Assessment of Health-Related Quality of Life in Patients with Type II Diabetes Mellitus: A Population-Based Study at a Tertiary Hospital



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ABSTRACT

Introduction: The rising incidence of diabetes, worldwide, has necessitated an evaluation of diabetes impacts on Health-Related Quality of Life (HRQoL). The recognition of risk factors that lower HRQoL can improve HRQoL in patients with Type 2 Diabetes Mellitus (T2DM).

Aim: To explore the impact of T2DM on HRQoL among adolescents/adults treated at a tertiary hospital in southern Vietnam.

Materials and Methods: This cross-sectional study was conducted from July–September 2017 at District 9 Hospital, Ho Chi Minh City, Vietnam. In total, 286 patients with T2DM underwent face-to-face interviews and completed the Diabetes-39 (D-39) questionnaire (previously evaluated for reliability). Each subscale score was summed and transformed into a scale of 0–100. HRQoL differences were evaluated by Mann-Whitney and Kruskal-Wallis nonparametric tests.

Results: The Cronbach's alpha coefficients were all over 0.80 and showed acceptable high internal consistency. The lowest Cronbach's alpha was obtained for 'Anxiety and worry' (0.81) and the highest for 'Diabetes control' and 'Sexual behaviour'

(0.93). The Intraclass Correlation Coefficient (ICC) ranged from 0.80 for 'Anxiety and worry' to 0.93 for 'Sexual behaviour' and agreed well for all subscales and the D-39 total score. The median D-39 total score was 35.0 (scale 0–100). Patients prescribed insulin or who had a family history of diabetes scored higher on 'Diabetes control' and 'Social behaviour' and the D-39 total score. Multiple linear regression analyses revealed that having an urban area residence, no income and high BMI predicted a lower impact of diabetes on HRQoL scores. Conversely, unemployment correlated with higher scores for 'Energy and mobility' and the total HRQoL, while family history had a higher impact on 'Anxiety and worry' and 'Social burden'. The presence of complications was associated with a higher 'Energy and mobility' score.

Conclusion: The Diabetes-39 Vietnamese version used in our study had acceptable reliability for evaluating HRQoL in patients with T2DM. The 'Energy and mobility' and 'Anxiety and worry' subscales were highly impacted by T2DM, indicating a need to address physical function and patient psychology. The independent predictors are useful additions to diabetes care programs suitable for individuals.

Keywords: Diabetes, D-39, Health-related quality of life, HRQoL, QoL, Vietnam

INTRODUCTION

Today, a growing epidemic of diabetes mellitus (DM) is recognised as a serious global threat [1], and possibly the largest global health emergency of the 21st century. According to the Diabetes Atlas published by the International Diabetes Federation (IDF), 415 million adults were estimated to have DM in 2015 across the world, and this number is projected to increase to more than 642 million by 2040. DM also has high mortality, causing 5 million deaths in 2015 alone, when Vietnam had 3.5 million diabetes cases and 53,457 deaths attributed to diabetes. The rate of DM has been increasing and has reached alarming levels, nearly doubling within the past 10 years, so that one in every 20 Vietnamese adults now has diabetes. The number of people with a pre-diabetic condition is also three times higher than the number with DM [2].

DM is a typical chronic disease that puts grave constraints on patient activities. Broad education and behavioural changes are required to manage this situation. The patient must combine lifestyle changes with strict dietary planning, regular exercise, use of medication and the use of insulin and home blood glucose measuring instruments to stabilise their condition [3]. When compared with non-diabetic patients, diabetic patients tend to be older, overweight, less likely to exercise and much more likely to have comorbidities (e.g., high blood pressure, hyperlipidaemia, coronary artery disease, etc.,) [4]. The complications (i.e., heart attack, stroke, kidney failure, vision loss, nerve damage, poor wound healing and circulatory issues leading to leg amputation) can all increase the risk of morbidity and mortality, and they significantly affect the HRQoL of the patients [5,6].

HRQoL can be defined as a broad multidimensional concept relating to an individual's subjective perception of positive and negative aspects of life, including their physical, psychological and social well-being [7]. Physical well-being generally refers to the ability to perform personal tasks independently.

Studies across the world using a number of instruments for evaluating HRQoL in DM patients has indicated that HRQoL is lower for patients with diabetes than in those not having the disease.

The aim of the present study was to use the Diabetes-39 instrument to explore the impact of T2DM on the HRQoL of adolescents and adults treated at a tertiary hospital in southern Vietnam.

MATERIALS AND METHODS

Study Design and Study Participants

A cross-sectional study was conducted within a 3-month period, from July 2017 to September 2017, at District 9 Hospital, Ho Chi Minh City, in southern Vietnam. A total of 286 patients with T2DM undergoing treatment in the endocrinology department of District 9 Hospital were invited to participate in the study. Patients with T2DM, treated at District 9 Hospital, over 18 years of age and able to communicate in Vietnamese were enrolled. Patients with type 1 DM or patients who had impaired cognitive abilities, obvious psychiatric disorders, paralysis or were comatose were excluded from this study.

Ethical Approval

The study protocols were approved by District 9 Hospital (IORG No. 0007146). All participants gave their informed consent after receiving an explanation of the study. All the information serves only for research purposes. During all data collection, each patient in the study was guaranteed anonymity by the creation of alphanumeric identity codes.

Data Collection

Face-to-face interviews were conducted with Patients with T2DM at District 9 Hospital to collect data by completing a questionnaire.

The structured questionnaire comprised two parts. The first form consisted of information about socio-demographic and clinical characteristics, namely age, gender, marital status, education level, monthly income and occupation, place of residence, duration and complications of diabetes, comorbidity and exercises. The second form was the D-39 instrument which was translated into Vietnamese from the original English version. The average time for completing the questionnaire was about fifteen minutes.

Measurement Tools

The D-39 instrument [8] consists of 39 items, which can be divided into five subscales (domains) of HRQoL for patients with T2DM: Energy and mobility (15 items), Diabetes control (12 items), Anxiety and worry (4 items), Social burden (5 items) and Sexual functioning (3 items).

The use of the D-39 instrument allowed patients to provide responses that indicated the extent that their HRQoL was affected within the previous month by DM and its treatment. The effects were expressed in specific items and the patients were asked to choose the number on a scale of 1 to 7 that best expressed the impact of the factors on their HRQoL. On the scale, 1 represented the case where HRQoL is 'not affected at all', and 7 the case where HRQoL was 'extremely affected' (i.e., the highest and lowest achieved values of HRQoL, respectively) [9].

Translation D-39 to Vietnamese

Forward - backward translation

Two forward translators independently translated the D-39 questionnaire into Vietnamese and then two backward translators translated them back into English. The researchers contacted a professional translation agency to choose those four translators. All of the translators were native speakers of Vietnamese who are fluent in English and also familiar with medical terminology. The researchers compared two translations and discussed with the translators for consensus. This resulted in the Vietnamese version.

Semantic analysis of items

Ten patients were invited to analyse their understanding of the 39 items and to explain why they chose their answers. They were asked any word or expression which they found unacceptable and gave suggestions to change these words, however, without any change in meaning. After discussing about their ideas, the last consensus version was achieved.

Data Analysis and Statistical Analysis

Data collected from the study were entered into an Excel spread sheet.

Treatment of missing data on the D-39 questionnaire was considered in specific cases. Questionnaires which have more than four missing items were excluded (Note: missing items in sexual functioning were not considered as reasons for exclusion, since some respondents refused or were unable to answer these questions. This sensitive scale was therefore given special treatment). The values of a scale were excluded when a certain number of items were missing and the scale was therefore not scored. These situations were as follows: 'Diabetes control' was excluded if > 3 items missing, 'Anxiety and worry' was excluded if > 1 item missing, 'Social burden' was excluded if > 1 item missing, 'Sexual functioning' was excluded if > 0 item missing and 'Energy and mobility' was excluded if > 3 items missing. In cases where a lower number of items in scale were missing, these were replaced by the mean score of the patient for that scale. (For example, if 2 items were missing on the 'Diabetes control', the mean of the remaining 10 items in 'Diabetes control' was used as the value for each of the 2 missing items in the 12 item scale). The sum of obtained scores for each subscale (raw score) was then calculated and transformed into a 0 to 100 scale by applying the formula: Transformed score = (raw score - lowest possible scale score)/(highest possible scale score - lowest possible scale score) x 100. A higher score indicates a greater impact on the HRQoL [10].

The SPSS-20 statistical software package was used for data analysis. Descriptive statistics were applied to investigate the distribution of socio demographic and clinical characteristics among the T2DM patients. Categorical variables were expressed using counts and percentage, whereas continuous variables were expressed using means, standard deviations, medians and interquartile ranges. Our study data were not normally distributed, so the Mann-Whitney and Kruskal-Wallis (for more than two categories) nonparametric tests were applied to evaluate associations between the various characteristics and HRQoL. Multiple linear regression analyses were used to identify independent predictors of domain-specific HRQoL and the overall HRQoL. A p-value of less than 0.05 was considered statistically significant.

Reliability

The Cronbach's alpha was used to calculate the internal consistency reliability of each scale. This analysis is based on the average correlation among items and the number of items in the instrument. A Cronbach's alpha of 0.70 or higher is considered 'acceptable', and an alpha value of >0.90 would demonstrate excellent reliability. In addition, the ICC was applied to assess the test-retest reliability of the D-39 questionnaire. This is a measure of the strength of agreement between repeated measurements by evaluating the ratio of the total variance related to between-patient variability. An ICC of 0.70 or higher is considered 'satisfactory' and an ICC of >0.90 would demonstrate excellent test-retest reliability [11].

RESULTS

Participants' Characteristics

[Table/Fig-1] Distribution of the demographic and clinical characteristics of 286 patients. {n (%)}.

This study included a total of 286 patients with T2DM. A total of 44.8% of the participants fell within the normal range for Body Mass Index (BMI), whereas about 23.1% were obese and about 27.3% were classified as overweight. The average duration of DM was 6.3 (SD=5) years, with a minimum of 1 month and a maximum of 24 years. About 34.3% of the patients had a family history of diabetes. The majority reported no smoking (87.4%) or drinking (86.7%). Of the subjects, 172 (60.1%) patients regularly performed exercise based on their own perception of performing exercise. Comorbidities were reported by 74.8% of the patients. With regards the use of drugs for DM control, nearly 82% of the patients controlled their disease with oral therapy, while the remaining patients had to use injected

insulin. More details about the characteristics of the patients are shown in [Table/Fig-1].

Characteristics	Frequency	Characteristics	Frequency	
Characteristics	N (%)	Characteristics	N (%)	
Age (years)		Living arrangements		
≤50	56 (19.6)	Alone	14 (9.8)	
50 – 65	128 (44.8)	With family	129 (90.2)	
>65	102 (35.7)	Duration of diabetes (years)		
Gender		< 5	130 (45.5)	
Male	104 (36.4)	5-10	98 (34.3)	
Female	182 (63.6)	> 10	58 (20.3)	
Residence		Cigarette smoking		
Urban area	158 (55.2)	Yes	36 (12.6)	
Rural area	128 (44.8)	No	250 (87.4)	
Marital status		Alcohol Drinking		
Single	32 (11.2)	Yes	38 (13.3)	
Married	224 (78.3)	No	248 (86.7)	
Separated/ divorced/ widowed	30 (10.5)	Exercise		
BMI (kg/m²)		Yes	172 (60.1)	
<18	14 (4.9)	No	114 (39.9)	
18-22.9	128 (44.8)	Family history		
23-24.9	78 (27.3)	Yes	98 (34.3)	
≥25	66 (23.1)	No	188 (65.7)	
Education level		Presence of comorbidities		
No school/ Illiterate	28 (9.8)	Yes	214 (74.8)	
Primary school	64 (22.4)	No	72 (25.2)	
Junior high school	68 (23.8)	Diabetes complication		
High school or over	126 (44.1)	Yes	104 (36.4)	
Employment		No	182 (63.6)	
Employed	112 (39.2)	Cardiovascular disease	86 (30.1)	
Unemployment	8 (2.8)	Retinopathy	24 (8.4)	
Retirement	36 (12.6)	Nephropathy	12 (4.2)	
Home-maker	68 (23.8)	Neuropathy	8 (2.8)	
Other	62 (21.7)	Treatment		
Monthly income (US\$)		Oral drugs	234 (81.8)	
No income	64 (22.4)	Insulin	52 (18.2)	
<200	144 (50.3)	Characteristics	Mean (SD)	
200-350	58 (20.3)	Age (years)	60 (13)	
350-500	8 (2.8)	BMI (kg/m²)	23.14 (3.25)	
>500	12 (4.2)	Duration of Diabetes (years)	6.3 (5)	

Reliability of the Diabetes-39 Instrument

The reliability of the data was supported by Cronbach's alpha coefficients of over 0.80 and acceptable high internal consistency scales. The lowest Cronbach's alpha was obtained for 'Anxiety and worry' (0.81) and the highest Cronbach's alpha were for 'Diabetes control' and 'Sexual behaviour' (0.93). The ICC for the 'Energy and mobility', 'Diabetes control', 'Anxiety and worry', 'Social burden' and 'Sexual functioning' subscales and the total score for the Diabetes-39 questionnaire were 0.91, 0.91, 0.80, 0.84, 0.93 and 0.95, respectively.

Contributing Factors of the Diabetes-39 Score

The median scores for each D-39 subscale and the D-39 total score are presented in [Table/Fig-2]. The participants scored highest in the

'Energy and mobility' subscale (median score = 41.1) and lowest in the 'Sexual functioning' subscale (median score=11.1).

[Table/Fig-2] The total and subscales scores and reliability of the Diabetes-39 instrument, $\{n (\%)\}$

Subscales	Medians (25 th to 75 th percentiles)	Range (Min-Max)	Cronbach's alpha	Intraclass correlation coefficient (ICC)		
Energy and mobility	41.1 (22.2-60.0)	0.0-91.1	0.92	0.91		
Diabetes control	27.8 (11.1-51.4)	0.0-86.1	0.93	0.91		
Anxiety and worry	33.3 (12.5-58.3)	0.0-100.0	0.81	0.80		
Social	26.7 (6.7-46.7)	0.0-96.7	0.86	0.84		
Sexual functioning	11.1 (5.6-33.3)	0.0-88.9	0.93	0.93		
Total	35.0 (18.4-49.1)	0.0-79.9	0.96	0.95		
[Table/Fig-2]: The total and subscales scores and reliability of the Vietnamese translation of the Diabetes-39 instrument {n (%)}.						

[Table/Fig-3] shows the comparison of domain-specific HRQoL scores and D-39 total scores among DM patients with various demographic characteristics. The DM subscale scores and the D-39 total scores did not differ statistically according to gender, living arrangements, employment, monthly income and cigarette smoking. Statistically significant differences were observed for the median scores of the 'Sexual functioning' subscale according to age, marital status, education level and alcohol drinking. Older participants scored lower on the 'Anxiety and worry' and 'Sexual functioning' subscales. Significantly lower scores were observed for the 'Diabetes control', 'Energy and mobility', 'Social burden' and 'Anxiety and worry' subscales and for the D-39 total score for patients living in urban areas than for patients residing in rural areas. Marital status and education level had significant impacts on the 'Social burden' and 'Sexual functioning' subscales. Marital status also was significantly associated with the 'Diabetes control' subscale and the D-39 total score. Patients who exercised scored lower on the 'Energy and mobility' subscales.

[Table/Fig-3]. Diabetes-39 subscale scores according to the demographic characteristics of the patients {Median (25^{th} to 75^{th} percentile)}

[Table/Fig-4] shows the comparison of domain-specific HRQoL scores of DM patients with various clinical characteristics. Notably, none of the DM subscales or the D-39 total score showed statistically significant differences according to the duration of diabetes. By contrast, clear differences were noted for 'Anxiety and worry', 'Diabetes control', 'Social burden' and D-39 total score for BMI. The patients treated with insulin and those with a family history of DM scored higher on the 'Diabetes control' and 'Social burden' subscales and the D-39 total score. The patients with complications also scored higher on 'Energy and mobility'.

[Table/Fig-4] Diabetes-39 subscale scores according to the clinical characteristics of the patients {Median (25th to 75th percentile)}.

[Table/Fig-5] shows the results of multiple linear regression analyses. Residence, employment, income, BMI and family history were independent predictors for certain domains or overall HRQoL. A statistically significant association was noted between residence and almost all domain scores ('Energy and mobility', 'Diabetes control', 'Social burden') and with overall HRQoL score, as patients were less affected if they lived in urban areas than in rural areas. Higher BMI and no income had lower impacts on the 'Anxiety and worry' and 'Social burden' domains and the overall HRQoL; in addition, higher BMI correlated with lower 'Diabetes control' scores. Unemployment was associated with higher 'Energy and mobility' domains and overall HRQoL, indicating a higher impact of DM, whereas family history predicted a higher impact on the 'Anxiety and worry' and

'Social burden' domains. The presence of complications correlated with a higher 'Energy and mobility' score, indicating a higher impact of DM.

[Table/Fig-5] Multiple linear regression analysis of the predictors of quality of life among patients { β (SD)}

DISCUSSION

This study was the first to use the Vietnamese translation of the D-39 questionnaire for assessment of the HRQoL in patients with T2DM; consequently, assessment of the reliability of this D-39 questionnaire was required. The Cronbach's alpha, used to evaluate the internal

	Total and domain-specific quality of life; Medians (25 th to 75 th percentiles) ^a					
Characteristics	Energy and mobility	Diabetes control	Anxiety and worry	Social burden	Sexual functioning	Total
Gender						
Males	40.0 (19.7-58.1)	27.1 (12.5-53.8)	35.4 (18.3-54.1)	21.7 (6.7-40.0)	13.9 (5.6-44.4)	36.5 (18.4-48.2)
Females	43.3 (23.3-62.2)	27.8 (9.7-50.0)	33.3 (16.7-62.5)	30.0 (6.7-56.7)	11.1 (5.6-16.7)	34.2 (18.4-51.3)
Age (years)						
≤50	38.9 (23.3-60.6)	36.8 (18.1-49.3)	45.8 (21.9-66.7)b	35.0 (15.0-62.5)	33.3 (5.6-77.8)°	40.8 (24.9-50.5)
50-65	43.3 (23.6-58.9)	25.7 (9.0-52.8)	37.5 (16.7-58.3)	25.0 (6.7-45.8)	11.1 (5.6-31.9)	34.8 (17.7-34.8)
>65	40.0 (14.4-62.2)	23.6 (9.7-52.8)	20.8 (8.3-45.8)	20.0 (3.3-56.7)	5.6 (0.0-16.7)	30.3 (13.2-49.1)
Residence						
Urban area	25.6 (11.1-48.9)c	18.1 (5.6-34.7)c	29.2 (4.2-54.2)b	13.3 (0.0-26.7)c	11.1 (5.6-16.7)	21.4 (8.5-41.5)c
Rural area	57.8 (41.4-65.3)	43.8 (22.6-63.2)	37.5 (20.8-62.5)	43.3 (30.0-65.9)	11.1 (5.6-44.4)	44.4 (34.6-57.9)
Marital status						
Single	41.1 (29.4-60.6)	44.4 (35.1-62.8)b	47.9 (25.0-75.0)	41.7 (33.3-61.7)b	38.9 (6.9-81.9)°	46.4 (34.8-54.4)b
Married	40.0 (19.2-59.7)	22.9 (10.1-48.3)	33.3 (8.3-58.3)	21.7 (6.7-45.8)	11.1 (5.6-26.40	30.8 (16.9-46.8)
Separated/ Divorced or Widowed	53.3 (24.4-64.4)	40.3 (8.3-52.8)	45.8 (16.7-62.5)	33.3 (2.3-63.3)	5.6 (0.0-11.1)	42.3 (16.2-54.3)
Living arrangements						
Alone	43.3 (28.6-61.4)	36.1 (27.1-50.3)	45.8 (20.8-56.3)	33.3 (12.5-46.7)	16.7 (4.2-77.8)	40.8 (27.2-52.1)
With family	41.1 (21.1-60.0)	26.4 (9.7-52.1)	33.3 (8.3-58.3)	23.3 (6.7-48.3)	11.1 (5.6-25.0)	34.2 (17.1-48.9)
Education level						
No school/ Illiterate	58.3 (35.3-64.4)	52.8 (25.7-65.3)	33.3 (20.8-45.8)	55.0 (33.3-77.5)b	8.3 (4.2-11.1) ^b	50.2 (39.6-54.4)
Primary school	37.2 (23.6-59.7)	22.9 (8.3-38.5)	33.3 (17.7-60.4)	20.0 (0.8-39.2)	11.1 (5.6-16.7)	29.1 (16.6-42.9)
Secondary school	38.9 (18.3-53.6)	22.2 (9.7-50.3)	37.5 (7.3-67.7)	13.3 (5.8-51.7)	5.6 (0.0-41.7)	26.1 (18.4-54.0)
High school or over	42.2 (20.0-61.1)	31.9 (12.5-52.8)	37.5 (8.3-58.3)	30.0 (6.7-46.7)	16.7 (5.6-44.4)	39.3 (15.0-48.3)
Employment						
Employed	40.6 (23.9-58.6)	29.9 (12.8-52.8)	35.4 (17.7-53.1)	31.7 (10.0-46.7)	11.1 (5.6-58.3)	38.9 (20.6-49.3)
Unemployment	70.0 (51.7-79.2)	55.6 (24.7-75.0)	66.7 (34.4-77.1)	51.7 (31.7-61.7)	36.1 (1.4-75.0)	63.0 (41.2-66.2)
Retirement	46.1 (10.8-62.2)	21.5 (8.0-21.5)	22.9 (7.3-58.3)	20.0 (0.0-36.7)	13.9 (0.0-30.6)	34.0 (7.1-45.9)
Home-maker	42.8 (19.7-56.4)	31.3 (8.3-31.3)	43.8 (7.3-64.6)	21.7 (2.5-42.5)	11.1 (5.6-18.1)	35.3 (13.6-50.0)
Other	34.4 (16.7-61.1)	26.4 (6.9-26.4)	20.8 (0.0-50.0)	23.3 (10.0-56.7)	11.1 (5.6-16.7)	30.3 (13.7-49.1)
Monthly Income (US\$)						
No income	43.9 (23.3-59.7)	31.3 (10.1-52.8)	33.3 (11.4-45.8)	31.7 (6.7-45.9)	11.1 (5.6-31.9)	42.3 (20.2-48.3)
<200	38.9 (19.4-58.6)	22.9 (8.3-48.3)	39.6 (16.7-62.5)	20.0 (3.3-46.7)	5.6 (5.6-16.7)	30.1 (14.1-48.2)
200-350	57.8 (21.7-63.3)	36.1 (16.0-56.3)	20.8 (8.3-54.2)	36.7 (13.3-61.7)	16.7 (5.6-66.7)	41.9 (19.9-58.3)
350-500	35.6 (30.0-39.5)	44.5 (27.1-59.7)	56.3 (18.7-65.7)	26.7 (15.0-33.3)	30.6 (7.0-70.9)	38.9 (28.7-45.6)
>500	44.5 (25.0-55.0)	36.8 (17.1-59.1)	37.5 (15.7-71.9)	20.0 (2.5-47.5)	5.6 (0.0-27.8)	35.5 (18.1-55.2)
Cigarette smoking						
Yes	30.0 (16.7-60.6)	24.3 (10.8-65.3)	41.7 (8.3-54.2)	20.0 (10.0-49.2)	16.7 (5.6-77.8)	34.2 (10.9-49.9)
No	43.3 (23.9-60.0)	27.8 (11.1-51.4)	33.3 (16.7-58.3)	26.7 (6.7-48.3)	11.1 (5.6-22.2)	35.0 (18.6-49.1)
Alcohol drinking						
Yes	37.8 (18.9-61.1)	47.2 (2.8-62.5)	45.8 (0.0-75.0)	33.3 (13.3-46.7)	38.9 (11.1-77.8)°	43.6 (10.3-53.4)
No	42.8 (23.3-59.7)	26.4 (11.1-48.3)	33.3 (16.7-58.3)	23.3 (6.7-49.2)	11.1 (5.6-22.2)	33.3 (18.4-48.6)
Exercise						
Yes	38.3 (17.5-58.9)b	25.7 (10.8-52.8)	37.5 (11.5-58.3)	20.0 (6.7-44.2)	11.1 (5.6-38.9)	30.1 (14.6-51.0)
No	46.7 (33.3-62.2)	33.3 (11.8-51.4)	33.3 (16.7-58.3)	30.0 (8.3-56.7)	11.1 (5.6-25.0)	40.2 (21.2-49.1)

[Table/Fig-3]: Diabetes-39 subscale scores according to demographic characteristics of the patients {Median (25th to 75th percentile)}. "Higher HRQoL scores indicates higher impacts of diabetes on the HRQoL (indicates a poorer HRQoL). "p-value<0.05.

°p-value<0.01

Characteristics	Total and domain-specific quality of life; Medians (25 th to 75 th percentiles) ^a						
Characteristics	Energy and mobility	Diabetes control	Anxiety and worry	Social burden	Sexual functioning	Total	
Duration (years)							
<5	44.4 (22.8-62.2)	33.3 (11.8-50.7)	37.5 (14.6-60.4)	30.0 (6.7-45.0)	11.1 (5.6-38.9)	39.3 (18.6-48.9)	
5-10	40.0 (23.3-58.3)	31.9 (16.0-52.8)	37.5 (16.7-62.5)	26.7 (10.0-56.7)	5.6 (5.6-22.2)	34.2 (21.6-53.0)	
>10	38.9 (17.2-61.1)	19.4 (8.3-45.1)	29.2 (4.2-45.8)	13.3 (0.0-45.0)	11.1 (5.6-19.4)	26.1 (14.3-50.2)	
BMI (kg/m ²)							
<18.5	46.7 (24.4-66.7)	73.6 (31.9-80.6) ^c	33.3 (20.8-70.8) ^b	66.7 (46.7-80.0) ^c	11.1 (5.6-72.2)	53.8 (33.3-70.1) ^c	
18.5-22.9	46.7 (24.2-62.2)	38.2 (15.6-53.8)	45.8 (20.8-66.7)	33.3 (10.0-60.0)	11.1 (5.6-43.1)	42.7 (20.7-55.8)	
23-24.9	40.0 (21.1-58.9)	18.1 (6.9-36.1)	29.2 (4.2-45.8)	16.7 (3.3-40.0)	11.1 (5.6-16.7)	27.4 (15.4-43.2)	
≥25	38.9 (7.8-54.4)	19.4 (11.1-39.6)	37.5 (8.3-52.1)	13.3 (1.7-33.3)	11.1 (2.8-33.3)	27.8 (12.2-42.5)	
Treatment							
Insulin	46.1 (31.9-68.3)	42.4 (21.1-65.6) ^b	45.8 (16.7-63.5)	41.7 (18.3-63.3) ^b	11.1 (5.6-48.6)	42.3 (29.1-58.9) ^b	
Oral drugs	40.0 (19.4-58.9)	26.4 (9.0-48.6)	33.3 (10.4-54.2)	23.3 (6.7-43.3)	11.1 (5.6-22.2)	32.1 (15.8-48.5)	
Family history							
Yes	48.9 (29.4-62.2)	38.9 (14.6-55.6) ^b	37.5 (20.8-64.6)	33.3 (13.3-56.7) ^b	11.1 (2.8-33.3)	43.2 (23.9-52.8) ^b	
No	36.7 (20.8-56.1)	23.6 (9.4-45.8)	33.3 (8.3-55.2)	20.0 (3.3-40.8)	11.1 (5.6-33.3)	30.8 (15.3-45.7)	
Presence of comorbidities ^d							
Yes	43.3 (27.8-58.9)	27.8 (12.5-52.8)	37.5 (16.7-58.3)	30.0 (6.7-56.7)	11.1 (5.6-22.2)	36.3 (22.2-49.6)	
No	26.1 (11.1-61.9)	23.6 (8.3-47.2)	27.1 (4.2-62.5)	18.3 (0.0-38.3)	16.7 (5.6-44.4)	21.6 (10.4-48.8)	
Presence of complications ^e							
Yes	49.4 (33.3-64.2) ^c	25.0 (16.7-47.2)	37.5 (20.8-58.3)	25.0 (10.8-55.8)	11.1 (5.5-16.7)	35.0 (23.7-50.7)	
No	37.8 (14.4-57.8)	31.9 (8.3-52.8)	33.3 (8.3-54.2)	26.7 (3.3-46.7)	11.1 (5.5-44.4)	35.0 (11.1-49.1)	

[Table/Fig-4]: Diabetes-39 subscale scores according to clinical characteristics of the patients {Median (25th to 75th percentile)}. "Higher HRQoL scores indicates higher impacts of diabetes on the HRQoL (indicates a poorer HRQoL). "p-value<0.05.

°p-value<0.01.

^aComorbidities include high blood pressure, hyperlipidaemia, coronary artery disease and depression. ^aComplications include neuropathy, retinopathy, nephropathy and cardiovascular disease.

Characteristics	Total and domain-specific quality of life; β^a (SD) ^a						
Characteristics	Energy and mobility	Diabetes control	Anxiety and worry	Social burden	Sexual functioning	Total	
Gender							
Males	6.27(5.03)	7.70(5.28)	7.10(6.98)	-0.06(5.24)	-6.19(6.58)	5.03(4.55)	
Females	NA ^b	NA ^b	NA ^b	NA ^b	NA ^b	NA ^b	
Age (years)	0.14(0.21)	0.14(0.22)	-0.16(0.28)	-0.04(0.21)	-0.38(0.27)	0.05(0.19)	
Residence							
Urban area	-22.32(4.38) ^e	-18.22(4.60) ^e	-9.98(6.08)	-24.07(4.57) ^e	-6.27(5.73)	-18.78(3.96) ^e	
Rural area	NA ^b	NA ^b	NA ^b	NA ^b	NA ^b	NA ^b	
Marital status							
Single	10.64(7.07)	13.16(7.41)	10.07(9.79)	13.63(7.36)	6.03(9.24)	11.38(6.39)	
Separated/Divorced/Widowed	8.37(5.96)	6.61(6.25)	4.88(8.27)	4.21(6.21)	-8.95(7.79)	5.60(5.39)	
Married	NA ^b	NA ^b	NA ^b	NA ^b	NA ^b	NA ^b	
Living arrangements							
Alone	-0.21(6.67)	0.02(7.00)	-0.31(9.26)	-4.56(6.95)	1.42(8.73)	-5.60(6.04)	
With family	NA ^b	NA ^b	NA ^b	NA ^b	NA ^b	NA ^b	
Education level							
No school/ Illiterate	-0.79(7.97)	14.27(8.36)	3.60(11.05)	14.69(8.30)	-1.17(10.42)	6.21(7.21)	
Primary school	-3.53(5.38)	-0.28(5.64)	7.68(7.46)	-0.95(5.60)	-8.02(7.03)	-1.40(4.86)	
Secondary school	-1.00(4.90)	3.47(5.14)	5.83(6.80)	4.14(5.11)	5.45(6.41)	2.23(4.43)	
High school or over	NA ^b	NA ^b	NA ^b	NA ^b	NA ^b	NA ^b	
Employment							
Unemployment	25.13(10.67) ^c	22.02(11.19)	22.11(14.80)	19.58(11.12)	9.24(13.95)	21.93(9.65) ^c	
Retirement	0.71(6.74)	-1.92(7.06)	-3.74(9.34)	0.46(7.02)	-0.19(8.81)	-0.65(6.09)	
Home-maker	3.45(5.40)	5.18(5.66)	10.80(7.48)	3.26(5.62)	-2.41(0.73)	4.27(4.88)	
Other	-1.45(5.64)	-5.02(5.91)	-0.06(7.82)	5.11(5.87)	5.28(7.37)	-1.86(5.10)	

Employed	NA ^b	NA ^b	NA ^b	NA ^b	NA ^b	NA ^b
Monthly Income (US\$)						
No income	-8.31(4.60)	-7.90(4.82)	-15.30(6.38) ^c	-10.37(4.79) ^c	2.40(6.01)	-8.34(4.16) ^c
200-350	0.76(4.86)	-2.57(5.10)	-11.84(6.74)	1.99(5.07)	10.16(6.36)	-0.68(4.40)
350-500	0.82(10.98)	10.25(11.52)	-1.85(15.23)	-2.14(11.44)	4.17(14.36)	3.33(9.93)
>500	0.44(8.94)	7.52(9.38)	3.45(12.40)	2.77(9.31)	-6.07(11.69)	2.73(8.08)
<200	NA ^b	NA ^b	NA ^b	NA ^b	NA ^b	NA ^b
Cigarette smoking						
Yes	-4.28(5.72)	-0.34(6.00)	1.06(7.94)	1.58(5.96)	1.69(7.48)	-1.31(5.18)
No	NA ^b	NA ^b	NA ^b	NA ^b	NA ^b	NA ^b
Alcohol drinking						
Yes	-7.71(6.19)	-0.62(6.49)	7.03(8.58)	-0.23(6.45)	14.87(8.09)	-1.32(5.60)
No	NA ^b	NA ^b	NA ^b	NA ^b	NA ^b	NA ^b
Duration (years)	-0.24(0.38)	-0.26(0.40)	-0.76(0.53)	-0.38(0.40)	0.33(0.50)	-0.27(0.35)
BMI (kg/m ²)	-0.10(0.57)	-2.24(0.59) ^e	-1.84(0.02) ^c	-2.27(0.59) ^e	0.61(0.74)	-1.50(0.51) ^d
Treatment						
Insulin	-2.51(4.95)	1.18(5.20)	1.61(6.87)	0.39(5.16)	6.69(6.48)	0.13(4.48)
Oral drugs	NA ^b	NA ^b	NA ^b	NA ^b	NA ^b	NA ^b
Family history						
Yes	6.04(3.69)	7.03(3.87)	11.37(5.12) ^c	8.28(3.84) ^c	-2.95(4.82)	6.49(3.34)
No	NA ^b	NA ^b	NA ^b	NA ^b	NA ^b	NA ^b
Presence of comorbidities ^d						
Yes	6.75(4.20)	1.78(4.41)	5.32(5.83)	8.36(4.38)	-4.64(5.49)	4.40(3.80)
No	NA ^b	NA ^b	NA ^b	NA ^b	NA ^b	NA ^b
Presence of complications ^e						
Yes	7.74(3.86) ^c	-3.22(4.04)	4.64(5.34)	-5.79(4.02)	-8.70(5.04)	1.05(3.49)
No	NA ^b	NA ^b	NA ^b	NA ^b	NA ^b	NA ^b

β: regression coefficient. Positive regression coefficients indicate higher impacts of diabetes on the HRQoL (indicates a poorer HRQoL).

^b Not applicable because this variable is the reference group p-value<0.05.

p-value<0.01

p-value<0.001

consistency scales, gave results ranging from 0.81 for 'Anxiety and worry' to 0.93 for 'Diabetes control' and 'Sexual functioning' and these values were similar to those obtained in the Carolina study (Cronbach's alpha 0.82 to 0.93) [9], in the Iowa study (Cronbach's alpha 0.81 to 0.93) [9] and in other studies conducted in the general populations of Norway (Cronbach's alpha 0.83 to 0.91) [12], Finland (Cronbach's alpha 0.83 to 0.92) [12] and Denmark (Cronbach's alpha 0.82 to 0.92) [12] and in Mexico (Cronbach's alpha 0.80 to 0.93) [13]. The Cronbach's alpha in this study (0.96) was also similar to that reported for the D-39 total score in Mexico (0.95) [13], and it indicated excellent reliability. The ICC for this study ranged from 0.80 for 'Anxiety and worry' to 0.93 for 'Sexual functioning' and showed good agreement in all subscales and the D-39 total score.

The median D-39 total score was 35.0 (on a scale of 0 to 100) and was similar to that reported for Mexico (29.0) [13] and the Caribbean (30.0) [8]. The score of 35.0 points indicated that the HRQoL of patients in this study was not much affected.

In this study, the place of residence was associated with Energy and mobility', 'Diabetes control', 'Social burden' scores and overall HRQoL score. Patients living in urban areas showed a lower impact of DM on these scores when compared with rural residents. A previous study using the SF-36 questionnaire reported that urban residence was associated with a higher HRQoL when compared with rural residence, and indicated disproportions in income, education level, occupation and access to healthcare systems between urban and rural residents [14]. Notably, no income was associated with lower 'Anxiety and worry' and 'Social burden' scores and D-39 total scores, indicating a higher HRQoL. Most patients who reported no income in the present study were elderly and were usually cared for by their family members, so they were less nervous about having a diabetic condition.

The results reported here also indicated no significant difference in HRQoL among respondents with different income levels. This outcome was similar to that reported previously in a South African research [15]. However, this result differed from other studies that showed a possible positive impact of higher income on HRQoL because higher income could reduce DM-related financial burdens and facilitate access to better healthcare systems, thereby contributing to a better HRQoL [16,17]. The results of a study conducted in Swaziland, which also used the D-39 questionnaire, suggested a correlation between higher income and a lower impact of diabetes on most HRQoL domains, except for 'Social burden'. In the present study, unemployment predicted a higher impact of DM on the 'Energy and mobility' score and the overall HRQoL score. The unemployed had debt overload and limited access to hospitals, which contributed to the process of diabetes and affected their energy and mobility, as well as their HRQoL in general.

Fal AM et al., reported that BMI affects HRQoL [18]. The findings of our study supported an association between BMI and HRQoL, but the relationship was inverse to that reported in the previous study. Remarkably, in our study, the patients who were overweight or obese showed a better HRQoL than those who were normal

weight. Namely, they scored lower on 'Diabetes control', 'Anxiety and worry', 'Social burden' and D-39 total score. Possibly, their DM was linked to being overweight and obese, so they were more aware of food restrictions or suitable diets that could help manage DM.

The knowledge and understanding obtained from a family history of DM could also help patients better manage their disease. A previous study showed that patients with a family history of DM were more successful in managing metabolic symptoms (including diabetes, hypertension, abnormalities in cholesterol levels, etc.,) when compared to those without a family history [19]. However, in the present study, our outcome was contradictory, as we found that a family history of DM predicted a higher impact on the 'Anxiety and worry' and 'Social burden' domains.

We also found that the presence of complications, including neuropathy, retinopathy, nephropathy and cardiovascular disease, had a significant adverse impact on 'Energy and mobility'. This finding agreed with those of a previous study by Camacho and colleagues [20], who investigated low-income patients with DM using selected subscales of both the D-39 and SF-36 questionnaires. They found that the number of past medical complications was a strong predictor of poor HRQoL in the SF-36 physical functioning subscale, but not in the other subscales.

The results of the present study showed statistically significant differences in the median scores of the 'Anxiety and worry' and 'Sexual functioning' subscales by age, as older patients had significantly lower scores for these subscales when compared with younger patients. This indicated that an older patient's life was less affected by DM in terms of these subscales. The reason for the lower 'Anxiety and worry' HRQoL score among older patients might reflect the fact that elderly patients were less anxious about their diabetic situation, whereas younger patients were more bothered about the progression of diabetes and its influences on their physical activities and social lives. Glasgow RE et al., using SF-20, reported that older patients had higher scores on the scale measuring mental health (indicating a better HRQoL), in agreement with our findings [21]. Moreover, they also found that the scores were significantly lowered in older than in younger patients for the scales measuring physical functioning.

A previous study in Mexico [13] showed that women scored higher on the 'Energy and mobility' subscale, while men showed a greater effect on the 'Sexual functioning' subscale. Other studies conducted in Pakistan, Greece [22] and India [23] (using SF-36 questionnaire) found significantly higher scores in males as compared to females in several domains among the eight domains of the SF-36. Our study was not consistent with these previous findings, as we found no association between gender and HRQoL scores of our T2DM patients. However, the outcomes of our study were analogous to those of a study conducted in South Africa [15].

Lifestyle changes related to loss of weight, increased physical exercise, adjustment of eating habits, cessation of cigarette smoking, and decreased alcohol consumption may play important roles in preventing the progression of DM and its complications. The present study found no association between HRQoL and cigarette smoking, but it indicated significant differences between patients' who consumed alcohol and others. The patients who drank alcohol scored higher on 'Sexual functioning' indicating greater impairment of sexual functioning. The reason for this could reflect that this impairment was one of the typical complications of diabetes and that alcohol consumption might increase the progression of these complications.

In the current study, patients who undertook regular exercise scored lower on 'Energy and mobility', in agreement with a previous study in Turkey [24] that evaluated the association between physical activity level and the HRQoL of T2DM patients. Our findings showed that, apart from the "Diabetes control" subscale, the scores for all the subscales and the D-39 total score had a statistically significant negative correlation with physical activity level.

Previous studies have also reported that higher education level was related to better HRQoL, presumably because education played an important role in understanding self-care and the self-management of DM [25,26]. In our study, the patients with different education levels showed significant differences in HRQoL of 'Sexual functioning' and 'Social burden'. This outcome of our study was similar to that reported by Glasgow RE et al., [27]. Therefore, we supposed that limited education could substantially contribute to a lack of awareness of the healthcare options available for patients with DM.

A previous study in Swaziland found no correlation between marital status and HRQoL in T2DM patients [28]. By contrast, the current study indicated significant differences among patients who had different marital status in terms of 'Diabetes control', 'Social burden', 'Sexual functioning' and D-39 total score.

The duration of DM has a reported relationship with reduced HRQoL [21]. One explanation is that the longer a patient has T2DM, the more likely complications are to progress, thereby worsening HRQoL. Nevertheless, Rubin RR et al., and Redekop WK et al., found no correlation between DM duration and HRQoL, in contradiction to the current study results [29,30]. A possible reason for this difference might be that the DM duration was not necessarily associated with good control or good experiences with treatment, and therefore did not necessarily affect HRQoL.

In terms of DM treatments, we found that patients on insulin treatment had significantly poorer HRQoL scores for 'Energy and mobility' in the present study, in agreement with previous studies [4,20] that reported lower physical functioning in patients taking insulin than in patients using oral agents for DM treatment. The decrease in physical functioning might be associated with an increased severity of diabetes, since insulin use for T2DM patients is usually related to increasing years with the disease, as well as the presence of complications of diabetes. In addition, our study also showed an impact on 'Social burden' in patients using insulin therapy.

LIMITATION

This study has several limitations. The D-39 questionnaire had not been used previously to assess HRQoL in T2DM patients in Vietnam, so it has not been validated for use in these study subjects. In addition, this was a cross-sectional study; hence, a causal relationship between the factors found in this study and the HRQoL cannot be established. Furthermore this study was implemented in only one hospital in southern Vietnam with a small sample size, so our outcomes cannot be generalised with respect to Vietnamese diabetes patients. Nevertheless, as this is the first time the Diabetes-39 instrument has been applied to evaluate HRQoL of T2DM in Vietnam, we believe that our results are useful and worth sharing with the research community.

CONCLUSION

This study found the statistically significant differences between HRQoL in T2DM patients in terms of age, residence, marital status, education level, alcohol drinking, exercise, BMI, DM treatment, family history and presence of complications. The results of the multiple linear regression analyses showed that residence, employment, income, BMI, family history and presence of complications were independent predictors for certain domains and overall HRQoL. A further study on the validation of D-39 and a larger scale or population-scale study are needed to identify factors related to HRQoL in T2DM patients in Vietnam.

ABBREVIATIONS

BMI: Body Mass Index; D-39: Diabetes-39 Instrument; HRQoL:

Health-Related Quality of Life; ICC: Intraclass Correlation Coefficient; US\$: United States Dollar; DM: Diabetes Mellitus; T2DM: Type 2 Diabetes Mellitus.

DISCLOSURE

The Authors declare that they have no relevant conflicts of interest to disclose.

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