Reliability and validity of European Quality of Life 5 Dimension (EQ-5D) for measuring health-related quality of life in knee osteoarthritis patients at Cipto Mangunkusumo General Hospital

A Pramono,[1] Sumariyono,[2] H Isbagio[2]

[1] Department of Internal Medicine, University of Indonesia School of Medicine/Cipto Mangunkusumo General Hospital
[2] Division of Rheumatology, Department of Internal Medicine, University of Indonesia School of Medicine/Cipto Mangunkusumo General Hospital

ABSTRACT

Background: Quality of life is very important to knee osteoarthritis (OA) patients. The term quality of life denotes one that is health-related. One of the questionnaires most frequently used to measure the quality of life is the European Quality of Life 5-Dimension (EQ-5D) questionnaire. At Cipto Mangunkusumo General Hospital, until today there has not been any instrument for measuring the health-related quality of life in knee OA patients that has been tested for its reliability and validity.

Objective: To prove the reliability and validity of EQ-5D as a measurement tool in determining the health-related quality of life in knee OA patients at Cipto Mangunkusumo General Hospital.

Methods: This is a validity study in which all patients were asked to complete both the EQ-5D form and 36-item short form (SF-36) on their first visit. They were subsequently asked again to complete only the EQ-5D form one week after their first visit.

Results: Data were obtained from 86 respondents. The value of the intraclass correlation coefficient of each EQ-5D dimension, EQ-5D index, and visual analogue scale (VAS) was excellent (>0.75). Cronbach's α value for internal consistency reliability in this study was 0.6772 (<0.7). The external validity of EQ-5D compared to SF-36 was analyzed with the Pearson's correlation test and revealed a significant correlation ($p<0.01$) of all EQ-5D dimensions, EQ-5D index, and EQ-5D VAS with total score of SF-36 except for the dimensions of self-care, pain, and anxiety/depression. The construct validity of EQ-5D showed that all of the dimensions were significantly correlated with the EQ-5D index ($p<0.01$) except for self-care dimension.

Conclusion: EQ-5D is a valid and reliable measurement tool. It is thus recommended for measuring the health-related quality of life in knee OA patients at Cipto Mangunkusumo General Hospital.

Osteoarthritis (OA) is a common joint disease and is one of the causes of disability and pain.[1–3] This disease often attacks the weight-supporting joints such as the knee, hip, and backbone.[1,3,4] According to a study conducted by Cushnaghan et al,[5] 41.2% of all the symptomatic osteoarthritis involve the knee. A study conducted in Malang showed that the issues of OA in Indonesia may be greater compared to those in western countries. More than 85% of OA patients in Indonesia have activity impairment, especially during squatting, going up and down the stairs, and walking. Those are crucial activities performed in the daily life of the Indonesian people.[6]

Health-related quality of life is defined by Cella and Tulsky as the perception of one's current functional capacity and satisfaction compared to that one expects. Health-related quality of life is an abstract variable. Basically, there are two components of quality of life: subjective expression/perception and objective component.[4] The objective data measured is the health status of a person.[5,7] The subjective expression is more difficult to measure but could still be measured indirectly by using a questionnaire. The respondent's answer is then converted into score that could be measured objectively.[4]

One of the commonly used questionnaires of quality of life is the European Quality of Life 5 Dimension (EQ-5D), which was constructed by the British-based EuroQol Group. EQ-5D is designed such that it could be filled out by the respondent him/herself because it contains easy-to-follow instructions. It could be used for postal questionnaire, self-administered response in the clinic, and direct interview. EQ-5D is simple and only needs a few minutes to fill out. EQ-5D contains two sheets. The first sheet consists of the 5 dimensions of measurement: mobility, self-care, usual activity, pain/discomfort, and anxiety/depression. Each dimension has 3 levels of scoring: no problem, some problems, or extreme problems. The second EQ-5D sheet contains the visual analogue scale (VAS) to describe the subject's perception about his/her quality of life using a particular scale.[6]

EQ-5D has been translated into various languages and used in various countries. Studies of EQ-5D in OA has previously been done, such as by Brazier et al[8] in 1993 in England and by Fransen

et al[9] in 1999 in Sydney; both confirmed the reliability and validity of EQ-5D. Until today, Indonesia has not performed a study of reliability and validity of EQ-5D as a measurement tool of health-related quality of life in knee osteoarthritis patients.

This study is aimed at proving that EQ-5D is a reliable and valid measurement tool to determine health-related quality of life of knee OA patients at Cipto Mangunkusumo General Hospital.

METHODS

This is a validation study using consecutive method, which involved all OA patients aged above 50 years old who visited the rheumatology clinic at Cipto Mangunkusumo General Hospital, Jakarta from March 2007 until May 2007. The inclusion criteria were knee OA patients who fulfilled the clinical and radiographic criteria based on the American College of Rheumatology (ACR) criteria and have Kellgren-Lawrence score of >2 (mild, moderate, or severe OA) and willing to participate in the study. The exclusion criteria were coexisting dementia, aphasia, and psychosis.

Necessary data were collected by performing anamnesis, physical examination, plain radiograph of the knee (if both knees suffer from OA, assessment was conducted on the more severe one), and completing the EQ-5D and 36-item short form (SF-36) questionnaires. After one week, respondents were again asked to fill the EQ-5D questionnaire. Intraobserver and internal consistency of each EQ-5D dimension for reliability was assessed using intraclass correlation coefficient (ICC) and Cronbach's α coefficient (Cα). External validity (the average of each EQ-5D and SF-36 component) was assessed using the Pearson's correlation coefficient. Construct validity was assessed using correlation formula.

RESULTS

Characteristics of the respondents

There were 86 respondents enrolled in the study, consisting of 73 females and 13 males. The mean age of the respondents was 58.22 years old, in which the oldest was 77 years old. Most (51.2%) of the respondents were homemakers, followed by entrepreneurs/small business owners (20.9%). Most (41.9%) had only grade school education, while 29.1% had a high school degree.

Reliability

In this study we used intraobserver test-retest and internal consistency to assess reliability. Intraobserver test-retest is the degree of agreement of the outcome of the study conducted by the same observer during the first visit and the visit one week after. Intraobserver test-retest to assess reliability was measured using ICC. The value ranges between 0 and 1, in which <0.4 means weak correlation, 0.4–0.75 means good correlation, and >0.75 means excellent correlation.[10]

The reliability outcome of EQ-5D could be seen in table 1. All the ICC values were >0.75, which indicated that the correlation was excellent and therefore reliability was excellent.

Table 1 Intraobserver test-retest for reliability of European Quality of Life 5 Dimension (EQ-5D)

EQ-5D	Intraclass correlation coefficient
Mobility	0.886
Self-care	0.907
Usual activtiy	0.907
Pain/discomfort	0.886
Anxiety/depression	0.883

Each item of the measurement tool must correlate with each other. This is called internal consistency and is measured using the Cronbach's α with values ranging from 0 to 1. Internal consistency of EQ-5D for assessing reliability in this study showed Cronbach's α value of 0.6772, which indicated that EQ-5D had reliability with a low level of confidence.

Validity

In the external validity, EQ-5D was compared to SF-36 using the Pearson's correlation coefficient test to obtain the r value. Table 2 shows the correlation between EQ-5D and SF-36.

In table 2, we could see that the EQ-5D index and EQ-5D VAS had significant correlation with SF-36 total score ($p<0.01$). Some scores of each EQ-5D dimension and SF-36 also had significant correlation ($p<0.01$).

A significant correlation indicated that there was either positive or negative correlation. A positive correlation means that the higher the score of a dimension, the higher the score is of the other dimension, i.e. the correlation of the EQ-5D index with total SF-36. From table 2, the r value = 0.293, meaning that the higher the score of EQ-5D index, the higher is the scores of SF-36. A more detailed correlation between the two are visualized in figure 1.

A significant negative correlation, for example, is the correlation between the dimensions of mobility, usual activity, pain/discomfort, anxiety in EQ-5D and the total score of SF-36. The basic idea that must be understood is that in EQ-5D the best score is 1. A score of 3 indicates many problems; therefore the lower the score of the mobility dimension in EQ-5D, the higher is the total score of SF-36.

Table 2 Pearson's correlation coefficients between European Quality of Life 5 Dimension (EQ-5D) and Short Form-36 (SF-36)

		EQ-5D						
SF-36		**Mobility**	**Self-care**	**Usual activity**	**Pain/ discomfort**	**Anxiety/ depression**	**Index**	**VAS**
Physical functioning	**r**	−0.163	−0.144	−0.185	−0.076	−0.303**	0.178	0.409**
	p	0.134	0.186	0.88	0.487	0.005	0.101	0.000
Role-physical	**r**	−0.345**	−0.011	−0.559**	−0.182**	−0.294**	0.230*	0.353**
	p	0.001	0.919	0.000	0.093	0.006	0.033	0.001
Bodily pain	**r**	−0.378**	0.036	−0.461**	−0.238*	−0.089	0.290**	0.222*
	p	0.000	0.739	0.000	0.028	0.415	0.007	0.04
General health	**r**	−0.19	0.004	−0.043	−0.191	−0.012	0.193	0.04
	p	0.079	0.968	0.695	0.078	0.914	0.076	0.717
Vitality	**r**	−0.187	−0.245*	−0.106	−0.082	−0.073	0.145	0.244*
	p	0.085	0.023	0.33	0.455	0.506	0.184	0.024
Social functioning	**r**	−0.152	−0.219*	−0.177	−0.148	−0.122	0.126	0.082
	p	0.163	0.043	0.103	0.173	0.246	0.249	0.451
Role-emotional	**r**	−0.226*	0.143	−0.365**	−0.08	−0.031	0.152	0.230*
	p	0.036	0.191	0.001	0.464	0.78	0.164	0.033
Mental health	**r**	−0.042	−0.183	−0.101	0.064	0.061	−0.021	0.131
	p	0.699	0.092	0.354	0.559	0.577	0.85	0.23
Total score	**r**	−0.377**	−0.093	−0.526**	−0.220*	−0.231*	0.293**	0.436**
	p	0.000	0.392	0.000	0.041	0.033	0.006	0.000

*A significant correlation existed at $p<0.05$; **A significant correlation existed at $p<0.01$.
VAS, visual analogue scale.

Figure 1 and 2 gives a clearer description of the correlation between EQ-5D and SF-36. Figure 1 shows the correlation between EQ-5D index and total SF-36 with an r value of 0.293. Figure 2 shows the correlation between EQ-5D VAS and total SF-36 with r value of 0.436.

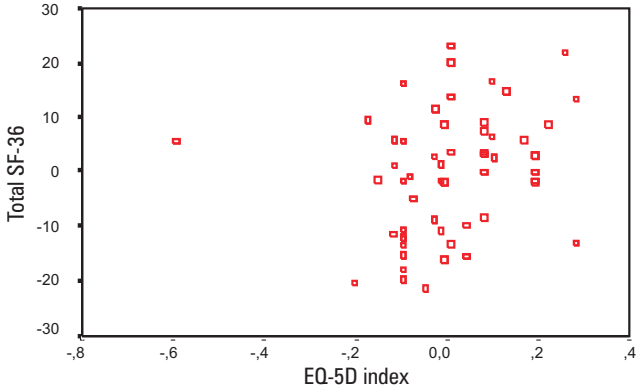

Figure 1 Correlation between European Quality of Life 5 Dimension (EQ-5D) index and total 36-item short form (SF-36) scores.

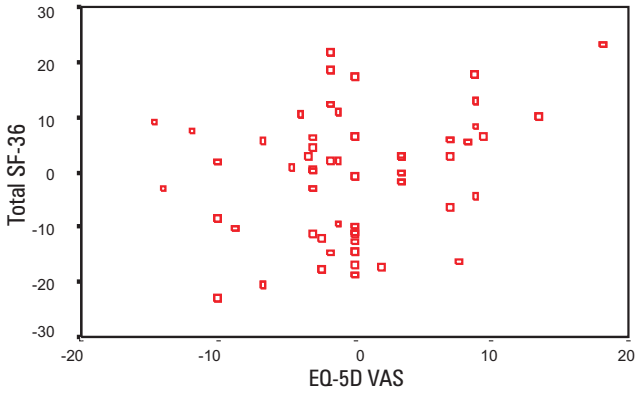

Figure 2 Correlation between European Quality of Life 5 Dimension visual analog scale (EQ-5D VAS) and total 36-item short form (SF-36) scores.

Table 3 shows the construct validity of EQ-5D. The EQ-5D dimensions were compared with the scores of EQ-5D index using the Pearson's correlation test to obtain the r value.

The result showed that the EQ-5D dimensions of mobility, usual activity, pain/ discomfort, and anxiety were significantly correlated with EQ-5D index ($p<0.01$). All the EQ-5D dimensions had negative correlation with EQ-5D index.

Except for the self-care dimension, the EQ-5D dimensions had r (absolute) value of >0.3. Kline[11] had determined the r value to be = 0.3 in assessing the validity of the psychometric measurement tool; thus all the EQ-5D dimensions were clinically correlated with the EQ-5D index.

Table 3 Pearson's correlation coefficients between each European Quality of Life 5 Dimension (EQ-5D) dimension and EQ-5D index

EQ-5D dimensions	**EQ-5D index**
Mobility	−0.684 (0.000)
Self-care	−0.166 (0.126)
Usual activity	−0.401 (0.000)
Pain/discomfort	−0.858 (0.000)
Anxiety/depression	−0.631 (0.000)

All values are r (p value).

Health-related quality of life

In this study, we obtained the scores of health-related quality of life of knee OA patients. The details could be seen in table 4.

Table 4 The scores of European Quality of Life 5 Dimension (EQ-5D) index, EQ-5D visual analogue scale (EQ-5D VAS), and total Short Form-36 (SF-36) (N = 86)

	Mean (SD)	**Range**
Total SF-36	59.461 (12.506)	34.17–82.50
EQ-5D index	0.734 (0.162)	0.124–1
EQ-5D VAS	71.98 (12.206)	60–90

Table 5 The score of each European Quality of Life 5 Dimension (N = 86)

	EQ1, mobility	EQ2, self-care	EQ3, usual activity	EQ4, pain/discomfort	EQ5, anxiety/depression
Score 1, no problem	43 (50)	80 (93)	49 (57)	19 (22.1)	48 (55.8)
Score 2, some problems	43 (50)	6 (7)	37 (43)	65 (75.6)	38 (44.2)
Score 3, extreme problems	0 (0)	0 (0)	0 (0)	2 (2.3)	0 (0)

All values are n (%).

The distribution of respondents according to the EQ-5D index could be seen in figure 3. There were 15.1% of respondents who had EQ-5D index score of 1 (maximum) and 2.3% who had the lowest EQ-5D index score of 0.124.

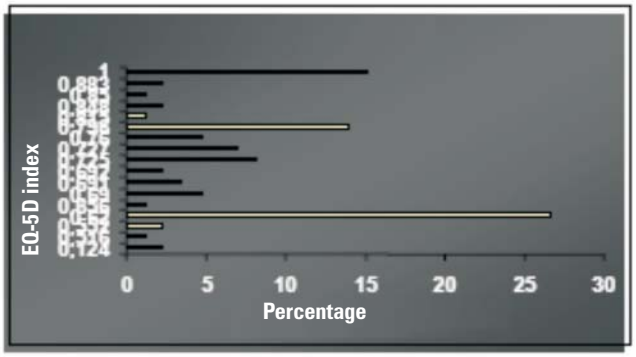

Figure 3 The distribution of European Quality of Life 5 Dimension (EQ-5D) index scores.

The outcome of EQ-5D of each dimension is presented in table 5. Most respondents (ranging between 22.1 and 93%) had no problem (score of 1) for the mobility dimension (EQ1), self-care (EQ2), usual activity (EQ3) and anxiety/depression (EQ5). Most (75.6%) respondents experienced moderate pain/discomfort (score 2) for the pain/discomfort dimension (EQ4).

The total score in the assessment of quality of life using SF-36 was 59.461 of the possible scores between 34.17 and 82.50. The dimension with the highest score (72.093) was the social functioning dimension while the bodily pain dimension had the lowest score (42.78). The physical component summary was the mean of the physical functioning, role limitations due to physical health problems (role-physical), bodily pain, general health, and social functioning with a value of 54.9093 (SD 13.8065). The mental component summary was the mean of the general health, social functioning, role limitations due to emotional problems (role-emotional), and mental health with a value of 67.373 (SD 11.7586). Further details could be seen in table 6.

Table 6 The score of each 36-item short form (SF-36) dimension (N = 86)

	Mean (SD)	Range
Physical functioning	56.92 (21.19)	15–95
Role-physical	47.38 (38.16)	0–100
Bodily pain	42.78 (15.52)	12–72
General health	55.49 (11.05)	10–100
Vitality	71.98 (16.26)	25–82
Social functioning	72.093 (17.328)	30–95
Role-emotional	59.054 (28.891)	37.50–100
Mental health	59.054 (16.59)	0–100
Physical component summary	54.9093 (13.8065)	28.2–79.4
Mental component summary	67.373 (11.7586)	45.8–94.25
Total score	59.461 (12.506)	34.17–95

DISCUSSION

This is a validity study with respondents consisting of knee OA patients whose ages ranged from 50 to 77 years old and had educational background ranging from grade school to associate degree. There was a variety of occupations. Female patients outnumbered male patients. The above distribution of respondents could represent the heterogeneity of the study population. We did not find any other chronic diseases, such as diabetes mellitus, hypertension, or asthma during this study.

Reliability was assessed using intraobserver test-retest and internal consistency. There has not yet any study conducted to assess the reliability of EQ-5D using ICC and Cronbach's α of knee OA patients. Studies that had been conducted so far was the evaluation of ICC in rheumatoid arthritis, stroke, the elderly, and general population.[9,13–18] Fransen et al[9] compared the reliability and validity of the EuroQol (EQ-5D) in knee OA patients with Western Ontario and McMaster Universities (WOMAC) index, OA index, and SF-36 and found reliability and construct validity of EQ-5D with an ICC value of 0.70 with a confidence level (95% CI) of 0.58–0.80 and test-retest analysis of each EQ-5D dimension with a correlation between 0.28 (p = 0.008) for mobility and 0.60 (p = 0.001) for anxiety/depression. The study revealed that the ICC value was 0.70; however, internal consistency using Cronbach's α was not evaluated.

As a comparison, the following are studies using ICC to determine the reliability of EQ-5D. A study conducted in Zimbabwe with respondents from the general population using EQ-5D in the local Shona language showed an ICC value of >0.75 in the dimensions of mobility and usual activity and between 0.4 and 0.75 for the dimension of self-care, pain/discomfort and anxiety/depression.[19] A study of EQ-5D in stroke patients conducted by Dorman et al[15] found that the ICC for mobility dimension and EQ-5D index was >0.75 while in other dimensions it was between 0.4 and 0.75. Hurst et al[13] conducted a study of EQ-5D in rheumatoid arthritis patients and found that the ICC of EQ-5D index and EQ-5D VAS was >0.75. The three studies found that EQ-5D had good to excellent intraobserver reliability and there was no bad ICC value (<0.4). Harmaini[17] found that the ICC value ranged from 0.611 to 0.936 with the highest ICC value for mobility and the lowest value for anxiety/depression while the Cronbach's α was in the elderly population.

We conducted an intraobserver test-retest instead of the interobserver test because the assessment and the measurement tool were performed by the respondents. The interobserver test is performed if the measurement tool that will be tested needs the evaluation from the researcher, for example in measuring the blood pressure using a manometer, reading plain chest X-ray, or reading plain radiograph of the knee. If

the interobserver test had been conducted in this study, the outcome would have been different from the intraobserver test because of the cognitive differences between those of the respondents and those of the observers.

The Cronbach's α value of the internal consistency reliability of this study was 0.6772. The use of internal consistency to evaluate the EQ-5D reliability is still debatable. Some authors state that it is not needed but others, such as Velarde-Jurado et al,[20] stated that EQ-5D internal consistency could be performed although he did not report the Cronbach's α value in his article. The Cronbach's α value obtained in this study was <0.7, indicating that EQ-5D in knee OA patients had a low level of confidence.[21–23]

The low level of confidence of Cronbach's α value in this study was caused by various factors: the anxiety/depression dimension was not always present in knee OA respondents, and self-care and pain dimension did not affect the daily activities of the knee OA patients. Because of the various factors above, a low Cronbach's α value did not indicate that EQ-5D had a low reliability. By passing two reliability tests—ICC value of EQ-5D was from good to excellent and Cronbach's α value was of low confidence level—we can say that the Indonesian version of EQ-5D had reliability to measure the health-related quality of life in knee OA patients with ICC ranging from 0.883 to 0.907 and Cronbach's α of 0.6772.

The validity of EQ-5D to measure health-related quality of life in knee OA patients in this study was assessed using two methods: external validity by comparing EQ-5D and SF-36 of the Indonesian version, and the construct validity of EQ-5D.

In Great Britain, EQ-5D and SF-36 had been proven valid for measuring the health-related quality of life in the elderly. SF-36 was also used to measure the quality of life in Indonesia.[14,21–25]

We analyzed the external validity of EQ-5D compared to SF-36 by using the Pearson's correlation coefficient test and found a significant correlation ($p<0.01$) that included the correlation between the EQ-5D dimension, EQ-5D index with SF-36 dimension and total score of SF-36. The correlation test for EQ-5D VAS with the physical function dimension and the SF-36 role-physical, or SF-36 total score also had significant correlation ($p<0.01$).

Such type of validation method, comparing one questionnaire with another, is commonly used to assess the validity of the quality of life questionnaire, including the questionnaire for knee OA patients. For example, Fransen et al[9] compared EQ-5D, WOMAC, and SF-36.

A similar study had been conducted by Brazier et al[8] in Great Britain in 1993, who studied the validity of EuroQol of the general population by comparing it with SF-36. EuroQol was a questionnaire similar to EQ-5D but with one additional question: family activity. They obtained a similar outcome, in which EuroQol had significant correlation with SF-36 with the exception of the correlation of SF-36 mental health dimension with EuroQol mobility and self-care dimension.

From the above data, comparing EQ-5D with SF-36 could be used as a mean to assess the external validity of EQ-5D; thereby we could say that the EQ-5D form has external validity to measure the quality of life of knee OA patients.

The construct validity in this study was conducted by finding the correlation of values of each dimension with the EQ-5D index score. Ancok[26] stated that this is a permissible method to determine construct validity. Ohinmaa et al[27] also used the same method to measure the health-related quality of life of the elderly in Finland.

The EQ-5D construct was tested using Pearson's correlation test, which showed that EQ-5D had a good construct. All EQ-5D dimensions were significantly correlated with EQ-5D index ($p<0.01$). A study in Finland conducted by Ohinmaa et al[27] obtained the same result, in which all EQ-5D dimensions were correlated with EQ-5D index.

By passing the two methods of validity test, this study proved that the EQ-5D form is a valid measurement tool to measure the health-related quality of life of knee OA patients.

The EQ-5D form could be used to assess health-related quality of life. In this study we could see an example of assessment of health-related quality of life of knee OA patients in table 4, table 5, and figure 2 in further detail.

The mean value of health-related quality of life of knee OA patients in this study using EQ-5D index was 0.734 and the mean value of EQ-5D VAS was 71.98. Below are studies from other countries for comparison. Fransen et al[9] in Australia in 1999 conducted a reliability and validity study of knee OA patients above 50 years old and found that the mean value of EQ-5D index was 0.58 and EQ-5D VAS was 71.3. Ohinmaa et al[27] in Finland in 2001 conducted a survey of health-related quality of life of a general population of above 75 years old and found that the mean EQ-5D index was 0.67 and EQ-5D VAS was 51. Brazier et al[16] in Great Britain in 1996 found that the mean EQ-5D index was 0.61 and the EQ-5D VAS was 68 in the female population of above 75 years old. Kind et al[28] in 1998 studied the health-related quality of life using EQ-5D in the general population and found that the mean EQ-5D VAS of those above 80 years old was 72. Badia et al[29] found that the value of EQ-5D VAS was 60.6 in those aged above 65.

The value of EQ-5D index in this study was higher than the ones of other countries. This is because the respondents in this study were patients of knee OA who must also had suffered from chronic diseases and have adapted to the Indonesian sociocultural environment while the respondents in the studies conducted in other countries were knee OA sufferers in the community with or without comorbidity and had a sociocultural environment that was different from that in Indonesia.[30–33]

The value of EQ-5D VAS in this study was similar to that in a study conducted by Fransen et al[9] in Australia.

We must note that in the assessment of the quality of life, it is difficult to determine whether the level of one's quality of life is better or worse than that of another by only comparing the outcome of one study with another.

Quality of life is dynamic and influenced by many factors.[34–43] When we use the EQ-5D index or EQ-5D VAS to assess the quality of life of an individual/society, it is better to evaluate the change of values rather than evaluate the value at

one point of time.

Although the score of EQ-5D index in this study was higher and the EQ-5D VAS was almost the same as those of other countries, the health-related quality of life in Indonesia is not always better than of those in other countries. Further studies are needed to obtain the data of quality of life of knee OA patients in Indonesia.

Kline[11] determined that the value of r = 0.3 was the level of correlation coefficient that could be accepted to assess the validity of a questionnaire if there are not any measurement tools as a gold standard to measure a variable. In Indonesia there has not been any gold standard to measure the health-related quality of life of knee OA patients.

The result in this study showed that the value of r (absolute) of all the EQ-5D dimensions was above 0.3. This indicated that all the EQ-5D dimensions could be used for clinical applications to determine the quality of life of knee OA patients.

The EQ-5D index had significant correlation with the SF-36 pain dimension and SF-36 total score while EQ-5D VAS was correlated with the SF-36 dimensions of physical functioning, role-physical, and SF-36 total score.

In clinical practice, if there is a difference in the scores of EQ-5D index and EQ-5D VAS (for example, if the EQ-5D index is maximum (score of 1) and EQ-5D VAS is only 50), the EQ-5D index is more reliable as the value of health-related quality of life since the value of health-related quality of life using VAS is the subjective expression of an individual and is influenced by cognitive factors.[44]

CONCLUSIONS

EQ-5D is a reliable tool to measure the health-related quality of life of knee OA patients in Cipto Mangunkusumo General Hospital. EQ-5D has internal consistency at a low level of confidence with Cronbach's α value of 0.6772, has construct validity with a weak correlation, and good external validity.

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