The Short Form-6 Dimension (SF-6D) Validity and Reliability in Hemodialysis Patients

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Abstract

Background*: Quality of life becomes an important parameter that is needed for assessing the clinical outcome of patients undergoing long-term therapy for chronic diseases, such as chronic kidney failure. Short Form-6 Dimension (SF-6D) is one of the generic instruments that can be used to assess health-related quality of life (HRQOL). The psychometric properties SF-6D test in hemodialysis patients in Indonesia has never been conducted.* ***Objective****: Aimed to evaluate the reliability and validity of SF-6D questionnaire in Indonesian version in patients with chronic kidney failure.* ***Methods****: This is an observational study with a cross-sectional design involving 117 patients who meet the inclusion and exclusion criteria in the hemodialysis unit in Dr. Sardjito Central General Hospital and UGM Academic Hospital Yogyakarta.* ***Results****: The SF-6D questionnaire has good internal consistency, as seen in Cronbach's alpha value of 0.771. In this study, the ceiling effect test showed 6.8% (< 15%). The measurement of convergent validity was carried out using Spearman rho to analyze the correlation of the questionnaires and see its correlation with other instruments (KDQOL-SF36). Based on the research, the correlation coefficient value of 0.768 (> 0.75) indicates very good result for a strong correlation. The SF-6D instrument was able to distinguish the quality of life with a significant value (p < 0.05) in age, occupation, and comorbid groups.* ***Conclusion****: SF-6D questionnaire is valid and reliable, so it can be used to measure the HRQOL of hemodialysis patients. The mean SF-6D utility score of hemodialysis patients is high (0.7975 ± 0.1488).*

Keywords*: hemodialysis, psychometric properties, quality of life, SF-6D*

Abstrak

Pendahuluan: Kualitas hidup menjadi parameter penting yang diperlukan dalam menilai luaran klinis pasien yang menerima terapi penyakit kronis jangka panjang seperti gagal ginjal kronis. Penilaian kualitas hidup menjadi *outcome* kesehatan yang penting untuk diukur pada studi evaluasi farmakoekonomi. *Short Form- 6 Dimension* (SF-6D) merupakan salah satu instrumen generik yang dapat digunakan untuk menilai HRQOL. Pengujian *psychometric properties* SF-6D pada pasien hemodialisis di Indonesia belum pernah dilakukan. **Tujuan**: Untuk mengevaluasi reliabilitas dan validitas kuesioner *Short Form- 6 Dimensions* (SF-6D) versi bahasa Indonesia pada pasien gagal ginjal kronis. **Metode**: Penelitian bersifat observasional dengan desain *cross sectional* yang melibatkan 117 pasien yang memenuhi kriteria inklusi dan eksklusi di unit hemodialisis Rumah Sakit Umum Pusat Dr. Sardjito dan Rumah Sakit Akademik UGM Yogyakarta. **Hasil**: Kuesioner SF-6D memiliki *internal consistency* yang baik, yang ditunjukkan dengan nilai *Cronbach's alpha* 0,771. Pada penelitian ini pengujian *ceiling effect* menunjukkan hasil 6,8% (< 15%). Pengukuran *convergent validity* dilakukan dengan uji non-parametrik menggunakan *Spearman rho*, untuk menganalisis hubungan kuesioner, melihat korelasinya dengan instrumen lain (KDQOL-SF36), dihasilkan nilai koefisien korelasi sebesar 0,768 (> 0,75) menunjukkan sangat baik untuk korelasi yang kuat. Instrumen SF-6D dapat membedakan kualitas hidup bernilai signifikan (p < 0,05) pada kelompok usia, pekerjaan dan komorbid. **Kesimpulan**: Kuesioner SF-6D valid dan reliabel digunakan untuk mengukur HRQOL pasien hemodialisis. Rata-rata skor utilitas SF-6D pasien hemodialisis tergolong tinggi (0,7975 ± 0,1488).

Kata kunci: hemodialysis, kualitas hidup, *psychometric properties*, SF-6D

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INTRODUCTION

The measurement of health-related quality of life (HRQOL) is getting common as an important indicator of health in recent years, including in assessing the clinical outcomes of patients undergoing long-term therapy for chronic diseases, such as chronic kidney failure. The importance of involving quality of life indicators in the clinical management of patient is due to the relationship between quality of life and clinical outcomes. Thus, in recent years, quality of life assessment has become an important health outcome to measure in pharmacoeconomic evaluation study. In cost-utility analysis (CUA), a pharmacoeconomic evaluation method, outcomes are measured in quality-adjusted life-year (QALYs), which also measure the quality of life. A generic instrument has been created to generate a single value on quality of life and allows for the measurement of CUA (Cost-Utility Analysis). Short Form-6 Dimension (SF-6D) is a measuring tool (generic instrument) that can be used to assess HRQOL. This questionnaire has been widely used to assess health status by several countries, but the evaluation may differ in each country due to differences in health care systems (Collister *et al*., 2016; Kularatna *et al*., 2019; Poder & Gandji, 2016; Wyld *et al.*, 2016). HRQOL research in hemodialysis patients in Indonesia using the SF-6D questionnaire is still limited. The Short Form-6 Dimension (SF-6D) has been used in several research in hemodialysis patients (Pan *et al.*, 2018; Wyld *et al*., 2016; Yang *et al.*, 2015). The research show that the SF-6D measurement results are better than the EQ-5D instrument in detecting various stages of disease and predicting a severe disease burden, such as chronic kidney failure, with little floor effect. The SF-6D is also better at describing differences among patients who are at the top of the measurement scale with a small ceiling effect (Kularatna *et al*., 2019; Thaweethamcharoen *et al*., 2019).

To assess quality of life in hemodialysis patients, valid and reliable measurement instruments must be used, so the Indonesian version of the SF-6D instrument must be tested for its psychometric properties. The Indonesian version of the valid and reliable SF-6D instrument can be used for pharmacoeconomic studies and as a tool for measuring quality of life in order to provide meaningful implications for decision-making in Indonesian national policy. In Indonesia, no SF-6D psychometric properties test has ever been performed on patients with chronic kidney failure.

MATERIALS AND METHOD

Materials

Medical records from hemodialysis patients and data from interviews were used in the study. The data include respondent characteristics such as gender, age, education level, occupation, income, and comorbidities.

Equipment

The instrument used is a generic Short Form-6 Dimension questionnaire (SF-6D). The Short Form-36 instrument (SF-36) is a classification system for assessing six health domains: physical function, role limitation, social function, mental health, body pain, and vitality. Each dimension of the SF-6D has four levels up to six levels, where the respondents 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 SF-6D health levels from a representative sample of the UK population (Brazier *et al*., 2002). The scoring consists of the healthy and unhealthy categories, where level 1 in each dimension describes that the patient is healthy and does not have a functional limitation, so the patient is given a score of 111111, which indicates that the respondent is perfectly healthy, while the lowest score is 645655. The score is then converted into a utility value of 0.29 to 1.0 using the SF-Converter program developed by the University of Sheffield. The SF-6D questionnaire is available in the Indonesian version, and it has been tested for its validation and reliability to the population in Yogyakarta City, where the results of the internal consistency reliability test show the Cronbach alpha coefficient value of 0.752 ($r > 0.5$), which indicates that the Indonesian version of the SF-6D instrument has good reliability (Andayani *et al*., 2020).

Method

Design and subject of research

This is an observational study with a cross-sectional design that was carried out from February to March 2020 at the hemodialysis unit of Dr. Sardjito Central General Hospital and UGM Academic Hospital in Yogyakarta. Based on the calculation of the minimum sample size, the number of respondents involved in this study was 117 patients. The inclusion criteria were patients aged 18 years and above, patients with end-stage chronic renal failure who had been on routine hemodialysis for at least 3 months prior to the study, patients who could communicate well, and patients who agreed to participate in this study by signing an informed consent form. Meanwhile, patients whose general condition was weak or uncooperative were excluded from the study, as were patients who were unable to

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follow the process in the middle of the interview for data collection due to conditions, such as nausea, vomiting, cramps to seizures, or who were psychologically affected by the condition of other patients, and patients with incomplete medical records. The ethics committee of the Faculty of Medicine UGM – Dr. Sardjito Central General Hospital, Yogyakarta, granted permission for this study (Ref. No.: KE/FK/0191/EC/2020).

Statistics analysis

All of the processes of analysis was performed using SPSS version 23. Instrument reliability was assessed using Cronbach's Alpha reliability. Construct validity is measured using convergent validity and known group validity. The statistical test of convergent validity was carried out using Spearman's rank correlation. To test and analyze the correlation of the questionnaire, its correlation with other instruments that measure the same trait or concept (KDQOL-SF36) was examined. The correlation value is interpreted using the following criteria: a value of 0 - 0.25 means there is no correlation, a value of 0.25 - 0.5 means there is a correlation, a value of 0.5 - 0.75 means moderate for a good correlation, and a value of more than 0.75 means very good for a strong correlation (Portney & Watkins, 2000). Known group validity was used to test discriminatory validity. Respondents will be grouped based on socio-demography and then the differences would be seen for several test groups. Mann-Whitney U test was used on the variables of gender, occupation and Kruskal-Wallis H test was used for variables of age, education, marriage and history of disease.

RESULTS AND DISCUSSION

Socio-demography of patients

This study involved 117 hemodialysis patients, which were dominated by males (54.7%) compared to females (45.3%), with a mean SD of patient age of 50.7 ± 13.3 years (Table 1). Percentage of age included 18 - 40 years (24.8%) 41-60 years (46.2%) and 60 years (29.1%). The prevalence of male hemodialysis patients is due to lifestyle factors such as smoking, obesity, and metabolic syndrome, all of which play a role in the progression of kidney disease severity (Agency for Health Research and Development, 2019; Halbesma *et al*., 2008).

Table 1. Socio-demography of hemodialysis patients

Characteristics of Patients	The Number of Subject (n = 117)	Percentage (%)
Sex		
Male	64	54.7
Female	53	45.3
Age		
18 - 40 years	29	24.8
41 - 60 years	54	46.2
> 60 years	34	29.1
Job Status		
Employed	37	31.6
Unemployed	80	68.4
Education Level		
< High School	19	16.2
High School	61	52.1
College	37	31.6
Duration of Hemodialysis		
< 1 year	13	11.1
1 - 5 years	64	54.7
> 5 years	40	34.2
Comorbidity		
Hypertension	76	65.4
Hypertension, DM	41	34.6

The proportion of kidney failure patients with a high school education (senior high school) was higher (55.1%) than the proportion of patients with a basic education (elementary and junior high school: 14.1%) and college education (30.8%). Patients were classified as employed or unemployed based on their employment status. The percentage of unemployed patients in both therapy groups was 66.7 percent, which was higher than the percentage of unemployed patients in the control group (33.3%). In line with other studies, retirees and housewives predominated among unemployed patients (Kalsoom, 2019).

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In this study, most patients with chronic kidney failure were also had comorbid hypertension (65.4%) compared to comorbid hypertension and diabetes mellitus (34.6%). This finding was consistent previous studies showing that comorbid of hypertension was more common in hemodialysis patients compared to diabetes and hypertension (Cha & Han, 2020; (Sihombing, 2019). The highest percentage were patients with hemodialysis duration of 1-5 years (Cha & Han, 2020; Sihombing, 2019). About 51.3% followed by patients with hemodialysis duration of more than 5 years (42.3%).

Internal consistency reliability

The value of Cronbach's Alpha reliability is presented in Table 2. Based on the psychometric property assessment conducted in this research, it is seen that the SF-6D questionnaire has good internal consistency, as indicated by Cronbach's alpha value of 0.771. Overall, the SF-6D questionnaire has a good reliability with Cronbach's alpha value of > 0.5.

Table 2. Result of internal consistency cronbach's alpha

SF-6D Domain	Corrected item-total correlation	Cronbach's alpha if item deleted
Physical Function	0.580	0.720
Role Limitation	0.545	0.734
Social Function	0.671	0.694
Body Pain	0.589	0.737
Mental Health	0.595	0.728
Vitality	0.262	0.789
Cronbach Alpha reliability = 0.771 (*N of domain* = 6)		

The ceiling effect was investigated in this study. It is known that instruments with good content do not have a ceiling effect. The ceiling effect test was used to examine the distribution of responses from respondents. If more than 15% of respondents answered with perfect numbers, the instrument is said to have a ceiling effect. The ceiling effect test resulted in a result of 6.8 percent (15 percent) in this study, indicating that the SF-6D instrument did not have a ceiling effect.

Convergent validity

Convergent validity is an analysis to see the validity of two instruments that measure the same concept or measure the concept with different methods. In this research, convergent validity was measured using a non-parametric test called Spearman's rho to test the correlation of the questionnaire and to see how it correlated with other instruments that measure the same trait or concept (specific questionnaire KDQOL-SF36). Because the obtained data were not normally distributed, they did not meet the requirements of the parametric test. This was noticed after performing a normality test on the data using the Kolmogorov-Smirnov statistical test, which resulted in a significance value of 0.000 (less than 0.05), indicating that the data is not normally distributed. Correlation analysis was performed using Spearman's rank correlation test between the utility value of SF-6D and KDQOL-SF36 score, resulting in a correlation coefficient of 0.768 (> 0.75), which indicates very good for a strong correlation. The higher the value of the correlation coefficient, the stronger the correlation and the better the validity of the instrument is. The correlation between the two instruments is significant because it has a significance value of less than 0.05.

Known-group validity

This validity test was carried out to determine whether the SF-6D instrument was able to distinguish the quality of life of hemodialysis patients between groups of age, sex, education, occupation, disease history, and marital status in several SF-6D instrument domains. Based on the research results, the validity of each question item obtained from the significance value was shown. The results showed that the SF-6D instrument was able to distinguish the quality of life with a significant value in the age group, occupation, and comorbidities in several domains while other groups did not provide significant results. The results of the known-group validity test can be seen in Table 3.

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Table 3. Results of *Known Group Validity*

Characteristics	SF-6D Domain					
	FF	KP	FS	RS	KM	V
Sex *p-value*	0.827	0.618	0.593	0.005*	0.487	0.965
Age *p-value*	0.000*	0.002*	0.003*	0.171	0.309	0.617
Education *p-value*	0.229	0.599	0.115	0.046	0.469	0.133
Occupation *p-value*	0.043*	0.033*	0.015*	0.010*	0.049*	0.305
Income *p-value*	0.934	0.188	0.225	0.029	0.099	0.600
Comorbidity *p-value*	0.000*	0.037*	0.011*	0.731	0.136	0.039
Dialysis Duration *p-value*	0.020*	0.365	0.159	0.906	0.947	0.421

*significance p < 0,05
**Description: FF (physical function); KP (role limitation); FS (social function), RS (body pain); KM (mental health); V (vitality)

Table 4. Assesment result of utility with short form 6 dimensions (SF-6D)

Quality of Life	N	Percentage	Average ± SD	Minimal Score	Maximal Score
Utility score with SF6D	117	100%	0.7975 ± 0.1488	0.3483	1.000

CONCLUSION

In this research, a valid and reliable SF-6D questionnaire is used to measure the HRQOL of hemodialysis patients. The mean SF-6D utility score of hemodialysis patients is high (0.7975 0.1488) (Table 4).

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