Original Research Article

Profile and factors associated with quality of life among outpatients with type 2 diabetes mellitus in Bali, Indonesia

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Abstract

Purpose: To map the quality of life (QoL) profile of type 2 diabetes mellitus (T2DM) patients and identify its influencing factors in Bali Province.

Method: This study was conducted in the Pharmacy Department of two Government Hospitals in Bali Province, Indonesia. The 89 participants were T2DM patients undergoing outpatient therapy from November 2023 to February 2024. A cross-sectional design was used to determine the QoL of T2DM patients using SF-36 questionnaire. The medical and demographic data investigated were gender, age, BMI, glycemic profile, duration of DM, comorbidities, type of diabetes medication and history of severe hypoglycemia.

Results: The quality-of-life profile of T2DM patients in Bali Province was generally poor while undergoing diabetes therapy (QoL score: 44.77 ± 24.71). The influential factors that could be modified included a history of severe hypoglycemia, BMI, glycemic control and comorbidities, while the non-modifiable factor was age.

Conclusion: Patients with T2DM undergoing therapy at the hospital polyclinics outpatients unit in Bali Province, Indonesia during the period of study had a relatively low QoL. Factors contributing to these outcomes include patients' history of severe hypoglycemia, age, diabetes complications, glycemic control and BMI. It would be necessary to analyze the influence of patients' behavior and motivation in receiving health services, support system conditions, compliance, and other social conditions on QoL.

Keywords: Type 2 Diabetes Mellitus, Quality of life, Factor, Profile, Modifiable

INTRODUCTION

Diabetes mellitus (DM) is a metabolic disease characterized by hyperglycemia due to impaired insulin secretion, resistance, or both. Chronic hyperglycemia in DM patients is closely related to various organ damage and dysfunction, including the nerves, kidneys, eyes, heart and blood vessels [1,2]. In 2021, Indonesia ranked fifth worldwide for the number of people with DM after China, India, Pakistan, and the United States [1,3]. Complications from DM are the third highest cause of death in Indonesia, after coronary heart disease and stroke. Indonesia also has the second-highest percentage of deaths due to diabetes after Sri Lanka [1,3,4].

Intensive blood sugar management is crucial for people with diabetes to prevent complications. Moreover, it can reduce the incidence of patients admitted to the hospital and lower death rate [5,6].

Quality of life (QOL) is a subjective perception by patients from various aspects regarding the disease. The QoL of DM patients can be influenced by physical health, psychological conditions, level of dependence on social relationships, and patients' relationship with the environment [2,7,8]. Patients suffering from DM are expected to maintain or even improve QoL, as they tend to have a lower QoL due to disease progression [9,10]. A study showed that 66.2 % of DM patients with foot ulcers had a relatively low QoL [11]. Another study reported that 54.2 % of T2DM patients had physical health problems, 62.5 % had psychological issues, and 66.6 % had problems with social relationships [11,12].

The low QoL affect the continuity of therapy, increasing risk of morbidity and death [13,14]. Clinicians, patients, and caregivers should consider factors that impact QoL, specifically the modifiable factors. Therefore, DM sufferers are expected to maintain a good QoL despite having chronic and progressive disease [9,10]. In the province of Bali, there is currently no data on QoL profile of DM patients or the influencing factors. The current study aimed to fill this gap by profiling and analyzing factors affecting DM patients' QoL. The results would provide valuable information to clinicians, patients and caregivers in order to focus on modifiable factors and maintain an excellent QoL.

METHODS

Study setting and participants

This study was conducted in the Pharmacy Department of two Government Hospitals in Bali Province, located in Badung and Buleleng districts, Indonesia. The participants were T2DM patients undergoing outpatient therapy. Patients receiving antihyperglycemic medication were given the pretested questionnaire when the pharmacist filled out prescriptions. This study received ethical approval from two commissions, namely the ethical commission of Buleleng District Government, Bali Province (approval no. 019/EC/KEPK-RSB/V/2023) and Medical Faculty Ethical Commission of Udayana University-Bali (approval no. 027/UN14.2.2.VII.14/LT/2024). Participants were included in the study after signing an informed consent form. All procedures were carried out by following the provisions in the Declaration of Helsinki [15].

Inclusion criteria

Inclusion criteria were T2DM patients aged > 30 years; those in stable condition to undergo outpatient treatment and those using at least one antidiabetic agent.

Exclusion criteria

Patients who did not provide complete information, had incomplete medical records or with inconsistent observable data were excluded.

Data collection and sample size

Data collection was carried out from November 2023 to February 2024 through direct observation of the participants during monthly health control at the Hospital Polyclinic. Supporting data were obtained from patients' medical records. The minimum sample size was determined using a cross-sectional design formula, requiring a minimum of 80 T2DM patients to adequately represent the population.

Study design

This is a cross-sectional study. Outpatients with Type 2 Diabetes Mellitus (T2DM) were observed for QoL, medical history, and demographic data. The QoL was analyzed to identify predictors with significant influence. In addition, the results were reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for cross-sectional design [16,17].

Subjects' recruitment and characteristics

During the observation period, 112 patients met the criteria, but only 89 were included and analyzed for the final stage. Patient recruitment flow chart is presented in Figure 1. These patients were mapped into a demographic profile, as shown in Table 1. The number of males and females was distributed proportionally, with a majority in the older adult age group.

Evaluation of parameters/indices

Demographic variables and medical history

Demographic variables and medical history observed were gender, age, body mass index (BMI), glycemic profile (HbA1C), DM duration, comorbidity, medication and history of severe hypoglycemia.
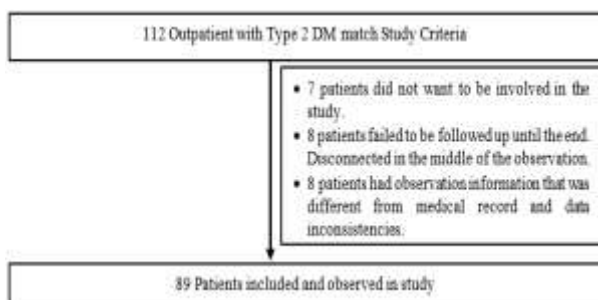
Figure 1: Flowchart of subject recruitment in study during the observation period

Quality of life

The QoL of T2DM patients was determined using SF-36 QoL instrument. This instrument evaluated physical functioning, mental health, social functioning, general health, physical fitness, emotional role, pain and vitality. The SF-36 instrument categorized QoL into five aspects, namely perfect (score 100), excellent (score 80 - 99), good (score 56 - 79), low (score 1 - 55) and limited/disabled (score 0) [18,19]. Analysis focused on the relationship between patients' QoL and medical history profile to determine the independent variables influencing QoL.

Data analysis

Data analysis was carried out both descriptively and analytically. Descriptive analysis was used to present the QoL profile of all participants, while analytical analysis examined the differences in QoL scores based on demographic clusters and medical history. Effect size and correlation analyses were conducted to assess the impact of independent variables on QoL. Furthermore, a parametric *t*-test was used for normal and homogeneous data distribution, while Mann-Whitney U and Chi-Square analyses were used for non-parametric analysis. Spearman Rank Test was used to evaluate the relationship between independent variables and QoL. Odds ratio (OR) analysis was also carried out to determine the effect size of independent variables on QoL.

RESULTS

QoL profile

The QoL of T2DM patients was categorized into two, namely good (score 56 - 100) and poor (score 0 - 55). This categorization aimed to simplify stratification, focusing on predictors that impact QoL. In general, QoL of T2DM patients was determined to be in the poor category, as shown in Figure 2 and Table 2. Moreover, the dimensions of physical functioning and mental

health were relatively good. This showed that T2DM patients undergoing outpatient therapy had relatively good physical function even though general fitness was not optimal. One dimension considered good was mental health, contributing to patients' adherence to monthly treatments at the hospital polyclinic. Pain was QoL dimension with the lowest score (33.68 ± 12.81), as all patients experienced pain related to diabetes and comorbidities. Physical fitness (40.17 ± 51.64) and vitality (41.38 ± 21.42) were also rated low.
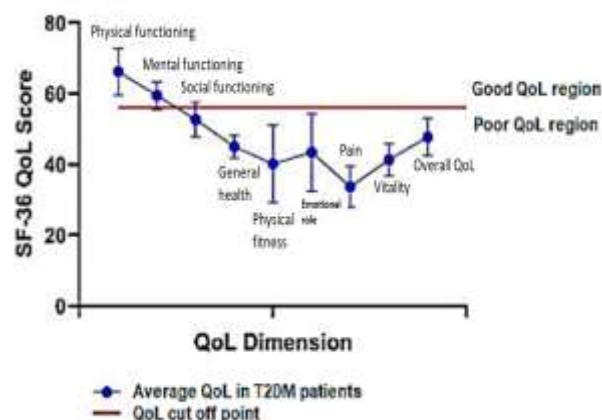

Figure 2: General QoL profile in outpatient T2DM

QoL scores

A more in-depth analysis of QoL of T2DM patients was carried out by groups based on demographic characteristics and medical histories such as gender, age, BMI, glucose control (HbA1C), DM duration, comorbidities, medication history and history of severe hypoglycemia. The QoL scores according to these groupings were subsequently analyzed using Mann-Whitney U test and independent *t*-test. The results are presented in Tables 2 to 7. There was no significant relationship between gender and QoL, as both males and females had similar scores ($p > 0.05$), which were generally poor. However, age grouping showed that adult T2DM patients between 30 - 55 years had a significantly better QoL than older adults (>55 years) ($p = 0.001$). Adults had better scores in the dimensions of mental health, social functioning, physical fitness, emotional role and vitality. With respect to the BMI and sugar control (HbA1C), similar results were obtained, where T2DM patients with normal BMI and controlled blood glucose (HbA1C < 7 %) had a better QoL than those with overweight or obese BMI and uncontrolled blood glucose (HbA1C > 7 %). Patients with controlled BMI and sugar outperformed others across all dimensions of QoL.

Table 1: T2DM patient's demography characteristic

Characteristic	Category	Number (n)	Percentage (%)
Gender	Male	44	49
	Female	45	51
Age (year)	30-35	2	2
	36-45	11	12
	46-55	24	27
	56-65	25	28
	>65	27	30
BMI (kg/m^2)	Normal (<25)	8	9
	Overweight (25-30)	49	55
	Obese (>30)	32	36
HbA1C (%)	Controlled (<7)	8	9
	Uncontrolled (>7)	81	91
DM duration (years)	0-5	24	27
	>5	65	73
Comorbidity	Without complication	8	9
	Neuropathy	61	69
	CVD	18	20
	CKD	2	2
DM medication	Metformin	30	34
	Metformin + SGLT2-I	6	7
	Metformin + DPP4-I	12	13
	Sulfonylurea	22	25
	Insulin rapid	19	21
History of severe hypoglycemia	Yes	58	65
	No	31	35

Tabel description: DM (diabetes mellitus); CVD (cardiovascular diseases), CKD (chronic kidney diseases); BMI (body mass index); SGLT2-I (sodium-glucose co-transporter 2 inhibitors); DPP4-I (dipeptidyl peptidase-4 inhibitors) SU (sulfonylurea), n (number).

Table 2: Comparative analysis of QoL scores based on gender grouping

QoL variable	Male (n=44)		Female (n=45)		*P*-value	Type of analysis
	Average QoL score	QoL status	Average QoL score	QoL status		
Physical functioning	63±32	Good	69±28	Good	0.489	MWU
Mental health	61±18	Good	58±23	Good	0.970	MWU
Social functioning	49±30	Poor	56±24	Good	0.164	MWU
General health	44±20	Poor	46±19	Poor	0.533	MWU
Physical fitness	39±20	Poor	41±49	Poor	0.798	MWU
Emotional role	43±50	Poor	44±49	Poor	0.884	MWU
Pain	34±26	Poor	33±23	Poor	0.821	MWU
Vitality	41±23	Poor	42±20	Poor	0.840	*t*-Test
Overall	**47±24**	**Poor**	**49±24**	**Poor**	**0.527**	**MWU**

QoL (quality of life), n (number), MWU (Mann Whitney U Test), T-Test (Independent Pair T-Test).

Based on diabetes duration grouping, T2DM patients who were newly diagnosed (0 - 5 years) had a better QoL compared to diabetes survivors with a duration > 5 years (*p* = 0.011). Newly diagnosed T2DM patients were superior in social functioning and general health dimensions compared to chronic sufferers with DM duration > 5 years. In the comorbid group, patients with comorbidities had worse QoL than patients without comorbidities (*p* = 0.001), which were superior in all dimensions of QoL.

In groups based on the type of medication used, patients were classified into those using antidiabetic drugs with a high risk of hypoglycemia (rapid-acting insulin or sulfonylureas agent and those using non-insulin-sulfonylurea agents (biguanide, DPP4-I, and SGLT2-I). There was no significant difference in QoL (*p* > 0.05) between the two groups, although the group using insulin and sulfonylureas scored lower in the social functioning dimension. The medication used to control blood sugar did not significantly affect patients' QoL, although effective blood regulation with medication was important for maintaining good QoL.

A significant difference was found among patients grouped by a history of severe hypoglycemia. Patients with T2DM who

experienced an episode of severe hypoglycemia had a worse QoL compared to those without the history ($p = 0.001$). Moreover, patients who had not experienced hypoglycemia were superior in all dimensions of QoL compared to other groups.

Size effect and correlation analysis

Proportion data were used to evaluate the effect size and correlation between independent variables influencing QoL of T2DM patients. The results of the analysis are presented in Table 8. Factors that significantly influenced QoL were age, BMI, sugar control, comorbidities and history of hypoglycemia ($p < 0.05$). Moreover, there was no significant relationship between QoL and gender, duration of diabetes and the type of medication used during outpatient care ($p > 0.05$).

Table 3: Comparative analysis of QoL scores based on age grouping

QoL variable	Adults (30-55 years old) (n=37)		Older adult (>55 years old) (n=52)		*P*-value	Type of analysis
	Average QoL score	QoL status	Average QoL Score	QoL Status		
Physical functioning	80±23	Good	56±31	Good	0.001*	MWU
Mental health	66±18	Good	55±21	Poor	0.007*	MWU
Social functioning	63±26	Good	45±26	Poor	0.002*	MWU
General health	55±20	Poor	38±16	Poor	0.001*	MWU
Physical fitness	68±34	Good	21±41	Poor	0.001*	MWU
Emotional role	73±44	Good	23±43	Poor	0.001*	MWU
Pain	44±25	Poor	26±20	Poor	0.001*	MWU
Vitality	52±19	Poor	34±20	Poor	0.001*	T-Test
Overall	**63±21**	**Good**	**37±21**	**Poor**	**0.001***	**MWU**

Note: QOL (quality of life), n (number) MWU (Mann Whitney U Test), T-Test (Independent Pair T-Test).

Table 4: Comparative analysis of QoL scores based on patients' BMI, HbA1C and comorbidity

QoL variable	Normal weight, Controlled glucose, and without comorbid (n=8)		Overweight-obese, uncontrolled glucose, and with comorbid (n=81)		*P*-value	Type of analysis
	Average QoL score	QoL status	Average QoL score	QoL status		
Physical functioning	95±6	Good	63±30	Good	0.001*	MWU
Mental health	83±8	Good	58±20	Good	0.001*	MWU
Social functioning	84±15	Good	50±26	Poor	0.001*	MWU
General health	80±4	Good	42±16	Poor	0.001*	MWU
Physical fitness	100±0	Good	34±47	Poor	0.001*	MWU
Emotional role	100±0	Good	38±48	Poor	0.001*	MWU
Pain	73±14	Good	30±22	Poor	0.001*	MWU
Vitality	74±10	Good	38±20	Poor	0.001*	*t*-Test
Overall	**85±4**	**Good**	**44 ±22**	**Poor**	**0.001***	**MWU**

Note: QoL (quality of life), n (number) MWU (Mann Whitney U Test), T-Test (Independent Pair T-Test)

Table 5: Comparative analysis of QoL scores based on patients' DM duration

QoL variable	< 5 Years (n=24)		>5 Years (n=65)		*P*-value	Type of analysis
	Average QoL score	QoL status	Average QoL score	QoL status		
Physical functioning	79±26	Good	62±30	Good	0.004*	MWU
Mental health	65±24	Good	58±19	Good	0.036*	MWU
Social functioning	67±23	Good	48±27	Poor	0.002*	MWU
General health	57±21	Good	41±17	Poor	0.002*	MWU
Physical fitness	51±50	Poor	36±48	Poor	0.189	MWU
Emotional role	51±50	Poor	41±49	Poor	0.330	MWU
Pain	45±25	Poor	29±22	Poor	0.008*	MWU
Vitality	52±23	Poor	38±20	Poor	0.006*	*t*-Test
Overall	**58±25**	**Good**	**44±23**	**Poor**	**0.011***	**MWU**

QOL (quality of life), n (number) MWU (Mann Whitney U Test), T-Test (Independent Pair T-Test).

Table 6: Comparative analysis of QoL scores based on patients' medication

QoL variable	SU – insulin user (n=41)		Non-SU – insulin user (n=48)		P-value	Type of analysis
	Average QoL Score	QoL Status	Average QoL Score	QoL Status		
Physical functioning	61±34	Good	70±26	Good	0.235	MWU
Mental health	58±20	Good	61±21	Good	0.411	MWU
Social functioning	43±28	Poor	61±25	Good	0.003*	MWU
General health	40±17	Poor	49±20	Poor	0.050	MWU
Physical fitness	40±49	Poor	40±49	Poor	0.917	MWU
Emotional role	42±49	Poor	44±50	Poor	0.842	MWU
Pain	29±22	Poor	37±25	Poor	0.094	MWU
Vitality	37±20	Poor	46±23	Poor	0.051	T-Test
Overall	**44±24**	**Poor**	**51±24**	**Poor**	**0.136**	**MWU**

QoL (quality of life), n (number) MWU (Mann Whitney U Test), *t*-Test (Independent Pair *t*-Test).

Table 7: Comparative analysis of QoL scores based on patients' history of hypoglycemia

QoL variable	YES (n=58)		NO (n=31)		P-value	Type of analysis
	Average QoL score	QoL status	Average QoL score	QoL status		
Physical functioning	56±31	Good	85±15	Good	0.001*	MWU
Mental health	52±21	Poor	73±12	Good	0.001*	MWU
Social functioning	41±24	Poor	74±20	Good	0.001*	MWU
General health	35±13	Poor	63±16	Good	0.001*	MWU
Physical fitness	10±28	Poor	97±18	Good	0.001*	MWU
Emotional role	15±35	Poor	97±18	Good	0.001*	MWU
Pain	22±17	Poor	56±19	Poor	0.001*	MWU
Vitality	31±18	Poor	60±15	Good	0.001*	T-Test
Overall	**33±15**	**POOR**	**76±8**	**GOOD**	**0.001***	**MWU**

QoL (quality of life), n (number) MWU (Mann Whitney U Test), *t*-Test (Independent Pair *t*-Test).

Patients with T2DM having a history of severe hypoglycemia were found to have QoL 11 times worse compared to patients without the history. Also, a history of severe hypoglycemia showed a strong correlation with QoL of T2DM patients (r^2 = 0.887; $p < 0.05$).

With respect to age, adult patients (30 – 55 years) had QoL six times better than older adults (>55 years). This factor was positively correlated with a fairly strong relationship (r^2 = 0.420; $p < 0.05$). Age, as an unmodifiable factor, could not be controlled. Other influencing factors were BMI, blood sugar control and comorbidities. Patients with a normal BMI, controlled blood sugar and without comorbidities had twice QoL as the opposite group. These three variables were found to be positively correlated (r^2 = 0.381; $p < 0.05$). Since BMI, sugar control and comorbidities were modifiable, efforts should be made to manage these factors.

DISCUSSION

Patients with T2DM in Bali Province generally had a low QoL. The top three dimensions significantly contributing to this trend were pain, physical fitness and vitality, with pain being the most dominant. This condition was often associated with diabetes complications such as cardiovascular disease, decreased kidney function, neuropathy and retinopathy [18,19]. Patients often felt less fit and had less energy during diabetes therapy, a condition that required further exploration to better understand the underlying causes. Therefore, clinicians and caregivers should consider these results and take steps to improve this condition. Diabetic neuropathic pain is commonly reported among patients with uncontrolled blood sugar, including symptoms like tingling, numbness, pricking, burning and chilling, significantly interfering with daily activities [7]. Serious macrovascular and microvascular complications significantly impacted the general QoL of DM patients [7,19].

The results of proportion and QoL score analyses identified five dominant factors directly related to patients' QoL in this study. These factors included patients' history of severe hypoglycemia, age, diabetes complications, glycemic control and BMI. Patients with a history of severe hypoglycemia were found to have a poor QoL [14,19]. This variable was the most influential, showing that preventing hypoglycemia in patients undergoing outpatient diabetes therapy was crucial for maintaining good QoL.

Table 8: Comparative, size effect and correlation analysis of QoL based on proportions in T2DM patients

Characteristic	QoL		χ2 *P*-value	OR (CI95%)	SRCC (r^2)
	Good (n%)	Poor (n%)			
Gender					
Male	10 (22.73)	34 (77.27)	0.667	0.809	-0.046
Female	12 (26.67)	33 (73.33)		(0.308-2.126)	(Low Correlation)
Age (years)					
Adult (30-55)	24 (64.86)	13 (35.14)	0.001*	6.154*	+0.420*
Older Adult (56 – >65)	12 (23.08)	40 (76.92)		(2.419-15.654)	(Quite Strong)
BMI (kg/m^2)					
Normal	8 (100.00)	0 (0.00)	0.001*	2.893*	+0.381*
Overweight and Obese	28 (34.57)	53 (65.43)		(2.144-3.903)	(Quite Strong)
HbA1C (%)					
Controlled (<7)	8 (100.00)	0 (0.00)	0.001*	2.893*	+0.381*
Uncontrolled (>7)	28 (34.57)	53 (65.43)		(2.144-3.903)	(Quite Strong)
DM duration (years)					
0-5	13 (54.17)	11 (45.83)	0.109	2.158	+0.170
>5	23 (35.38)	42 (64.62)		(0.834-5.582)	(Low Correlation)
Comorbidity					
Without Complication	8 (100.00)	0 (0.00)	0.001*	2.893*	+0.381*
With Complication (Neuropathy, CVD, CKD)	28 (34.57)	53 (65.43)		(2.144-3.903)	(Quite Strong)
Medication					
Non-Insulin and SU User (Metformin, Metformin + SGLT2-I, Metformin + DPP4-I)	20 (41.67)	28 (58.33)	0.800	1.116	+0.027
Sulfonylurea and Insulin Rapid Acting User	16 (39.02)	25 (60.98)		(0.477-2.612)	(Low Correlation)
History of severe hypoglycemia					
Yes	5 (8.62)	53 (91.38)	0.001*	0.086*	-0.887*
No	31 (100.00)	0 (0.00)		(0.037-0.199)	(Very Strong)

Note: DM (diabetes mellitus); CVD (cardiovascular diseases); CKD (chronic kidney diseases); BMI (body mass index); SGLT2-I (sodium-glucose co-transporter 2 inhibitors); DPP4-I (dipeptidyl peptidase-4 inhibitors); SU (sulfonylurea); n (number); OR (odd ratio); * (statistically significant) (+) (In line with the test hypothesis); (–) (Opposite direction to the test hypothesis) χ2 (chi-square analysis); SRCC (Spearman's Rank Correlation Coefficient).

Those with a history of adverse drug reactions (ADR) tended to experience residual adverse effects that could impact QoL. Age, being an unmodifiable factor, necessitated special attention to elderly patients in maintaining good QoL [7]. Diabetes complications, glycemic control and BMI were interconnected. Diabetes complications tend to progress when glycemic control and weight risk factors are not controlled [1,6,18]. By adopting a healthier lifestyle, controlling glycemic profile and maintaining an ideal body weight, patients could slow disease progression and delay complications [13].

In Bali Province, the QoL of T2DM patients had not received adequate attention from health workers, stakeholders, caregivers and patients. Ensuring a well-maintained QoL could improve life expectancy and positively impact the nation's health development. Based on these results, it is recommended that clinicians, patients, and caregivers focus on modifiable factors influencing patients' QoL.

Limitations of this study

This study was biased as the entire population was drawn from two districts in Bali province, limiting generalization to patients with similar characteristics. Furthermore, the medical history data observed at the final stage only included gender, age, BMI, glycemic profile (HbA1C), DM duration, comorbidity, medication, and history of severe hypoglycemia, causing the analysis to be confined to these variables.

CONCLUSION

Patients with T2DM undergoing therapy at the hospital polyclinics outpatients unit in Bali Province had a relatively low QoL. Factors contributing to these outcomes include patients' history of severe hypoglycemia, age, diabetes complications, glycemic control and BMI. Other data that might influence QoL, such as patients' behavior and motivation in receiving health services, support system conditions, compliance,

and other social conditions, will need to be further analyzed.

DECLARATIONS

Ethical approval

None provided.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Conflict of Interest

No conflict of interest associated with this work.

Contribution of Authors

The authors declare that this work was done by the authors named in this article and all liabilities pertaining to claims relating to the content of this article will be borne by the authors. Zullies Ikawati was the study leader and primary drafter of the manuscript. Made Krisna Adi Jaya contributed to data collection, processing and writing the manuscript. Fita Rahmawati and Nananag Munif Yasin contributed to designing the data analysis and developing reporting standards for this study.

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