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RESEARCH ARTICLE

Comparison and validation of EuroQol-5 Dimension level and Short Form-6 Dimension in cataract patients

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Abstract

Background: EuroQol-5 Dimension (EQ-5D) and Short Form-6 dimension (SF-6D) are instruments that have been widely used to assess utility index as an outcome parameter in pharmacoeconomic studies. The choice of an instrument will have an important effect and can influence the decision making of an economic health evaluation. **Objectives**: The aim of this study was to compare the SF-6D and EQ-5D instruments to assess utility index in cataract patients. **Methods**: The study was conducted with on 448 cataract patients in a hospital in Yogyakarta. The subjects of the study were outpatient cataract patients over 45 years of age. The patient's health-related quality of life (HRQoL) was assessed using the SF-6D, EQ-5D, and visual function questionnaire instruments. The construct validity was tested including known group validity using the independent sample t test and ANOVA, convergent validity with the Spearman correlation, ceiling effect, and bland and Altmand plots. **Results**: A total of 448 cataract patients, mean age 64.7 (10.1) years, showed utility index assessed using the EQ-5D-5L and SF-6D instruments, which were 0.7 (0.2) and 0.8 (0.1), respectively. Convergent validity shows that the EQ-5D-5L dimensions have a moderate to very strong correlation (0.4-0.9) with the dimensions on VFQ-25, as well as the SF-6D (0.4-0.8). The known group validity shows that both EQ-5D-5L and SF-6D can differentiate the patient's health status based on cataract surgery, visual acuity, and comorbidity. The Bland Altman plot shows the level of agreement between EQ-5D-5L and SF-6D of 91.7%. In better health status, the utility index of EQ-5D-5L is higher and vice versa, in the worse health status the utility index of SF-6D is higher. **Conclusion**: Both the EQ-5D-5L and SF-6D instruments are valid for assessing the utility index in cataract patients. By using different instruments, there are differences in the utility value of cataract patients based on their health status. Therefore it is necessary to consider in choosing the instrument in assessing utility as an outcome parameter in pharmacoeconomic study.

Introduction

The improving health technology assessments to make decisions in healthcare service policies makes economic evaluation a very important tool. Quality-Adjusted Life Years (QALYs) is the main outcome in health economic evaluation. QALYs describes the disease burden that combines utility and length of life into a single index summary measure (Chen *et al*., 2014; McCaffrey *et al*., 2016). There are tools that can be used to directly measure utility, such as standard gamble (SG), rating scale, and time trade-off (TTO) and tools that can be used to indirectly measure utility, such as the Quality of well-being scale (QWB) questionnaire, Health Utility Index (HUI), the 5-level EuroQol-5-dimensional (EQ-5D-5L) and 6-dimensional health state short form (SF-6D). Measuring utility with the SG and TTO is time-consuming, complex, and may not be ethical. Therefore, the indirect measurement of utility

is more often used (Obradovic *et al*., 2013; Chen *et al*., 2014).

EQ-5D-5L and SF-6D are the two most widely used generic preference measures. The differences between the two instruments are their dimensions, question items, and preference weights. There is no consensus on which one is better or more useful for an individual's health condition (Obradovic *et al*., 2013; Chen *et al*., 2014). The Indonesian Health Technology Assessment Committee recommends the use of EQ-5D-5L to assess utility because it is available in the Indonesian version, and the value set is based on the Indonesian population. However, several studies have shown that SF-6D has a wider dimension and level so that it has the ability to better differentiate health levels and lower ceiling effect than the EQ-5D questionnaire. Previous studies have also stated that the SF-6D questionnaire was more sensitive than the EQ-5D questionnaire to measure the quality of life of patients with visual impairment caused by glaucoma (Bozzani *et al*., 2012). This was also supported by previous studies, which stated that the EQ-5D instrument was insensitive to differentiate the quality of life of patients based on the visual acuity (Visser *et al*., 2017).

A cataract is a vision impairment characterised by opacification or clouding of the eye lens, which is the most common cause of blindness in Indonesia. This visual impairment can cause a decrease in quality of life due to the negative impact of cataracts on daily activities that require visual function. In addition, since most of the patients with cataracts are older people, it can cause an increased risk of falls, femoral fracture and medication errors which will increase the health burden (Morris *et al*., 2007; Groessl *et al*., 2013; Hwang *et al*., 2018; Breheny *et al*., 2020). This study aimed to compare the SF-6D and EQ-5D-5L to assess utility in cataract patients so that it could be used as a basis for selecting instruments in the health technology assessment in cataracts. The Visual Function Questionnaire-25 (VFQ-25), which was developed by the National Eye Institute to measure visual function, has been widely used in many countries. In this study, VFQ-25 was used as a standard to assess the sensitivity of the EQ-5D and SF-6D to measure Health-related quality of life (HRQoL) in cataracts.

Methods

This study used a cross-sectional design on 448 respondents diagnosed with cataracts in the eye hospital in Yogyakarta. The sampling was conducted by using the convenience sampling method with inclusion criteria of patients diagnosed with cataracts who were examined or had a check-up in the eye hospital in the period of July 2019 to January 2020, outpatients aged more than 40 years old, and agreed to be involved in this study with informed consent. Patients were asked to complete a questionnaire in order to collect sociodemographic data, cataract characteristics, and the completed SF-6D, EQ-5D-5L and Visual Function Questionnaire-25 (VFQ-25) questionnaires at the time of the patient's examination at the hospital. This study had been approved by the ethics commission of Dr YAP Hospital of Yogyakarta with a number of 16/KEH/EC/VI/2019.

Instruments

SF-6D was adopted from short-form 36 (SF-36), a classification system that assesses six health domains, namely: physical function, role limitation, social function, pain, mental health, and vitality. Each dimension of the SF-6D has four to six levels, where the respondent can choose one statement (level) from each of these dimensions. The SF-6D scoring algorithm was developed using the standard gamble (SG) method from a sample of 249 health levels of SF-6D obtained from a representative sample of the United Kingdom's (UK) population (Brazier *et al*., 2002; Brazier *et al*., 2004; Brazier *et al*., 2014). The assessment is categorised into healthy and unhealthy, where level 1 in each dimension illustrates that the patient is healthy and has no functional limitations and that the score 111111 indicates that the respondent is perfectly healthy, while the worst score is 645655. The score was converted into a utility score of 0.29 to 1.0 using the SF-Converter programme developed by the University of Sheffield.

EQ-5D-5L consists of two parts. The first part describes five dimensions of the problem, each of which consists of five levels. From the five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), respondents choose one of the five levels (no problem, mild problem, moderate problem, severe problem, and very severe problem). The second part is the Visual Analogue Scale (VAS) which has the lowest score of 0, indicates the worst quality of life, and the highest score of 100, indicates the best quality of life. Respondents were asked to imagine the score that indicates his/her health. The scoring of utility on the EQ-5D-5L questionnaire used a value set from Indonesia developed by Purba and authors (2017) (Euroqol, 2019).

Visual Function Questionnaire-25 (VFQ-25) is one of the specific instruments used to assess the quality of life of patients with visual impairments. There are 11 domains of the instrument or questionnaire related to visual functions. This instrument or questionnaire is an

instrument developed by the National Eye Institute in the United States. VFQ-25 is often used to study the quality of life of patients with visual impairments in Indonesia since it has also been translated into Bahasa Indonesia, and validation has been made to it. The VFQ-25 has 25 questions representing 11 domains related to visual function, with an additional question measuring general health (Laitinen, 2009; Akkaya *et al*., 2016).

Statistical analysis

There was a convergent validity test conducted on the SF-6D and EQ-5D-5L questionnaires using Spearman's Correlation with the VFQ-25 questionnaire as the standard comparison to determine the correlation between dimensions. The score of the Spearman's correlation coefficient (r) 0.00 – 0.25 indicates no correlation; 0.25 – 0.5 indicates correlation; 0.5 – 0.75 indicates moderate correlation; and >0.75 indicates strong correlation (Andayani *et.al*., 2019). Known-group validity was tested using the Mann-Whitney U Test for dichotomous data and Kruskal Wallis for polychromous data. The ceiling effect analysis was carried out by looking at the proportion of respondents who have a score categorised as perfectly healthy. The data used to determine the ceiling effect was the per centage of respondents who had perfect health scores; 111111 for SF-6D and 11111 for EQ-5D-5L. The agreement analysis was conducted using a Bland-Altman plot by making a scatter-plot graph between the mean utility scores of the SF-6D and EQ-5D-5L and the difference in utility scores of SF-6D and EQ-5D-5L. The agreement is said to be good if the percentage within the limits of the agreement is 95% (Guillemin *et al*., 1993; Brazier *et al*., 2014; Chen *et al*., 2014; Wu *et al*., 2014; Islam *et al*., 2016; Andayani *et al*., 2020).

Result

A total of 448 cataract patients with an average age of 64.7 years old, and 48% of the patients were more than 65 years old. A total of 73.2% of patients were diagnosed with cataracts for more than a year. Approximately 75% of patients had cataracts in both eyes, 15% of them were in the very severe category, and 11% were almost blind. The utility index score assessed using the SF-6D (0.8) was higher than that of the EQ-5D-5L (0.7). There was a ceiling effect found in the EQ-5D-5L (17.9%), but no ceiling effect was found in SF-6D (13.8%).

Convergent validity showed that the correlation between the EQ-5D-5L and VFQ-25 domains ranged from no correlation to a very-strong correlation (r > 0.700) (Table I). All domains of the VFQ-25 questionnaire had a moderate correlation with the domains of EQ-5D-5L, except for the driving domain in VFQ-25. All domains of SF-6D had a strong correlation with VFQ-25 (Table II). Known group validity showed that the SF-6D and EQ-5D-5L could differentiate utility scores based on gender, cataract position (right eye, left eye, or both eyes), and severity of visual acuity (Table III). The EQ-5D-5L could also differentiate utility index scores based on the presence or absence of comorbidity. The Bland-Altman plot showed that the level of agreement between the EQ-5D-5L and the SF-6D was 91.7%. In patients with better health status, the EQ-5D-5L utility index score was higher than the SF-6D utility index score, and vice versa; the SF-6D utility index score was higher in patients with worse health status (Figure 1).

Table I: Correlation between EQ-5D-5L and VFQ-25 domain

	Mobility EQ-5D	Self-care EQ-5D	Usual activities EQ-5D	Pain/ discomfort-EQ-5D	Anxiety/ depression EQ-5D
General health	-0.384	-0.519	-0.400	-0.425	-0.038
General vision	-0.666	-0.740	-0.681	-0.546	-0.170
Ocular pain	-0.440	-0.682	-0.662	-0.672	-0.138
Near activities	-0.492	**-0.852**	**-0.771**	-0.420	-0.002
Distance activities	-0.495	**-0.889**	**-0.786**	-0.484	-0.009
Vision specific	-0.673	-0.687	-0.676	-0.527	-0.168
Driving	-0.141	-0.100	-0.098	-0.014	-0.074
Color vision	-0.436	**-0.944**	**-0.791**	-0.545	-0.074
Peripheral vision	-0.520	**-0.918**	**-0.808**	-0.586	-0.163

Table II: Correlation between SF-6D and VFQ-25 domain

	Physical function	Role limitation	Social function	Pain	Mental health	Vitality
	SF-6D	SF-6D	SF-6D	SF-6D	SF-6D	SF-6D
General health	-0.505	-0.487	-0.434	-0.476	-0.448	-0.452
General vision	**-0.781**	**-0.757**	-0.678	**-0.711**	-0.585	-0.614
Ocular pain	-0.633	-0.644	-0.619	-0.632	-0.509	-0.584
Near activities	-0.684	**-0.715**	**-0.755**	-0.616	-0.552	**-0.706**
Distance activities	**-0.720**	**-0.746**	**-0.775**	-0.657	-0.603	**-0.746**
Vision specific	**-0.748**	**-0.721**	**-0.741**	-0.591	-0.608	-0.588
Driving	-0.040	-0.049	-0.077	-0.037	-0.037	-0.107
Color vision	**-0.726**	**-0.786**	**-0.768**	**-0.725**	-0.629	**-0.792**
Peripheral vision	**-0.799**	**-0.876**	**-0.792**	**-0.778**	-0.682	**-0.765**

Table III: Univariate analyses for SF-6D and EQ-5D-5L utility scores within subgroups

Demographic variables	n=448	SF-6D utility index		EQ-5D-5L utility index	
		Mean ± SD	*p*	Mean ± SD	*p*
Gender			0.028		0.016
Male	215	0.764 ± 0.153		0.722 ± 0.228	
Female	233	0.753 ± 0.141		0.695 ± 0.211	
Mean of age (years)		63,98 ±10,64			
Age (years)			0.059		0.251
36-45	2	0.822 ± 0.250		0.789 ± 0.298	
46-55	112	0.784 ± 0.151		0.735 ± 0.218	
56–65	119	0.732 ± 0.128		0.678 ± 0.198	
> 65	215	0.759 ± 0.152		0.710 ± 0.230	
Vision impairment			0.0001		0.0001
OD	59	0.869 ± 0.116		0.864 ± 0.175	
OS	54	0.846 ± 0.134		0.847 ± 0.182	
ODS	335	0.725 ± 0.139		0.658 ± 0.210	
Duration (years)			0.617		0.377
< 1	131	0.766 ± 0.135		0.731 ± 0.200	
1-5	215	0.752 ± 0.143		0.695 ± 0.219	
> 5	118	0.763 ± 0.166		0.708 ± 0.239	
Visual acuity			0.0001		0.0001
Mild	166	0.886 ± 0.100		0.926 ± 0.081	
Moderate	79	0.800 ± 0.149		0.704 ± 0.233	
Severe	88	0.666 ± 0.038		0.587 ± 0.080	
Very severe	66	0.637 ± 0.044		0.535 ± 0.076	
Near blind	49	0.591 ± 0.043		0.427 ± 0.086	
Comorbidity			0.053		0.018
Yes	234	0.746 ± 0.149		0.685 ± 0.227	
No	214	0.772 ± 0.144		0.734 ± 0.208	

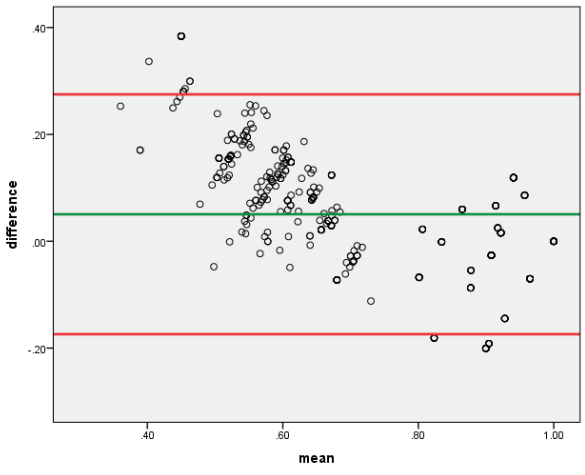

Figure 1: Bland Altman Plot for SF-6D and EQ-5D-5L

Discussion

It is important to compare the preference-based measures of health because the selection of instruments will have an effect on decision making based on the results of health technology assessment. The main objective of this study was to compare SF-6D and EQ-5D-5L questionnaires as instruments to assess utility in patients with cataracts. The visual impairment will have an effect on Health-Related Quality of Life (HRQoL) and cause difficulty in carrying out daily activities, reduce self-reliance and life satisfaction, reduce physical and mental function and increase the risk of depression (Groessl *et al*., 2013). The results of the study on 448 cataract patients in Yogyakarta showed the score of the SF-6D utility index was 0.8, and

of the EQ-5D-5L utility, the index was 0.7. The results of this study are in line with the research of Groessl and the authors. (2013) reported that the quality of life of cataract patients was 0.7. SF-6D and EQ-5D-5L are different in utility valuation techniques, classification systems, dimensions and coverage of these dimensions, causing different utility values. EQ-5D-5L tends to provide a higher utility score in milder health conditions. The results of this study showed that the utility score in cataract patients who were assessed using the SF-6D was higher than that of the EQ-5D-5L (Kontodimopoulos *et al*., 2011; Chen *et al*., 2014;). The variation of the utility score estimates and QALYs will affect the decision making on the resources used (Chen *et al*., 2014). In Table III, it can be seen that the utility index score for mild visual impairment is higher, while the utility index for cataract patients who is almost blind is higher.

The convergent validity test showed that almost all SF-6D domains had a strong correlation with the similar dimensions in VFQ-25, whereas, in the EQ-5D-5L, only the self-care and usual activities domains had a strong correlation with the dimensions of VFQ-25. Both SF-6D and EQ-5D-5L can differentiate utility based on differences in health status in patients with cataracts, namely the severity of visual impairment as assessed from visual acuity, the position of cataracts and the presence of comorbidity. In patients with comorbidity, the utility score is lower. The majority of respondents in this study had diabetes mellitus as the comorbidity, with a percentage of 51.7%. The presence of diabetes mellitus as the comorbidity was one of the triggers for cataracts and worsened cataracts (Akkaya *et al*., 2016). There was no difference in utility score based on the length of suffering from cataracts, either with SF-6D or EQ-5D-5L. At the beginning of suffering from cataracts, there will be interference in life activities, and a patient tends to be sad/hopeless, as can be seen from the value of the quality of life, which has decreased quite significantly. However, over time, a patient will be able to adapt to the conditions (Bozzani *et al*., 2012).

Bland-Altman plot showed that the level of agreement of SF-6D and EQ-5D-5L was 91.7%, which indicated that both instruments could not be used interchangeably (Kontodimopoulos *et al*., 2011). From Figure 1, it can be seen that the EQ-5D-5L utility index score is higher in cataract patients with milder severity and vice versa; in patients with more severe visual impairment, the SF-6D utility index score is higher. Harper and the authors reported that SF-6D was better than EQ-5D-5L in detecting minor HRQoL changes in mild disease.

The patients included in this study had an average age of 64.7 years old. The visual acuity played a very vital role as a strong independent factor on the physical function of the respondents, especially for those aged over 55 years old. In addition, a decrease in vision causes an increase in disturbances or limitations in carrying out daily activities (Laitinen *et al*., 2009). A decrease in vision in patients with cataracts is directly proportional to a decrease in their quality of life (Lamoureux *et al*., 2011).

The limitation of this study was that it used a cross-sectional study design so that any changes in the health status of cataract patients could not be identified from time to time. In addition, this study was only conducted in one eye hospital only; however, since the eye hospital where the study was conducted is a referral eye hospital, some patients may come from other regions in Indonesia. It was expected the patients had represented the population of cataract patients in Indonesia. In addition, in order to assess utility in SF-6D, this study used the algorithm developed by the University of Sheffield so that it might not represent the Indonesian population

Conclusion

Both EQ-5D-5L and SF-6D were valid and could be used to assess the utility of patients with cataract**s**. The SF-6D showed no ceiling effect and had a strong correlation strongly with a specific instrument in assessing HRQoL in eye disorders/diseases (VFQ-25). SF-6D and EQ-5D-5L were not interchangeable, where the EQ-5D-5L showed a greater score for milder eye disorders and, conversely, the SF-6D showed a higher utility score in more severe health conditions. Further studies are needed to compare the sensitivity and specificity of both instruments with the prospective cohort study.

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