RESEARCH ARTICLE

The Development of Quality of Life Questionnaire for Indonesian Breast Cancer Patients: INA-BCHRQoL

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Abstract

Introduction: The breast cancer related incidence and mortality rate in Indonesia are included in the top 10 and top 5 highest in the world. A country-specific Health Related Quality of Life measurement tool is required to help clinician observe and improve the management of the disease. **Methods:** We developed the questionnaire, namely Indonesian Breast Cancer Health Related Quality of Life (INA-BCHRQoL) by incorporating not only the generic variables such as physical, psychological, and social; but also spiritual variable which is suitable for Indonesian population. The questionnaire was validated to the same population using the value of corrected item-total correlation and the value of Cronbach Alpha. **Results:** Fourty three questions were considerably valid and reliable on evaluating the HRQoL of early state of breast cancer patients in Indonesia as the value of Cronbach Alpha for physical, cognitive, social and spiritual domain were higher than 0.8 and the corrected item-total correlation were also higher than 0.3. Each domain of the questionnaire was not influenced by the treatment options. Twenty four early stage breast cancer (10 FAC based chemotherapy and 14 Taxan based chemotherapy) were enrolled in the main study and the score of HRQOL obtained from INA-BCHRQoL were considerably high. **Conclussion:** The INA-BCHRQoL questionnaire can be implemented as a valid and reliable tool to assess quality of life in early stage breast cancer patients in Indonesia.

Keywords: Breast cancer- QoL- INA-BCHRQoL- Indonesia

Introduction

Breast cancer is the most common cancer among women in the entire part of the world including Indonesia (Ferlay et al., 2013). Recently, Indonesia is included as the top 10 and top 5 highest for breast cancer-related incidence and mortality in the world, respectively (Ferlay et al., 2013). The age-standardized breast cancer incidence rate and the mortality rate was 40.3 and 16.6 per 100,000 in Indonesia, consecutively. There are several recommendations on breast cancer in order to not only prevent the incidence of late stage breast cancer but also manage the disease itself using surgery, chemotherapy, and or radiotherapy (Team et al., 2016; Cardoso et al., 2017). In Indonesia, the use of combination therapy between surgery and chemotherapy, particularly Fluorouracil-Adriamicyn-Cyclophosphamid (FAC) dan Taxane-based chemotherapy, was considerably high (Aragon and Negara, 2014) as most of breast cancer patients were diagnosed at the early-stage (Stage I to IIIA) (Ng et al., 2011).

Cancer, particularly breast cancer, and also its treatment consequently affect not only the physical but also psychosocial condition of the patients including their daily activities, social interaction, and spiritual well-being (Humpel et al., 2007). The evaluation of psychological and spiritual aspects, represented by Health-Related Quality of Life (HRQoL) (Vrettos et al., 2012; Gandhi et al., 2015), are as important as clinical aspects in order to achieve and maintain the desired outcomes. Recently, the use of HRQoL information not only used for assessing the burden of the disease but also the effectiveness of the disease management (Maric et al., 2015).

Several HRQoL measurement instruments were developed and widely accepted for cancer patients including generic questionnaires such as European Quality of Life-5 Dimension (EQ-5D) ("Eq-5d-5l-Value-Sets @ Www.euroqol.org," n.d.; Galante et al. 2011) and cancer-specific questionnaire such as The European Organization for Research and Treatment of Cancer Quality of Life Core Questionnaire (EORTC QLQ-C30) (Awad et al., 2008; Kim et al., 2012a). However, personal perspective on the valuation of HRQoL is apparently influenced by several aspects including age, gender, social class, race and culture (Kemeny et al., 1988).

A local language is a vital aspect that has to be

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incorporated in the questionnaire, therefore, there are two options in order to have a local-language questionnaire: translate the available questionnaire and develop a new questionnaire according to the socio-cultural aspects of the population (Perwitasari et al., 2011; Rivany, 2014). While the currently available questionnaire is failed to capture the spiritual aspect of the patients, the development of Indonesia Breast Cancer patients-specific health-related quality of life (INA-BCHRQoL) questionnaire is considerably substantial. In this study, we developed a new questionnaire in order to capture not only patients' physical, cognitive and psychological aspects but also the spiritual aspect.

Materials and Methods

This study was conducted in "Dharmais" National Cancer Hospital, Jakarta, Indonesia. The inclusion criteria for study population were women who were diagnosed breast cancer stage I to IIIA, confirmed by pathology and anatomy (PA) assessment or cytology test, received surgery and combined with fluorouracil, Doxorubicin and cyclophosphamide (FAC)- or Taxan-based chemotherapy. The exclusion criteria were patients who were in the middle of their scheduled radiation treatment or refused to participate in this study.

The development and validation of the questionnaire

In order to provide a comprehensive HRQoL measurement tool-specific for Indonesian breast cancer patients, INA-BCHRQoL questionnaire was developed by incorporating not only the generic variables such as physical, psychological, and social but also spiritual variable as it is suitable for Indonesian population (Rivany, 2014). The questionnaire was developed, instead of translated using forward and backward translation, in order to provide a questionnaire that is suitable for Indonesian breast cancer patients. The initial phase of BCHRQoL questionnaire development was performed in 4 different stages including (i) the degree of severity classification, (ii) including the classification into the INA-BCHRQoL development matrix, (iii) fill the matrix with breast cancer's attribute. Finally, (iv) compare qualitatively the collected attributes with existing attributes from the literature including several generic and breast cancer-specific quality of life questionnaire such as Indonesia-Health Related Quality of Life (INA-HRQoL), European Organization for Research and Treatment of Cancer QOL (EORTC QLQ-C30), Functional Assessment of Cancer Therapy-Breast Symptom Index (FACT-B), Life Satisfaction Questionnaire (LSQ), Short-Form Health Survey (SF-36), Spiritual SELF- M Questionnaire, Early Stage Breast cancer (ESBC), and European Quality of Lofe 5 Dimension (EQ-5D).

In order to make understandable options, Common Terminology for Adverse Events v3.0 (CTCAE) (National Institute of Cancer 2010) was implemented in this development process. This process considering all breast cancer-symptoms and treatment related adverse event, including upper arm symptomps, pain, shorthen of breath, weakness, appetite, nausea, vomit, defecate,

dhiarrea, hair loss, headache, sprue, fingertip numbness, cognitive and psycological changes, and mobility disturbance. Furthermore, the language validation process was performed by translating the options from CTCAE into Indonesian Language and the complete version of the questionnaire was translated back to English by a Native speaker from World Bank in Indonesia. The scoring system of the developed questionnaire were

The validation process was performed from December 2009 until December 2010. The first and second validation processes were performed by testing the questionnaire to 30 patients. The questionnaire was considered valid and reliable if the value of corrected item-total correlation and the value of Cronbach Alpha were higher than 0.361 and higher than 0.80, respectively (Tripathy et al., 2015; Perwitasari et al., 2011; Awad et al., 2008; Lang et al., 2010). Questions with the value of corrected item-total correlation of 0 to 0.361 and lower than 0 were modified and excluded from the questionnaire, respectively. Additionally, discriminant and convergent validity was evaluated in the third validation test in order to put each question into their suitable domain according to the Pearson correlation value of higher than 0.4 (Tripathy et al., 2015; Perwitasari et al., 2011; Group, 1998). Furthermore, the sensitivity test was performed by estimating the average value of each domain from two different groups of study populations, FAC- and Taxan-based combination therapy, and estimated the differences using t-test (Awad et al., 2008; Lang et al., 2010; Pickard et al., 2007; Group, 1998). Finally, the fourth validity test was done to ensure the validity and reliability of the questionnaire.

Main Study

The study population consisted of all early stage breast cancer patients from the "Dharmais" National Cancer Hospital, Indonesia who were treated in the hospital from January 2011 to December 2012. We studied patients with these two regiments which are mostly used in Indonesia, particularly this hospital. The measurement was performed after the patients were diagnosed but before they received any therapy in the hospital with the intention of identifying the score of Quality of Life at the baseline condition. In addition, several information, including patient's demographic and immunohistochemistry status, were also collected during the interview. A positive response was valued higher score depend on the number of options in each question. Patients responses to each question from developed questionnaire were used to estimate the QoL score using the average score from each question.

Results

The development of the questionnaire

With regards to the initial phase of the development process, the INA-BCHRQoL development matrix was developed by combining the breast cancer degree of severity classifications, covering impairments, disabilities, and handicaps (American Cancer Society, 2016), and the quality of life aspects including physical, psychological, social and spiritual (I et al., 2014; Pattanaphesaj, 2014).

Table 1. Classification and Attributes of INA-BCHRQoL Development Matrix

	Physical	Cognitive and psycological	Social	Spiritual
Impairments	Therapy-related Physical disorder Attributes: 1. Arm condition 2. Pain 3. Fatigue 4. Medication side effect 5. Weakness 6. Appetite 7. Nausea 8. Vomiting 9. Defecate 10. Diarrhea 11. Hair 12. Headache 13. Sprue 14. Numbness in fingertips	Cognitive and psychologic disorder Attributes: 1. Concentration 2. Sadness 3. Anxious 4. Sensitive 5. Sleep disorder	Social activities disorder Attributes: 1. Communication 2. Intervention 3. Social activities	Life orientation disorder Attributes: 1. Calm and peace 2. Positive to everything 3. Comfort and stable in religion
Disabilities	Reduction of mobility and daily activities Attributes: 1. Mobility 2. Daily activity	Reduction of adaptation ability Attributes: 1. Desperate 2. Fear 3. Worry about recurrence	Limitation of social activities Attributes: 1. Social activity	Cognitive spiritual Attributes: 1. Grateful 2. Self confidence 3. Explore new interest 4. Be positive 5. New life orientation
Handicaps	Loss of working ability Attributes: 1. The ability on finishing the work	Loss of adaptation ability Attributes: 1. Body expression 2. Sexual function	Loss of social contact with society	Reduction on praying activities Attributes: 1. The frequency of praying

Furthermore, classification and the inclusion of attributes for each component (order) of the matrix was collected from other HRQoL studies elsewhere (Kim et al., 2012a; Lang et al., 2010; Whynes, 2008; I et al., 2014; Kim et al., 2012b; Pattanaphesaj, 2014) (Table 1).

Validation process

Generally, the validation process was performed in 4 stages in order to obtain a valid, reliable and applicable tool on estimating the HRQoL on early stage breast cancer in Indonesia. The first validation test was performed by testing the questionnaire,

Table 2. The Quality of Life Score and It's Domain for FAC-and Taxan-based Group

Group	Physical	Cognitive and psycological	Sosial	Spiritual
Taxan based (± SD)	79.2 ± 7.7	86.7±6.9	98.9±3.0	89.5±12.0
FAC based (± SD)	73.2 ± 16.2	78.5±17.1	90.9±20.1	84.8±15.7
P value	0.308	0.130	0.087	0.434

with 19 attributes, to 30 respondents. This initial test showed that the questionnaire was considerably valid (Cronbach alpha of 0.822). However, there were negative values of corrected item-total correlation for question number 5 (friend or family support), 18 (satisfaction with adaptation to the disease) and 19 (hope for future health). Therefore, those three questions were excluded from the questionnaire for the next validation test.

Although the second validation trial showed that the reliability was also high (Cronbach alpha>0.800), there some questions showed the value of corrected item-total correlation lower than 0.361. A question about sexual changes was excluded from the questionnaire.

As the questionnaire has been modified according to the previous validation test. The third validation test showed that there several questions which are not suitable for its current domain, therefore, several movements were generated including "fatigue" and "medication's side effect" were moved from physical to psychology domain, "daily activity" was moved from physical to psychology domain, "the ability on finishing the work" were moved from physical to social, "communication" and "social activities" were moved from social to spiritual domain,

and "new life orientation" was moved from spiritual to social domain.

Furthermore, the sensitivity test showed that there were no differences between FAC- and Taxan-based group (Table 2). Therefore, this questionnaire was considered applicable for all early stage breast cancer patients. Finally, the last validity test showed the questionnaire was considerably valid and reliable since the value of Cronbach Alpha for physical, Cognitive, Social and spiritual were mostly higher than 0.8 and there were no negative or value lower than 0.3 for corrected item-total correlation (Appendix 1).

Main Study

Twenty-four patients (10 FAC-based chemotherapy and 14 Taxan based chemotherapy) were enrolled in the main study from January 2011 until December 2012. In the FAC group, most of the patients were treated using FAC-based combination therapy (90%), have lower education level (60% had high school or lower diploma) while patients in the Taxan-based combination therapy apparently have different characteristics as most of them were older than 40-year-old (79%),

Table 3. Patients Characteristics

Patient's characteristics	FAC (n= 10)	Taxan (n=14)	Total (n=24)
Age (%)			
- <40	1 (10)	3 (21)	4 (17)
- >40	9 (90)	11 (79)	20 (83)
Education level (%)			
- < Highschool	6 (60)	5 (36)	11 (46)
- > highschool	4 (40)	9 (64)	13 (54)
Stadium (%)			
I	0 (0)	1 (7)	1 (4)
IIA	2 (20)	4 (29)	6 (25)
IIB	5 (50)	4 (29)	9 (38)
IIIA	3 (30)	5 (35)	8 (33)
Occupation (%)			
Housewife	6 (60)	7 (50)	13 (54)
Private sector	1 (10)	3 (21)	4 (17)
Public sector	3 (30)	4 (29)	7 (29)
Types of surgery			
MRM	5 (50)	8 (57)	13 (54)
Mastectomy	2 (20)	3 (21)	5 (21)
BCT	3 (30)	3 (21)	6 (25)
Payer			
No insurance	6 (60)	7 (50)	13 (54)
Askes/jamkesmas	4 (40)	6 (43)	10 (42)
Others	0 (0)	1 (7)	1 (4)

Table 4. Immunohistochemistry Status of Early Stage Breast Cancer in the Dharmais National Cancer Hospital

Patients characteristics	FAC (N=10)	Taxan (N=14)	Total (N=24)
CergB2 atau Her2 (%)			
Positive	2 (20)	7 (50)	9 (37.5)
Negative	4 (40)	5 (36)	9 (37.5)
missing	4 (40)	2 (14)	6 (25)
Estrogen Receptor (%)			
Positive	5 (50)	7 (50)	12 (50)
Negative	3 (30)	6 (43)	9 (37.5)
Missing	2 (20)	1 (7)	3 (12.5)
Progesteron Receptor (%)			
Positive	2 (20)	5 (36)	7 (29)
Negative	6 (60)	7 (50)	13 (54)
Missing	2 (20)	2 (14)	4 (17)
P53 (%)			
Positive	2 (20)	3 (21.5)	5 (21)
Negative	1 (10)	3 (21.5)	4 (17)
Missing	7 (70)	8 (57)	15 (62)
Swollen Lymph Node (%)			
Positif	8 (80)	11 (79)	19 (79)
Missing	2 (20)	3 (21)	5 (21)

Table 5. The Score of Quality of Life from INA-BCHRQoL of Early Stage Breast Cancer Patients in "Dharmais" National Cancer Hospital, Indonesia

Measurements	FAC (N=10)	Taxan (N=14)	Total	P value
Physical domain (±SD)	89.4 ± 6.4	93.0 ± 2.1	91.5 ± 5.99	0.156
Cognitive and psychological domain (±SD)	91.8 ± 5.9	80.7 ± 12.4	85.3 ± 15.79	0.091
Social domain (±SD)	95.8 ± 1.3	96.4 ± 0.7	96.2 ± 7.76	0.858
Spiritual domain (±SD)	93.9 ± 1.0	93.1 ± 1.7	93.5 ± 4.7	0.683

had higher education level (64%). However, most of the patients are the housewife for both groups (60% for FAC-based-group and 50% for the Taxan-based group) (Table 3). In the clinical aspect, the patients on the FAC-based group were mostly diagnosed at the stage of IIB (50%) while in the Taxan-based group most of them were diagnosed at the stage of IIIA, however, both of them mostly received Modified Radical Mastectomy (MRM) and didn't have health insurance.

The immunohistochemistry status for FAC-based was mostly negative for a human epidermal growth factor receptor 2 /HER2 (40%) and Progesteron receptor (60%) and positive for Estrogen receptor (50%) and Lymph node-positive (80%). The Taxan-based group showed comparable immunohistochemistry status as most of the having positive Estrogen receptor status (50%), negative Progesterone receptor status (50%), and Lymph node-positive (79%). However, most of the status of p53, 80% and 79% for FAC group and Taxan group, respectively, could not be examined by the examiner (Table 4).

According to the information collected using INA-BCHRQoL questionnaire (Table 5), the highest and lowest reduction on HRQoL was experienced by breast cancer patients for cognitive and psychological

(85.3 ± 15.79) and social domain (96.2 ± 7.76), respectively. additionally, all of the HRQoL from both group are comparable since the p-value is higher than 0.05. in FAC group, the highest reduction on HRQoL was in the physical domain (89.4 ± 6.4) while in the Taxan-based group it was the cognitive and psychological domain (80.7 ± 12.4).

Discussion

Health-Related Quality of Life (HRQoL) measurement becomes more important in cancer management. Our study showed that Indonesian Breast Cancer Health-Related Quality of Life (INA BCHRQoL), with 41 final questions, is valid and reliable for measuring the Health-Related Quality of Life in early stage breast cancer in Indonesia. compared to several existing HRQoL questionnaire (Krabbe et al., 2004; Kim et al., 2012b), this new questionnaire will measure the HRQoL comprehensively as it incorporates not only physical, cognitive, psychological, and social domain (Endarti et al., 2015) but also spiritual domain which is suitable for Indonesian population as the most religious country in the world.

The final version of INA-BCHRQoL is extensively comprehensive in order to identify and measure every

aspect related to the Quality of life of early stage breast cancer patients. Every domain of the questionnaire covering the most common symptoms, cognitive and psychological changes, social and spiritual changes experienced by breast cancer patient due to the disease itself and or the adverse effect of the treatment.

In order to provide an acceptable tool for local patients in Indonesia, translating an existing HRQoL questionnaire could be an acceptable option (Perwitasari et al., 2011). However, there is an issue on translating the original version of available HRQol questionnaire into a local language such as the difficulties in capturing the cultural equivalency due to some values which are not possible to be translated into local language (Robson, 2015). In addition, the existing and mostly used questionnaire for cancer patients generally failed to explicitly capture the spiritual aspect of the patients which is also considerably important for Indonesian population. Therefore, in order to capture the cultural equivalency, this new tool could assist a clinician in their daily practice on breast cancer management particularly measuring the treatment outcome on the humanistic aspect for a multicultural population.

In the validation process, HRQoL results comparison was performed with the purpose of examining its applicability on the general early stage breast cancer patients. Moreover, our results showed that the results were not influenced by the patients' group or in the other word the INA BCHRQoL is applicable for all early stage breast cancer patients. This questionnaire applicability is substantial as early stage breast cancer was considered as the patient group who has higher chance of recovery and lower rate of relapse (Ludman et al., 2010; Winther et al., 1997; Johnson et al., 2010).

During the last (fourth) validation test, there were several questions in the physical domain which have corrected item-total correlation lower than 0.3 (<0.3). However, since the exclusion of those questions did not generate significant changes in the value of alpha Cronbach, it means that that questionnaire doesn't have to be excluded and the physical domain remains valid and reliable. Nevertheless, there were two attributes, "changes of sexual behavior" and "frequency of sexual behavior", which were not valid as their correlation coefficient were lower than 0.361 and minus, respectively, and excluded from the final questionnaire.

There is some limitation regarding this study. Firstly, the number of early-stage breast cancer which is included in the main study is limited. This issue was seemingly caused by the location of the study, "Dharmais" the national cancer hospital, which is a referral hospital for all cancer patients from all regions in Indonesia, therefore, the patients who visit this hospital are mostly in the later stage of breast cancer.

Lately, utility score is considerably getting more important in the Pharmacoeconomic studies (Setiawan et al., 2016). Luckily, 5 out of 41 questions from this new questionnaire can be used to calculate the utility value according to the appropriate value set provided by EQ-5D. Again, since the number of patients which is included in the main study is limited, the generalization of utility score for all early stage breast cancer patients was

fairly acceptable.

Several recommendations, with regard to the implementation of this questionnaire, are proposed including a further study about the use of INA-BCHRQoL for a higher number of early stage breast cancer patients in several sites or hospital in Indonesia. The inclusion of regional or more local hospital will be more effective in detecting the eligible patients since most of the patients with breast cancer complaints mostly visit a local hospital instead of the national hospital.

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