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UTILITIES OF DIABETES PATIENTS WITH COMPLICATIONS IN A MEDICAL CENTER, THAI NGUYEN, VIETNAM

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ABSTRACT

Background: Complications are considered the critical contributors to lower health-related quality of life among diabetes patients. **Objectives:** This study aimed to estimate utility of diabetes patients and identify potential predictors of health-state utilities among these populations. **Methods:** A cross-sectional study was implemented to assess the health state utilities and potential predictors among diabetes patients who suffered from diabetes complications. The SF-36v2^{TM} was utilized to collect data regarding health-state utilities. Possible predictors of the utilities were assessed using a linear regression model. **Results:** Mean ±Standard deviation of the utility was 0.62±0.05. The predictors of health-state utilities were found including age (Coef. = -0.001, 95%CI -0.002; 0.000), blood glucose (Coef. = -0.008, 95%CI -0.013; -0.003), and insulin therapy (Coef. = -0.504, 95%CI -0.064; -0.045). **Conclusion:** The health-state utilities found among diabetes patients with complications in this study were comparable to recent investigations. Age, blood glucose levels, and insulin therapy were predictors of the health-state utility.

Keywords: Diabetes; Complication; Health-state utilities; Utility; Predictors.

INTRODUCTION

The prevalence of diabetes among adults aged 20 to 79 worldwide was 1.5% in the year 2021, and it is predicted to be 12.2% (78.3 million) in 2045[1]. Diabetes can lead to many complications such as diabetic retinopathy, kidney complications,

neurological complications, and infectious complications[2]. The quality of life of the diabetic patient is significantly impacted by the complications. Studies have revealed that diabetic patients with complications had lower quality of life than healthy individuals, even with the mildest complication[3]. Diabetes-mellitus related complications could be the key contributors to lower health-related quality of life of the patients[4,5].

To assess the outcomes of diagnosis and therapy, many outcome measures can be used as critical elements for disease management cost-effectiveness analysis. Health related Quality of Life (HRQoL) is one of the measures. Notably, precise assessments of diabetes patients' utilities can help health economists evaluate proposed diabetes care programs. Currently, relatively limited information about diabetes patients' health-state utilities is accessible in Vietnam.

Researchers have used the Quality Metrics' Short-form 36 version 2^{TM} (SF-36v2^{TM}) to gather HRQoL data[6]. This tool has also been used in diabetic patients' management in several countries[7-10]. This instrument has previously been validated in several Asian countries[11-14], particularly in Vietnam[15].

In this study, the SF-36v2^{TM} questionnaire was used to collect data from diabetes patients with at least one complication who were being under the management of the Medical Center of Thai Nguyen City to measure their HRQoL expressed in utilities. Besides, this study aimed to identify potential predictors of health-state utilities among the study population.

METHODS

Subjects: All confirmed diabetic patients with at least one diabetes complication and being managed by the Medical Center of Thai Nguyen City were invited to enroll in the study. Inclusion criteria were (1) diabetes patients being managed by the department and, (2) being diagnosed as having at least one of the diabetes complications by a doctor at the department and (3) able to respond to the questionnaire and (4) agree to enroll in the study.

Location: Diabetes patients who are managed at the Medical Center of Thai Nguyen City.

Timeline: Data was collected from 1 September to 30 November 2021.

Methods

Study design: A cross-sectional study was applied in this study.

Sample size: There was a total of 307 diabetes patients who satisfied the inclusion criteria among 1224 patients being managed by the medical center at the time of this study.

Variables

The following independent variables were collected: (1) demographic information including urban or rural residence, age, sex, occupation, education, marital status, perceived economic status, and marital status; (2) diabetes management-related variables such as duration from diabetes diagnosis time point, duration of receiving treatment, complications of diabetes, blood glucose and HbA1c concentration; insulin therapy (Yes/No). The dependent variables to assess health-state utilities was collected using the SF-36v2™.

Instruments and measurements: Some instruments can be used to measure utility scores among diabetes patients such as EQ-5D, SF-6D (SF-36v2), SD-6Dv2[16,17]. Particularly, original valuation of SF-36v2™ data was utilized by Brazier et al. to produce an algorithm with no potential mapping errors[6]. This algorithm has been recently reported to explain about 60% of the reasonable share of variances and as a reliable measurement of health impacts, particularly when only minor differences in health are expected[18], as in diabetes management. Therefore, the estimation of health utilities in this study was performed using Brazier et al.'s algorithm based on SF-36v2™ data and the Vietnamese version of SF-36v2™ was used to gather data on health status.

For the application of the algorithm, there were eleven specific questions in six domains of SF-36 were chosen to estimate health-state utilities: questions 3, 4 and 12 in the physical domain; questions 15 and 18 in the role domain; question 32 in the social domain; question number 21 and 22 in the pain domain; questions 24 and 28 in the mental domain; and question 27 in the vitality domain. Utilities were subsequently estimated based on responses

elicited by standard gambling techniques[18]. Procedures to acquire health utility scores using the algorithm were described in a recent study[15].

To mitigate information bias, investigators from Thai Nguyen University of Medicine and Pharmacy were trained to perform face-to-face interviews in both fundamental interview skills and interview structure based on the questionnaire. A practical component was also included to ensure that all the investigators had a comparable understanding and used the questionnaire consistently.

Data on patients' demographic characteristics were collected during interviews and diabetes management-related variables were gathered from participants' medical records.

Statistical analysis

Descriptive statistics included frequency, percentage, mean, and standard deviation. Since the utility score was normally distributed, independent T-test, and ANOVA were utilized to determine associations between the outcome and independent variables. The independent variables were gender, age group, education level, occupation, marital status, perceived economic status, time of diabetes diagnosis, duration of treatment, blood glucose level, HbA1c, BMI, and insulin therapy. A multivariate linear regression model with all the independent variables included for predictors determination. Normality of data, linearity assumption, autocorrelation, and multicollinearity were checked for the linear regression model. In case of multicollinearity occurred, the related variables were removed from the model. Data was analyzed by using SPSS Statistic for Windows, Version 23.0.

Ethical consideration

Those invited to complete the questionnaire were provided with a brief description of the study and its objectives. The participants were enrolled after they consented to participate and for the data provided to be used. No identifying information was collected. The study was approved by the Ethics Committee of Thai Nguyen University of Medicine and Pharmacy (No 1156/ĐHYD-HĐĐĐ).

RESULTS

Table 1. General characteristics of the participants (n=307)

Variables		n	%
Gender			
	Male	152	49.5
	Female	155	50.5
Age groups (years)			
	Under 50	25	8.1
	From 50 to 59	74	24.1
	Above 59	208	67.8
Occupation			
	Farmer	135	44.0
	Retired	72	23.5
	Freelancer	71	23.1
	Worker	15	4.9
	Officer	14	4.6
Education level			
	Primary school/None	12	3.9
	Secondary school	42	13.7
	High school	161	52.4
	College and above	92	30.0
Perceived self-economic status			
	Independence	163	53.1
	Partially independence	101	32.9
	Dependence	43	14.0
Marital status			
	Married	278	90.6
	Divorced/widow	23	7.5
	Single	6	1.9
Total		307	100

The baseline characteristics of 307 participants are shown in Table 1. Half of the participants were female (50.5%). Most of the patients were over 60 years old (67.8%). The education levels of

the participants were mainly high school (52.4%) and college and above (30.0%). The main occupations included farmer (44.0%), retired (23.5%), freelancer (23.1%).

Table 2. Characters regarding diabetes among the participants (n=307)

Variables		n	%
Duration from diabetes diagnosis to time of study (years)			
	Under 1	5	1.6
	From 1 to 5	137	44.6
	From 6 to 10	148	48.2
	Above 10	17	5.5
Duration of treatment			
	Under 1	7	2.3
	From 1 to 5	161	52.4
	From 6 to 10	126	41.0
	Above 10	13	4.2
Glucose			
	7.0 mmol/l or under	203	66.1
	Above 7.0 mmol/l	104	33.9
HbA1c			
	6.5% and above	272	88.6
	Under 6.5%	35	11.4
Complications			
	Cardiovascular	233	75.9
	Kidney	68	22.1
	Eyes	21	6.8
	Nerve	19	6.2
	Others	25	8.1
Number of complications			
	One	257	83.7
	Two	41	13.4
	Three	9	2.9

BMI			
	Under 18.5	15	4.9
	From 18.5 to 22.9	199	64.8
	23.0 and above	93	30.3
Insulin therapy			
	Yes	133	43.3
	No	174	56.7

Characters regarding diabetes management of the participants are shown in Table 2. The primary complications of the patients were cardiovascular (72.0%) and kidney complications (19.5%). A large proportion of the patients had blood glucose levels less than 7.0 mmol/l, while the HbA1c level at 6.5% or higher was 88.6%. Most patients had been diagnosed and received diabetic treatments from 1 to 10 years. Nearly half of them received insulin therapy (43.3%).

Table 3. Distribution of health-state utilities by participants' characteristics (n=307)

Variables		**Mean**	**Standard deviation**	**p-value**
Health-state utility		0.62	0.05	
Age groups (years)				
	Under 50	0.67	0.07	<0.001
	From 50 to 60	0.63	0.04	
	Above 60	0.6	0.05	
Gender				
	Male	0.62	0.04	0.022
	Female	0.61	0.05	
Education level				
	Primary school/None	0.61	0.03	0.916
	Secondary school	0.62	0.05	
	High school	0.62	0.05	
	College and above	0.62	0.06	
Occupation				

	Officer	0.67	0.04	<0.001
	Freelancer	0.63	0.04	
	Farmer	0.61	0.04	
	Worker	0.66	0.09	
	Retired	0.6	0.05	
Marital status				
	Single	0.67	0.05	0.052
	Married	0.62	0.05	
	Divorced/widow	0.62	0.06	
Perceived self-economic status				
	Independence	0.62	0.06	0.082
	Partially independence	0.61	0.04	
	Dependence	0.6	0.05	
Duration from diabetes diagnosis to time of study (years)				
	Under 1	0.72	0.08	<0.001
	From 1 to 5	0.64	0.05	
	From 6 to 10	0.6	0.05	
	Above 10	0.59	0.04	
Duration of treatment				
	Under 1	0.69	0.08	<0.001
	From 1 to 5	0.63	0.05	
	From 6 to 10	0.6	0.05	
	Above 10	0.59	0.04	
Glucose				
	7.0 mmol/l or under	0.63	0.05	<0.001
	Above 7.0 mmol/l	0.59	0.05	
HbA1c				

	6.5% and above	0.62	0.05	0.006
	Under 6.5%	0.59	0.04	
Complications				
	Cardiovascular	0.63	0.05	0.01
	Kidney	0.58	0.06	<0.001
	Eyes	0.58	0.04	0.004
	Nerve	0.63	0.07	0.317
	Others	0.57	0.06	<0.001
Number of complication				
	One	0.62	0.05	<0.001
	Two	0.59	0.05	
	Three	0.53	0.06	
BMI				
	Under 18.5	0.61	0.03	0.005
	From 18.5 to 22.9	0.61	0.05	
	23.0 and above	0.63	0.05	
Insulin therapy				
	Yes	0.58	0.04	<0.001
	No	0.65	0.04	

The distribution of health-state utilities by the participants' characteristics is revealed in Table 3. Mean ± Standard deviation of the utility was 0.62±0.05. In terms of baseline characteristics, mean utility was significantly different between age groups ($p<0.001$), genders ($p<0.022$), and BMI ($p=0.005$). Occupation was found significantly associated with health-state utility ($p<0.001$). Perceived self-economic status and marital status were not associated with health-state utility among the study participants. Regarding diabetes management, mean health-state utilities were significantly associated with duration from diagnosis time point, duration of treatment, blood glucose level, types of complications, insulin therapy (all $p<0.001$), and HbA1c level ($p=0.006$).

Table 4. Predictors of health-state utilities in the study participants (n=307)

	Coef.	95% CI (Lower; upper)	p-value
Age (years)	-0.001	-0.002; 0.00001	0.053
Gender			
Female	Ref.		
Male	0.004	-0.005; 0.012	0.427
BMI	0.001	-0.002; 0.003	0.586
Glucose (mmol/l)	-0.008	-0.013; -0.003	0.003
HbA1c (%)	0.0003	-0.007; 0.008	0.946
Cardiovascular complication			
No	Ref.		
Yes	0.01	-0.009; 0.032	0.279
Kidney complication			
No	Ref.		
Yes	-0.0002	-0.022; 0.022	0.984
Eyes complication			
No	Ref.		
Yes	0.015	-0.008; 0.039	0.19
Nerve complication			
No	Ref.		
Yes	0.022	-0.002; 0.046	0.072
Number of complications			
One	Ref.		
Two	-0.004	-0.024; 0.015	0.665
Three	-0.046	-0.082; -0.011	0.011
Duration from diagnosis			
Less than 5 years	Ref.		
From 5 years and above	0.005	-0.01; 0.022	0.501
Duration of treatment			
Less than 5 years	Ref.		
From 5 years and above	-0.008	-0.023; 0.008	0.321
Insulin therapy			

	No	Ref.		
	Yes	-0.054	-0.064; -0.044	<0.001
Occupation - Officer				
	No	Ref.		
	Yes	0.022	-0.002; 0.046	0.075
Occupation - Farmer				
	No	Ref.		
	Yes	0.001	-0.013; 0.015	0.912
Occupation - Worker				
	No	Ref.		
	Yes	0.009	-0.014; 0.032	0.426
Education level				
	High school or under	Ref.		
	College and above	-0.009	-0.025; 0.006	0.224
Perceived economic status				
	Dependence/partially independence	Ref.		
	Independence	0.008	-0.003; 0.019	0.146
Marital status				
	Single/Divorced/Widow	Ref.		
	Married	0.004	-0.01; 0.019	0.556

Results from the multivariate analysis revealed the predictors significantly associated with the health-state utility were illustrated in Table 4. Health-state utility was lower in higher age patients (Coef. = -0.001, 95%CI -0.002; 0.000). Blood glucose was negatively associated with the utility (Coef. = -0.008, 95%CI -0.013; -0.003). The utility of those receiving insulin therapy was lower than their counterparts (Coef. = -0.504, 95%CI -0.064; -0.045)

DISCUSSION

The mean score of the participants' health-state utility was lower than in the previous studies conducted on general diabetes patients[19]. Factors affecting the participants' utility included age, insulin therapy, and blood glucose concentration.

The mean of the utility among the participants was 0.62. This result was similar to the result from the work of Paul Glasziou which was conducted on diabetic patients with eye complications, cardiovascular, and stroke, which was 0.68[20]. Ollvan Soilli's study in type-2 diabetes patients with complications in Norway using EQ-5D resulted in a utility score of 0.73[21]. The differences in the utility score could be due to the difference in the instruments used. The SF-36 questionnaire was used in this study and Paul Glasziou's research and the utility scores were quite similar in both studies. In addition, both the EQ-5D and the SF36v2™ were applied in Paul Glasziou's study, and the EQ-5D resulted in a utility score of 0.8. It can be seen that utility scores based on EQ-5D tended to be higher than those from other instruments. Moreover, the differences in study populations and definitions of the complications might contribute to variations in the utility scores between studies.

In the study of Elbert S. Huang on quality of life related to complications and treatment, the utility score of patients having anginas (cardiovascular) was 0.64, that of the neurological complication group was 0.66, the retinopathy complication group was 0.53, and the kidney complication group was 0.64[22]. In this study, the utility scores among patients with cardiovascular/neurological/kidney complications were higher than those with retinal complications, but the difference is relativelysmall. Similar to the results of this study, our findings revealed the similarities in the utility scores between groups of patients categorized by types of complications including cardiovascular, neurological, and renal complications.

According to M M Brown, the mean health utility score for the diabetic retinopathy group was 0.77[23]. In the review paper by Sanjay Sharma, diabetic retinopathy was from 0.77 to 0.8[24]. In our study, the health utility score among patients with eye complications was 0.62+/-0.04, which was lower than in previous studies. Again, it may be different due to the definition of complication, the previous studies considered diabetic retinopathy but we defined all categories which belong to the eyes.

In the study of K Venkataraman which used a 100-point scale to the outcomes, there was also a decrease in the quality of life score

in the patients having complications, peripheral neurologic complications. The patients with peripheral neuropathy complications witnessed the highest reduction in quality of life (11.46 points, $p < 0.001$), the microvascular and macrovascular complication group and the coronary heart complication were both decreased by 4.67 points, and there was a decline of 4.46 points in retinopathy complication group[25]. It is unable to compare the results from this study and our findings due to the different algorithms being used. However, both studies found that peripheral neuropathy complications caused the highest decline and had the most significant impact on the quality of life of the patients.

Our study found a significant difference in the utility between age groups in which the under 50 years old group had a higher utility score than others. The multivariate analysis also revealed a significant negative correlation between age and quality of life. Nguyen Ngoc Tam's study, which used the WHOQoL-Bref questionnaire to measure the quality of life of diabetic patients with kidney complication, showed that the average quality of life score of the group over 60 years old in all physical, mental, and environmental aspects were decreased compared with the group under 60 years old ($p<0.05$)[9]. The results from the study of W. Ken Redekop also saw a similar patent that the quality of life score among the group under 50 years old was 0.79, meanwhile, the score among the group over 70 was only 0.7[26]. John Yfantopoulos also found that older age was an important factor contributing to the reduction in the quality of life of the patients[27]. Miodrag Stojanovic in Serbia compared the quality of life between diabetes patients with and without complications, the multivariate linear regression model showed that the coefficient of age was - 0.289 ($p<0.001$), which means that there was a statistically significant negative correlation between age and the quality of life[28]. Therefore, it can be seen that there is an inverse correlation between age and the utility scores in several countries. It might be because the younger people would have better health and disease tolerance than the older people, so they could enjoy a better quality of life.

In our study, insulin therapy was associated with the utility scores that the participants who received insulin therapy had lower utility scores compared to those getting treatment without insulin. This was also found in Ping Zang's study, received insulin treatment group saw a reduction in quality of life[29]. John Yfantopoulos' study found that one important factor that reduced the quality of life among the patients was the increase in the duration of insulin therapy[27]. In contrast, recent findings reported significant quality of life improvements in patients who were receiving insulin glargine in combination with oral antidiabetic agents compared to those who used oral antidiabetic agents alone, another study assessed the effects of intensive multi- therapy on quality of life among patients with type 2 diabetic patients and found an improvement in quality-of-life scores among patients who started an insulin therapy[30]. On the one hand, insulin helped to improve quality of life by leading to better glycemic control, which is positively related to the quality of life levels. However, the difference may be due to some aspects. First, the reduction in the utility could be because of the difference in methods, doses, duration of insulin use, and combination treatments/support applied in the above studies. Secondly, the participants in our study were mainly receiving insulin therapy via an inconvenient way (insulin injections) instead of insulin pens or inhaled insulin. Finally, it could be because of the side effects of insulin injections.

Our findings showed a negative correlation between blood glucose level and the utility score in which the utility among the high blood glucose group was lower than that of the remaining group. The findings of Enwu Long's study agreed with the results from this study that diabetic patient's quality of life was generally lower than that of prediabetic and normal glycemic level populations[19].

Other factors such as education level, occupation, and marital status positively correlated with the quality of life score. Still, these factors are not statistically significant, similar to the results from Miodrag Stojanovic with $p > 0.05$[28].

Due to scarce resources, capacity, and funds, this study was conducted in only one medical center with small sample size,

therefore, it might not possible to generalize the results to the entire diabetes population with complications.

CONCLUSION

The health-state utilities among diabetes patients with complications in Thai Nguyen, Vietnam, were comparable to the findings in both previous international and national investigations. The older patients had higher glucose levels, and getting insulin treatment, had poorer health status utilities than the reference groups, respectively. However, further research with larger sample size and conducted in other locations are needed. The results from this study can be utilized to perform a cost-effectiveness analysis of diabetic interventions in the future. Furthermore, this can serve as a reference for other comparable communities regarding social and economic elements.

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