: QLQ-BR23 scores by co-morbidities of participants

Co-morbidities	Osteoarthritis (*n*=6)		Diabetes (*n*=14)		Hypertension (*n*=35)		Hyperlipidemia (*n*=36)	
	Mean±SD	*P*	Mean±SD	*P*	Mean±SD	*P*	Mean±SD	*P*
Body image functioning	77.78±22.15	0.160	84.52±21.89	0.469	90.95±15.57	0.248	89.81±14.52	0.457
Sexual functioning	02.78±06.80	0.351	11.90±13.76	0.737	05.71±11.39	0.133	05.09±13.70	0.081
Sexual enjoyment	NA	NA	33.33±00.00	0.381	33.33±00.00	0.381	33.33±33.33	0.105
Future health function	33.33±36.51	0.006*	54.76±42.58	0.079	77.14±30.00	0.146	74.07±34.83	0.390
Systemic therapy side effects	35.71±21.19	0.019*	17.86±15.54	0.945	12.04±13.28	0.028*	17.46±18.58	0.793
Breast symptoms	25.00±30.62	0.130	15.18±21.47	0.734	11.79±15.44	0.541	14.58±20.59	0.707
Arm symptoms	24.07±24.76	0.154	11.11±15.71	0.657	12.38±18.23	0.756	13.27±17.78	0.999
Hair loss	11.11±17.21	0.907	02.38±08.91	0.211	03.81±13.46	0.083	05.56±18.69	0.207

*Significant level at *P*<0.05, SD: Standard deviation, NA: Not applicable (participant did not answer the questionnaires on sexual enjoyment)

Table 7: Reliability test between EORTC QLQ-C30, QLQ-BR23 with EQ5D questionnaires

Questionnaires	Cronbach's alpha	No. of items
EORTC QLQ-C30	0.846	30
QLQ-BR23	0.873	23

Table 8: Correlations between EORTC QLQ-C30 with EQ5D questionnaires

Questionnaires		EORTC QLQ-C30 global health status and quality of life	EQ-5D imaginable health status
EORTC QLQ-C30 global health status and quality of life	Pearson correlation	1	0.597
	Sig (2 tailed)		0.000

*Correlation is significant at the 0.05 level (2-tailed)

and future health function (*P*=0.016) of the participants [Tables 1 and 9].

The stage of breast carcinoma affected the QOL in emotional functioning (*P*=0.015), cognitive functioning (*P*=0.049) and arm symptoms (*P*=0.001) [Table 3 and 10]. The number of year(s) post-interventions affected the financial scores (*P*=0.011) [Table 4]. Systemic therapy side effects (*P*=0.028) and hair loss (*P*=0.003) were significant concerns for participants in different types of surgery that included wide excision and mastectomy for breast carcinoma [Table 10].

Discussion

Validation of the EORTC QLQ-C30 and QLQ-BR23 instruments

One of the key objectives of the current study was to examine the concurrent validity of EORTC QLQ-C30 using EQ5D as the comparison instrument. The findings of this study provided support for the reliability of both QOL measures. There was acceptable good Cronbach's alpha score of 0.846 for EORTC QLQ-C30. Cronbach's alpha score for QLQ-BR23 was 0.873 with strong internal reliability. There was also a moderately strong correlation between the two QOL instruments of EORTC QLQ-C30 and EQ 5D (r=0.597, P<0.001). Hence, the EORTC QLQ-C30 and QLQ-BR23 appeared to be promising instruments to assess the levels of HRQOL among women with breast cancer in Singapore.

HRQOL in the first 4 years of breast cancer survivorship

Another main objective of this study was to describe the HRQOL levels of EORTC QLQ-C30 and QLQ-B23 in the first 4 years of breast cancer survivorship among 170 Singaporean women. The researchers had examined the entire sample and mean scores for QOL reported by women in their first 4 years of breast cancer survivorship. Overall, Singaporean women in this study population reported generally high QOL outcomes and good physical, role, emotional, cognitive, social functioning and symptoms well-being.

The high levels of QOL scores among Singaporean women might be because they had completed active breast cancer treatments and had integrated well to their social environments. This result was consistent with a study that reported women with breast cancer in their first 2 to 5 years of survivorship had achieved high QOL outcomes.[19] This was because they had overcome the physical and psychological issues of the disease and had adjusted to their new situation. Another study also reported improvements in symptoms such as pain and fatigue 1 year after breast cancer interventions.[20]

Interestingly, another main important finding was Singaporean women who were in their third year of breast cancer survivorship appeared to have more financial concerns than those women in the first and second year.

Table 9: QLQ-BR23 scores by sociodemographic characteristics of participants

Characteristics	Body image function	Sexual function	Sexual enjoyment	Future health function	Systemic therapy side effects	Breast symptoms	Arm symptoms	Hair loss
	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD
Age, yrs								
30-39	68.52±16.02	11.11±23.57	50.00±23.57	37.04±26.06	23.81±22.30	22.22±16.27	24.69±31.32	22.22±28.87
40-49	83.97±21.70	17.31±23.79	53.85±21.68	63.46±32.51	21.02±19.05	15.38±16.72	13.89±16.00	15.38±31.28
50-59	90.09±15.09	09.20±19.03	61.90±23.00	68.97±37.91	17.63±21.57	12.93±20.67	12.45±18.51	08.62±21.23
60-69	91.86±14.21	04.55±13.14	33.33±47.14	81.82±24.33	16.18±13.30	10.23±19.11	12.63±20.28	03.79±12.89
≥70	97.62±06.30	00.00±00.00	00.00±00.00	90.48±16.27	07.14±07.14	14.29±19.67	04.76±08.74	04.76±12.60
F	5.00	3.24	0.76	5.18	1.27	0.96	1.24	2.22
P	0.001*	0.014*	0.529	0.001*	0.285	0.433	0.297	0.070
Education level								
Primary and below	91.28±13.11	04.65±09.84	33.33±00.00	82.17±27.55	12.46±12.08	14.24±16.27	10.34±16.52	03.88±13.03
Secondary	91.16±15.04	12.37±21.94	58.33±20.72	73.74±33.85	19.16±18.63	10.61±17.57	11.78±16.41	09.09±21.52
Post-secondary	80.26±23.60	10.96±22.35	50.00±34.96	57.89±35.25	23.09±23.81	19.41±24.78	20.18±22.79	16.67±30.76
University	84.09±18.88	13.63±22.20	58.33±16.67	56.06±29.79	18.51±17.59	11.36±13.86	11.62±21.54	13.64±30.27
F	4.10	1.64	0.71	5.51	2.34	1.90	2.27	2.19
P	0.008*	0.182	0.555	0.001*	0.075	0.132	0.083	0.091
Income level (SGD)								
≤$2000	93.02±11.78	08.53±19.76	59.26±32.39	76.74±30.28	16.36±16.61	11.92±17.67	12.27±17.80	07.75±21.50
$2001-$5000	83.04±21.79	10.71±17.24	44.44±16.67	64.88±37.83	19.52±20.50	13.62±16.73	13.50±15.96	11.31±24.02
>$5000	81.55±20.33	14.29±24.31	61.11±13.61	58.33±29.57	21.13±20.62	18.30±25.34	15.87±26.61	14.29±29.30
F	8.02	0.92	1.25	4.25	0.90	1.21	0.39	0.93
P	0.000*	0.400	0.307	0.016*	0.407	0.300	0.680	0.398

*Significant level at *P*<0.05, SD: Standard deviation, SGD: Singapore dollar

Table 10: QLQ-BR23 scores by medical profile of participants

Characteristics	Body image function	Sexual function	Sexual enjoyment	Future health function	Systemic therapy side effects	Breast symptoms	Arm symptoms	Hair loss
	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD
Breast carcinoma stage								
0	86.67±23.32	13.33±20.12	50.00±23.57	71.11±41.53	16.67±17.22	15.00±19.59	08.15±14.22	06.67±18.69
I	88.62±16.22	10.16±20.37	57.14±31.71	64.23±36.81	25.26±23.80	15.55±22.50	08.67±14.17	13.01±27.77
IIA	91.41±13.50	07.69±17.70	47.62±26.23	74.36±28.73	14.85±16.42	10.96±14.41	11.45±13.74	10.26±24.95
IIB	82.74±17.99	17.26±26.64	58.33±15.43	69.05±31.33	17.77±18.41	20.09±23.90	26.19±30.87	04.76±11.88
IIIA	82.94±25.61	06.35±11.15	NA	66.67±38.01	16.33±11.33	07.74±12.79	14.29±16.53	12.70±26.82
F	1.68	1.46	0.29	0.64	2.13	1.82	4.70	0.64
P	0.156	0.217	0.833	0.638	0.079	0.128	0.001*	0.632
Year post-interventions								
1 year	87.39±14.29	13.68±23.53	55.56±16.67	72.65±30.47	20.51±19.81	16.66±21.14	14.25±18.55	05.13±18.00
2 years	89.02±17.50	05.68±13.42	44.44±19.25	71.97±27.79	15.75±19.21	10.80±14.41	11.87±14.26	09.09±23.14
3 years	87.06±17.40	09.65±22.80	75.00±31.91	64.04±39.04	19.52±19.84	17.76±23.54	16.08±23.06	13.16±26.33
4 years	87.76±21.18	11.90±18.63	45.83±24.80	70.07±36.16	17.49±16.31	10.20±15.66	11.56±19.51	12.25±26.08
F	0.10	1.30	1.67	0.53	0.54	1.84	0.53	0.94
P	0.963	0.275	0.205	0.664	0.658	0.142	0.666	0.424
Type of treatment								
Wide excision	88.77±16.32	12.04±21.16	53.85±28.99	69.44±33.45	21.84±21.46	14.24±19.26	10.65±14.50	16.20±31.15
Mastectomy	87.16±18.93	08.84±18.72	54.55±16.82	70.07±33.67	15.50±15.83	13.01±18.65	15.19±21.43	05.44±14.90
F	0.34	1.08	0.01	0.01	4.92	0.17	2.42	8.93
P	0.562	0.300	0.944	0.905	0.028*	0.677	0.122	0.003*

*Significant level at *P*<0.05, SD: Standard deviation

Meanwhile, women who were in their second year of post-treatments were more worried about financial issues than those women in their first year of breast cancer survivorship. One of the possible explanations is that breast cancer is a costly disease. It influences the economic well-being of the women and their family members.

A systematic review expounded that with increasing years, breast cancer survivors and family members often experience financial burdens associated with the illness.[21] The financial needs include the direct medical cost of physician fees and other health care services, the purchase of new bras, make-up, new clothes and prosthesis for aesthetic purpose. They may engage in more social activities as a form of distraction therapy from breast cancer which can lead to an increase in expenditure.

Results of QOL and sociodemographic factors

QOL and advanced age

The findings of the study showed that women who were in the younger age group of 30 to 39 years old experienced more nausea and vomiting worries than the older age group. They also had more concerns in the aspects of body image and future health function than women who were 40 years old and above.

Several other studies supported the study findings that women in the younger age group had a lower QOL in terms of body image and future health function as compared to the older women.[22-24] Many younger women often have major concerns of getting married and having children in the future after going through various cancer interventions such as chemotherapy that may cause premature menopause and fertility loss. They are also worried about the possibility of cancer recurrence that may affect their health, families, work and career. The other possible explanation that women of the younger age group had reported more worry over the symptoms of nausea and vomiting was because chemotherapy regime ordered for the younger women were more aggressive than the older women.[25] This might increase the intensity of nausea and vomiting and caused physical discomfort.

QOL in relation to education and income

This study revealed that Singaporean women with higher educational (post-secondary and university group) and income levels (>$5000) had more emotional functioning disturbances with concerns over future health function and body image than those women in the lower educational (primary and below) and income (≤ $2000) background. The study also showed that women who were highly educated and graduated from post-secondary and university had experienced symptoms of fatigue and insomnia more than those women who were less educated at the primary and below level.

The possible explanation for these results is women with better education are more likely to obtain information about breast cancer treatments and outcomes for the future.[26] In this process, they tend to focus on their illness which can impact their QOL of physical and psychosocial functioning. Whereas women who have lower educational background may not source for more information about their illness and may be less affected physically and emotionally.

Results of QOL and medical variables

QOL and co-morbidities

The study showed that women with knee osteoarthritis (OA) and diabetes mellitus (DM) had reported a decrease in their physical and role functioning QOL variables. They were also affected by the symptom of pain. This is consistent with the study conducted by Schlenk *et al.*[27] whom reported that patients with OA had poorest level of physical and role functioning as well as experienced pain symptom that greatly affected their QOL.

The findings of the study also revealed that symptoms such as fatigue, appetite loss and diarrhea were significant in both chronic diseases of OA and DM. Whereas symptoms of dyspnea and insomnia were only prominent in the subjects with knee OA. Kartz and McHorney also reported similar result that pain from OA is the common cause for insomnia.[28] Moreover, this study found that both disease groups of OA and DM have significant financial impact as this was the common problem encountered by most patients with chronic diseases. This is also addressed by Sun *et al.*[29] whom highlighted that significant proportion of patients with chronic diseases face catastrophic healthcare costs and these are especially heavy for the poor.

QOL and breast cancer stage

The study revealed that women with stage 0 and stage I of breast cancer as compared to women with stage 2A and stage 3A had significantly higher levels of emotional distress of anxiety, depression and irritability. This finding was consistent with several other studies that found that women with early breast cancer attain psychological disturbance of anxiety and depression that affect their QOL.[30,31] Some studies also indicated that the psychological response to breast cancer is independent of cancer stage as women with non-invasive breast cancers also experience intense emotions.[32,33]

QOL and type of surgery

This study found that women who had undergone breast-conserving surgery experienced more systemic therapy side effects such as dryness of mouth and taste alterations of food and drink as compared to women who had mastectomy. It also discovered that women with wide excision were more

affected with hair loss resulted from chemotherapy than women with mastectomy.

A possible explanation for this was that women who had selected mastectomy had stronger convictions regarding the benefits of mastectomy that it totally eradicated the cancer and might be less affected with body image disturbances such as temporary hair loss resulted from chemotherapy.[34] On the other hand, women who had chosen wide excision or lumpectomy felt that the loss of a breast was worse than cancer itself. They were more bothered with altered body image and in turn afraid of hair loss that could affect their self-esteem. Thus, it appears that women who are treated with breast conserving surgery have the concerns of systemic side effects that can impact on their QOL.

Limitations

This was a single-tertiary cancer center-based study and thus the results could not be generalized for the population of women with breast cancer in Singapore. Another limitation was that this was a cross-sectional study that measured the HRQOL of women with breast cancer in their first 4 years of survivorship. Hence, there was no baseline and data to compare their HRQOL before and during cancer interventions in facilitating the assessment of HRQOL that changes over time. The third limitation was that the number of subjects with knee OA was rather small which may not be representative for HRQOL assessment.

Implications for research and practice

There are several implications for healthcare professionals who are caring for the women with breast cancer. This study evaluated and found considerable support for the concurrent validity and reliability of the EORTC QLQ-C30 and QLQ-BR23 instruments which are HRQOL instruments specific to breast cancer in the HRQOL study for women with breast cancer in Singapore. These instruments can be promising measures to examine the levels of HRQOL among Singaporean women with breast cancer in future studies in improving their health outcomes.

The study reflected that the younger women in Singapore had experienced more physical symptoms distress such as nausea and vomiting as well as psychosocial concerns that included sexual dysfunction and fear of cancer recurrence which affected their HRQOL. Women who had selected breast-conserving surgery also showed that they had concerns over systemic therapy side effects and the loss of hair. Ganz *et al.* highlighted that women who had less contact time with healthcare professionals after their primary cancer treatments would encounter more adjustment difficulties.[35] Hence, adequate support is needed to address the physical and psychosocial needs for the younger survivors who have more adaptation challenges after their primary cancer interventions. The healthcare providers may establish various support groups that caters specifically for the patients' needs such as a young patient support group and a general support group.

Moreover, the study had highlighted that breast cancer could cause significant financial impact in women with breast cancer in Singapore. Healthcare providers can help to explore the financial needs of the women. They can listen to the women's concerns and refer them to the appropriate personnel such as a medical social worker who may provide the necessary resources and reduce their financial burdens of healthcare cost.

A longitudinal follow-up study is recommended for future study. This is to examine the progress of HRQOL in Singaporean women with breast cancer over time in gaining valuable information to meet their specific needs in the various stages of their lives. In conclusion, healthcare professionals can make a difference to the lives of women with breast cancer when they pay attention to identify their physical and psychosocial needs by using good HRQOL instruments such as the EORTC QLQ-C30 and QLQ-BR23 measurements in improving the quality of patient care.

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How to cite this article: Tan ML, Idris DB, Teo LW, Loh SY, Seow GC, Chia YY, *et al*. Validation of EORTC QLQ-C30 and QLQ-BR23 questionnaires in the measurement of quality of life of breast cancer patients in Singapore. Asia Pac J Oncol Nurs 2014;1:22-32.

Source of Support: Nil. **Conflict of Interest**: None declared.