

# The Effect of Outcome Therapy to the Quality of Life Type 2 Diabetes Mellitus Patient on West Nusa Tenggara Hospital, Indonesia

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## ABSTRACT

**Background:** Diabetes is a chronic disease that requires long-term treatment. The results of therapy will indirectly affect the quality of life of patients with diabetes mellitus. This study was done to determine the effect of therapeutic results on the quality of life of patients with type 2 diabetes mellitus (T2DM). **Methods:** This study uses a cross-sectional design. The inclusion criteria of this study were T2DM patients aged 45-65 years with ICD code X E. 11 and the subjects in this study involved 60 T2DM outpatients. This study was divided into 2 groups (oral hypoglycaemic and insulin group). Quality of life data was collected using the SF 36 questionnaire. **Results:** The results of this study showed no significant differences between the quality of life of T2DM patients in both groups. There were a significant relationship between Physical functioning domain with HbA1c and FBG, emotional domain with HbA1c, general health domain with FBG, physical

role domain with FBG, mental health domain with HbA1c and bodily pain domain with HbA1c and FBG. **Conclusion:** Outcome therapy affects the quality of life of T2DM patients in HbA1c and FBG.

**Key words:** Outcome therapy, Quality of life, SF-36, Type 2 diabetes mellitus, Indonesia.

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## INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a chronic, non-curable chronic disease that can reduce Health-Related Quality of Life (HRQOL) and cause less optimal physical and mental function and premature death.<sup>1,2</sup> The prevalence of people with diabetes in Indonesia shows a tendency to increase, from 5.7% (2007) to 6.9% (2013). In 2015, Indonesia was ranked seventh in the world for the highest diabetics in the world along with China, India, the United States, Brazil, Russia and Mexico with an estimated 10 million people with diabetes.<sup>3</sup>

Diabetic patients need continuous therapy so that the effectiveness and side effects of treatment can affect the quality of life.<sup>4</sup> Quality of life is a health outcome related to the patient's condition from psychological, social and emotional perspectives.<sup>5</sup> HRQOL refers to the physical, psychological and social health domains that are influenced by one's experience, beliefs, expectations and perceptions, therefore health care providers must strive to understand the physical, emotional and social effects of chronic diseases such as diabetes.<sup>6</sup> Many factors that affect the quality of life of patients with diabetes mellitus include complications, hypertension, duration of diabetes, physical exercise, diet with more red meat, diet control, glucose check frequently and depression.<sup>5-7</sup> Quality of life has become a relevant measurement tool in clinical trials, its use is increasingly widespread and developing as a valid and beneficial indicator in a medical study. Quality of life can be seen from an individual, group and large population of patients.<sup>8</sup>

Quality of life can be measured by instruments such as questionnaires. Short Form-36 (SF-36) is one instrument that can be used to measure the quality of life, practical and has good psychometric properties.<sup>9</sup> SF 36 has been widely used with clinical studies involving a diverse population of patients by assessing eight health concepts.<sup>10</sup> This study aimed to

determine the effect of outcome therapy on the quality of life-based on SF 36 in patients with T2DM.

## MATERIALS AND METHODS

A cross-sectional study was carried out in West Nusa Tenggara Hospital during April-July 2017 in T2DM outpatients. The inclusion criteria were T2DM patients received oral antidiabetics or insulin at least 6 months with ICD code X E.11 before quality of life measurements and were willing to sign the informed consent form. Exclusion criteria are deaf patient, illiterate and pregnant patient. Subjects who met the inclusion criteria were 60 T2DM patients. They were classified into two groups namely: (i) oral antidiabetic therapy and (ii) insulin therapy. This research has been approved by the ethics committee of West Nusa Tenggara Hospital, Indonesia.

Quality of life was measured by using an Indonesian version of Short-Form 36 (SF-36) has been validated. Validation the questionnaire was carried out via conducting a pilot study. The pilot study was conducted with 20 patients. The reliability analysis of the questionnaire was performed by calculating Cronbach alpha value. The results of the validity and reliability test of the SF-36 questionnaire to measure the quality of life in 20 T2DM can be seen in Table 1. The domain which includes the SF-36 were domains of physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional and mental health. The item and scale of the SF-36 Health Survey were built by using the like method of the summed rank. Answers for each question are given scoring. This score is then added to generate a standard score scale for each later health concept transformed to a scale of 0-100, with a value of 100 as a quality of life best.<sup>11</sup>

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**Table 1: Validity and reliability test results of the SF-36 health questionnaire survey.**

Domain	Question item	r-count	Criteria	Reliability Cronbach's alpha	Criteria
General health	Q1	0,555	Valid	0.707	Reliable
	Q2	0,718	Valid		Reliable
	Q33	0,637	Valid		Reliable
	Q34	0,571	Valid		Reliable
	Q35	0.626	Valid		Reliable
	Q36	0,703	Valid		Reliable
	Q3	0,492	Valid		Reliable
	Q4	0,523	Valid		Reliable
	Q5	0,715	Valid		Reliable
	Q6	0,720	Valid		Reliable
	Q7	0,796	Valid		Reliable
	Q8	0,502	Valid		Reliable
Physical functioning	Q9	0,644	Valid	0.731	Reliable
	Q10	0,906	Valid		Reliable
	Q11	0,906	Valid		Reliable
	Q12	0,853	Valid		Reliable
	Q13	0,759	Valid		Reliable
	Q14	0,843	Valid		Reliable
	Q15	0,919	Valid		Reliable
	Q16	0,851	Valid		Reliable
	Q17	0,734	Valid		Reliable
	Q18	0,856	Valid		Reliable
	Q19	0,903	Valid		Reliable
	Q20	0,746	Valid		Reliable
Role physical	Q21	0,903	Valid	0.932	Reliable
	Q22	0,903	Valid		Reliable
Role emotional	Q23	0,551	Valid	0.914	Reliable
	Q24	0,610	Valid		Reliable
Social functioning	Q25	0,570	Valid	0.854	Reliable
	Q26	0,626	Valid		Reliable
Bodily pain	Q27	0,506	Valid	0.943	Reliable
	Q28	0,928	Valid		Reliable
Vitality	Q29	0,913	Valid	0.718	Reliable
	Q30	0,570	Valid		Reliable
Mental health	Q31	0,626	Valid	0.856	Reliable
	Q32	0,506	Valid		Reliable
	Q33	0,928	Valid		Reliable
	Q34	0,881	Valid		Reliable
	Q35	0,396	Valid		Reliable

Data collection was done by an interview with SF-36 questionnaire and medical records or patient status which include name, age, gender, diagnosis, treatment and laboratory data. Data were analyzed descriptively to describe patients' characteristics. The Independent sample t-test was used to analyze the difference of quality of life domains differences among the two groups and linear regression analysis was conducted to analyze the association between patient's quality of life and outcome therapy T2DM patients.

## RESULTS

T2DM patients who met the inclusion and exclusion criteria in this study were 60 people. Table 2 shows list the subject characteristics. Most of the study subject were female (61.67%), had an education level up to senior high school (80%), was aged  $\geq 55$  years (61.67%), who had occupation (68.33%), had an average treatment duration of more than equal 5 years

**Table 2: Subject characteristic.**

Characteristic	N	%	
Gender	Male	23	38.33
	Female	37	61.67
Education	Up to Senior High School	48	80.00
	Undergraduate	12	20.00
Age	< 55 years old	23	38.33
	$\geq 55$ years old	37	61.67
Occupation	Jobless	19	31.67
	Occupied	41	68.33
Treatment duration in years	< 5 years	21	35.00
	$\geq 5$ years	39	65.00
Treatment	Oral antidiabetic	27	45.00
	Insulin	33	55.00

**Table 3: Quality of Life Domains Differences between Treatment Groups.**

Domain	Therapy		P Value
	Oral hypoglycemic	Insulin	
Physical functioning	76.85 $\pm$ 30.00	76.81 $\pm$ 30.48	0.921
Role emotional	70.07 $\pm$ 27.78	63.27 $\pm$ 25.52	0.328
Social functioning	84.00 $\pm$ 26.43	91.60 $\pm$ 17.15	0.204
General health	74.77 $\pm$ 11.69	72.36 $\pm$ 12.71	0.451
Role physical	76.85 $\pm$ 42.13	71.21 $\pm$ 41.51	0.402
Mental health	76.51 $\pm$ 42.18	68.66 $\pm$ 44.83	0.444
Bodily pain	68.00 $\pm$ 27.05	65.93 $\pm$ 29.45	0.850
Vitality	50.74 $\pm$ 28.34	48.03 $\pm$ 29.23	0.731
Average of QoL	71.85 $\pm$ 20.65	69.33 $\pm$ 19.61	0.631

(65%) and the dominant treatment was insulin therapy (55%). Table 3 show quality of life domains differences between treatment groups. The analysis show there were not significant among two groups in each domain quality of life. Table 4 show the results of linear regression analysis the association between patients' quality of life and outcome therapy T2DM patients. The results of the analysis indicate that quality of life can affect the outcome therapy such as HbA1c and FBG.

## DISCUSSION

In this study, there were 60 T2DM patient's outpatient in the provincial West Nusa Tenggara hospitals in April-July 2017 who were interviewed regarding the quality of life. Based on the results of the study, the average quality of life of patients receiving oral hypoglycemic has a higher quality of life (71.85  $\pm$  20.65) than patients who received insulin (69.33 $\pm$ 19.61). However, statistically using the independent sample t-test showed no significant differences ( $p= 0.631$ ).

The measurement of quality of life with SF-36 in this study includes eight domains, namely physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional and mental health.<sup>12</sup> The results of measurements of quality of life in this study based on each domain showed no significant differences between the two groups. In contrast to previous studies using the Diabetes Quality of Life Clinical Trial Questionnaire (DQLCTQ) to measure the quality of life of T2DM

**Table 4: Linear Regression Analysis Results between Quality of Life and Outcome Therapy.**

Domain	HbA1c	FBG	2-h PG
Physical functioning	0.023*	0.007*	0.490
Role emotional	0.006*	0.199	0.619
Social functioning	0.629	0.385	0.495
General health	0.061	0.003*	0.477
Role physical	0.053	0.013*	0.985
Mental health	0.024*	0.086	0.571
Bodily pain	0.049*	0.004*	0.545
Vitality	0.077	0.439	0.541
Average of QoL	0.003*	0.004*	0.980

\**p* value < 0.05.

patients, there were differences between the three therapy groups used in the domain of a physical function, energy, satisfaction and treatment effects.<sup>13</sup>

Anti-diabetes therapy can affect the quality of life both negatively and positively. negatively impact can improve symptoms of low blood sugar and positively impact can reduce symptoms of high blood sugar.<sup>14,15</sup> HbA1c, FBG and 2H PG are the most widely used clinical indicators for diabetic patients.<sup>16</sup> This study shows that there were a relationship between HbA1c and FBG on the quality of life of T2DM patients, different from previous studies, there was a statistically significant relationship between the results of therapy (2H PG) and the quality of life of diabetic patients.<sup>17</sup> HbA1c and FBG were not accurate to represent the level of blood sugar control because they do not reflect what happens after eating. 2H PG has a strong correlation with microvascular, macrovascular and cardiovascular compared to HbA1c and FBG.<sup>18</sup> However, the American Diabetes Association recommends measuring HbA1c as a substitute for fasting blood glucose for the diagnosis of diabetes. HbA1c is an important indicator for seeing long-term glycemic control up to three months earlier.<sup>19,20</sup>

Blood sugar levels can affect the quality of life, the more controlled blood sugar levels, the better the quality of life for T2DM patients.<sup>21</sup> In addition, controlling blood sugar levels is very important to measure the quality of life of T2DM patients because it can affect the functional health, psychological and social of patients.<sup>22</sup> The limitation of this study is the limited number of research samples and requires a long time to explain the contents of the questionnaire to patients.

## CONCLUSION

We found that HbA1c and FBG can affect the quality of life of T2DM patients.

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## CONFLICT OF INTEREST

The authors declare no conflict of interest.

## ABBREVIATIONS

**T2DM:** Type 2 diabetes mellitus; **ICD:** International Classification of Diseases; **SF 36:** Short-Form 36; **HbA1c:** Hemoglobin A1c; **FBG:** Fasting Blood Glucose; **HRQOL:** Health-Related Quality of Life; **DQLCTQ:** Diabetes Quality of Life Clinical Trial Questionnaire; **2-h PG:** 2 hour plasma glucose; **QOL:** Quality of Life.

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