DEVELOPMENT THE VALIDATION OF INDONESIAN VERSION OF SF-36 QUESTIONNAIRE IN CANCER DISEASE

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ABSTRACT

A Cancer patients need long term therapy in the treatment of their disease. One of the outcome of cancer treatment in patients of quality of life. Because of the limited instrument for measuring cancer patients' quality of life in Indonesian version, thus this study is aimed to develop the validation of Indonesian version of Short Form-36 questionnaire in cancer patients. The observational study was carried out in this study. Data were collected from cancer patients in the Oncology Department of Sardjito Hospital, Yogyakarta, Indonesia, who were treated with cisplatin at the dosage of $\geq 50 \text{mg/m}^2$ as monotherapy or in combinations. The validation process involved known-group validity, discriminant validity, convergent validity and factor analysis. About 203 subjects who were diagnosed with cancer were recruited in this study. The known-group validity test showed that there were no significant differences of SF-36 domains among different diagnosa. All of the questions met the criteria of convergent validity except for the questions number 26, 28, 30 and 32. Furthermore, the questions number 2 and 28 did not meet the criteria of discriminant validity. This study presents that many questions are needed to be reconstructed, due to the result of factor analysis which showed that those questions are loaded significantly with other domain's guestions. The development of Indonesian version of SF-36 scales in cancer disease is still less unstatisfactory. According to the result of this study, future study with new construction of questions in this version is still necessary.

Key words: validation, SF-36, Indonesia, cancer

INTRODUCTION

In Indonesia, approximately 200.000 people were diagnosed with cancer every year. Similar to the other Asia countries, the cervical cancer is the most diagnosed cancer as well in Indonesia (Female Cancer Program, 2012). According to the WHO, the mortality due to cancer in Indonesia approximately 1.000.000 per year in 2008 (World Health Organisation, 2012). Because of the cancer burden, the appropriate monitoring of treatment, following the appropriate treatment, should be implicated in the standard treatment of cancer in Indonesia.

Cancer is one of the diseases which needed long term of treatment. Because of the therefore, patients' quality of life should be considered as outcome of the therapy, especially in patients with palliative treatment to understand the benefit of treatment in specific

setting (Chase et al., 2012). Even, patients' quality of life are more often to be measured as outcomes in some clinical trials, but in Indonesia. The cancer patients' quality of life should be considered as one of the outcome therapy, because many serious side effects of chemotherapy could give negative impact to the patients quality of life (Perwitasari et al., 2012). For example, nausea and vomiting are the most distressing side effect of chemotherapy in cancer patients therefore, patients refused to follow next cycle of treatment (Sussman, 1995). The nausea and vomiting were often underreported, because the delayed effect of chemotherapy presented after the patients went homes. To avoid this negative impact, health providers should give closed monitoring in patients' quality of life.

The availability of reliable and valid instruments for measuring the patients' quality

of life are still limited in Indonesia. The specific instruments for cancer disease according to European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire with 30 items questions (QLQ C30) has been available in Indonesian version (Perwitasari et al., 2011). The challenge of developing the generic instruments, such as, Short Formulary-36 (SF36) in Indonesian version, is still being opened. SF-36 is a multidimensional questionnaire which has been translated worldwide, validated in much number of populations and could be applied in health and pathologic conditions (Gale et al., 2012, Scarpa et al., 2011, Xie et al., 2012). Thus this study is aimed to develop the validity of the SF-36 in Indonesian version. The forwardbackward translation and reliability procedures of the Indonesian version of SF-36 has been published in the previous study (Perwitasari et al., 2011).

METHODOLOGY Subjects

Subjects in this study were cancer patients in the Oncology Department of Dr Sardjito Hospital, Yogyakarta, Indonesia, who were treated with a cisplatin dosage ≥ 50mg/m² as monotherapy or in combined chemotherapy regimens. The subjecs aged ≥ 18 years old with a Karnofsky Index ≥ 50% were included. This study included subjects who treated by cisplatin because cisplatin is one of the cytotoxic agents which has a severe emetogenic effect and has a significant effect on patients' quality of life.

Data collection

The demoghraphic data, such as: age, sex, education, diagnosa of cancer and subjects' Karnofsky Performance Status (KPS) were collected from their medical records. The questionnaire were given to the subjects a few hours prior chemotherapy asministration. The study was approved by the local ethics committee of the Faculty of Medicine, Gadjah Mada University, Yogyakarta.

Statistical analysis

The demographic data was presented as descriptive data with means and standard deviations (SDs). The convergent and

discriminant validity was revealed if the item-domain correlation was ≥ 0.40, while the requirements for discriminant validity were satisfied if the value of correlation coefficients between the item and its own domain was higher than other domains. The sensitivity validity was evaluated based on different diagnoses using ANOVA-test. Factor analysis was used to extract factors quality of life in SF-36. Kaiser-Meyer-Olkin (KMO) and Bartlett's Test were tested to know whether the data were suitable for factor analysis. The loading criterion was set at less than 0.40 of absolute value (Awad *et al.*, 2008, Fredheim *et al.*, 2007, McPherson & Martin, 2012).

RESULT AND DISCUSSION

This study recruited two hundred and three cancer subjects in Dr. Sardjito Hospital Yogyakarta. Table I presents the subjects' characteristics. Most of the subjects were female, with the mean average of 48.3 (SD=9.4) and the performance scale average is 82.3 (SD=6.1). According to the female cancer organisation of Indonesia and Netherland, cervical cancer was found as the most diagnosed cancer in Indonesia for the recent that years. This study supported the data that subjects diagnosed with cervical cancer where aaroximately 60.1%.

The known group validity or the sensitivity test is presented in Table 2. There are no significant differences among the different diagnosa (P>0.05). The score of physical function, has limited role because of the physical and emotional limitation, social function, pain and general health of cervical cancer are the lowest among the other diagnosa. However, the other diagnosa of cancer have the lowest score of fatigue and emotional function. This result show that the SF-36 could be given to in various cancer patients. The results are different to the study from the previous study in China, which suggested that in different groups of age and gender, the score of SF-36 dimensions were different as well (Hoopman et al., 2009, Li et al., 2003). In this study, the gender and age were not taken into account as known-group validity, because the small sample size of opposite group.

Table I. Subject's characteristics (n=203)

Characteristics					
Age (Mean ± SD)	48.3 ± 9.4				
Indeks Karnofsky (Mean ± SD)	82.3 ± 7.1				
	Number	%			
Gender					
Male	13	6.4			
Female	190	93.6			
Education (n=201)					
No schooling	68	33.8			
Elementary	55	27.4			
High School	65	32.3			
Undergraduate	13	6.5			
Diagnosa of cancer					
cervix	122	60.1			
ovarium	53	26.1			
others	28	13.8			

Table II. Known-group validity

-	Mean	Mean	Mean	Mean	Mean	Mean	Mean	Mean
	±SD	±SD	±SD	±SD	±SD	±SD	±SD	±SD
Type of Cancer	PF	RPF	REF	F	EF	SF	P	GH
Cervical	$59.5 \pm$	$27.3 \pm$	$32.2\pm$	$59.7 \pm$	$63.8 \pm$	$52.7 \pm$	55.4±	$50.7\pm$
	27.3	39.5	43.3	18.3	22.6	23.3	27.5	13.8
Ovarium	$60.3 \pm$	$33.5 \pm$	$32.7\pm$	$79.4 \pm$	$64.6 \pm$	52.6±	63.3±	$52.7\pm$
	26.7	43.3	44.1	110.3	22.6	20.0	29.2	17.7
Others	$62.7 \pm$	$29.9\pm$	36.9±	57.9±	$60.9 \pm$	$57.5 \pm$	$58.5 \pm$	51.0±
	28.1	43.8	45.5	19.9	22.2	19.1	26.7	11.5
P value	0.88	0.65	0.88	0.10	0.76	0.55	0.23	0.68

PF: Physical Function; RPF: Role limitation because of Physical problem; REF: Role limitation because of Emotional problem, F: Fatigue; EF: Emotional Function; SF: Social Function; P: Pain; GH: General Health

Table III shows the discriminant and convergent validity of all questions in SF-36. All of the questions met the convergent validity, except for questions number 26, 28, 30 (emotional function), and question no 32 (social function). This study suggested that the questions which did not meet the convergent validity had low correlation with their domain. Thus the questions should be constructed so that each questions in one domain have closely meaning which more represent the emotional function. The other plausible explanation is because the subjects have some problems in translating the questions into what they were exactly feel. The previous study in China

population also showed that the questions in social function had low correlation with their domain (Li et al., 2003). The social domain only had two questions and one of them is more correlated with the other domain. Thus, the question should be constructed so that the subject will easier to understand and to translate the question into their daily activity.

According to the discriminant validity, the question number 28 (emotional function) is more correlated with fatigue. This result is supported with the previous study in China (Li et al., 2003). This finding showed that the downhearted and blue feeling are translated into the fatigue condition by the subjects.

Table III. Discriminant and convergent validity

	Physical function	Limited role due to emotional problem	Limited role due to emotional problem	Fatigue	Emotional function	Social function	Pain	General health
1	0.08	0.13	0.07	0.06	-0.001	0.05	0.08	0.30
2	0.12	0.12	0.15	0.083	0.042	0.10	0.10	0.40
3	0.50	0.36	0.40	0.08	0.21	0.12	0.01	0.10
4	0.58	0.30	0.35	0.073	0.03	0.29	0.10	0.17
5	0.62	0.17	0.25	0.02	0.32	0.23	0.22	0.31
6	073	0.01	0.06	0.02	0.38	0.26	0.23	0.27
7	0.76	0.04	0.03	0.05	0.44	0.26	0.27	0.33
8	0.65	0.08	0.02	0.01	0.49	0.20	0.27	0.34
9	0.05	0.27	0.36	0.00	0.04	0.29	0.14	0.06
10	0.76	0.13	0.23	0.02	0.31	0.34	0.31	0.32
11	0.76	0.07	0.17	0.02	0.37	0.30	0.29	0.33
12	0.40	0.20	0.01	0.01	0.36	0.08	0.14	0.21
13	0.14	0.73	0.63	0.05	0.36	0.09	0.02	0.08
14	0.16	0.79	0.76	0.03	0.13	0.15	0.10	0.01
15	0.17	0.77	0.66	0.12	0.18	0.09	0.06	0.04
16	0.16	0.77	0.67	0.02	0.15	0.12	0.05	0.01
17	0.24	0.69	0.76	0.02	0.22	0.23	0.06	0.01
18	0.18	0.70	0.76	0.03	0.11	0.18	0.11	0.04
19	0.19	0.71	0.78	0.03	0.08	0.23	0.10	0.03
20	0.17	0.15	0.17	0.04	0.03	0.75	0.22	0.04
21	0.25	0.04	0.06	0.02	0.30	0.20	0.84	0.27
22	0.24	0.02	0.03	0.02	0.28	0.31	0.78	0.28
23	0.09	0.08	0.02	0.40	0.10	0.04	0.18	0.21
24	0.21	0.20	0.14	0.09	0.75	0.18	0.23	0.24
25	0.28	0.36	0.26	0.04	0.80	0.06	0.20	0.30
26	0.07	0.02	0.02	0.03	0.24	0.09	0.02	0.05
27	0.40	0.74	0.80	0.59	0.01	0.90	0.71	0.48
28	0,20	0.16	0.23	0.28*	0.20	0.22	0.21	0.22
29	0.24	0.18	0.11	0.40	0.75	0.16	0.19	0.32
30	0.18	0.14	0.13	0.27	0.35	0.25	0.21	0.29
31	0.02	0.05	0.03	0.42	0.15	0.03	0.08	0.31
32	0.29	0.07	0.06	0.24	0.38*	0.13	0.17	0.37
33	0.40	0.08	0.20	0.08	0.17	0.74	0.15	0.40
34	0.18	0.10	0.04	0.05	0.46	0.07	0.22	0.70
35	0.10	0.15	0.12	0.03	0.15	0.07	0.22	0.45
36	0.32	0.33	0.23	0.01	0.74	0.08	0.24	0.42

The numbers in the box indicated significant correlation of questions with their domain. The number with* indicated the questions which did not meet the criteria of discriminant validity.

The question number 2 of social function is also more correlated with the emotional function, meaning that the subjects had problem to translate the impact of physical and emotional problem into their social activity.

The last analysis is the factor analysis of all questions in SF-36 questionnaire. According to the KMO and Bartlett test, the data was suitable for factor analysis with KMO value was 0.843 and Bartlett test was 5.46 x 10^3 , P =0.000). The extraction of factors was based on the criterion of an eigenvalue greater than one that is nine-factor solution with 72.92% of total variance. All of the questions are loaded significantly in one factor. The interesting point in our finding is some questions are loaded together with the other questions in different domains. For instance; question number 3 are loaded together with questions which are correlated physical problem and emotional problem domains in factor 2. Furthermore some questions which are related with emotional, social, fatigue and general health domains are also loaded together with questions in physical function (data was not shown). This finding supported the previous finding that subjects could be have some difficulties in translating the questions into their real condition. Most of the questions are translated into physical condition because they did not aware of emotional, social and fatigue functions.

This study was conducted in cancer subjects who might have more depressed condition due to their disease or treatment than the other disease. Therefore the future studies on developing the Indonesian version of SF-36 scales are still needed.

CONCLUSION

The development of Indonesian version of SF-36 scales in cancer disease is still less satisfactory. According to the result of this study, most of the questions in this version should be reconstructed.

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