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Pharmacogenetics of antiemetics in Indonesian cancer patients

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Citation

Perwitasari, D. A. (2012, January 11). *Pharmacogenetics of antiemetics in Indonesian cancer patients*. Retrieved from <https://hdl.handle.net/1887/18326>

Version: Corrected Publisher's Version

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Note: To cite this publication please use the final published version (if applicable).

5

Translation and validation of EORTC QLQ-C30 into Indonesian version for cancer patients in Indonesia

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Jpn J Clin Oncol 2011; 41(4):519-529.

ABSTRACT

Objective: Quality of life studies in Indonesia are still uncommon. This research was aimed to validate the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire – C30 (EORT QLQ-C30) in an Indonesian version. The standard procedure of forward-backward translation was adhered to in the translation procedures. The validity procedure included reliability, convergent and discriminant validity, known-groups validity, factor analysis and external convergent validity.

Methods: Data were collected from cancer patients in the Oncology Department of Sardjito Hospital, Yogyakarta, Indonesia, who were treated with cisplatin at the dosage $\geq 50 \text{ mg/m}^2$ as monotherapy or in combinations. The Short Form-36 to assess the external convergent validity of our translated questionnaire.

Results: One hundred twenty-eight patients with different cancer diagnoses were recruited in the validation process from March 2009 to November 2009. The internal consistency with values of > 0.70 was observed in the Indonesian version of the EORTC QLQ-C30 scales. All items in the questionnaire met the criteria of convergent and discriminant validity, except for items 5. Both of the EORTC QLQ-C30 and the SF-36 showed that different diagnoses were associated with a similar impact on quality of life. Factor analysis showed that only the role function and social function loaded onto the second factor together. Correlations between the Indonesian versions of both questionnaires were moderate: between 0.18 and 0.48 for the physical, emotional, social, fatigue and pain domains.

Conclusions: The Indonesian version of the EORTC QLQ-C30 can be used as a questionnaire to assess quality of life in Indonesian cancer patients with high-emetogenic treatments.

BACKGROUND

Cancer and the side effects of cancer treatment are often associated with reduced quality of life (QoL).¹ Although advances in cancer treatment could improve the outcome of therapy in cancer patients, such as survival rate and disease-free conditions, patients continue to experience a major impact of cancer and its treatment on numerous physical and psychosocial conditions. This may consequently affect the patients' normal patterns in their social activities, psychosocial and spiritual well-being.²⁻⁴ Combining treatment strategy with QoL assessment, is considered necessary. In modern cancer care, the views of patients are key in cancer treatment and patient reported outcomes assessment is the future trend in cancer therapy. Moreover, QoL assessment is required to consider the impact of cancer treatment on functional and psychosocial health of patients.² The researches of instrument development to measure cancer patients' QoL have been developed in many countries and they are published annually.³

Several instruments have been developed to assess QoL in cancer patients in past decades.⁴ Combinations of generic and disease specific instruments have been applied to define QoL in patients with multipathology. The European Organization for Research and Treatment of Cancer Quality of Life Core Questionnaire (EORTC QLQ-C30) has been used internationally in "more than 3,000 studies" as a generic questionnaire among cancer patients. As stated in the paper by Kleijn and colleagues "this questionnaire has been translated into and validated into more than 50 languages".⁵

The EORTC QLQ-C30 and the Medical Outcomes Study Short Form 36 (SF-36) have five domains in common: physical function, mental health/emotional function, social function, vitality/fatigue, and pain. The two questionnaires are often used to discover the convergent validity of the similar constructs between them. A previous study in nonmalignant pain used these questionnaires and demonstrated that both of the questionnaires had acceptable psychometric characteristics.⁴

Information about cancer patients' QoL in the Indonesian population is inadequate. The publications in this field are focused on children. A study about health-related quality of life in childhood with acute lymphoblastic leukemia suggested that the patients and their family should be supported by psychosocial care during the cancer treatments. Psychosocial care during cancer interventions could improve patients' quality of life.⁶ Consequently, the area of quality of life research needs to be developed urgently in Indonesia in order that better supportive care during cancer interventions may be proposed.

The limited research on QoL in Indonesia is associated with the unavailability of validated questionnaires in Indonesian versions. Therefore, the objective of this study was to translate and linguistically validate the Indonesian version of the EORTC QLQ-C30 in cancer

patients. In this study, the SF-36 was used as a gold standard to test the external convergent validity of QLQ-C30. The SF-36 questionnaire has been translated into Indonesian version.⁷ The reason for using SF-36 as gold standard was that the SF-36 has been used and validated in Indonesian version.⁸⁻¹² The Indonesian version of the EORTC QLQ-C30 encompassed translations from the original English versions with forward-backward translation, pilot testing, and review. In order to obtain the Indonesian version of SF-36, the reader can contact the author. The validity procedure includes reliability, multi-factorial analysis, known-groups validity, factor analysis, test-retest validity and external convergent validity.

PATIENTS AND METHODS

Step 1: Translation procedures

The procedures for translation into the Indonesian language were adapted from Koller et al.¹³ The translation coordinator contacted two experts in the English Department of two universities independently to do the forward translation of EORTC QLQ-C30. The research coordinator compared the two forward translations and checked them for any discrepancies. The discrepancies between the two translations were discussed with the translators until we agreed on the single provisional forward translation. Modifications were made in this draft to diminish discrepancies and it was adjusted with a view to the habits of Indonesian people. The single forward translation was then back translated by two native speakers of English independently. The English back translations and the original English version were compared with assure that there was no different meaning of the questions in the questionnaires. The discrepancies were discussed and resolved until agreement within the translation group was reached.

Step II: Pilot test

The translated version of the EORTC QLQ-C30 was pilot tested in 20 patients, who were recruited from a university hospital in Yogyakarta, Indonesia. Inclusion criteria for the pilot test were: cancer patients and healthy people; aged 18 years or older; ability to read and write standard Indonesian; and willing to participate in the study. The Indonesian version of EORTC QLQ-C30 was distributed to the patients before their chemotherapy treatment, and to the healthy people. Any difficulties that the patients had experienced with the questionnaire were recorded by the researcher during the time the patients completed the questionnaire. The patients' obstacles in understanding and completing the questionnaires were reviewed and used to modify the questionnaires by the translation group.

Step III: Main study

Subjects

The study population was made up of cancer patients in the Oncology Department of Dr Sardjito Hospital, Yogyakarta, Indonesia, who were treated with a cisplatin dosage ≥ 50 mg/m² as monotherapy or in combined chemotherapy regimens. Patients aged ≥ 18 years old with a Karnofsky Index $\geq 50\%$ were included. Exclusion criteria were: patients with the presence of nausea or vomiting 24 hours before chemotherapy; use of other anti-emetics, benzodiazepines or neuroleptics, or the application of radiotherapy within 24 hours before start of chemotherapy and use of opioids within the previous 2 weeks.

We studied patients with cisplatin as subjects because cisplatin is one of the cytotoxic agents which has a severe emetogenic effect and has a significant effect on patients' quality of life. Dr. Sardjito Hospital, Yogyakarta, is a tertiary care public hospital with approximately 750 beds, and 250 beds among them were third class services. Most of the third class patients are supported by government health insurance in public and private hospitals. Nevertheless, there are some third class patients who are not supported by government health insurance. Thus, these patients could not pay to get good services from a private hospital. This is due to the fact that the health services in this hospital are dedicated to poor people.

Data collection

Patient's sociodemographic data such as age, sex, education, diagnoses of cancer and performance status of patients based on Karnofsky Performance Status (KPS) were collected from their medical records. The procedure of the patients' data collection in the main study was done before administration of cytotoxic drugs. After informed consent procedures were completed, patients filled out questionnaires a few hours before chemotherapy and on day 5 after chemotherapy administration at the hospital. The time of administration of the questionnaire was based on a previous study.⁹ The study was approved by the local ethics committee of the Medical Faculty, Gadjah Mada University, Yogyakarta.

Statistical analysis

Descriptive data are presented with means and standard deviations (SDs). Discrimination of the instruments was tested by floor and ceiling effects. Large floor and ceiling effects are assumed to show poor discrimination of the instruments.

The internal consistency of each subscale was assessed by using Cronbach's alpha coefficient. It was considered to be acceptable as good internal consistency occurs when Cronbach's

alpha is 0.70 or greater. Multi-trait scaling analysis was used to test the convergent and discriminant validity of the EORTC QLQ-C30. Convergent 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. Known-groups validity was evaluated based on different diagnoses using *T*-test or ANOVA-test. Factor analysis was used to extract factors from 15 indicators of quality of life in EORTC QLQ-C30. Kaiser-Meyer-Olkin (KMO) and Bartlett's Test were tested to know if the data were suitable for factor analysis. The loading criterion was set at less than 0.40 of absolute value. Convergence between instruments (external convergent validity) evaluates correlations between similar domains of the SF-36 and EORTC QLQ-C30. If one domain has a similar underlying construct, it will show a high correlation with the other domain. Pearson's correlation was used to compute construct validity. Correlations above 0.40 are considered satisfactory for convergent validity. However, if this correlation is too high (> 0.70), it can be caused by different concept measurements, or there may be some useful information obtained by including the two domains compared to including only one of the domains. Correlation coefficients of > 0.5 , 0.35-0.50 and < 0.35 were considered to represent strong, moderate, and low correlations, respectively. The discriminant validity means that scales measuring different constructs should have a low correlation, i.e., < 0.40 .^{2-4,14,15}

RESULTS

Step I: Translation and back-translation

In the Indonesian version of SF-36, some questions were adjusted to Indonesians' habits and occupations. For example: moderate activities such as moving a table, using a vacuum cleaner, bowling, or playing golf in item 3b, was translated into "moving a table, cycling and working in the garden", as "using a vacuum cleaner, bowling and playing golf" are not done by most Indonesian people. Another example, in the original version of SF-36, "walking more than one mile" in item 3g, was translated into "walking more than 1.6 kilometers", as Indonesian people use "kilometers". In the first draft of EORTC QLQ-C30, the medical words such as insomnia, constipation and depression were translated into non-medical word such as, difficult to sleep, difficult to defecate and feeling stress.

There were some differences in the back-translations of the questionnaire but the translators were of the opinion that the differences would not change the meaning of word, because the Indonesian language has less vocabulary than the English language. The differences in

expression of the response choices of the Likert-type scales were also present between the back-translation versions and the original version. But the translators were of the opinion that the differences were only about the formal style of the language and would not change the meaning of the expression. Therefore, the expression of the response choices used the less formal style which is appropriate with the lower and middle levels of education in these cancer patients.

Step II: Pilot test

Twenty people (10 healthy people and 10 cancer patients) were enrolled in the pilot test. The age range for the healthy people varied from 19 to 49 years with a mean of 26.10 years (SD = 8.88); the age range of cancer patients varied from 26 to 63 years with a mean of 49.60 years (SD = 9.83). The average completion time of translated version of the EORTC QLQ-C30 were 4.54 min (SD = 1.00) for healthy people and 5.88 min (SD = 1.97) for cancer patients. Most patients were able to fill out the questionnaires by themselves, except for items 29 and 30 in EORTC QLQ-C30, where the patients needed an explanation about the meaning of the quality of life in the less formal language style and about the differences between items 29 and 30. Item 29 in EORTC QLQ-C30 asks the patients to rate their overall health during this past week, whereas item 30 asks the patients to rate their quality of life. Generally, the subjects asked about the meaning of quality of life or asked to the researcher to give a short description about quality of life.

Step III: Main study

Patients' demographic data

One hundred and twenty eight patients were recruited in this study from March 2009 to November 2009. Patients had different diagnoses of cancer. The most prevalent diagnostic category was cervical cancer. Out of 57% cancer patients had KPS of < 90%, which means that more patients needed some efforts to carry on normal activity with some signs or symptoms of cancer than patients with normal activity and minor signs or symptoms of cancer. When we dichotomized the sample on the basis of KPS < 80 and 80-100 ($n = 118$), we found that the number of patients in the < 80 group was 10 and the number of patients in the 80- 100 group was 118. Furthermore, sensitivity analyses regarding this point by for instance dichotomizing the sample in < or \geq than 70 on the KPS would run into difficulties as that would imply comparing $n = 4$ (for KPS < 70) with $n = 124$ (for KPS ≥ 70). The demographic data of the patients are shown in Table 5.1. In regard to educational status, most of the patients only attended elementary school level. This illustrates the low

educational level experienced by most of the patients in Dr. Sardjito Hospital where the services of this public hospital are dedicated to poor people.

Discrimination and internal consistency

Table 5.2 lists floor and ceiling effects of EORTC QLQ-C30 and SF-36.

The large floor and ceiling effects were found in single items, emotional function and cognitive function of EORTC QLQ-C30 (0.8% to 92.2%). Whereas, the large floor and ceiling effects in SF-36 were seen on physical and emotional roles (11.1% to 76.2%).

The physical and role functions in SF-36 and the pain, fatigue and single items in EORTC QLQ-C30 were questionable following psychometric analysis (mean and SD), i.e., mean: 16.5 and SD: 33.3 in the physical role domain of the SF-36.

Cronbach's alpha coefficients are presented in Table 5.2 for all domains of the two questionnaires. This study found that for the SF-36 values above 0.70 were observed in following domains: physical function, social function, pain, physical role, and emotional role. In EORTC QLQ-C30, those five domains were also valued above 0.70. This finding means that for those five domains, EORTC QLQ-C30 has the same reliability as SF-36.

Table 5.1 Sociodemographic data of the patients

	<i>n</i>	%
Age, years (<i>n</i> = 128)		
Mean (SD)	47.6 (10.5)	
Range	22-70	
Sex (<i>n</i> = 128)		
Male	9	7.0
Female	119	93.0
Education (<i>n</i> = 128)		
No schooling	46	35.9
Elementary school	35	27.3
High school	36	28.1
Undergraduate	7	5.5
Diagnosis of cancer (<i>n</i> = 128)		
Cervical cancer	77	60.1
Ovarian cancer	35	27.4
Others	16	12.5
KPS		
< 90%	73	57.0
90-100%	55	43.0

SD, standard deviation; KPS, Karnofsky Performance Status.

Table 5.2 Means, floor and ceiling effects, and Cronbach's α coefficients of the domains in the QLQ-C30 and SF-36

Domain	Mean	SD	Floor (%)	Ceiling (%)	Cronbach's α coefficient
QLQ-C30					
Physical function	74.0	21.8	1.6	23.0	0.82
Role function	63.3	24.0	3.2	12.7	0.79
Emotional function	93.5	12.2	0.8	68.3	0.78
Social function	65.8	23.7	0.8	17.5	0.83
Cognitive function	93.8	14.3	0.8	79.4	0.82
Global QoL	58.7	16.4	0.8	2.4	0.80
Pain	34.5	26.5	24.6	3.2	0.85
Fatigue	30.2	21.6	15.1	0.8	0.72
Nausea and vomiting	12.4	21.9	68.3	0.8	0.70
Dyspnea	5.2	18.5	91.3	1.6	Single item
Insomnia	32.4	30.7	39.7	4.0	Single item
Appetite loss	20.0	28.5	60.3	4.0	Single item
Constipation	17.6	27.4	65.1	3.2	Single item
Diarrhea	3.9	15.5	92.1	1.6	Single item
Financial difficulties	42.2	29.6	22.2	7.1	Single item
SF-36					
Physical function	63.9	25.1	1.6	9.5	0.82
Mental health	75.3	18.1	0.8	9.5	0.66
Social function	65.8	23.7	1.6	11.1	0.70
Energy	63.8	18.9	0.8	5.6	0.60
Pain	63.1	29.4	0.8	21.4	0.87
General health	55.3	15.8	0.8	0.8	0.60
Physical role	16.5	33.3	76.2	11.1	0.92
Emotional role	23.2	40.7	73.0	20.6	0.97

QLQ-C30, quality of life core questionnaire; SF-36, Study Short Form 36; QoL, Quality of Life.

Furthermore, in EORTC QLQ-C30 the values above 0.70 were not only observed in those five domains, but also in all domains. We excluded the outlier factor in the cognitive function to get a better value of Cronbach's alpha.

Multi-trait analysis

Table 5.3 shows that the convergent validity was revealed due to all of the value of coefficient correlations between the item and its own domain were ≥ 0.40 , except for items 5, 10, 15 and 25. Table 5.3 also shows that all items meet the discriminant validity criterion except for item 5 with the value of 0.38.

Table 5.3 Multi-trait scaling analysis of EORTC QLQ-C30

Item no	Description	PF	RF	EF	CF	SF	FA	NV	PA	QL
1	Strenuous activity	-0.75	-0.41	-0.04	-0.05	.08	.22	.07	-.01	.03
2	Long walk	-0.75	-0.32	-0.11	-0.09	.08	.12	-.03	-.02	.09
3	Short walk	-0.69	-0.40	-0.09	-0.11	-0.08	.31	.05	.08	.03
4	Stay in bed/chair	-0.61	-0.30	-0.22	-0.05	-0.03	.43	.17	.15	-.15
5	Needed help in eating/dressing/washing	-0.38	-0.37	-0.45*	-0.21	-0.17	.25	.05	.34	-.13
6	Limited work	-0.34	-0.65	-0.25	-0.12	-0.35	.25	-0.06	.28	.09
7	Limited hobbies	-0.30	-0.57	-0.18	.02	-0.27	.31	.13	.28	-.04
21	Tense	-0.14	-0.17	-0.65	-0.08	-0.25	.14	.10	.25	-.05
22	Worried	-0.11	-0.17	-0.64	-0.12	-0.25	.16	.06	.21	-.08
23	Irritable	-0.15	-0.15	-0.54	-0.05	-0.12	.12	.05	.14	-.10
24	Depressed	-0.03	-0.03	-0.49	-0.11	-0.13	-0.12	.01	.13	-.12
20	Concentration	-0.10	-0.09	-0.25	-0.58	-0.07	-0.11	-0.01	-.26	-.14
25	Memory	-0.08	-0.01	-0.01	-0.34	-0.18	-0.04	-0.17	.04	-.04
26	Family life	.28	-0.01	-0.12	-0.12	-0.75	-0.03	-0.01	.05	-.11
27	Social life	-0.16	-0.33	-0.09	-0.02	-0.71	.17	-0.06	.24	.02
10	Need rest	-0.14	-0.17	-0.14	-0.10	-.21	.28	-0.04	.05	-.08
12	Feel weak	-0.30	-0.27	-0.29	-0.04	-0.19	.40	.03	.29	-.10
18	Tired	-0.34	-0.26	-0.32	-0.11	-0.17	.50	.14	.31	-.10
14	Nausea	-0.08	-0.09	-0.21	-0.02	-0.24	-0.06	.40	.15	-.15
15	Vomiting	-0.05	-0.11	-0.21	-0.09	-0.19	.13	.34	.14	-.15
9	Pain	-0.20	-0.27	-0.26	-0.14	-0.07	.16	.09	.59	.07
19	Relation of pain with daily activities	-0.29	-0.38	-0.33	-0.19	-0.15	.27	.03	.60	-.29
29	Overall physical condition	.07	.06	.23	.03	.14	-0.07	-.20	-.05	.62
30	Quality of life	.14	.07	.25	-0.07	.03	-.19	-.22	-.19	.65

EORTC QLQ-C30, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire; PF, Physical Function; RF, Role Function; EF, Emotional Function; CF, Cognitive Function; SF, Social Function; FA, Fatigue; NV, Nausea and Vomiting; PA, Pain; QL, Quality of Life.

The bold numbers show that the coefficient correlation between the items and its own domain are ≤ 0.40 .

The number with * show that the coefficient correlation between the item and other domain is higher than the coefficient correlation of the item and its own domain. All the values in the boxes are significantly correlated.

Known-groups validity

The known-groups validity of the two questionnaires among three groups of diagnoses is presented in Table 5.4. We measured the five domains between in the EORTC QLQ-C30 questionnaire, that is, physical function, emotional function, social function, pain, and energy/fatigue. There were no significant differences in both EORTC QLQ-C30 when they were applied in different diagnoses of cancer ($P > 0.05$).

Table 5.4 Scores of the five QoL domains of QLQ-C30 in the cancer diagnosis groups

Diagnosis	n (%)	PF Mean (SD)	EF Mean (SD)	SF Mean (SD)	FA Mean (SD)	PA Mean (SD)
Cervical cancer	77 (60.1)	72.3 (22.5)	93.9 (11.5)	66.2 (22.5)	31.5 (23.6)	33.9 (26.9)
Ovarian cancer	35 (27.4)	72.7 (21.6)	92.9 (14.5)	68.0 (24.0)	32.2 (19.6)	35.4 (27.9)
Others	16 (12.5)	81.5 (19.9)	90.0 (14.2)	58.2 (27.9)	23.5 (17.1)	40.4 (25.6)
<i>P</i> value*		0.24	0.72	0.46	0.37	0.80

PF, Physical Functioning; EF, Emotional Function; SF, Social Function; FA, Fatigue; PA, Pain.

* One way ANOVA test or Kruskal-Wallis test.

Factor analysis

Based on the KMO and Bartlett test, the data was suitable for factor analysis (KMO value was 0.708 and Bartlett test was 1.765×10^3 , $P = 0.000$). The extraction of factors was based on the criterion of an eigenvalue greater than one that is ten-factor solution with 70.41% of total variance.

Factor analysis results are presented in Table 5.5. All items in each domain loaded significantly on one factor of 10 factors. All of the items in physical function, except item 5, loaded significantly on the first factor. The emotional function items loaded significantly on the second factor, except item 23. Pain items loaded significantly on the third factor, role function and social function items on the fourth factor, nausea and vomiting items on fifth factor, general quality of life items on the sixth factor, fatigue items on seventh factor, and cognitive function' items on the eight factor. Item 23 loaded significantly on the ninth factor, and item 5 loaded significantly on the fifth factor.

External convergent validity

The external convergent validity of the questionnaires is presented in Table 5.6. This analysis was performed for physical functioning, social functioning, emotional functioning, fatigue, and pain.

Moderate correlations ($0.35 < r < 0.5$) were observed in the physical function and pain domains, whereas the other functions showed low correlations between the questionnaires ($P < 0.05$). Otherwise all of the discriminant validity in the two questionnaires met the $r < 0.40$ criterion ($P < 0.05$).

Table 5.5 Factor analysis of EORTC QLQ-C30

Item	Factor									
	1	2	3	4	5	6	7	8	9	10
PF	.833	.016	-.021	.225	-.169	.018	.092	-.075	-.051	-.008
Long walk	.832	.075	.068	.062	-.131	-.093	.085	.011	.089	-.100
Short walk	.790	.053	.116	.199	.064	.004	.028	-.048	-.078	.025
Stay in bed/chair	.668	-.095	.033	.187	.193	.233	.194	.064	.109	.184
Need help with eating/dressing/washing	.324	.220	.097	.169	.463	.017	-.020	.120	.049	.020
RF	.307	.166	.216	.747	-.004	-.031	.052	.044	.100	.031
Limitation of work or other daily activities	.288	.186	.049	.737	.134	.169	-.019	-.051	-.107	.115
EF	.009	.892	.159	.183	.144	.027	.060	-.107	.080	.008
Tense	.003	.891	.138	.141	.101	.104	.076	.045	.107	-.044
Worried	.228	.307	.156	-.103	.256	.082	-.019	.275	.517	.344
Irritable	.080	.538	.054	-.140	.391	.216	.173	.335	.030	.070
CF	.034	.323	.248	-.101	.144	.018	.076	.399	-.383	.095
Concentration	-.099	-.022	-.002	.084	-.140	.021	.051	.805	-.095	.024
Memory	-.490	.209	-.055	.403	.054	.038	.005	.436	.267	-.148
Family life	.095	-.007	-.007	.719	.152	-.111	.314	.040	.066	.005
Social life	-.025	-.097	-.119	-.022	-.109	-.855	-.042	-.189	-.067	.034
Overall physical condition	-.012	-.091	-.142	-.002	-.092	-.867	-.177	.149	.004	-.095
Overall QoL	.185	-.164	.223	.370	.221	.236	.160	.223	.141	-.040
FA	.284	.017	.252	.144	.229	.108	.707	.063	.107	.077
Need rest	.297	.133	.178	.147	.204	.156	.748	.041	-.046	.095
Felt weak	-.150	.104	.027	.077	.654	.180	.390	-.175	.043	-.097
18	-.120	.141	-.009	.131	.793	.073	.055	-.060	-.063	.045
Nausea	.054	.080	.753	.150	.133	.103	.221	-.035	-.024	.083
Vomiting	.133	.194	.771	.226	.007	-.055	.210	-.063	-.001	.158
Pain										
Pain interfered with daily activities										

PF, Physical Function; RF, Role Function; EF, Emotional Function; CG, Cognitive Function; SF, Social Function; QL, Quality of Life; FA, Fatigue; NV, Nausea Vomiting; PA, Pain. The bold numbers show that the absolute values for loading factor are less than 0.40. All the numbers in the boxes have significant values.

Table 5.6 Pearson's correlation coefficient among the subscales in the Standard Indonesian version of SF-36 and QLQ-C30

		SF-36 PF	SF-36 MH	SF-36 SF	SF-36 E	SF-36 PA
QLQ-C30	PF	0.40	-0.03	0.33	0.21	0.28
QLQ-C30	EF	0.05	0.25	0.20	0.28	0.25
QLQ-C30	SF	0.04	0.07	0.11	0.16	-0.02
QLQ-C30	FA	-0.28	0.11	0.36	-0.17	-0.27
QLQ-C30	PA	-0.20	-0.20	-0.16	0.27	-0.45

PF, Physical Functioning; MH, Mental Health; EF, Emotional Function; SF, Social Function; E, Energy; FA, Fatigue; PA, Pain. The bold numbers show the significant Pearson's correlation coefficients between the same subscales of the SF-36 and the QLQ-C30.

DISCUSSION

This study showed the acceptable psychometric properties of reliability and validity evaluation of EORTC QLQ-C30 in our Indonesian version. This scale development will help clinicians to describe the human side of cancer treatment in Indonesia. The practicing oncologist can benefit greatly from the work that was performed in developing and validating this scale, by applying the instrument to the selection of treatment modalities based on both treatment efficacy and the patient's wishes. In the future, QoL research in Indonesia will continue to be integrated into the practice of oncology.

The translation of EORTC QLQ-C30 into the Indonesian language was in compliance with the procedures developed by the EORTC Quality of Life Study Group.¹³ The backward translation of the modified items was compared with the original versions and was found to be satisfactory. In the pilot study, the cancer patients were able to complete the questionnaire in a somewhat longer time than the healthy subjects. This could be due to the severity of the diseases which made the patients need more time to focus on completing the questionnaires. The patients' cognitive function in understanding the questionnaires, could be affected by multiple and severe symptoms in cancer.¹⁶ Nevertheless, all of the patients in pilot testing were able to fill in the questionnaire by themselves.

Discrimination in physical function, role function, social function, global quality of life, pain and fatigue in EORTC QLQ-C30 were good (i.e., 0.8% for floor effects and 17.5% for ceiling effects in social function). However, in the single items, emotional and cognitive function showed poor discrimination (i.e., 4.0% for floor effects and 60.3% for ceiling effects in appetite loss). The poor discriminations could be related to the mean and SDs

value of the domains. All of the functions in SF-36 showed good discrimination, except for physical role and emotional role. Poor ability of patients to distinguish the physical and emotional role or the narrow response of these domains could give rise to this poor discrimination. All functions with poor discrimination had less than clear descriptions of cancer patients' feelings.

Poor discrimination and cancer patients' feeling could be affected by anxiety and depression during chemotherapy. Anxiety and depression may result from excessive feelings of distress. This psychological distress had significant association with memory and concentration.¹⁷ Indeed, the small sample size could effect the poor discrimination. For example in the nausea symptoms, there were 109 patients who answered "not at all", and the other patients answered the other responses. It showed that the patients' responses were not distributed normally in all of the responses. Thus, the floor effect was shown by nausea symptom. A larger sample size could result in better distribution responses. Therefore, the interpretation of this scale in a broad spectrum of cancer patients must be careful and might need to be validated when applying it to other types of cancer. This phenomenon may contribute significantly to poor discrimination and descriptive assessments. Ideally, the questionnaires should be given 72 hours before the administration of the chemotherapy.⁹ However, the system in this hospital could not trace the patients 2-3 days before administration of chemotherapy. As a result, the questionnaires were given only a few hours before chemotherapy. Patients' memory and concentration levels a few hours before chemotherapy could be affected by patients' psychological distress.

Another possible explanation of these results is that certain symptoms (dyspnea, insomnia, appetite loss, constipation and diarrhea) were not experienced by the patients, or that these symptoms were experienced by the patients but the patients could cope despite these symptoms.

In the SF-36 questionnaires, the internal consistency was somewhat problematic for mental health, energy and general health. The low to middle education level of the subjects could have affected the internal consistency: the subjects needed more explanation about the response options. The Cronbach's α of EORTC QLQ-C30 was acceptable in all scales.

The convergent and discriminant validity of EORTC QLQ-C30 were consistent with the results of previous studies. The EORTC QLQ-C30 in simplified Chinese version and in Korean cancer patients also met the convergent and discriminant validity.^{3,18} The low coefficient correlation in item 5, 15, 20 and 25 may be caused by the skewed distribution of the responses. Out of 93% patients answered "not at all" response for item 5, only 4.7 %

of patients answered “very much” for item 10, 93.8% and 91.4% of patients also answered “not at all” for item 20 and 25. The previous study in Korean cancer patients also reported the same problem.¹⁸

In order to examine an additional issue of the psychometric characteristics of the Indonesian version of the EORTC QLQ-C30 questionnaire, it was decided to compute known-groups validity. The known-groups validity analyses which were performed using different diagnoses of cancer showed that there were no statistically significant differences among groups. This fact explained that all of the domains in EORTC QLQ-C30 were not better in discriminating ovarian, cervical and other diagnoses of cancer. We acknowledge that this is just one phase in addressing this issue. Further study should include additional questionnaires from samples with varying diagnostic categories of cancer.

The factor analysis showed the satisfactory result that all items in each domain loaded on one factor. Only role function and social function loaded on the second factor together. This factor described the effect of limited role to social life.

The external convergent validity correlation between domain of SF-36 and EORTC QLQ-C30 values was under 0.70. Physical function and pain had strong correlations in both questionnaires. However, the moderate and low correlation coefficient in the other domains of SF-36 and EORTC QLQ-C30 suggest that the subscales were assessing distinct components of the construct of quality of life. The differences can be explained in the physical function of the SF-36 which contains 10 items, while the EORTC QLQ-C30 only contains five items. In some items SF-36 has more specific questions than EORTC QLQ-C30. Nevertheless, the EORTC QLQ-C30 has a broader spectrum of symptoms, such as nausea/vomiting, pain, insomnia, dyspnea, appetite loss, constipation and diarrhea.

The patients had difficulties in completing the questions number 29 and 30 in EORTC QLQ-C30. Therefore the instructions of number 29 and 30 were modified to facilitate the patients' understanding. We also gave some explanations to the patients related to question number 29 and 30. Another study in China also modified the questions number 29 and 30 in EORTC QLQ-C30 to increase the patients' understanding.² The translation procedures of previous studies on EORTC QLQ-C30 in Turkish and Moroccan minority ethnic groups in the Netherlands suggested that the “questionnaire was produced for oral administration and needed some modifications because of the high illiteracy in Moroccans' first generation in Netherlands”. The subjects in this study also need additional information about the meaning of “quality” word.¹⁹ Results of our study were consistent with the two previous studies, especially in the short description of questions number 29 and 30, also in the description of the word “quality”.

The high internal consistency of EORTC QLQ-C30 is also consistent with a previous study in patients with chronic nonmalignant pain. Generally, the Cronbach's α values observed in this study are higher than those in the patients with chronic nonmalignant pain.⁴ The low Cronbach's α value for cognitive function was also found in the previous study with various diagnoses of cancer; also homogenous diagnoses of cancer.^{20,21} Otherwise, the other studies in China and Singapore had a lower internal consistency (< 0.70) for physical function and cognitive function in various diagnoses of cancer.^{2,15} The finding in our study was consistent across different cultures.

The known-groups validity of the EORTC QLQ-C30 is different from a previous study which compared the same instruments. The emotional function, social function and pain were significantly different between EORTC QLQ-C30 and SF-36 in the previous study.⁴ Future research on this issue is called for.

Factor analysis results of this present study were not consistent with the factor analysis of EORTC QLQ-C30 in Korean cancer patients, which showed two factors with more than one domain loaded. The "emotional distress" factor was appear because the emotional function and cognitive function were loading together in one factor.¹⁸ The variability of cancer diagnoses, patients' supportive care and patients' condition during they filled in the questionnaire may cause different result of factor analysis among the countries.

The result of convergent validity is also consistent with two previous studies in cancer patients, where the convergent validity coefficient values ranged from 0.47-0.74 and 0.40 to 0.68.^{22,23} Conversely, the study in cancer patients with chronic pain showed that the coefficients values ranged from 0.70 to 0.80.⁴ The correlation coefficients of pain symptoms in cancer diagnoses were lower than those in chronic non-malignant pain patients. This finding illustrates that the pain level in cancer diagnoses is less important than those of chronic non malignant pain. The other symptoms could have important impacts on QoL, such as nausea and vomiting. Otherwise, the correlation coefficients between mental and physical function, energy and mental function in cancer patients were higher than those in chronic non malignant pain patients. Results showed that the correlation of physical and mental functioning in cancer patients is more important than the coefficient correlation of physical and mental function in chronic non-malignant pain. Another study in Germany indicated that patients had different interpretations of health subscales of EORTC QLQ-C30, SF-36 and Functional Living Index Cancer Questionnaire (FLIC), even though all three questionnaires had convergent validity in physical function, emotional function, pain, fatigue and nausea/vomiting. These results were caused by the different views of QoL in three questionnaires.²³

The convergent validity in our study was consistent with another study of questionnaire validation which was done in Indonesia between Nepean Dyspepsia Index (NDI) and SF-36. This research also showed low and moderate correlation between the functions in both questionnaires (0.036-0.638) with $P < 0.05$.⁸

A limitation of our study is the relatively small and unequal sample size in each disease group. Even though the sample size was small and unequal, we believe that this study is still valid and relevant, because all of the domains in the EORTC QLQ-C30 were reliable and met the convergent validity, construct validity and test-retest validity. We also supported the validation analysis with factor analysis which showed that every domain in the EORTC QLQ-C30 loaded significantly on one factor. A larger sample size of patients with each type of cancer will facilitate conclusions on how different types of cancer may affect patients' responses to the questionnaires.

The result of this scale development process could be applied to hospitalized patient. Moreover, the scale that we developed may be limited to those patients treated with cisplatin. For the time being, our study results will be used in future to study QoL only for high-emetogenic cancer treatment. At the same time, we would like to point out that the sample size in our study as such is not uncommon in related research.

Conclusion

In conclusion, this study provides an Indonesian version of the EORTC QLQ-C30 and SF-36 questionnaires. Despite the fact that overall psychometric properties of both instruments were acceptable, this study indicates the further development of the instruments in an Indonesian version is required to achieve ideal tools to measure psychometric properties. The results of the present study should be confirmed in a study with an increased sample sizes.

Acknowledgements

This work was supported by the Netherlands Organization for International Cooperation in Higher Education (Nuffic).

The authors thank the patients, nurses and members of the translation group for their participation in this study.

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APPENDIX

Indonesian version of EORTC QLQ-C30

Kami ingin mengetahui beberapa hal yang berkaitan dengan Anda dan kesehatan Anda. Jawablah semua pertanyaan dengan melingkari angka yang paling sesuai. Tidak ada jawaban “salah” atau “benar”. Informasi yang Anda berikan akan dirahasiakan.

		Tidak	Sedikit	Sering	Sangat Sering
1	Apakah Anda mengalami kesulitan saat melakukan kegiatan yang berat, seperti membawa barang belanjaan atau koper yang berat?	1	2	3	4
2	Apakah Anda mengalami kesulitan jika berjalan kaki dalam <u>jarak yang jauh</u> ?	1	2	3	4
3	Apakah Anda mengalami kesulitan saat berjalan kaki meskipun dalam <u>jarak yang pendek</u> , <u>misalnya</u> di sekitar rumah Anda?	1	2	3	4
4	Apakah setiap hari Anda harus berbaring di tempat tidur atau duduk di kursi ?	1	2	3	4
5	Apakah Anda memerlukan bantuan orang lain saat makan, berpakaian, mandi atau buang air?	1	2	3	4
	Dalam seminggu terakhir:	Tidak	Sedikit	Sering	Sangat Sering
6	Apakah Anda mengalami keterbatasan saat bekerja atau melakukan kegiatan sehari-hari lainnya,?	1	2	3	4
7	Apakah Anda mengalami keterbatasan saat melakukan kegiatan santai atau kegiatan yang merupakan hobi Anda?	1	2	3	4

	Dalam seminggu terakhir:	Tidak	Sedikit	Sering	Sangat Sering
8	Apakah Anda merasa sesak nafas?	1	2	3	4
9	Apakah Anda merasa nyeri?	1	2	3	4
10	Apakah Anda perlu beristirahat?	1	2	3	4
11	Apakah Anda sulit tidur?	1	2	3	4
12	Apakah Anda merasakan badan Anda lemah?	1	2	3	4
13	Apakah Anda kehilangan nafsu makan?	1	2	3	4
14	Apakah Anda merasa mual?	1	2	3	4
15	Apakah Anda muntah?	1	2	3	4
16	Apakah Anda sulit buang air besar?	1	2	3	4
17	Apakah Anda diare?	1	2	3	4
18	Apakah Anda kelelahan?	1	2	3	4
19	Apakah nyeri yang dirasakan mengganggu aktivitas Anda sehari-hari?	1	2	3	4
20	Apakah Anda sulit berkonsentrasi pada sesuatu hal, seperti membaca koran atau menonton televisi?	1	2	3	4
21	Apakah Anda merasa tegang?	1	2	3	4
22	Apakah Anda merasa khawatir?	1	2	3	4
23	Apakah Anda merasa mudah tersinggung?	1	2	3	4
24	Apakah Anda merasa depresi?	1	2	3	4
25	Apakah Anda mengalami kesulitan untuk mengingat sesuatu?	1	2	3	4

	Dalam seminggu terakhir:	Tidak	Sedikit	Sering	Sangat Sering		
26	Apakah kehidupan keluarga Anda terganggu oleh kondisi fisik atau terapi medis yang Anda jalani?	1	2	3	4		
27	Apakah aktivitas sosial Anda terganggu oleh kondisi fisik atau terapi medis yang Anda jalani?	1	2	3	4		
28	Apakah Anda mengalami kesulitan keuangan akibat kondisi fisik atau terapi medis yang dialami?	1	2	3	4		
Untuk pertanyaan-pertanyaan berikut ini, lingkari angka yang paling sesuai.							
29	Bagaimanakah Anda menilai kondisi kesehatan Anda secara keseluruhan selama seminggu yang lalu?						
	1	2	3	4	5	6	7
	Sangat buruk						Sangat baik
30	Bagaimanakah Anda menilai kualitas hidup Anda selama seminggu yang lalu?						
	1	2	3	4	5	6	7
	Sangat buruk						Sangat baik