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Quality of Life of Patients with Diabetic Foot Ulcer in Surabaya, Indonesia, Using the Indonesian Version of EQ-5D-5

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Abstract

Background. Diabetic foot ulcer (DFU) is a complication of diabetes mellitus that can increase morbidity, mortality, and economic burden for the Indonesian government. Utility index is needed as an outcome parameter in assessing health technology in diabetes mellitus.

Objective. The purpose of this study was to assess the level of Quality of Life (QoL) of DFU patients and differences in QoL based on patient characteristics and ulcer severity.

Methodology. The study was conducted with a cross-sectional design in DFU patients at two public hospitals and a private wound care clinic in Indonesia (Dr. Sardjito General Hospital, Dr. Ramelan Naval Hospital, and D Wound Care). Utility index assessment used the EQ-5D-5L questionnaire and the Indonesian version of the value set. Health-related quality of life assessments were carried out based on DFU severity, as well as the correlation of EQ-5D-5L dimensions with the Diabetic Foot Ulcer Scale-Short Form (DFS-SF).

Results. Of the 133 DFU patients, the majority were aged 40 to 60 years (62.4%), 28.6% of patients had DM for more than 10 years, as many as 30.8% with Wagner grade 3. The problems most frequently reported by patients were in the dimensions of mobility (78.2%), self-care (62.4%), and usual activities (66.2%). The utility index in DFU patients was 0.346 (SD = 0.423), where amputation history, patient mobility, and Wagner grade had a significant effect on the utility index.

Conclusion. The higher the severity of the patient, the lower the utility index. There was a strong correlation between the utility index and the quality of life score assessed using the DFS-SF.

Key words: diabetes, utility, DFU, EQ-5D-5L, QoL, HRQoL

INTRODUCTION

Diabetic ulcers are a complication of diabetes mellitus (DM), which results in increased morbidity, mortality, and economic burden for patients and the Indonesian government. The incidence of diabetic foot ulcers in people with diabetes ranges from 19-34%, with the first-year onset of 5%.[1] Patients with diabetic foot ulcers are susceptible to infection and resistance. The healing process is further complicated due to diabetic neuropathy, so that 12% of patients with diabetic ulcers require lower limb amputation.[2-4] Within 2.5 years, approximately 40% of patients with diabetic foot ulcers have a recurrence, and about 12.3% of patients do not recover.[5-7] Furthermore, the data show that 82.4% of patients with diabetes admitted to hospital experience amputation, 34.9% of them undergo re-amputation, and 70% of patients with diabetic ulcers die within 5 years after amputation.[8-11]

The economic burden of patients with diabetic foot ulcers is 5.4 times that of patients without DFU.[12] Direct costs for treatment, hospitalization, and therapy, as well as indirect costs, including loss of productivity, loss of time, patient dependence on others, and premature death, cause a high economic burden. The economic burden of health services for the Indonesian government is very high because the prevalence and incidence of diseases, especially catastrophic diseases, are increasing from year to

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year.[13] With limited government funding, quality and cost controls are necessary. Pharmacoeconomics is a tool for making financing policies when available funds are limited. Cost-utility analysis is the recommended pharmaco-economic analysis method for policy making on a national scale.[14] In this analysis process, utility data is required as an output parameter. Utility is a numerical value that indicates the level of quality of life related to health. In pharmacoeconomic studies, utility is a measure of a person's preference for a particular health condition. The outcome parameter in cost-utility analysis is the Quality-Adjusted Life Year (QALY), which is obtained by combining quality of life (utility) with quantity of life (survival).

The EQ-5D-5L is a recommended tool by the Ministry of Health for measuring utility. In addition to being simple, this measuring tool can be sensitive in assessing changes in health status in various diseases and has an Indonesian version of the value set for scoring the utility index.[15] Validity and reliability tests are necessary to ensure that the EQ-5D-5L can correctly measure health status in patients with DFU. Construct validity can be measured by assessing the correlation of this generic measuring instrument and a specific instrument. The Diabetic Foot Ulcer Scale-Short Form is an instrument to assess the quality of life of patients with DFU with dimensions relevant to the symptoms and signs of DFU, namely leisure, physical health, dependency/daily life, negative emotions, worried about ulcer/feet, and bothered by ulcer care.[16] This study aimed to (1) analyzing the correlation between EQ-5D-5L dimensions and the quality-of-life dimensions of a disease-specific questionnaire (the Diabetic Foot Ulcer Scale-Short Form); (2) determine the level of quality of life (utility) of patients with DFU; and (3) identify health problems in patients with DFU based on the EQ-5D-5L dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression). Additionally, this study aimed to evaluate the known-groups validity of the EQ-5D-5L by assessing its ability to discriminate utility index scores across distinct demographic groups and clinical severity stages.

METHODOLOGY

Research design

The study was conducted using a cross-sectional design on patients with diabetic ulcers who underwent foot care at Dr. Sardjito General Hospital, Dr. Ramelan Surabaya Naval Hospital, and D Wound Care from March 2024 to October 2024. This multi-center study included type A public hospitals and a private clinic. Inclusion criteria included patients with diabetic ulcers aged 18 years and over who were willing to participate in the study and complete the questionnaire. Participants who were willing to participate in the study provided informed consent. This research has been approved by the Medical and Health Research Ethics Committee of the Faculty of Medicine, Public Health, and Nursing, Universitas Gadjah Mada No. KE/FK/1655/EC/2024. The sample size calculation used the single mean sample size formula with SD = 0.25, d = 0.05, and Z = 1.96, determined to be 96.04. To account for dropouts or incomplete data, the sample size was increased. The determination of the sample size of 133 respondents was based on statistical power analysis calculations for a two-tailed correlation test with a significance level (α) of 0.05 and a test power of 80%, which is able to detect a minimum correlation (r) of 0.25 between the EQ-5D-5L and DFS-SF instruments (123 respondents). In addition to meeting sufficient statistical power to test the correlation between quality of life instruments, this sample size also complies with the psychometric rules of the respondent-to-questionnaire item ratio, which is sufficient for up to 15 respondents per item for the largest subscale on the DFS-SF (8 items) and exceeds the minimum ratio of 4.6 respondents per total instrument items (29 items). This number is considered adequate to validate the instrument in a specific clinical population while providing a tolerance limit for potential incomplete data.

Research instrument

The tool used in this study was the European Quality of Life 5 Dimension (EQ-5D) questionnaire. EQ-5D is a generic instrument used in various countries to measure the quality of life of a population. The EQ-5D has two parts, namely the EQ-5D descriptive system and the EQ-5D Visual Analogue Scale (VAS). The EQ-5D descriptive system has two types of instruments, namely EQ-5D-3L and EQ-5D-5L, which are used to measure the health status of an individual using 5 domains, namely mobility/ability to walk/ability to move, self-care, activities that can be done, pain/discomfort, and anxiety/depression. The EQ-5D-5L questionnaire consists of 5 dimensions of questions with 5 levels of answer choices. Level 1 indicates no problem, level 2 indicates slight problems, level 3 indicates moderate problems (quite problematic), level 4 indicates severe problems (very problematic), and level 5 indicates extreme problems (extremely problematic). The EQ-5D VAS is used to record respondents' assessment of their health status using a vertical visual analogue scale with a scale of 0-100, where a scale of 0 indicates the worst health status and a scale of 100 indicates perfect health.[17,18] The Indonesian EQ-5D-5L value set was developed and validated by Purba, representing the health preferences of the Indonesian people. This value set can validly measure health-related quality of life (HRQoL) in Indonesia, particularly in the context of health economic evaluations. Value set is used to assess utility by subtracting the dimension-specific decrements (coefficients) from the maximum value of 1 from the value of each patient problem in each dimension. The reduction coefficient used for each dimension is different.[15] The coefficients are obtained from EQ-5D-5L value sets to indicate that various health issues influence a patient's overall utility to varying extents.

The Diabetic Foot Ulcer Scale-Short Form (DFS-SF) was first developed and validated in the UK and has been widely used in China, Greece, Korea, Turkey, Poland, Brazil, and

the Netherlands.[16,19-25] The Diabetic Foot Ulcer Scale-Short Form (DFS-SF) has undergone validation for its construct and reliability in Indonesia, achieving a Cronbach's alpha and composite reliability all domain >0.80.[26] The DFS-SF is a specific and sensitive questionnaire to assess HRQoL in patients with DFU. It consists of 29 items with 6 subscales: leisure, physical health, dependency/daily life, negative emotions, worried about ulcer/feet, and bothered by ulcer care. Each item is rated on a 5-point Likert scale, from 1 (not at all or none of the time) to 5 (a great deal, all the time, or extremely). Each item is then reverse coded, and high scores on the DFS-SF indicate good HRQoL.

Data analysis

Demographic characteristics and item distributions are described in numbers and percentages. Continuous variables, including utility scores, are presented in means and standard deviations. The Kolmogorov-Smirnov test was carried out to determine data distribution. Validation of the EQ-5D-5L questionnaire was conducted by examining the correlation between the dimensions of the generic questionnaire (EQ-5D-5L) and those of the specific questionnaire (DFS-SF). Statistical tests were conducted to determine differences in utility based on patient and disease characteristics. To identify health problems, the percentage of patients responding to each domain (score) was calculated by dividing the number of responses by the total number of patients. The independent *t*-tests and ANOVA were conducted to determine the difference in utility index based on patient characteristics. If the data were not normally distributed, the Mann-Whitney and Kruskal-Wallis tests were used. Multiple testing across demographic and clinical subgroups was addressed by controlling the False Discovery Rate (FDR) using the Benjamini-Hochberg procedure. Adjusted *p*-values were calculated using the Benjamini-Hochberg method in R software version 4.6.1, with an FDR-adjusted *p*-value <0.05 considered statistically significant. To evaluate convergent validity, correlation analysis between the EQ-5D-5L and DFS-SF domain scores was performed using Pearson's correlation coefficient.

RESULTS

The results of 133 patients with diabetic foot ulcers (DFU) showed that the majority were aged between 40 and 60 years, with an average age of 56.4 years; the majority of patients had secondary education (60.2%); and most of the patients were members of the national health insurance (JKN) scheme (69.9%). The utility value of patients with DFU was 0.346 ± 0.494. There were differences in utility index scores based on age, gender, employment status, and financing, where patients over 60 years of age, female patients, unemployed patients, and patients with JKN insurance showed lower utility values (Table 1).

The duration of suffering from DM and ulcers did not show significant differences in utility values. However, the history of amputation, patient mobility, and Wagner grade affected patient quality of life (Table 2). Patients with a history of amputation showed very low utility scores (0.041), and so did patients who used wheelchairs (-0.062) and those with Wagner grade 4 (0.090).

Mobility (Table 3) is the most common problem in patients with DFU, with only 21.8% experiencing no problems and 24.1% unable to walk. Other severe problems patients reported are usual activity (24.8%) and self-care (21.8%). Table 4 shows the correlation between the EQ-5D-5L dimensions and specific DFS-SF dimensions. A very strong correlation exists between dependency/daily life and usual activities (0.729). There is a strong correlation between the leisure dimension and mobility, self-care, and usual activity; between physical health and pain/discomfort; between dependency/daily life and mobility and self-care; and between worried about ulcer/feet and anxiety/depression. There is a strong correlation between the EQ-5D-5L score and the DFS-SF score (0.629).

Table 1. Utility index based on characteristics of diabetic ulcer patients (n = 133)

Characteristics	n (%)	Utility index	*p*-value	Adjusted *p*-value*
Age group (years)				
<40	2 (1.5)	0.940 ± 0.084	0.040	0.074
40 – 60	83 (62.4)	0.393 ± 0.489		
>60	48 (36.1)	0.240 ± 0.486		
Gender				
Male	64 (48.1)	0.429 ± 0.470	0.061	0.099
Female	69 (51.9)	0.269 ± 0.506		
Education Level				
Primary School	26 (19.5)	0.215 ± 0.546	0.223	0.297
High School	80 (60.2)	0.354 ± 0.487		
Graduate	27 (20.3)	0.449 ± 0.449		
Occupation				
Employed	71 (53.4)	0.516 ± 0.419	0.000	0.000
Unemployed	62 (46.6)	0.197 ± 0.509		
Health Insurance Status				
Uninsured	40 (30.1)	0.562 ± 0.323	0.001	0.002
Insured	93 (69.9)	0.253 ± 0.526		

**p*-values were adjusted for multiple comparisons using the Benjamini-Hochberg correction.

Table 2. Utility Index based on clinical characteristics of diabetic ulcer patients (n = 133)

Characteristic	n (%)	Utility index	*p*-value	Adjusted *p*-value*
Duration of diabetes (years)				
<1	10 (7.5)	0.528 ± 0.402	0.377	0.445
1 – 5	53 (39.8)	0.301 ± 0.502		
5 – 10	32 (24.1)	0.281 ± 0.536		
>10	38 (28.6)	0.415 ± 0.463		
Duration of DFU				
<1 month	47 (35.3)	0.189 ± 0.522	0.081	0.117
1 – 6 months	62 (46.6)	0.447 ± 0.461		
6 – 12 months	10 (7.5)	0.382 ± 0.498		
1 – 5 years	9 (6.8)	0.481 ± 0.398		
>5 years	5 (3.8)	0.258 ± 0.553		
Diabetes treatment				
Oral antidiabetics	54 (41.9)	0.400 ± 0.453	0.285	0.370
Insulin and oral antidiabetics	20 (15.5)	0.400 ± 0.542		
Insulin	55 (42.6)	0.259 ± 0.520		
Blood sugar profile (mg/dL)				
≤130	23 (17.3)	0.392 ± 0.507	0.884	0.957
130 – 250	72 (54.1)	0.303 ± 0.461		
>250	38 (28.6)	0.364 ± 0.553		
History of amputation				
No	115 (86.5)	0.394 ± 0.477	0.004	0.001
Yes	18 (13.5)	0.041 ± 0.502		
Mobility of patients			0.000	0.000
Walking	18 (13.5)	0.658 ± 0.306		
Difficult walking	77 (57.9)	0.474 ± 0.428		
Wheelchair	38 (28.6)	-0.062 ± 0.445		
Wagner grade				
1	22 (16.5)	0.647 ± 0.320	0.000	0.000
2	63 (47.4)	0.406 ± 0.509		
3	41 (30.8)	0.136 ± 0.456		
4	7 (5.3)	0.090 ± 0.448		

**p*-values were adjusted for multiple comparisons using the Benjamini-Hochberg correction.

Table 3. Frequency distribution of EQ-5D-5L scores based on health dimensions

Level*	Mobility (%)	Self-care (%)	Usual activities (%)	Pain/discomfort (%)	Anxiety/depression (%)
1	21.8	37.6	33.8	43.6	60.9
2	21.8	10.5	9.8	23.3	27.1
3	21.8	24.1	25.6	21.8	9.8
4	10.5	6.0	6.0	6.0	2.3
5	24.1	21.8	24.8	5.3	0.0

*Level 1 = no problems, 2 = slight problems, 3 = moderate problems, 4 = severe problems, 5 = extreme problems.

Table 4. Correlation of EQ-5D-5L dimensions with the Diabetic Foot Ulcer Scale-Short Form (DFS-SF)

	Mobility	Self-care	Usual activities	Pain/ discomfort	Anxiety/ depression	EQ-5D-5L index
Leisure	**-0.638**	**-0.552**	**-0.545**	-0.144	-0.067	**0.671**
Physical Health	-0.144	-0.227	-0.238	**-0.579**	-0.401	0.323
Dependency/daily life	**-0.541**	**-0.553**	**-0.729**	-0.263	-0.137	0.693
Negative emotions	-0.183	-0.163	-0.092	-0.041	-0.447	0.230
Worried about ulcer/feet	0.025	0.025	0.008	-0.061	**-0.522**	0.088
Bothered by ulcer care	-0.236	-0.242	-0.206	-0.319	-0.353	0.332
DFS-SF	-0.492	-0.469	**-0.533**	-0.322	-0.345	**0.629**

DISCUSSION

Utility assessment is necessary for DFU since it is an outcome parameter in pharmacoeconomic evaluation. The economic burden of DFU is very high, about 5.4 times compared to uncomplicated DM.[27] The prevalence of DFU in the world is around 6.4% due to decreased peripheral circulation and neuropathy, which can lead to amputation in around 50% of patients.[28] DFU has a negative effect on patient health, causing serious consequences for psychological, physical, social, and economic activities.[29]

The results showed that the average EQ-5D-5L index in patients with DFU was 0.346 (SD 0.423). This value is lower than that of patients with DFU in Iran, which is 0.55 (SD 0.21), and in Thailand was 0.799 (SD 0.25).[12,30] This is due to differences in severity. The subjects in Iran are patients with DFU with Wagner grades 1 to 3, and in Thailand are patients with diabetic foot pproblems while in this study, patients with grades 1 to 4 were used.[12,30] Wagner grading scales indicate the severity of the ulcer by considering the depth of the ulcer, the presence of gangrene, and the level of tissue necrosis.

Previous studies have shown that factors influencing the EQ-5D-5L index (quality of life) of patients with DFU include advanced age, poor glycemic control, and increased BMI.[31] Education level and unemployed status also affect QoL. The results of this study are in line with previous studies, where patients aged >60 years showed the lowest score (0.240), as did unemployed patients (0.197) (Table 1). Patients with higher levels of education showed higher scores, but they were not significantly different.

Other characteristics that affect QoL are duration of DFU, Wagner grade, ulcer size, and pain.[29] Arab-Zozani also reported that age, gender, ulcer grade, and complications are determinants of the EQ-5D-5L index.[12] The results of this study revealed that patients with higher Wagner grades had the lowest utility score (0.090). As many as 30.8% of patients had Wagner grade 3 (deep ulcer with abscess/osteomyelitis) and 5.3% of patients had grade 4 (localized gangrene). Patients with a history of amputation and using a wheelchair showed the lowest utility scores, at 0.041 and -0.062, respectively. The duration of suffering from DM and DFU did not show significant differences in QoL. Meanwhile, mobility problems significantly affected QoL, where patients with wheelchairs showed very low EQ-5D-5L index values (-0.062).

The average EQ-5D-5L index in female patients (0.269) was lower than in male patients (0.429). Pain and depression problems were more frequently reported by female patients than male patients, 64% and 45% vs 48% and 33%, respectively. This is in line with research by Udovichenko et al., which states that female patients experience depression and anxiety more often than male patients (48% and 46% vs 27% and 25%, respectively).[33] Depression in patients is caused by frustration with lifestyle changes and the therapy they must undergo. Symptoms of depression, such as decreased energy and motivation, as well as cognitive impairment, will affect the patient's quality of life. Depression also causes patients to be non-compliant with diet and affects their therapy management, affecting blood glucose control.[12] Anxiety and depression are determinants of poor mental QoL, while the main determinants of poor physical quality include pain, depressive symptoms, and performance.[34,35]

Pain is another dimension that causes low EQ-5D-5L index scores. About 5.3% of patients reported extreme pain. Pain is a predictor of low utility value in patients with chronic leg ulcers.[12] About 24.1% of patients reported being unable to walk, 21.8% were unable to perform self-care, and 24.8% reported severe problems in daily activities (Table 3). The frequency of pain has a negative effect on social functioning and leisure activities. Pain limits patients from doing daily activities and communicating with friends or relatives. Therefore, a strategy is needed for pain management. Pain therapy support, both non-pharmacological and pharmacological, is necessary to improve patients' quality of life.

The strong correlation between the EQ-5D-5L index and DFS-SF indicates that the EQ-5D-5L questionnaire is valid for assessing utility (health-related quality of life) in patients with DFU. EQ-5D-5L strongly correlates with the dimensions of leisure and dependency/daily life (Table 4). Therapy for chronic diseases aims to improve HRQoL. The HRQoL should be addressed and assessed using validated measurement tools. Current clinical practice guidelines recommend annual foot examinations to prevent foot problems.[35] Promoting foot care management can prevent DFU and worsening foot problems. HRQoL assessment can detect problems in patients, thus helping in clinical management. Poor HRQoL is a risk factor associated with wound healing.[36]

This study has several limitations. First, utility assessment was only conducted once when the patient underwent DFU examination. Longitudinal measurements were not performed, so how utility changes based on disease progression remains unknown. Second, the study used a cross-sectional research design, so the number of patients based on the severity of DFU was not proportional. Third, the patient's clinical condition was assessed based on the Wagner grade recorded in the medical record, and no discriminant or convergent validation was performed based on the clinical condition of the DFU. Fourth, there was no HbA1c data at the time of the study, so the correlation between HbA1c levels and the utility index could not be determined.

CONCLUSION

The utility index in diabetic foot ulcer patients was 0.346 (SD = 0.494). The main problems in diabetic foot ulcer patients are mobility, self-care, and usual activities. There

are differences in utility index based on severity of DFU, history of amputation, and walking ability. The more severe the patient's severity, the lower the utility index.

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Statement of Authorship
All authors certified fulfillment of ICMJE authorship criteria.

CRediT Author Statement
TMA: Conceptualization, Methodology, Software, Validation, Investigation, Resources, Data curation, Writing – original draft preparation, Writing – review and editing, Visualization, Project administration, Funding acquisition; **AKF**: Project administration; Investigation; **DW**: Validation, Resources, Review; **YN**: Resources, Writing – review and editing.

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Datasets generated and analyzed are included in the published article.

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