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Research Article

Health-related Quality of Life among Patients with Type II Diabetes Mellitus

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Abstract:

Background: Diabetes mellitus is a chronic disease that causes considerable morbidity and mortality worldwide, resulting in an impaired quality of life in affected people.

Aim: To assess health-related quality of life among patients with type II diabetes mellitus and its associated factors.

Methods: A cross-sectional study design was conducted from January to July 2022 at Ribat University Hospital in Khartoum and Abdallah Khalil Diabetic Centre in Omdurman. A total of 400 patients with type II diabetes who visited the referred clinics were enrolled in the study. Data was collected by face-to-face interview using the revised Diabetes Quality of Life instrument to assess the health-related quality of life. Data was analyzed using SPSS version 23.0 and summarized using tables and charts. The association between health-related quality of life and sociodemographic characteristics, clinical factors and lifestyle factors was obtained using chi-square test.

Results: The mean score for overall health-related quality of life was 29.3 ± 11.5 while each domain of "satisfaction", "impact" and "worry" had mean scores of 13.7 ± 4.9 , 8.5 ± 4.4 and 7.1 ± 3.7 , respectively. Since the scores obtained were only approximately half of the possible range of scores for quality of life, the overall health-related quality of life is considered to be moderate. This study also revealed that 40% of the participants have poor health-related quality of life. The relationship between HbA1c level & health-related quality of life was statistically significant (P value = 0.044) in which high glycosylated hemoglobin levels was associated with poor quality of life. Gender, age, education level, marital status, duration of diabetes and the presence of comorbidities and complications had statistically significant association with health-related quality of life.

Conclusion: This study demonstrates a moderate overall health-related quality of life among patients with T2DM. Besides, it also demonstrates a low quality of life among 40% of patients with T2D, suggesting that quality of life should be included in any modality used for treating diabetic patients.

Keywords: health-related quality of life; type II DM; quality of life

Introduction

The World Health Organization (WHO) defines health as a state of complete physical, mental, and social well-being ⁽¹⁾. This definition has served as the foundation for the development of multiple definitions of health-related quality of life (HRQOL), as well as measures to assess it. According to United States Centers for Disease Control and Prevention (CDC), quality of life (QOL) is a multidimensional concept that includes evaluations of both positive and negative aspects of a person's life. Since the 1980s, the term health-related quality of life has comprised those aspects of QOL that can be shown to affect physical or mental health ⁽²⁾. On the individual level, HRQOL includes physical and mental health perceptions including health risks and conditions, functional status, social support, and socioeconomic

status. On the community level, HRQOL includes community-level resources, conditions, policies, and practices that influence a population's health perceptions and functional status. On the basis of a synthesis of the scientific literature and advice from its public health partners, CDC has defined HRQOL as "an individual's or group's perceived physical and mental health over time" (3). Another definition by the WHO is that HRQOL refers to "the physical, psychological, and social domains of health that are influenced by a person's experiences, beliefs, expectations, and perceptions" (4). The issue of HRQOL is particularly important for diseases such as diabetes, for which the health care regimen requires ongoing self-care behaviors that can interfere with patients' desired lifestyles; therefore,

healthcare providers should strive to understand the physical, emotional, and social impact of chronic diseases such as diabetes.

Diabetes is a chronic disease that occurs either when the pancreas fails to produce enough insulin or when the body cannot effectively utilize the insulin it produces. It is a major cause of blindness, kidney failure, heart attacks, stroke and lower limb amputation (4). Diabetes mellitus and its complications have contributed tremendously to the burden of mortality and disability worldwide (4). The prevalence of this debilitating illness has increased dramatically in all parts of the world. The number of people with diabetes has raised from 108 million in 1980 to 422 million in 2014 (5). The prevalence has been rising more rapidly in low- and middle-income countries than in high-income countries (4). Globally, the number of patients with diabetes is expected to rise to 643 million by 2030 and 783 million by 2045. Indeed, the prevalence of diabetes in adults aged 18–99 years was estimated to be 8.4% in 2017 and predicted to rise to 9.9% in 2045 (6). The Middle East and North Africa (MENA) region has the highest regional prevalence of 16.2% and the second highest expected increase (86%) in the number of people with diabetes reaching 136 million by 2045 (7).

Based on the International Diabetes Federation's (IDF) diabetes atlas published in 2019, Sudan is included among countries with a diabetes prevalence of more than 12% (7). This is consistent with a recent study from Sudan that documented the prevalence to be around 20.8% ⁽⁸⁾.

Since diabetes is a chronic illness, therefore there is a need for assessing the HRQOL of patients at regular intervals. The complications of diabetes affect the organ system and are responsible for the majority of morbidity and mortality associated with the disease ⁽⁹⁾. The HRQOL is very important because it is a powerful tool to predict an individual's capacity to manage the disease and maintain long-term health and wellbeing ⁽¹⁰⁾. The routine assessment of QOL as part of clinical practice can improve communication between patients and health care providers, identify frequently overlooked problems, assess them, and evaluate the effectiveness of the therapeutic efforts ⁽¹¹⁾.

In spite of the fact that HRQOL is an important input for decision makers and policymakers and also for the development of guidelines, Sudan remains with scanty comprehensive studies about HRQOL in diabetics; a situation that will undermine the management of diabetes. In other words, it is questionable whether the factors associated with HRQOL of diabetic patients in the other studies apply to the patients in Sudan. These studies however provide a basis for obtaining an understanding of the factors associated with HRQOL of diabetic patients in the country. Particularly, this study seeks to establish how the factors in the literature related to diabetic patients in the Sudan.

Methods

A cross-sectional, descriptive, observational study design was conducted between January _ July 2022. The study was carried out at two diabetic clinics in Khartoum state: one in Ribat University Hospital in Khartoum and the other in Abdalla Khalil Diabetic Centre in Omdurman. The patients were recruited from the referred clinics. All male & female patients with type II diabetes mellitus on follow-up fulfilling the eligibility criteria were included in the study. The inclusion criteria were male & female patients with type II diabetes aged 40 years and above, and patients diagnosed for more than a year. The exclusion criteria were being pregnant, patients with cognitive impairment, patients with co-morbid conditions not directly related to diabetes, and patients with severe illness.

Sample size was calculated using a single population proportion formula assuming proportion of HRQOL among type 2 DM patients 50%, 5% margin of error (ϵ) and 95% (za/2 = 1.96) and thus, the final sample size was calculated to be 385. The 50% was purposively selected so that it provided the largest minimum sample size. After adjusting for non-response, the sample size was calculated to be 400.

All diabetic patients who came to the hospitals were recruited consecutively until the minimum required sample size was reached. Proportional allocation was used to decide the number of participants from each hospital.

Data collection and questionnaire were carried out through face-to-face interviews with the patients after obtaining informed consent. The participants were interviewed in Arabic at the referred clinics. During the interview patients were asked about socio-demographic data (age, sex, marital status, educational level, occupation), clinical data (duration of diabetes, type of diabetes, type of treatment, diabetes-related complications, co-morbidities & HbA1c level) and lifestyle measures (diet control, smoking, alcohol consumption, foot care). HbA1c result within the last 6 months was recorded from the patients' follow up cards. Glycaemic control was defined in accordance with the specifications of the ADA for nonpregnant adults and the IDF as follows: Good glycaemic control was determined when the HbA1c target was < 7.0%, and glycaemic control was considered uncontrolled if HbA1c levels were ≥ 7.0%. The HRQOL was assessed using a Diabetes-specific HRQOL questionnaire which includes aspects of health that are considered to pertain to diabetes and to be most important to diabetic patients, in order to show the impact of diabetes on patients' functionality and well-being. Diabetes-specific instruments have the advantage over generic ones in that they can detect small changes with clinically relevant differences, as well as provide insights into the specific mechanisms of self-care in diabetes. In this study, the revised Diabetes Quality of Life Questionnaire (DQOL) instrument was used. A shorter version of DOOL instrument was developed including 13 items and maintaining the same three domains. The participants rank on a 5-point Likert scale with 1 (very satisfied) to 5 (very dissatisfied) for "satisfaction" domain as well as 1 (never) to 5 (all the time) for "impact" and "worry" domains. The total score ranges from 13 to 65; satisfaction (6 items, range 6_30), impact (4 items, range 4_20) and worry (3 items, range 3_15). The HRQOL score is the algebraic sum of the three scores and ranges between the minimum value of 13, corresponding to the highest HRQOL level, and a maximum of 65, corresponding to the lowest HRQOL level. There are no validated cut-off points to define poor/good HRQOL, therefore, higher average score indicated a poorer HRQOL. The original DQOL instrument was validated in Arabic to be used in Arabic speaking patients but the revised instrument was not (12). Since the revised version included items from the original version, these items which were translated in Arabic in the original instrument were used.

The dependent variable was Overall HRQOL score, and the independent variables were socio-demographics (age, sex, marital status, educational level, occupation), clinical data (duration of diabetes, type of diabetes, type of treatment, HbA1c, diabetes-related complications and co-morbidities), and lifestyle measures (diet control, smoking, alcohol consumption, foot care).

Data was entered in Excel sheet then exported to SPSS version 23.0. Descriptive statistics was done for all variables then summarized by percentages for categorical variables and mean and standard deviation (SD) for scale variables then presented into tables and diagrams as appropriate. The data obtained on Likert scale were analysed by presenting each domain in a custom table, the sum score for each domain and the overall score was calculated and summarized by mean and SD and the minimum and maximum scores were documented as well. The outcome variable was binary. The overall DQOL was indicated as 'low/poor quality of life' (DQOL score> population mean) or 'good quality of life (total DQOL score < population means). As for domains, we have low life satisfaction (satisfaction score> population mean), high diabetes impact (impact score> population mean), and high diabetes worry (worry score> population mean). The association between DOOL and sociodemographic characteristics, clinical factors and lifestyle factors was obtained using chi-square test. For each test, a p-value of less than 0.05 was considered statistically significant. The scale variable was tested by independent t-test and again a p-value of less than 0.05 was considered statistically significant.

Regarding the ethical consideration, the written ethical clearance and approval for conducting this research was obtained from Sudan Medical Specialization Board Ethical Committee & Education & Development center. Written permission was obtained from the Ministry of Health & the administrative authority of each hospital included in the study. Written informed consent was obtained from all study participants before being involved in the study. Data collected was used for research purposes only and confidentiality issues were considered by using a serial number to identify participants.

Results

The mean age of the participants was 58.4 ± 8.6 . More than half of the participants were male (60%). The majority received formal education, however, only 6.3% were university graduates. Almost half of them were on oral drugs while one third was on insulin. Very few were on both of them [table-1].

Variable		Frequency	Percentage %	Mean	SD
Age	_			58.4	8.6
Gender	Female	160	40.0%		
	Male	240	60.0%		
Marital status	Divorced	8	2.0%		
	Married	279	69.8%		
	Single	70	17.5%		
	Widow	43	10.8%		
Education	No Formal Education	98	24.5%		
	Primary	123	30.8%		
	Secondary	154	38.5%		
	University	25	6.3%		
Occupation	Employee	63	15.8%		
	Housewife	68	17.0%		
	Retired	19	4.8%		
	Self-employed	151	37.8%		
	Un-employed	99	24.8%		
Medical Insurance	No	143	35.8%		
	Yes	257	64.3%		
Type of treatment	Diet only	38	9.5		
	Diet + Insulin	130	32.5		
	Diet + Oral hypoglycemic drug	199	49.8		
	Diet + Oral hypoglycemic drug + Insulin	33	8.3		

Table-1: Distribution of Diabetic Patients' Characteristics. (n=400)

The majority of the patients diagnosed with DM within 5 to 10 years. 94.8% of the participants had poor glycemic control. The most prevalent comorbidity was hypertension (72.8%), while the most prominent complication is retinopathy (25.5%) [table-2].

	Disease		Frequency	Percentage %
Complications	Nephropathy	No	359	89.8%
		Yes	41	10.3%
	Neuropathy	No	350	87.5%
		Yes	50	12.5%
	Retinopathy	No	298	74.5%
		Yes	102	25.5%
	Diabetic foot	No	375	93.8%
		Yes	25	6.3%
	Myocardial infarction	No	360	90.0%
		Yes	40	10.0%
	Peripheral Artery Disease	No	392	98.0%
		Yes	8	2.0%
	Stroke	No	362	90.5%
		Yes	38	9.5%
Comorbidities	Hypertension	No	109	27.3%
		Yes	291	72.8%
	Dyslipidemia	No	338	84.5%
		Yes	62	15.5%
	Obesity	No	366	91.5%
		Yes	34	8.5%

Table-2: Complications of DM and Associated Comorbidities among the Participants (n=400)

Approximately one third of the participants (35%,32.5%) performed physical exercise and followed diet control, respectively. The majority were non-smokers & none of them consumed alcohol (79.3%, 100%), respectively [table-3].

Variable		Frequency (n=400)	Percentage (%)
Physical Exercise	No	260	65.0%
	Yes	140	35.0%
Diet control	No	270	67.5%
	Yes	130	32.5%
Smoking	No	317	79.3%
	Yes	83	20.8%
Alcohol consumption	No	400	100.0%
	Yes	0	0.00%
Foot Care	No	354	88.5%
	Yes	46	11.5%

Table 3.3 Distribution of Lifestyle Factors.

Regarding DQOL statistics, the mean and SD for satisfaction, impact and worry were $(13.7 \pm 4.9, 8.5 \pm 4.4, \text{ and } 7.1 \pm 3.7)$ respectively [table-4.1 and table-4.2].

Satisfaction Domain	Very Satisfied		Moderately Satisfied		Neither		Moderately Dissatisfied		Very I	Very Dissatisfied	
Time it takes to manage diabetes Time spend getting checkups Time it takes to determine the sugar level Current treatment Knowledge about diabetes Life in general	174 159 124 184 69 30	43.5% 39.8% 31.0% 46.0% 17.3% 7.5%	159 173 163 128 188 65	39.8% 43.3% 40.8% 32.0% 47.0% 16.3%	21 9 16 8 75 148	5.3% 2.3% 4.0% 2.0% 18.8% 37.0%	36 59 89 35 45 116	9.0% 14.8% 22.3% 8.8% 11.3% 29.0%	10 0 8 45 23 41	2.5% 0.0% 2.0% 11.3% 5.8% 10.3%	
Impact Domain	Never	Never		Very Seldom		Sometimes		Often		All The Time	
Pain associated with the treatment Physically ill Diabetes interferes with the family life Diabetes limits social relationships and friendships	195 133 205 197	48.8% 33.3% 51.2% 49.3%	103 101 88 69	25.8% 25.3% 22.0% 17.3%	38 70 30 74	9.5% 17.5% 7.5% 18.5%	35 59 50 33	8.8% 14.8% 12.5% 8.3%	29 37 27 27	7.2% 9.3% 6.8% 6.8%	
Worry Domain	Never		Very S	Seldom	Somet	imes	Often		All Th	ie Time	
Whether you will pass out Your body looks different because you have diabetes Getting complications	149 198 83	37.3% 49.5% 20.8%	121 66 124	30.3% 16.5% 31.0%	58 60 88	14.5% 15.0% 22.0%	29 25 45	7.2% 6.3% 11.3%	43 51 60	10.8% 12.8% 15.0%	

Table-4.1: DQOL Responses of the Participants in Each Domain

	Items	Mean	SD	Minimum	Maximum
Satisfaction domain	6	13.7	4.9	7	27
Impact domain	4	8.5	4.4	4	20
Worry domain	3	7.1	3,7	3	15
Overall DQOL	13	29.3	11.5	15	61

Table-4.2: Summary Statistics on DQOL

The mean age of those with poor quality of life is significantly higher than those with good quality of life. The relationship is statistically significant. [table-5].

L	Overall Quality of Life	N	Mean Age	SD	Std. Error Mean	Independent t-test
	Poor	160	62.97	6.7	.550	P value < 0.001
L	Good	240	55.36	8.8	.527	

Table-5: The Association between HRQOL and age of the participants (n=400)

Regarding, the association between HRQOL and other demographic characteristics, there was a statistically significant association between HRQOL and gender, medical insurance, marital status, education and occupation [table-6].

		Overall Qualit	Chi square	df	p-value			
		Poor		Good				
		Frequency	Percentage	Frequency	Percentage			
Gender	Female	97	60.6%	63	39.4%			
	Male	63	26.3%	177	73.8%	47.266	1	< 0.001
	No	75	52.4%	68	47.6%			

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Medical Insurance	Yes	85	33.1%	172	66.9%	14.369	1	< 0.001
Maritals	Divorced	3	37.5%	5	62.5%			
Status	Married	105	37.6%	174	62.4%			
	Single	19	27.1%	51	72.9%			
	Widow	33	76.7%	10	23.3%	29.683	3	< 0.001
Education	No formal education	72	73.5%	26	26.5%			
	Primary	39	31.7%	84	68.3%			
	Secondary	49	31.8%	105	68.2%			
	University	0	0.0%	25	100.0%	70.228	3	< 0.001
Occupation	Employee	9	14.3%	54	85.7%			
	Housewife	41	60.3%	27	39.7%			
	Retired	10	52.6%	9	47.4%			
	Self-employed	26	17.2%	125	82.8%			
	Unemployed	74	74.7%	25	25.3%	112.748	4	< 0.001

Table-6: The Association between HRQOL and other Demographic characteristics of the participants (n=400)

Also, there was a statistically significant association between HRQOL and diabetes related factors [table-7].

		Overall Quali	ty of Life			Chi square	df	P-value
		Poor		Good				
		Frequency	Percentage	Frequency	Percentage			
Duration	< 5 years	2	3.4%	56	96.6%			
	5 - 10 years	58	30.5%	132	69.5%			
	> 10 Years	100	65.8%	52	34.2%	81.515	2	< 0.001
Treatment	Diet only	11	28.9%	27	71.1%			
	Diet + Insulin	79	60.8%	51	39.2%			
	Diet + OHD	44	22.1%	155	77.9%			
	Diet + OHD + Insulin	26	78.8%	7	21.2%	72.522	3	< 0.001
HbA1c	< 7	4	19.0%	17	81.0%			
	= > 7	156	41.2%	223	58.8%	4.054	1	0.044

Table-7: The Association between HRQOL and Diabetes related factors

In terms of association between HRQOL and complications, comorbidities, and life-style factors, there was a statistically significant association between them and HRQOL, except the foot care [table-8 - 10].

		Overall Qual	ity of Life			Chi	df	P value
		Poor		Good		square		
		Frequency	Percentage	Frequency	Percentage			
Nephropathy	No	132	36.8%	227	63.2%			
	Yes	28	68.3%	13	31.7%	15.237	1	< 0.001
Neuropathy	No	152	43.4%	198	56.6%			
	Yes	8	16.0%	42	84.0%	13.714	1	< 0.001
Retinopathy	No	87	29.2%	211	70.8%			
	Yes	73	71.6%	29	28.4%	56.852	1	< 0.001
Diabetic foot	No	135	36.0%	240	64.0%			
	Yes	25	100.0%	0	0.0%	40.000	1	< 0.001
Myocardial	No	125	34.7%	235	65.3%			
Infarction	Yes	35	87.5%	5	12.5%	41.782	1	< 0.001
Peripheral	No	152	38.8%	240	61.2%			
Arterial Disease	Yes	8	100.0%	0	0.0%	12.245	1	< 0.001
Stroke	No	134	37.0%	228	63.0%			
	Yes	26	68.4%	12	31.6%	14.132	1	< 0.001

^{*.} The Chi-square statistic is significant at the .05 level

Table-8: The Association between HRQOL and Complications

Overall Quality of Life		

		Poor		Good	Good		df	p-value
		Frequency	Percentage	Frequency	Percentage			
Hypertension	No	20	18.3%	89	81.7%			
	Yes	140	48.1%	151	51.9%	29.265	1	< 0/001
Dyslipidemia	No	108	32.0%	230	68.0%			
	Yes	52	83.9%	10	16.1%	58.841	1	< 0/001
Obesity	No	135	36.9%	231	63.1%			
	Yes	25	73.5%	9	26.5%	17.406	1	< 0.001

^{*.} The Chi-square statistic is significant at the .05 level

Table-9: The Association between HRQOL and Comorbidities

		Overall Quality of Life						
		Poor		Good		Chi	df	p-value
		Frequency	Percentage	Frequency	Percentage	square		
Physical Exercise	No	126	48.5%	134	51.5%			
	Yes	34	24.3%	106	75.7%	22.161	1	< 0.001
Diet Control	No	102	37.8%	168	62.2%			
	Yes	58	44.6%	72	55.4%	1.709	1	0.191
Smoking	No	150	47.3%	167	52.7%			
	Yes	10	12.0%	73	88.0%	34.095	1	< 0.001
Alcohol	No	160	40.0%	240	60.0%			
Consumption	Yes	0	0.00%	0	0.00%			
Foot Care	No	140	39.5%	214	60.5%			
	Yes	20	43.5%	26	56.5%	.262	1	0.609

Table-10: The Association between HRQOL and Lifestyle Factors

Discussion

The current study assessed the HRQOL in Sudanese patients with T2DM using the revised DQOL questionnaire. It is sometimes difficult to compare studies using DQOL, since some authors use an inverse scoring system (higher scores reflecting better QOL). In the present study, the original scoring method was used; a high average score indicates a poor QOL. This study revealed that the mean ± SD score for overall revised DQOL instrument was 29.3 ± 11.5 while each domain of "satisfaction", "impact" and "worry" had mean scores of 13.7 ± 4.9 , 8.5 ± 4.4 and 7.1 ± 3.7 , respectively. The scores obtained were only approximately half of the possible range of scores for QOL. Since a higher average score would signify a poorer QOL, it seems that the disease did not badly affect the QOL among T2DM patients. As a result, it can be said that the participants had a moderate HRQOL. They were satisfied with the amount of time they spent due to T2DM, the current treatment, knowledge and life in general. Apart from that, they also felt that T2DM had very seldom impact on their life and therefore were not really worried. These results are similar to a previous study in Malaysia where the results were also half of the possible range of scores for QOL and it concluded that patients with T2DM had an acceptable HRQOL (13). Since the majority of the participants had diabetes for more than 5 years, the moderate HRQOL finding can be justified by the fact that longer duration of illness means long duration on follow-up, therefore better experience in diabetic self-care practice, life style modification and adherence of medication. Moreover, it might signify a mean of coping strategy to reduce anxiety.

This study also revealed that 40% of the participants have overall score above the mean, i.e., poor DQOL. This is in consistency with previous studies in South Benin and Malaysia that reported that poor DQOL in 43% and 43.6% of the participants respectively (14,15). Studies conducted in Ethiopia (16) and Saudi Arabia (17) used different measurement scales and affirmed our findings. However, these results should be interpreted with caution when comparing the scores as the QOL value sets for each country depending on the choice of instruments, the number of levels, the quality of diabetes care, or the availability of access to support services.

Regarding each domain, the results reveal that the highest percentage of participants have a poor QOL in "Satisfaction" and "Worry" domains, (39.8% and 39.5% respectively), while 36.5% have a poor QOL in "Impact" domain; there is no much variation between the domains. These findings are almost similar to a recent study in Malaysia where participants had worse QOL in "Satisfaction" domain (40.4%), however in contrast to this study, the least percentage (31.9%) of participants had a poor QOL level in the "Worry" domain (15). Not only this, but also another study aimed to assess the factors associated with QOL in Patients with T2DM in South Benin using the revised DQOL instrument concluded that more than half of participants reported problems in the impact and satisfaction domains, whereas one third in the worry domain (14). The reason for this may be due to sociocultural variations and lifestyle differences.

Although the overall HRQOL score was moderate/acceptable, 40% of patients have a poor QOL. Hence, it is important to assess the influencing factors of HRQOL in patients with T2DM for the better planning of interventions to improve the physical and psychosocial burden of the disease, and hence to attain better HRQOL.

The findings in the literature regarding the QOL of patients with T2DM and its association with sociodemographic factors have been variable. To begin with, this study revealed that the mean age was 58.4 ± 8.56 years. This result is similar to a study in Egypt (18) which similar mean age of 54.74 years. This indicates that type 2 diabetes is more commonly observed among the middleaged. This could be explained as diabetes can go silently, undetected for a long time, without symptoms and many people first became aware that they had diabetes when they developed one of its potentially life-threatening complications, such as heart disease. The mean age of those with poor quality of life is significantly higher than those with good quality of life (P value <0.001). This finding is consistent with a study that reported that patients who are less than 40 years of age have significantly better QOL than other age groups (19). This can be explained by the fact that age is related to several changes in the body and increases the risk of developing co-morbid diseases and further reduces individual well-being. The ADA also shows that the aging process leads to a degeneration of muscles, ligaments, bones, and joints and that diabetes may exacerbate the problem (20). The findings in this study imply that gender differences have an impact on HRQOL. Women appeared to have a worse QOL than men (P value <0.001). This coincides with a previous study in Saudi Arabia (21). Diabetes has also more impact on women than men, emphasizing the need for sex-specific approaches in diabetes management (22). One probable reason is that females report greater burden and restriction in their social interactions and less leisure time flexibility in addition to the greater responsibilities at home. Marital status has a significant association with the QOL (P value < 0.001), in which poor QOL is significantly higher among widowed (76.7%) compared to married, divorced and single participants (37.6%, 37.5% and 27.1% respectively). This relationship between marital status and QOL is also observed in previous studies conducted on DM patients (23). The possible explanation for the finding is that being widowed may increase social isolation by the population, feeling lonely, and lack of confidence in the community, family health instability and economic crisis while married patients might be psychologically stable, have spouse support and better social interaction.

Regarding the level of education, the current study has shown that low educational levels adversely affect patients' QOL. Illiterate patients have the worse QOL scores compared to those with higher educational levels. Not only this, but it also showed that all patients who are university graduates had a good QOL. This finding was consistent with previous studies conducted in Ethiopia (24). The possible explanation of this finding is that patients who were educated in university level might have better social relationship with the community, adapted to the environment easily, might have planned recreational time, better understanding regarding behavioural risk factors and diabetic self-care practice and the effects of diabetes on their health; thus, they are more likely to adjust to their recommended treatment and diet regimen.

HRQOL of unemployed patients with T2DM is poor as compared with those patients who are employers. A national survey conducted in Iran has also reported a significant association between employment and HRQOL of patients with T2DM ⁽²⁵⁾. A study done in Nigeria on QOL of patients with DM and Benin has also showed significant association of occupation with QOL ^(26,14). This may be explained by the fact that improvement in socioeconomic status can improve QOL. Furthermore, the subjects with health insurance had a better QOL than those without insurance, this can be attributed to regular check-ups, and the insurance company covering medications and other costs therefore promoting medication adherence.

Many studies reported an association between increased duration of diabetes and poor HRQOL, in both types of diabetes (27,24,14). On the other hand, there are also contradicting findings about the association between duration of diabetes and HRQOL (28,29). In this present study we found a negative association between diabetes duration and HRQOL. The longer duration of diabetes is associated with the poor HRQOL. This may be due to the fact that long disease duration increases renal, eye, neural and other complications of diabetes, and being dependent on medications for a longer time which may cause side effects and then contributes to impairment in HRQOL.

Patients who are taking insulin and oral anti diabetic medication treatment regimen had negatively affected HROOL as compared with those patients who are taking oral anti diabetic medication only. This study finding was consistent with studies conducted in China, Indonesia and Malaysia (30,31). This might be the physiological side effect of insulin and oral anti diabetic medication. Taking insulin and oral anti diabetic medication may disturb the metabolic process of the body and developing brain cell toxicity followed by disturbing body image and headache. On the contrary, other studies reported that insulin-treated diabetic patients had reduced impact on HRQOL than oral hypoglycaemic drugs/diet-treated patients (32). The difference might be due to genetic variation for medication side effects, diabetic self-care practice difference may be interrupting regular medication intake and sociodemographic factors. In Uganda, the type of treatment was not significantly associated with the quality of life of diabetic patients. The nonsignificant influence of type of medication on quality of life of diabetic patients in Uganda supports the argument of mixed conclusion reached by whether or not insulin is administered (33). Furthermore, another study in India concluded that the QOL of patients on combination therapy with insulin and OHA was better than the patients on monotherapy with only insulin or OHA (34). These may be attributed to the fact that using combination therapy of insulin and OHA gives a better glycemic control.

The relationship between glycemic control and QOL is the subject of debate. This study revealed a statistically significant relationship between HbA1c level & poor QOL (P value = 0.044). This result was also documented previously ⁽³⁴⁾. Glycaemic control was shown to be a definitive determinant of HRQOL, with high glycosylated haemoglobin levels identified as an independent determinant of impaired overall DQOL score as well as scores of every domain in DM ⁽³⁵⁾. It can be summarized from these data that maintaining adequate metabolic control is essential to maintaining QOL in patients with DM; the way each patient achieves this control seems to be irrelevant. On the other hand, tight glycemic control has also been found to have negative impact on quality of life due to restrains on daily life activities ⁽³⁶⁾.

Diabetic patients are more susceptible to macro or microvascular complications than those without T2DM. The most commonly observed diabetic complication was diabetic retinopathy (25.5%). The present study indicated a significantly worse HRQOL among patients with diabetes complication than the patients with diabetes alone. This is similar to previous results (21,16). The long-term complications, particularly microvascular disease, have been directly related to poor glycemic control (37). As many patients are likely to remain undiagnosed for several years before symptoms appear, many will show evidence of diabetic complications at diagnosis.

In this study, the most predominant comorbidity is hypertension 72.8%. Similar results were seen in previous studies ⁽³⁸⁾. A previous study reported that more than 50% of the total diabetes patients had hypertension and the similar observation is reported in our study ⁽³⁹⁾. Several studies have shown that the presence of comorbidities decreases the QOL of patients with diabetes ^(40,41). Likewise, this study supported this by revealing a statistically significant relationship between the presence of comorbidity and poor QOL. (P value <0.001). This could be justified by the patient's dependency on many different medications, the money much needed to afford these drugs and the demand for healthcare services since they were comorbid, contributing to impairment of the physical health and environmental health domains. This could also be due to the contributions of different chronic diseases in patients with diabetes and the side effects/drug interactions of the different drugs, which impair all aspects of HRQOL.

This study reveals that lifestyle factors such as smoking and physical exercise were significant predictors of quality of life of diabetic patients. In this study, patients who had history of smoking had worse HRQOL. This result was supported by the report from CDC and a study from the USA that indicated the direct impact of smoking altering the health condition of the patients with diabetes and reduced their HRQOL. Smokers are more likely to have central fat accumulation than non-smokers, and smoking is known to induce insulin resistance and compensatory insulin secretion responses. which could explain the increased risk of diabetes in those who smoke. An interventional study in Sandiego, California showed that exercising and adhering to the recommended diet had a positive impact on the HRQOL of patients (42). Studies in Nigeria (43) and Ethiopia (40) are also in line with this finding. Although the result in this study is similar with regards to physical exercise, diet control did not show similar results. This study showed that physical exercise has a significant association with QOL but diet control does not; the relationship was not statistically significant (P value <0.116). As a result, younger age, male gender, being a university graduate, the absence of comorbidities and complications and having a good glycemic control are identified as the factors that can be considered as predictors of good OOL. This study used a standardized validated tool for measuring HROOL, which allows the measurement of satisfaction, impact, and worrying aspects of life in diabetes, however, there are certain limitations as follow; the utilization of a cross-sectional design; which lacks reporting of causal relationship of the variables, considering the different educational level of respondents, data was collected using face-to-face interview, which may make the finding prone to social desirability bias and could overestimate or under-estimate the result, the study was carried out on patients recruited in healthcare environment. While it might accurately reflect the well-being perception of the subjects it is administered on, it could not adequately reflect the overall perception of HRQOL among the general population of diabetic patients, which includes subjects with various ranges of adherence to treatment and medical follow-up, and varying degrees of contact with healthcare systems, and participants were selected from two diabetic clinics which does not include all diabetic patients in Khartoum, therefore the results cannot be representative for all the diabetic patients in the Khartoum.

Conclusion

To conclude, this study demonstrates a moderate overall HRQOL among patients with T2DM. Besides, it also demonstrates a low QOL among 40% of patients with T2DM, suggesting that QOL should be included in any modality used for treating diabetic patients. Glycaemic control was shown to be a definitive determinant of HRQOL, with high glycosylated haemoglobin levels identified as an independent determinant of impaired overall DQOL score. Thus, younger age, male gender, being a university graduate, the absence of comorbidities and complications and having a good glycemic control are all factors that can be considered as predictors of good QOL.

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