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Health-related quality of life and its determinants among patients with diabetes mellitus: a multicentre cross-sectional study in Northwest Ethiopia

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ABSTRACT

Objectives This study assessed the health-related quality of life (HRQoL) and its determinants in patients with diabetes.

Design and setting An institutional-based multicentre prospective cross-sectional study design was conducted in diabetes follow-up clinics of selected hospitals in Northwest Ethiopia from April to July 2022.

Participants All eligible adult patients with diabetes at the selected facilities.

Main outcome measures HRQoL was measured using EuroQol 5-dimensions 5-levels (EQ-5D-5L) and the EuroQol-Visual Analogue Scales (EQ-VAS) instruments. A lower EQ-5D-5L utility mean score for each dimension and/or an overall lower utility score of EQ-5D-5L and EQ-VAS scores are intended to show poor HRQoL. Linear regression analysis was used to identify the association of HRQoL and other variables.

Results Out of the 422 samples approached, 402 (95.3%) participated in the study. Most of the participants (>85%) reported having moderate-to-severe problems in all five EQ dimensions. The overall EQ-5D-5L utility and EQ-VAS scores were 0.56 (±0.11) and 56.7 (±10.1), respectively. A higher body mass index (BMI) ($p < 0.001$), a higher number of medications ($p = 0.037$), a high level of blood glucose ($p < 0.001$), the presence of comorbidities and/or complications ($p = 0.031$), hypoglycaemia ($p = 0.043$) and taking insulin ($p < 0.001$) were associated with worsened HRQoL, whereas practicing self-monitoring of blood glucose ($p = 0.002$) and taking aspirin ($p = 0.008$) had a significant association with increased HRQoL.

Conclusion This study concluded that the HRQoL of patients was compromised in all five measuring dimensions. The EQ-5D-5L utility and EQ-VAS scores were far lower than other findings. Clinical and medication-related variables, such as a higher BMI, a higher number of medications, the presence of comorbidities and/or complications, hypoglycaemia and insulin use were associated with poor HRQoL in patients with diabetes. As a result, interventions should be individualised and focused on determinant factors.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study presents comprehensive findings that may add to practitioners' and patients' knowledge of diabetes treatment practices.
⇒ The study finding's may be helpful for health utility evaluation.
⇒ The health-related quality of life (HRQoL) score is determined through patients' self-reported measuring scales, which depend on the respondents' trustworthiness and belief and may affect their responses, resulting in an overestimation or underestimation of the scores.
⇒ A study design cannot establish a causal relationship between HRQoL and independent factors.
⇒ The study was conducted over a short period of time, so any changes in patients' health conditions over time are unknown.

INTRODUCTION

Diabetes mellitus (DM) is a common chronic disease marked by elevated blood glucose level.[1 2] Diabetes is characterised by progressive and gradual deterioration in pancreatic beta-cell function, decreasing insulin level and increasing its resistance, which eventually leads to chronic hyperglycaemia.[3–5] Thus, uncontrolled hyperglycaemia is a direct cause of the development of macrovascular and microvascular complications, which deteriorates patients' health-related quality of life (HRQoL) and eventually lead to premature death.[2] Diabetes has been reported as a public threat in Africa, and it was 24 million in 2021 and predicted to be 55 million in 2045.[6] In Ethiopia, there has been an observable change in lifestyle and significant increases in population and urbanisation in the past 2–3 decades, which are the identified risk factors for diabetes. About 2.5 million adults in Ethiopia have diabetes,[7] which makes Ethiopia one of the sub-Saharan African countries with the largest population with diabetes. An estimated prevalence of DM had increased from 3.8% to 5.2%.[8]

The treatment goal of patients with diabetes is to prevent the progression of the disease and maintain HRQoL. However, diabetes causes a serious deterioration in the HRQoL of patients by affecting physical, social and mental HRQoL components.[9–11] HRQoL affects patients' self-care behaviours, disease management and lifestyle and compliance with their therapy. Additionally, their social lives have been greatly disturbed because of poor glycaemic control and changes in dietary habits and lifestyle.[12] Furthermore, patients with diabetes have experienced psychological complications,[13 14] with psychiatric disturbance symptoms, such as depression and anxiety, being more commonly associated (a twofold to fourfold increase) in patients with diabetes than the general population.[15] Consequently, this evidence indicates that the HRQoL of patients with diabetes is compromised. Disturbances from comorbid complications of patients with DM could be exacerbated in a stressful environment; the COVID-19 pandemic effects and other socioeconomic crises might affect patients' daily experience of life.

Different researchers have used different tools to measure health outcomes among patients with diabetes. Aside from clinical outcomes, healthcare providers and researchers use patients' self-reported HRQoL measures to assess the burden of the disease and its treatment.[16–18] HRQoL is a multidimensional patient's self-reported health outcome based on their physical, cognitive, social, emotional and psychological status and evaluates how diseases, interventions and treatments impact their health status.[16–19]

Different independent determinants of HRQoL have been identified in patients with diabetes. Ageing is among the demographic factors negatively associated with HRQoL in patients.[20 21] Moreover, reduced HRQoL has been linked with poor glycaemic control and diabetes-related complications.[9 22 23] The presence of comorbidities also negatively affects the HRQoL of patients with diabetes.[23–26] Furthermore, the duration of diabetes and insulin use, which might be related to the pain of injections, are associated with poor HRQoL.[16 17 27 28]

There are several generic and disease-specific tools that have been developed for measuring the HRQoL of patients with diabetes.[29–31] Though more options are available, the EuroQol 5-dimensions 5-levels (EQ-5D-5L) standardised questionnaire has received attention in recent times,[29] which is a patient preference-based multiattribute utility HRQoL measure validated for clinical and economic evaluators. However, except for a few studies that looked at patients' reports in patients with type 2 diabetes mellitus (T2DM),[17 32] HRQoL of patients with diabetes is rarely studied using the EQ-5D-5L in Ethiopia. Furthermore, the available studies employed a varied and small sample size, considering only patients with T2DM and using varied measuring tools in a single health facility, which may make it difficult to draw conclusions for all diabetes populations in the country. Therefore, this multicentre prospective cross-sectional study assessed HRQoL and determining factors in patients with diabetes at selected hospitals in Northwest Ethiopia.

METHODS AND MATERIALS

Study design and settings

An institutional-based multicentre cross-sectional study was conducted at selected hospitals in Northwest Ethiopia from April to July 2022. The participants were recruited from outpatient chronic care clinics of governmental hospitals selected randomly among other public and university hospitals found in the region. The selected hospitals are the University of Gondar Comprehensive Specialized Hospital (UoGCSH), Felege Hiwot Comprehensive Specialized Hospital (FHCSH), Tibebe Ghion Comprehensive Specialized Hospital (TGCSH) and Debre Markos Comprehensive Specialized Hospital (DMCSH). Selected hospitals have chronic outpatient care clinics, including those for patients with diabetes. In total, the hospitals served around 25 million people in their catchment area. All selected hospitals provide diabetes care in their chronic patient care clinics.

Study participants and inclusion criteria

This study included all adult patients with diabetes who could be interviewed and had completed medical records for some printed laboratory tests and clinical parameters. The eligible participants met the following criteria: (1) patients could be diagnosed with DM and be adults (age greater ≥18 years); and (2) patients had followed the outpatient chronic clinic for a minimum of 3 months. While pregnant mothers, patients who were unable to communicate due to severe illnesses, psychiatric disorders or neurological illnesses were excluded in this study. Patients with incomplete records and/or who refused to participate were also excluded from this study.

Sample size determination and sampling technique

Sample size was determined based on a single population proportion formula with the following assumptions: p=0.5 (considering 50% of the population distribution of patients with DM regarding HRQoL) to obtain a maximum sample size; W=0.05 (5% of the marginal error for the two-tailed type I error); Z=1.96 (at a two-sided 95% confidence level).

$$n=p\,(1-p)\times Z^2/W^2$$

where, n is the sample size.

After considering 10% of the possible non-respondents, the final sample size resulted in 422. Then, the final sample size was proportionally allocated to the selected hospitals based on the number of patients with diabetes identified from the hospital records before the start of the study. Consequently, we approached 154, 113, 102 and 53 samples from UoGCSH, FHCSH, DMCSH and TGCSH, respectively.

Participants from the selected hospitals were approached using a systematic random sampling technique using their unique medical identification cards.

Initially, a simple random sampling technique was used to select the initial sample used as the starting point. Then, using a sampling interval, eligible participants were included until the final sample size was maintained.

Data collection instruments and procedures

The data was collected using a structured questionnaire through a face-to-face interview. Following extensive reviews of previous literature, the data collection tool was created. The tool is organised into three parts. The first part consists of the patients' socio-demographic characteristics, such as age, sex, weight, marital status, level of education, working or employment status, average monthly household income, social history, self-monitoring of blood glucose (SMBG) practice, lifestyle practices, physical activity and smoking status. The second section includes the sample population's diabetes-related clinical characteristics such as duration of diagnosis, medications, comorbidities, diabetes-related complications and laboratory parameters. The third part of the data collection questionnaire comprises items assessing the HRQoL of the patients with diabetes using the EQ-5D-5L and EuroQol-Visual Analogue Scales (EQ-VAS) instruments.

The data was collected by four nurses and two pharmacists from the selected hospitals. Once the medical record identification numbers of the participants were entered into Microsoft Excel 2013 and checked for repetition, the data was extracted from medical records and at the same time, the patients were interviewed.

Operational definitions

Body mass index

It was calculated by dividing weight (kg) by height squared (m^2) and classified into four categories based on WHO classification: underweight (≤18.5); normal weight (18.5–24.9); overweight (25–29.9) and obese (≥30) kg/m^2.

SMBG

It indicates the method by which the study participants measured their blood glucose at home using a glucose metre.[33]

Level of glycaemic control

It indicates the level of blood glucose of the participants, and the glycaemic control was measured using the level of average glycated haemoglobin (HbA1c) categorised as poor (HbA1c ≥7%) and good (HbA1c level <7%) for adult patients.[34 35]

HRQoL outcome measures

HRQoL was measured using a validated tool developed by the EuroQol Research Foundation,[36 37] which is a EQ-5D-5L questionnaire. The tool has two sections. The first section of the EQ-5D-5L involves the patient's self-reported components: patients report their health status in a descriptive system that comprises five domains (mobility, self-care, usual activities, pain or discomfort and anxiety or depression). Each dimension has five levels of problems: no problems, slight problems, moderate problems, severe problems and extreme problems. It was developed in English and then translated to a local language (Amharic) by experts to maintain consistency. The EQ-5D-5L is a reliable and valid instrument for the measurement of HRQoL in the Ethiopian population. The intraclass correlation coefficient (ICC) value was high (ICC>0.7, p<0.001) for all EQ-5D-5L dimensions, EQ-5D-5L utility and EQ-VAS scores.[38 39] The reliability test of the tool in this study was performed, yielding a Cronbach's alpha (α) value of 0.78.

Participants were asked to choose a level that reflected their current health state for each dimension. Then, patients' EQ-5D utility scores were calculated using disutility coefficients obtained from the Ethiopian general population.[39] The higher the mean EQ-5D utility score, the better the HRQoL of the patients. The second section of the instrument is the EQ-VAS, an instrument used for subjective assessment of the current state of health from the patient's perspective, which has also been used in Ethiopia.[17] Using this method, each patient self-rated their health status on a vertical scale that ranges from 0 (the worst health state) to 100 (the best health state). The mean EQ-VAS was computed and presented as a mean and SD.

Data quality control measures

Before the actual data collection period, the data collection instrument was pretested on 20 patients (around 5% of the participants) at the UoGCSH to check its consistency, clarity and ease of collection. Pretested participants were excluded from the final study. After some modifications to the questionnaire, the actual data collection was performed. The data collectors received a half day of training regarding the purpose of the study, the nature of the data collection instruments and ethical considerations for data collection producers. On each day of the data collection period, the filled questionnaire was checked for its completeness, clarity and cleanness. The principal investigator also explicitly followed the data collection procedure closely.

Data entry and statistical analysis

Before the data entry, its quality, completeness, consistency and clarity were checked. The data was then entered into Epi Info V.8 before being transported to Statistical Packages for Social Sciences (SPSS) V.26 for analysis. The normal distribution of the data was examined using a Q–Q/P–P plot and histogram. Descriptive statistics, such as means with SDs (±SD) were used to display results for continuous variables. To present categorical variables, frequency with percentage was used. An independent sample t-test was used to examine the difference in HRQoL measurement scores between patients with type 1 and type 2. Linear regression analysis was used to identify the association between the independent variables and the HRQoL measuring score. Variables with a p value of ≤0.2 in the bivariable analysis were included in the multivariable analysis to identify the factors potentially

linked with poor HRQoL. Results of the regression analysis were expressed as an unstandardised coefficient β. β coefficients are measured in units of SD and refer to the average change in HRQoL for a unit increase in the predictor variables. A p value<0.05 at 95% CI was statistically significant.

Patient and public involvement

Patient and public involvement in the study design and methodology was not applicable.

RESULTS

Socio-demographic characteristics of study participants

Only 402 of the 422 approached samples were included in the study (a 95.3% response rate). Relatively, proportional participants of men (54.2%) and women (45.8%) with a mean age of 55.1 (±10.7) years were taking part in the study. The participants were over-represented with urban residents (59.7%). More than two-thirds (68.9%) of the participants did not practice SMBG. While the majority of the participants (85.3%) reported that they practiced lifestyle interventions, a higher proportion of respondents practiced dietary modifications (>63%) (table 1).

Clinical characteristics of the study participants

The majority of the study participants had T2DM (85.1%) with a hypertension comorbidity (71.9%). Each patient had an average of 2.7 (±0.9) medical conditions. The average fasting blood glucose (FBS) was found to be 176.5 (±51.6) mg/dL (table 2).

Medications used for treating patients

Among the diabetes medications, a higher proportion of the patients received metformin plus insulin (29.1%). While enalapril (60.2%) and atorvastatin (34.6%) were frequently prescribed cardiovascular and lipid-lowering agents, respectively. The average number of medications per patient was found to be 4.2 (±1.4) (table 3).

Measuring HRQoL of participants

A majority of the participants (>85%) reported that they faced either moderate, severe or extreme problems in the HRQoL measuring dimension. The overall mean EQ-5D utility score of participants' health-related problems was 0.56 (±0.11). Overall, most of the study participants (70.4%) had poor HRQoL, with a score below the overall mean utility score of EQ-5D. Moreover, the mean EQ-5D utility scores of most of the dimensions, such as mobility, self-care and pain/discomfort, were also lower or equal to the overall mean utility score of EQ-5D. The mean EQ-VAS score was found to be 56.7 (±10.1) (figure 1, table 4).

HRQoL difference between patients with T1DM and T2DM

An independent sample t-test revealed that there is a statistical difference in HRQoL among patients with T1DM and T2DM. The result showed a lower mean EQ-5D utility score (0.23 (±0.15)) for patients with T1DM compared with T2DM (0.28 (±0.17)) (table 5).

Determinants of HRQoL

The linear regression model was applied to determine variables associated with the overall mean EQ-5D utility score, intended to identify determinants of poor HRQoL. All socio-demographic, clinical and medication-related variables listed in this study that were potentially linked with HRQoL were tested using bivariable analysis in a simple linear regression. However, only variables that fulfilled the assumptions and criteria for further analysis in the multivariable to identify a possible association with HRQoL were included. As a result, multivariable linear regression revealed that body mass index (BMI), number of medications, blood glucose level, SMBG practice, presence of comorbidity and/or complications, hypoglycaemia, macrovascular complications, taking insulin and aspirin had a statistically significant association with participants' HRQoL.

As shown in the table, BMI (β=0.026, 95% CI (0.016 to 0.035); p<0.001), number of medications (β=0.016, 95% CI (0.009 to 0.041); p=0.037), level of blood glucose (β=0.002, 95% CI (0.001 to 0.003); p<0.001), the presence of comorbidity and/or complications (β=0.054, 95% CI (0.003 to 0.158); p=0.031), hypoglycaemia (β=0.044, 95% CI (0.034 to 0.1120; p=0.043), macrovascular complications (β=0.261, 95% CI (0.196 to 0.326); p<0.001), having insulin in the treatment regimens (β=0.350, 95% CI (0.289 to 0.412); p<0.001) were found significantly associated with poor HRQoL scores. In contrast, patients who practiced SMBG and were treated with aspirin were found to be less likely to have poor HRQoL compared with patients who could not practice SMBG and were non-user of aspirin, (β=−0.013, 95% CI (−0.447 to −0.006); p=0.002) and (β=−0.101, 95% CI (−0.175 to −0.026); p=0.008), respectively (table 6).

DISCUSSION

Although different studies have been employed regarding the HRQoL of patients with diabetes in Ethiopia, comprehensive evidence is critical for drawing a conclusion. This multicentre, institutional-based cross-sectional study is the first to present a comprehensive HRQoL of patients with diabetes in the study area, based on the authors' best searching strategy. Consequently, this multicentre prospective cross-sectional study has gone through the process of exploring HRQoL and determining factors in patients with DM. The finding also highlighted the extent of problems faced by patients using recently promoted HRQoL measuring tools, which can assess the patient's daily activity and feelings related to diabetes. A majority of patients in this study had comorbidities, received multiple medications and had poor glycaemic control that is similar to previous studies in the country.[17 32 40] This may imply that the current study may reflect the

Table 1 Socio-demographic characteristics of patients with diabetes at selected hospitals in Northwest Ethiopia from April to July 2022 (N=402)

Variables	Category	Frequency (%)	Mean (±SD)
Sex	Male	218 (54.2)	
	Female	184 (45.8)	
Age in years		–	55.1 (±10.7)
Weight in kg		–	66.7 (±8.1)
Residence	Urban	240 (59.7)	
	Rural	162 (40.3)	
Marital status	Single	47 (11.7)	
	Married	292 (72.6)	
	Divorced	63 (15.7)	
Educational status	Unable to read or write	53 (13.2)	
	Primary school	133 (33.1)	
	Secondary school	150 (37.3)	
	University or college and above	66 (16.4)	
Occupation	Farmer	75 (18.7)	
	Government employee	100 (24.9)	
	Self-employed	97 (24.1)	
	Student	44 (10.9)	
	Unemployed	64 (15.9)	
	Others	22 (5.5)	
Monthly income (Ethiopian birr)	<1500	37 (9.20	3744.5 (±1407.4)
	1500–2999	75 (18.7)	
	3000–4999	196 (48.80	
	≥5000	94 (23.4)	
Source of healthcare costs	Health insurance	231 (57.5)	
	Out-of-pocket	124 (30.8)	
	Free	47 (11.7)	
Cigarette smoking status	Currently smoker	68 (16.9)	
	Previously smoker	98 (24.4)	
	Non-smoker at all	236 (58.7)	
Frequent alcohol drinking habit	No	183 (45.5)	
	Yes	219 (54.5)	
SMBG practice	Yes	125 (31.1)	
	No	277 (68.9)	
Practicing of lifestyle modification	Yes	243 (85.3)	
	No	59 (14.7)	
Lifestyle methods used	Dietary modification	134 (33.3)	
	Physical activity	84 (20.9)	
	Dietary and physical activity	121 (30.1)	
Work-related physical activity	Sedentary	182 (45.3)	
	Moderate	136 (33.8)	
	Vigorous	84 (20.9)	

BMI, body mass index; SMBG, self-monitoring of blood glucose.

general population in the country and be better used to draw conclusions.

Indeed, the current study showed that a majority of the participants reported having compromised HRQoL, which was and below the general population. It has also been revealed that the majority of the participants faced moderate-to-severe problems in all dimensions of the EQ-5D-5L. Furthermore, HRQoL was found to have a significant association with blood glucose levels, BMI, the number of medications, the status of SMBG practice, the

Table 2 Clinical characteristics of patients with diabetes at selected hospitals in Northwest Ethiopia (N = 402)

Variables	Category	Frequency (%)	Mean (±SD)
BMI (kg/m^2)	Low	35 (8.7)	25.8 (±2.8)
	Normal	234 (58.2)	
	Overweight	56 (13.9)	
	Obese	77 (19.2)	
Duration of diabetes since diagnosis (years)	–	–	13.3 (±3.9)
Family history of DM	Yes	261 (64.9)	
	No	141 (35.1)	
Type of diabetes	Type 1 diabetes	60 (14.9)	
	Type 2 diabetes	342 (85.1)	
Presence of comorbidities and/or complications	Yes	366 (91)	
	No	36 (9)	
Medical conditions (comorbidities and complications)	Hypertension	289 (71.9)	
	Dyslipidaemia	182 (45.3)	
	Macrovascular complications	81 (20.1)	
	Hypoglycaemia in recent time	48 (11.9)	
	Microvascular complications	29 (7.2)	
	Renal disorders	21 (5.2)	
	Diabetes ketoacidosis	17 (4.2)	
	Others*	14 (3.5)	
Glycaemic control	Good	96 (23.9)	
	Poor	306 (76.1)	
Number of medical conditions		–	2.7 (±0.9)
Laboratory parameters			
Average fasting blood glucose (mg/dL) levels			176.5 (±51.6)
Average glycated haemoglobin (%) levels			7.8 (3.2)
Systolic blood pressure (mm HG)			138.4 (±11.5)
Diastolic blood pressure (mm HG)			81.6 (±9.3)

*Bacterial infections, retroviral infections, thyrotoxicosis, bronchial asthma, malaria, skin disorders.
BMI, body mass index; DM, diabetes mellitus.

presence of comorbidities and/or complications, macrovascular complications, hypoglycaemia and insulin and aspirin usage.

Consistent with the previous evidence,[17 32 41] this study found that the HRQoL of patients with diabetes was compromised. The overall mean EQ-5D utility and EQ-VAS scores were very low and, in the range, to indicate poor HRQoL compared with previous studies. In this study, the majority of patients also showed poor HRQoL scores in all five dimensions of EQ-5D, and they reported to have moderate, very severe and/or extreme severe levels of problems for all dimensions. This finding implies that the majority of patients with diabetes have poor HRQoL. However, in contrast to this finding, a study conducted in the Middle East has shown that the HRQoL scores were within a moderate range.[20] The discrepancy might be because of the differences in healthcare facilities and population differences in attitudes and practices of patients towards self-management of diabetes and lifestyle modification methods. Furthermore, the previous study was conducted in a single centre and used only patients with T2DM. Regarding the level of problems in each dimension, in contrast to the current study, an earlier study conducted in Ethiopia has also shown that a significant proportion of patients reported no problems. However, the earlier study was also a single-facility study conducted only in patients with T2DM.[17] In addition, the current study was conducted in patients who had comorbidities and received multiple medications, which have an impact on HRQoL. However, in supporting this finding, evidence has shown that patients with diabetes suffer from different physical complications, such as cardiovascular diseases, neuropathy, diabetic foot and other diabetes-associated problems. Additionally, their social and mental components have been greatly disturbed because of poor glycaemic control and changes in dietary habits and lifestyle.[12–14] This would eventually cause serious deterioration in the HRQoL of patients, which would result in

Table 3 Medications used for treating study participants at selected hospitals in Northwest Ethiopia

Variables	Category	Frequency (%)	Mean (±SD)
Antidiabetics	Metformin plus insulin	117 (29.1)	
	Metformin plus glibenclamide	90 (22.4)	
	Metformin	76 (18.9)	
	Metformin plus glibenclamide plus insulin	61 (15.2)	
	Insulin	58 (14.4)	
Cardiovascular medications used for hypertension and other complications	Enalapril	242 (60.2)	
	Hydrochlorothiazide	73 (18.2)	
	Amlodipine	21 (5.2)	
	Furosemide	18 (4.5)	
	Atenolol	16 (4.0)	
	Metoprolol	14 (3.5)	
	Nifedipine	14 (3.5)	
Lipid-lowering agents	Atorvastatin	139 (34.6)	
	Simvastatin	48 (11.9)	
Aspirin		70 (17.4)	
Others*		14 (3.5)	
Number of medications			4.2 (±1.4)
Average daily dose of insulin[5]			16.7 (±7.6) 23.5 (±79.3)†
Average daily dose of metformin (mg)			1450.6 (±113.5)
Average daily dose of glibenclamide (mg)			7.5 (±1.4)
Average daily dose of atorvastatin (mg)			40.8 (±9.3)

*Antiasthmatic agents, antiretrovirals, antithyroid agents, gastrointestinal agents, antibiotics; 23.5 (±79.3).
†Average daily dose of insulin for patients with type 1 diabetes.

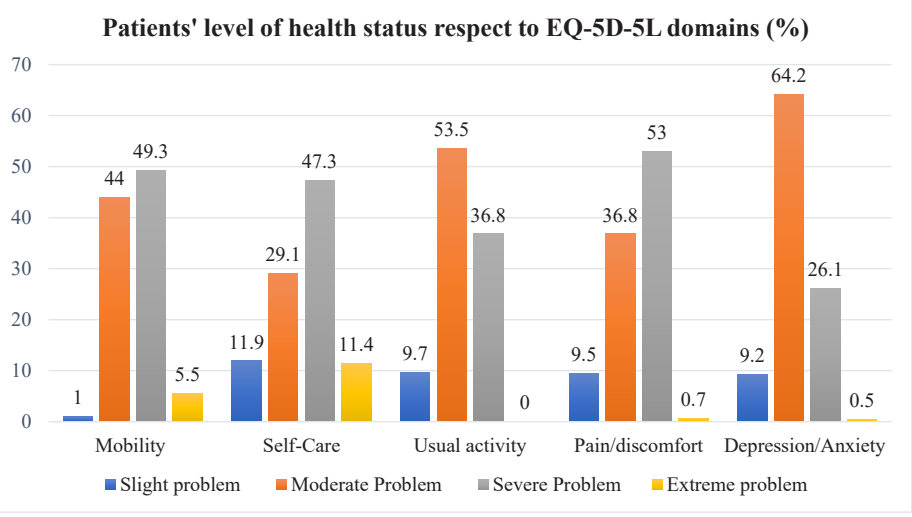

Figure 1 Distribution of patients' self-reported health problems with respect to EQ-5D-5L dimensions. EQ-5D-5L, EuroQol 5-dimensions 5-levels.

Table 4 Patients' EQ-5D-5L utility mean score with respect to HRQoL measuring dimensions

EQ-5D-5L dimensions	Mean (±SD)
1. Mobility: Problems during walking.	0.52 (±0.26)
2. Self-care: Problems during washing and dressing myself.	0.47 (±0.37)
3. Usual activity (work, study, housework): Problems during performing usual work.	0.61 (±0.10)
4. Pain/discomfort: Pain or discomfort during the time.	0.58 (±0.14)
5. Anxiety/depression: Anxious or depression during the time.	0.62 (±0.12)
Overall EQ-5D-5L utility mean score	0.56 (±0.11)
EQ-VAS	56.7 (±10.1)
Overall level of HRQoL	
Good	119 (29.6%)
Poor	283 (70.4%)

EQ-5D-5L, EuroQol 5-dimensions 5-levels; EQ-VAS, EuroQol-Visual Analogue Scales; HRQoL, health-related quality of life.

discomfort, anxiety and depression. In general, studies have also disclosed that patients with diabetes have poor HRQoL compared with patients without diabetes.[42–45] Therefore, healthcare providers should ensure that patients with diabetes seek close follow-up, multidirectional support and interventions. Patients must also be vigilant and motivated to maintain their HRQoL in an optimum range by following their healthy lifestyle modifications and adhering to their management interventions.

This study demonstrated that HRQoL was significantly associated with important independent determinant variables that potentially affect the health status of patients with diabetes. Consequently, the multivariable linear regression showed that patients with a higher BMI were found to have poor HRQoL scores. This finding agrees with the previous studies.[17 26 46] This finding justifies the fact that patients with diabetes with unhealthful body weight may be associated with high glucose circulating in the bloodstream, which leads to increased blood glucose levels and poor glycaemic control in these patients. This may in turn affect patients' daily lives and result in poor HRQoL. Additionally, obesity causes increased levels of fatty acids and inflammation, leading to insulin resistance, which in turn can result in poor glycaemic control and compromised HRQoL in patients. The earlier study also disclosed that patients with obesity were found to have poor glycaemic control,[33] which in turn could result in poor HRQoL. Health weight can prevent the progression of diabetes by improving blood glucose, blood pressure and lipid profiles that reduce the risk of complications, which in turn can maintain the HRQoL of patients at the optimum level. Therefore, patients with diabetes could maintain a healthy weight using the recommended daily physical exercises and healthy diets.

Table 5 HRQoL measurement score difference between patients with T1DM and T2DM

	An independent sample t-test		
Diabetes type	EQ-5D-5L utility mean (±SD) score	T	P value
Type 1	0.42 (±0.15)	−2.28	0.031
Type 2	0.58 (±0.17)		

EQ-5D-5L, EuroQol 5-dimensions 5-levels; HRQoL, health-related quality of life.

The current study also observed that patients with poor blood glucose levels were more likely to have poor HRQoL scores. This finding is supported by previous studies[9 17 20 22 23] showing that patients with poor blood glucose levels have poor HRQoL. More importantly, a poor blood glucose level can result in the deterioration of patients' HRQoL because it can cause disease progression and result in diabetes-associated complications. Therefore, maintaining the blood glucose level at the glycaemic target can delay the progression of diabetes, which keeps patients' HRQoL at an optimal level. Moreover, the number of medications that patients had been taking was found to have a significant association with the HRQoL of patients with diabetes. The findings indicate that patients with polypharmacy have a poor HRQoL score because of medication regimen complexity, medication adverse effects, the inability of patients to afford multiple medications and pill or injection burdens. This finding is in line with earlier studies conducted in patients with polypharmacy.[47 48] A higher number of medications may also contribute to the loss of time for administration and non-adherence to medications, which affects patients' HRQoL negatively. Generally, increasing the number of medications can affect patients' HRQoL negatively because of the burden of multiple medications related to adverse effects, medication costs and adherence issues. Therefore, clinicians, in particular prescribers, could focus on prescribing the optimum number of medications by considering the need for medication treatment of the medical conditions in patients' diabetes.

This study also revealed that patients with comorbidities and/or complications were more likely to have poor HRQoL scores. This is in agreement with previous studies.[23–26 32 49] Furthermore, patients with macrovascular complications and hypoglycaemia were also found to be more likely to have poor HRQoL scores. These findings show that the presence of comorbidities and diabetes-related complications results in multiple burdens on patients' health conditions and negatively affects HRQoL. This finding agrees with earlier studies that have shown that the presence of diabetes-related complications results in poor HRQoL.[17 20] Although the treatment goal of patients with diabetes is to prevent the progression of the disease and maintain HRQoL, patients have suffered from different diabetes-related complications, such as cardiovascular diseases, peripheral neuropathy, diabetic

Table 6 Determinants of poor HRQoL in patients with diabetes using a simple and multivariable linear regression model

Variables	β-coefficient (95% CI)		P value
	SLR	MLR	
Age (years)	0.005 (0.001 to 0.008)	0.002 (0.0001 to 0.003)	0.579
Household income	−3.97	−1.27	0.115
Duration of diabetes (years)	0.004 (−0.006 to 0.014)	0 (−0.007 to 0.06)	0.961
BMI (kg/m^2)	0.059 (0.047 to 0.072)	0.026 (0.016 to 0.035)	<0.001*
Number of medical conditions	0.031 (0.01 to 0.052)	0.048 (0.007 to 0.034)	0.078
Number of medications	0.025 (0.02 to 0.03)	0.016 (0.009 to 0.041)	0.037*
Blood glucose level	0.004 (0.002 to 0.006)	0.002 (0.001 to 0.003)	<0.001*
Healthcare cost coverage			
Health insurance	0.114 (−008 to 0.236)	0.012 (−0.067 to 0.092)	0.307
Out-of-pocket	0.096 (−0.035 to 0.227)	−0.021 (−0.106 to 0.065)	0.159
Free	1	1	
Marital status			
Single	0.030 (−0.115 to 0.176)	0.044 (−0.140 to 0.053)	0.377
Married	−0.145 (−0.25 to 0.041)	0.015 (−0.085 to 0.055)	0.681
Divorced	1	1	
SMBG practice			
Yes	−0.184 (−0.264 to 0.103)	−0.013 (−0.447 to −0.006)	0.002*
No	1	1	
Lifestyle modification practice			
Yes	−0.097 (−0.205 to 0.011)	0.006 (−0.064 to 0.76)	0.087
No	1	1	
Family history of diabetes			
Yes	0.06 (−0.02 to 0.14)	0.001 (−0.050 to 0.053)	0.059
No	1	1	
Type of diabetes			
Type 1	0.115 (0.008 to 0.222)	0.030 (−0.039 to 0.099)	0.395
Type 2	1	1	
Presence of comorbidity and or complications			
Yes	0.081 (0.007 to 0.214)	0.054 (0.003 to 0.158)	0.031*
No	1	1	
Hypoglycaemia			
Yes	0.117 (0.06 to 0.294)	0.044 (0.034 to 0.112)	0.043*
No	1	1	
Macrovascular complications			
Yes	0.418 (0.332 to 0.504)	0.261 (0.196 to 0.326)	<0.001*
No	1		
Taking insulin			
Yes	0.545 (0.80 to 0.611)	0.350 (0.289 to 0.412)	<0.001*
No	1	1	
Amlodipine			
Yes	0.157 (−0.013 to 0.327)	0.078 (−0.033 to 0.188)	0.167
No	1	1	
Aspirin			
Yes	−0.206 (−0.094 to 0.006)	−0.101 (−0.175 to −0.026)	0.008*
No	1	1	

*Indicated p value<0.05.
BMI, body mass index; MLR, multivariable linear regression.; SLR, simple linear regression; SMBG, self-monitoring of blood glucose.

foot and nephropathy. In addition, these complications and changes in dietary habits and lifestyle have had a significant impact on patients' social and environmental environments. Furthermore, patients with diabetes have more psychological complications than the general population, such as psychiatric disturbance symptoms, depression and anxiety.[13 14]

This study also revealed that there is a difference in HRQoL between patients with T1DM and T2DM, with a compromised HRQoL measuring score in patients with T1DM compared with T2DM. This disparity could be attributed to the fact that patients with T1DM receive insulin, which can contribute to poor HRQoL. In line with previous studies,[16 17 27 28] patients who received insulin in their treatment regimens were found to be more likely to have a compromised HRQoL compared with patients who did not receive insulin. This finding may imply that pain associated with the administration of multiple insulin injections might be the reason for patients' discomfort, which results in decreased HRQoL for patients. Furthermore, hypoglycaemia episodes associated with insulin injection might be also the cause of poor health in patients who have been injected with insulin. Patients who receive insulin need close follow-up.

However, this study showed that patients who practiced SMBG were less likely to have poor HRQoL scores compared with patients who did not practice SMBG. These findings indicate that patients who practice SMBG can obtain direct feedback regarding their blood glucose and may use that information to adjust their management and lifestyle modifications. The earlier findings also showed that practicing SMBG results in good glycaemic control,[33 50] which in turn can help patients maintain their HRQoL. As a result, because SMBG is an important tool for improving patient self-management and clinicians may use it to guide management interventions, patients may be encouraged to use it, share their testing results with physicians and the clinicians may then act to make management decisions.[51 52] Similarly, patients who received aspirin in their management regimens were found to be less likely to have poor HRQoL scores compared with patients who could not receive aspirin in their treatment regimens. This finding justifies the fact that aspirin plays a well-established role in the prevention and management of cardiovascular risks, delays the progression of the disease and prevents the occurrence of complications in patients with diabetes. This improves the physical and psychological well-being of patients compared with those who have not received aspirin. Consequently, it could be important to initiate aspirin in patients with diabetes if they are found to be candidates.

Generally, the current study presented a compressive finding regarding the extent of HRQoL in patients with diabetes using a recently advocated measuring tool in a multifacility-based study. The findings showed that patients with diabetes had a compromised HRQoL compared with non-diabetic general populations. It has also demonstrated an association between HRQoL and important independent determinant factors. However, poor HRQoL in patients with diabetes may be influenced not only by the factors discussed in the current study but might also be associated with multifactorial contributing factors, including the progressive nature of the disease itself, the medication regimens preferred, the level of medication adherence, the patients' level of adherence to healthy lifestyle modifications and the socioeconomic status of the patients. Consequently, both healthcare professionals and patients and/or caregivers could play a role in maintaining the quality of life of patients with diabetes. More importantly, interventions and management could focus on delaying the progression of diabetes to prevent the occurrence of diabetes-related complications that are the potential cause of patients compromised HRQoL. The findings of this multicentre study may provide practitioners and patients in the study areas with more comprehensive background knowledge, which may aid in treatment decisions and modifications.

CONCLUSION

This study demonstrated that all HRQoL measuring domains in patients with diabetes were found to be compromised, with moderate-to-severe levels of problems. The overall EQ-5D-5L utility and EQ-VAS scores were also far lower than other findings. A higher BMI, a higher number of medications, a high level of blood glucose, the presence of comorbidities and/or complications, hypoglycaemia and taking insulin were associated with poor HRQoL. Patients who practiced SMBG and took aspirin were less likely to have poor HRQoL than their counterparts. As a result, management and interventions should be individualised and tailored to specific factors. In addition, the prevention of diabetes-associated complications will be necessary to maintain the patients' HRQoL.

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Ethics approval The study was ethically approved by the ethical review committee of the Debre Markos University with a reference number ፋ.ጤ.ክ/143/01/14. Participants gave informed consent to participate in the study before taking part. Then, permission was confirmed from the selected hospitals to proceed with the

study. Participants were asked for written consent forms after the objectives of the study were briefed (online supplementary file). They were in a condition to give consent, and after accessing it they were interviewed. Confidentiality was maintained and sufficiently anonymised, and the study was conducted according to the Helsinki legislation. The data was sufficiently anonymised.

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