Health Related Quality Of Life among Type 2 Diabetes Patients in Southern Province of Saudi Arabia Using WHOQOL-BREF: Cross Sectional Study

Areej Hamdi (1), **Osama Albasheer** (2), **Amenah Bajawi** (1), **Shatha Hamdi** (3) **Aisha Awaf** (1), **Tahani Madkhali** (1), **Abdallah Sabai** (4) **Mohammad R Zaino** (5) **Mohammed Somaili** (6),

(1) Family Medicine and Primary Health Care, Ministry of Health, Jazan, Saudi Arabia
(2) Department of Family Community Medicine Department, Faculty of Medicine, Jazan University, Jazan, Saudi Arabia
(3) Health educator, Ministry of Health, Jazan, Saudi Arabia
(4) Consultant of Community Medicine, Ministry of Health, Jazan, Saudi Arabia
(5) Physical Therapy Department, Faculty of Applied Medical Sciences, Jazan University, Jazan, Saudi Arabia
(6) Department of Medicine, Faculty of Medicine, Jazan University, Jazan, Saudi Arabia

Correspondending author:
Osama Albasheer
Department of Family and Community Medicine, Faculty of Medicine, Jazan University
Jazan, Saudi Arabia
Email: oalbasheer@jazanu.edu.sa

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Abstract

Background: Quality of life has become a more important health outcome with advancements in medical therapies and disease management, leading to better lives of people in general and in particular those living with chronic diseases. Diabetes has a direct impact on physical, psychological and social aspects of personal health. The aim of this study is to determine the health related quality of life and its predictors in patients with type 2 diabetes

Method: A cross-sectional study was carried out among 420 patients with type II diabetes who presented to primary health care centers in Samtah town, Saudi Arabia from March 2017 to February 2018. The HRQoL of the study participants was determined with reference to the World Health Organization Quality of Life-BREF. Multi-level linear regression was employed to ascertain associated factors with HRQOL among patients with type II diabetes.

Results: Females had significantly higher HbA1c, anxiety, depression and stress scores, and a lower HRQL in subscales physical, psychological and environmental health as compared with the males (P<0.001). All subscales of HRQL were significantly lower in age group > 50 years. When compared to those with low level of education (Illiterate, Primary or Elementary school), patients with secondary and bachelors education had significantly higher HRQOL in all subscales of HRQL (P<0.001). In addition, there were significant differences in glycemic control and HRQL with longer duration of diabetes, presence of one or more diabetes complications and presence of comorbid hypertension (P<0.001). However, no significant differences in Depression, Anxiety and Stress Scale (DASS) index were observed with longer duration of diabetes and the presence of comorbid hypertension. Diabetes patients on combined therapy and healthy diet and exercising showed significantly higher HRQOL on physical functioning (P<0.001).

Conclusion: Presence of type 2 diabetes greatly impaired health related quality of life and mental health among the study participants. Females had the worse quality of life and mental health compared with the males. The age, duration of diabetes, comorbid hypertension, diabetes complications and the levels of education were significant predictors of HRQOL and mental health. Healthy diet and exercising when combined with hypoglycemic and insulin therapy greatly improve HRQOL and mental health among diabetes patients. Scales that are based on a broad definition of health such as the WHOQOL-BREF are appropriate for use in the primary care setting and can enhance patient management and care.

Key words: Quality of life; Type 2 diabetes; Depression; Anxiety; Hypertension; Complications

Introduction

Diabetes mellitus constitutes an important health concern. The prevalence of it is increasing in both developed and developing countries. Worldwide, the number of diabetic patients has increased from 110 million in 1994 to 240 million in 2010 and is estimated to rise to 300 million in 2025 (1).

In Saudi Arabia, the prevalence of diabetes has steadily increased over the last several decades (2-4). The mere existence of diabetes deteriorates a person's quality of life (QoL). When diabetes is complicated, poorly controlled, or coexists with other chronic illnesses this effect is even worse (5). Quality of life (QoL) is a subjective, multidimensional and dynamic construct that is reputed an important outcome in its own right and reflects a personal evaluation of how good or bad one's life is (6). Quality of life assessment represents a valid indicator of whether or not a medical treatment is beneficial (7). There are numerous scales available for assessing diabetes-specific quality of life (8-11). A diabetes-specific quality of life questionnaire was the first to measure diabetes-specific QoL. Some of these scales focus on the general perceived health and social relations. Some of them expanded to assess physical complaints, leisure time flexibilities, worry about future and daily hassles. Since the 1990s, an ever-increasing number of international guidelines have recommended routine assessment of psychological and/or psychosocial factors associated with diabetes in order to improve such integration into clinical care planning (12). World Health Organization (WHO) generates the WHOQOL-BREF, an abbreviated version of the WHOQOL-100, to include measures of the impact of disease and impairment on daily activities and behavior in addition to disability / functional status measures (13). Women with diabetes are reported to have worse health related quality of life (HRQOL) and mental health than the men with diabetes in many previous studies (14-16). The age, socioeconomic status, level of education, duration of diabetes and type of diabetes treatment were other parameters that have effect on the HRQOL of diabetic patients (17-20). Several studies have shown that the presence of diabetic complications has a major influence on QOL (21-24).

All domains of quality of life are affected in a study done in Eastern Province, Saudi Arabia using EuroQol for patients with type 2 diabetes mellitus (25). Male gender, high monthly income, having no diabetes-related complications and having random blood glucose level less than 200 mg/dl were the main predictors of quality of life. Previous studies in Riyadh City, Saudi Arabia, have reported poor quality of life among type 2 diabetic patients (16, 26).

There is a paucity of data related to quality of life assessment among diabetic patients in Southern province of Saudi Arabia, including Samtah town. One previous study done in Jazan region revealed poor quality of life among diabetic patients with depressive symptoms (27). Therefore, this study is to evaluate health related quality of life and its predictors among patients with type 2 diabetes in Samtah town.

Study area and study design

This cross sectional questionnaire based study was conducted among type 2 diabetic Saudi patients who presented to primary health care centers in Samtah town from March 2017 to February 2018. Samtah town, a subdivision of Jazan Province, lies in the southwest of Saudi Arabia, with a total area of 1,126.9 km2 and a population of 341,269 (28). There are three primary health care centres in Samtah town, from which participants were recruited.

Study population

Adult ≥ 18 years, both male and female known cases of type 2 diabetes for at least 6 months were recruited for this study.

Those unwilling to participate, those who were very ill or unable to communicate, and women with gestational diabetes, were excluded from the study.

Sample Size and sampling technique

Stratified random sample technique was employed in this study. Epi Info 7 software was used for calculation of sample size (29). Four hundred and twenty participants were selected randomly from the three primary health care centres in Samtah town based on the following assumptions: confidence level (95%), margin of error (0.05%), a 10% non-response rate, and estimated prevalence in the population (50%).

Data collection

Structured questionnaire was used for data collection. The questionnaire was drafted in English and translated into Arabic before distribution to the participants.

The first page of the questionnaire encompassed clear information about the study's background and objectives and explained information about participation, withdrawal, confidentiality, and informed consent.

The questionnaire involved four primary sections. The first collected information on the participants' socio-demographic characteristics, including age, sex, marital status, education level, work status, monthly income, and region of residence. The second assessed the participants' lifestyle factors (like smoking, khat chewing, physical exercise) and disease characteristics (like duration of diabetes, comorbid diseases, current use of anti-diabetic medications, and diabetes complications). The third gathered information related to the quality of life assessment using World Health Organization Quality of Life – Brief (WHOQOL-BREF). The fourth section assessed their mental health using Depression, Anxiety and Stress Scale (DASS).

The WHOQOL-BREF is a 26-item, self-directed, non-specific questionnaire that is a short form of the WHOQOL-100 scale (13). It is based on four domains; Physical health, Psychological, environment, and Social relationships. The WHOQOL-BREF is available in different languages and permission for using it was obtained from The WHOQOL Group. Interviewer-assisted forms were used in this study.

Standardized instructions to the interviewers helped in acquisition of the WHOQOL-BREF administration.

Scoring the WHOQOL-BREF

The first two items in the scale ask about an individual's overall perception of quality of life and an individual's overall perception of their health. The four domain scores represent a person's perception of their quality of life in each of the four domains. The domain score is calculated using the mean score of items within each domain. To make domain scores comparable to those used in the WHOQOL-100, mean scores are multiplied by four.

Depression, Anxiety and Stress Scale (DASS) is a 26-item, 4-point scale measuring present symptoms of depression, anxiety, and stress over the last week (30). A printed overlay was used to obtain total scores for each subscale. Higher scores on each subscale stipulate increasing severity of depression, anxiety, or stress.

Data analysis

Data analysis was carried out using SPSS version 17 (SPSS Inc., Chicago, IL, USA). In addition, descriptive statistics were used to summarize Socio-demographic and disease characteristics of the participants. For analysis of the differences between two groups or more t-test, one way analysis of variance were used respectively, and Tukey post hoc tests were conducted to look at differences carried out. Multilevel linear regression analysis was done to understand the variables associated with HRQOL. P value of <0.05 was considered to be statistically significant.

Results

Table 1 displays the participants' socio-demographic and disease characteristics; 194 (46.2%) and 226 (53.8%) of the participants were male and female, respectively; 187 (44.5%) were ≤50 and 233 (55.5%) >50 years, respectively. With regard to the level of education, 101 (24.0%), 68 (16.2%), 44 (10.5%), 91 (21.7%), and 116 (27.6%) had no schooling, had primary school, elementary school, secondary school, and bachelor and postgraduate (masters/doctorate), respectively. Concerning duration of diabetes, 193 (46.0%), 124 (29.5%), 49 (11.7%), and 54 (12.9%) had diabetes for ≤ 5, 6-10, 11-15 and > 15 years, respectively. Furthermore, 26.9% of the diabetes patients have 3 or more complications, 23.1% of the cases have2 complications, 25.7% have 1 complication and 24.3% of the cases were without complications. Comorbid hypertension was present in 245 (58.3%) of the participants. About 60.2% of the diabetes patients in the sample had a BMI ≥ 30 (i.e. obesity, severe obesity, morbid obesity), overweight prevalence was 28.3%, 11.0% were normal and 0.2% were under weight.

Table 2 shows the levels of glycemic control, anxiety, depression and stress score of the study population. Females had significantly higher HbA1c, anxiety, depression and stress scores (P<0.001), as compared with the males. Likewise, the presence of one or more diabetes complications and being overweight or obese, significantly affected glycemic control and degree of anxiety, depression and stress score, (P<0.001). In addition, there were significant differences in glycemic control with longer duration of diabetes and presence of comorbid hypertension (P<0.001). However, no significant differences in DASS index were observed with longer duration of diabetes and the presence of comorbid hypertension. Compared to users of hypoglycemic alone, those on combined hypoglycemic with insulin had better glycemic control and anxiety, depression and stress score (P<0.001). Even though, the levels of glycemic control and degree of anxiety, depression and stress score is even better with healthy diet and exercising regardless of type of medication. Smoking status significantly affects anxiety (mean; 5.8±4.2 vs. 3.5±3.4) and stress (mean; 6.6±3.9 vs. 5.1±3.3) subscales of DASS test, while its effects on glycemic control and depression subscale of DASS test was not significant (mean; 8.4±1.7 vs. 8.1±1.3 and 4.3±3.4 vs. 3.8±3.7 respectively).

Table 3 represents the association between health related quality of life profile and participants' socio-demographic and disease variables. All domains of quality of life were significantly lower in females, less educated and age group > 50 years (P<0.001). However, there was no significant difference found in the domain Social relations between Secondary and lower educated patients (P>0.05). Smoking status significantly affects physical, psychological and environmental domains of quality of life (mean; 74.6±17 vs. 57.7±18.8, 72±17.7 vs. 66.5±15.8 and 68.2±18.3 vs. 60.2±17.7 respectively), while its effects on social relation was not significant. Longer duration of diabetes and presence of comorbid hypertension also significantly affects all domains of HRQOL (P<0.001). Furthermore, presence of one or more of diabetes complications significantly affects physical, social, psychosocial and environmental domains of quality of life. No significant differences were observed in HRQOL and treatment types. However, those on combined therapy and healthy diet and exercising showed significantly higher HRQOL on physical functioning (P<0.001). Current smokers surprisingly were observed to have better quality of life in all domains except social relation (P<0.001). With regard to the body mass index (BMI), significant differences were observed in physical, psychosocial and environmental domains of quality of life and severe or morbid obesity (P<0.001). However, no significant difference was observed in social relationship (mean; 68.3±16.3 vs. 68.1±17.7).

Table 4 shows the results of regression analyses with Beta-coefficient and 95% confidence interval for 26-item dimensions adjusted for significant confounders; gender, age group, education, smoking, duration of diabetes, comorbid hypertension, complications of diabetes, treatment type and BMI classification were the independent risk factors for HRQOL.

Gender difference had an independent significant effect on HRQOL in the subclasses psychological health and environment. We also found that the factor "education level" affected significantly and independently (in positive direction) the HRQOL in all subclasses for diabetic patients.

Likewise the complications of diabetes were found to be an independent significant effect in the opposite direction for HRQOL in all subclasses, (complications of diabetes coded from 1, no complication, to 4 with ≥3 complications). BMI variable was coded from 1 underweight, to 6, morbid obesity. It was observed it had an independent significant affect (in negative direction) on HRQOL only in the subclass Physical Health. Smoking was a parameter, which also had an effect on the HRQOL of diabetic patients in the subclass physical Health.

Table 1: Socio-demographic and disease characteristics of the study population

Variable	Category	Frequency n=420	%
Gender	Male	194	46.2
	Female	226	53.8
Age	<=50	187	44.5
	>50	233	55.5
Education	Illiterate	101	24.0
	Primary	68	16.2
	Elementary	44	10.5
	Secondary	91	21.7
	Bachelors and above	116	27.6
Smoking	Current Smoker this month	68	16.2
	Ex-smoker	61	14.5
	Never smoked	291	69.3
Duration of DM2	<=5 years	193	46.0
	6 - 10 years	124	29.5
	11 - 15 years	49	11.7
	>15 years	54	12.9
HTN	No	175	41.7
	Yes	245	58.3
Complication of DM2	No complication	102	24.3
	One complication	108	25.7
	Two complications	97	23.1
	≥3 complications	113	26.9
Treatment type	Hypoglycemic alone with diet-exercise	136	32.4
	Hypoglycemic alone without diet-exercise	132	31.4
	Insulin alone with diet-exercise	17	4.0
	Insulin alone without diet-exercise	44	10.5
	Combination with diet-exercise	31	7.4
	Combination without diet-exercise	60	14.3
BMI	Under	2	.5
	Normal	46	11.0
	Over weight	119	28.3
	Obese	125	29.8
	Severe obesity	101	24.0
	Morbid obesity	27	6.4

HTN, Hypertension

Table 2: Levels of glycemic control, anxiety, depression and stress score of the study population

Variable	Category	Glycemic Control	Arabic DASS		
		HgbA1c	Depression	Anxiety	Stress
Gender	Male[a]	8.3±1.5	3.2±3.6	3.4±3.7	4.8±3.8
	Female[b]	8.3±1.7	**5±3.7*[a]**	**6.7±4.3*[a]**	**7.3±4.2*[a]**
Age	≤ 50	8.4±1.8	4.4±4	5.6±4.8	6.3±4.6
	> 50	8.2±1.4	4±3.6	4.8±4	6±3.9
Education	Illiterate[a]	8.1±1.4	4.9±3.8	6.2±4.3	6.9±4.3
	Primary[b]	8.5±1.7	4±3.3	5.5±3.8	6.3±3.6
	Elementary[c]	8.7±1.7	4.3±3.8	5±4.4	6.3±3.8
	Secondary[d]	8.4±1.6	4.1±4.2	4.9±4.7	5.8±4.9
	Bachelors and above[e]	8.1±1.6	3.7±3.5	**4.4±4.2*[a]**	5.5±3.9
Smoking	Current Smoker this month[a]	8.1±1.3	3.8±3.7	3.5±3.4	5.1±3.3
	Ex-smoker[b]	8.2±1.6	3.8±5.3	4.1±5.3	5.2±5.9
	Never smoked[c]	8.4±1.7	4.3±3.4	**5.8±4.2*[ab]**	**6.6±3.9*[a]**
Duration of DM2	≤ 5 years[a]	8±1.5	4±4.1	5.2±4.9	5.8±4.6
	6 - 10 years[b]	8.4±1.6	4.5±3.5	4.9±3.9	6.5±3.8
	11 - 15 years[c]	**9.1±1.9*[ab]**	4±3.4	6.1±4.1	6.3±4.6
	> 15 years[d]	**8.7±1.3*[a]**	4.4±3.1	4.8±3.2	6.2±3.2
HTN	No[a]	8±1.4	4.2±3.8	4.9±4.4	5.9±4.5
	Yes[b]	**8.5±1.7*[a]**	4.2±3.7	5.4±4.3	6.3±4
Complication of DM2	No complications[a]	7.4±0.7	2.6±3.3	3.1±3.7	4±3.9
	One complication[b]	**8.2±1.6*[a]**	**3.9±3.3*[a]**	**5.2±4.4*[a]**	**5.9±4.2*[a]**
	Two complications[c]	**8.1±1.2*[a]**	**4.9±4.0*[a]**	**6.1±4.6*[a]**	**7.3±4.2*[a]**
	>= 3 complication[d]	**9.5±1.8*[abc]**	**5.3±3.8*[ab]**	**6.3±4.1*[a]**	**7.3±3.8*[a]**
Treatment type	Hypoglycemic alone[a] with diet-exercise	7.4±0.8	2.8±3.6	3.4±4.2	4.4±4.1
	Hypoglycemic alone[b] without diet-exercise	**8.4±1.4*[a]**	**4.6±4.0*[a]**	**5.7±4.3*[a]**	**6.8±4.3*[a]**
	Insulin alone with diet-exercise[c]	**8.9±2.2*[a]**	4.2±4.3	**7.4±5.7*[a]**	7±5.3
	Insulin alone without diet-exercise[d]	**9.4±1.8*[ab]**	**5.6±3.0*[a]**	**7.4±3.7*[a]**	**8.2±3.7*[a]**
	Combination with diet-exercise[e]	**8.9±2.0*[a]**	3.3±2.1	4.6±3.6	5.7±3.0
	Combination without diet-exercise[f]	**9.1±1.7*[ab]**	**5.7±3.5*[ae]**	**6.1±3.8*[a]**	**7.1±3.3*[a]**
BMI	Under[a]	8±0	8±0	10±0	8±0
	Normal[b]	8.3±1.8	**6±4.1*[cd]**	**7.3±4.4*[cde]**	**8.3±4.1*[cde]**
	Over weight[c]	7.9±1.3	3.3±3.2	4.1±3.6	5.1±3.9
	Obese[d]	8.2±1.4	3.9±3.9	5±4.6	6.1±4.6
	Severe obesity[e]	**8.7±1.8*[c]**	4.1±3.9	5±4.5	6±4.1
	Morbid obesity[f]	**9.3±1.9*[cd]**	**6±3.3*[c]**	**7.5±3.7*[c]**	7.3±2.6

Values are presented as Average±standard deviation,
(t-test, one way ANOVA, and Tukey post hoc test), *P<0.001. Subscript letter for a category indicates a significant relation with this category with that letter.
HgbA1c, Glycosylated haemoglobin; Arabic DASS, Arabic Version of the Depression Anxiety Stress Scales; HTN, Hypertension; Complication variables of DM2, Cardiovascular, Retinopathy, Nephropathy, Neuropathy, Diabetic foot, Dyslipidaemia, Stroke.

Table 3: The association between health related quality of life profile and participants' socio-demographic and disease variables

Variable	Category	Arabic version of WHOQOL- BREF			
		Physical Health	Psychological Health	Social relations	Environment
Gender	Male[a]	66.1±24*[b]	72.8±17.2*[b]	74.4±21	67.4±19*[b]
	Female[b]	56.2±17.6	64±15.9	71.4±20.4	58.4±17.2
Age	≤50[a]	68.2±21.1*[b]	70.5±18.2*[b]	75.4±21.8*[b]	65.5±19.2*[b]
	>50[b]	54.8±19.6	66.1±15.9	70.6±19.6	60.1±17.8
Education	Illiterate[a]	50.8±15.3	60.8±15.8	68.8±18.6	53.4±16.2
	Primary[b]	48.8±18.2	64.1±15.6	68.1±21.6	55.2±15.5
	Elementary[c]	51.5±16.1	62.5±16.3	66.2±19.7	55.5±14.5
	Secondary[d]	69.2±20.3*[abc]	73±16.1*[abc]	76.4±19.2	65.4±16.5*[abc]
	Bachelors and above[e]	73.4±20.5*[abc]	75±16.3*[abc]	78.6±21.7*[abc]	75.2±17.6*[abcd]
Smoking	Current Smoker this month[a]	74.6±17*[bc]	72±17.7*[c]	73.6±20.2	68.2±18.3*[c]
	Ex-smoker[b]	60.1±29.9	70.9±21.1	75.6±24.7	67.2±21*[c]
	Never smoked[c]	57.7±18.8	66.5±15.8	72±19.9	60.2±17.7
Duration of DM2	≤5 years[a]	67.9±21.4*[bcd]	70.5±19.1*[d]	75.5±23.1*[c]	68.1±19.3*[bcd]
	6 - 10 years[b]	59.4±18.1*[d]	67.8±14.7	71.5±18.2	58.8±17.5
	11 - 15 years[c]	53.4±22.4	64.3±16.1	66.5±20	55.4±15.4
	>15 years[d]	45±15	63.4±14.2	71.5±16.2	57.8±15.3
HTN	No[a]	69.2±20.5*[b]	72±17.6*[b]	76.2±21.8*[b]	66.9±18.9*[b]
	Yes[b]	54.8±19.9	65.2±16.2	70.3±19.6	59.4±17.7
Complications of DM2	No complications[a]	77.6±19*[bcd]	80.1±15.2*[bcd]	81.8±19.1*[bcd]	74.4±19.1*[bcd]
	One complication[b]	65.4±17.8*[cd]	69.4±14.2*[d]	71.8±19.5	64.5±17*[cd]
	Two complications[c]	55±16.3*[d]	64.2±15.5	71.2±22.1	56.2±17.2
	>=3 complications[d]	46.1±18	59.3±16.2	66.8±19.5	55.3±14.6
Treatment type	Hypoglycemic alone[a] with diet-exercise	74.1±19*[bcdef]	77.8±16*[bcdef]	80.5±19*[bde]	72.9±18*[bdf]
	Hypoglycemic alone[b] without diet-exercise	55.4±20.1	62.9±16.5	69.9±22.2	55.8±16.7
	Insulin alone with diet-exercise[c]	54.1±16.2	65.8±14.2	65.5±27.1	61.1±14.4
	Insulin alone without diet-exercise[d]	46.1±21.5	62.8±13	63.3±18.1	58.3±15.1
	Combination with diet-exercise[e]	61.9±16.5*[d]	67±14.4	68.1±15.3	63±16
	Combination without diet-exercise[f]	54.4±17.4	62.3±15.5	73±19	57.1±18.4
BMI	Under[a]	56.0±0	44.0±0	44.0±0	44.0±0
	Normal[b]	62±19.3*[f]	68.6±13.1*[f]	68.1±17.7	58.5±17.5
	Over weight[c]	66.8±22.1*[ef]	71.6±18*[ef]	73.6±20.9	67.3±19.4*[f]
	Obese[d]	61.1±21*[f]	70.5±15.6*[f]	75.8±19.3	62.9±18.9
	Severe obesity[e]	58.5±20*[f]	65±17.5*[f]	71.9±23.8	60.9±17.3
	Morbid obesity[f]	39.2±12.8	53.7±14.8	68.3±16.3	54.3±15.1

Values are presented as Average±standard deviation,
(t-test, one way ANOVA, and Tukey post hoc test), *P<0.001.
HgbA1c, Glycosylated hemoglobin; Arabic DASS, Arabic Version of the Depression Anxiety Stress Scales; HTN, Hypertension; Complication variables of DM2, Cardiovascular, Retinopathy, Nephropathy, Neuropathy, Diabetic foot, Dyslipidemia, Stroke.

Table 4: Regression analyses with Beta-coefficient and 95% confidence interval (n=420)

	Physical Health				Psychological Health			
Variable	Beta	95% CI		P-Value	Beta	95% CI		P-Value
Gender	-0.07	-6.9	0.6	0.100	-0.21	-10.9	-3.9	0.000
Age category	-0.03	-4.7	2.5	0.549	0.06	-1.2	5.5	0.204
Education	0.29	2.7	5.1	0.000	0.26	1.8	3.9	0.000
Smoking	-0.13	-6.1	-1.3	0.003	0.06	-0.8	3.7	0.199
Duration of DM2	-0.07	-3.2	0.2	0.081	0.08	-0.2	2.9	0.096
HTN	-0.05	-5.5	1.2	0.215	0.00	-3.3	2.9	0.915
Complication of DM2	-0.38	-8.9	-5.5	0.000	-0.39	-7.4	-4.3	0.000
Treatment type	-0.05	-1.6	0.3	0.189	-0.08	-1.6	0.1	0.082
BMI classification	-0.15	-4.2	-1.4	0.000	-0.10	-2.8	-0.3	0.019
	Social relations				Environment			
Gender	-0.04	-6.4	3.4	0.542	-0.12	-8.1	-0.6	0.024
Age category	0.01	-4.3	5.2	0.849	0.13	1.3	8.6	0.008
Education	0.16	0.6	3.7	0.006	0.41	3.7	6.1	0.000
Smoking	0.03	-2.3	4.0	0.601	0.01	-2.1	2.7	0.802
Duration of DM2	0.06	-1.0	3.4	0.296	-0.02	-2.1	1.3	0.609
HTN	-0.05	-6.4	2.3	0.353	0.00	-3.5	3.2	0.940
Complications of DM2	-0.22	-6.2	-1.8	0.000	-0.31	-6.8	-3.4	0.000
Treatment type	-0.06	-1.9	0.6	0.300	-0.04	-1.4	0.5	0.337
BMI classification	0.07	-0.5	3.1	0.152	-0.03	-2.0	0.8	0.406

Multilevel Regression Analysis, CI Confidence Interval, DM2 diabetes mellitus. HTN Hypertension. BMI Body Mass Index. Negative Beta indicates negative effect.

Discussion

Quality of life is an important health outcome that is commonly used to monitor the physical, psychological and social aspects of personal health (31). Numerous studies have found that people with diabetes have a lower quality of life compared to people with no chronic illness and the factors that contribute to this are not precisely explained (14-16). The aim of this study is to evaluate the health related quality of life and its predictors in patients with type 2 diabetes using WHOQOL-BREF questionnaire. In this study, all domains of quality of life were observed to be affected by type 2 diabetes. In addition to that, the presence of type 2 diabetes greatly impacts on depression, anxiety and stress subscales.

Females with type 2 diabetes were observed to have worse HRQOL than males. Gender differences and quality of life with T2DM have been intensively investigated, manifesting that the women with diabetes appeared to have worse HRQOL than the men with diabetes (14-16). A similar finding was reported by a recent study conducted in the Eastern Province, of Saudi Arabia (25). The female gender is an independent predictor of poor HRQoL and the gender differences in quality of life could be explained by the socio-cultural differences between men and women in the Arab world including Saudi Arabia.

A negative correlation between the age and HRQOL was another predictor observed in this study. Those more than 50 years were found to have worse HRQOL than their counterpart. The previous studies showed variable correlation between age and HRQOL (16,17,32). Similar findings were reported that patients who are less than 40 years of age have significantly better QOL than other age groups (25,32); however, Hanninen et al. (33), in his study reported that age has no effect on diabetic patient's HRQOL. Theoretically, patients having diabetes with age more than 50 years are expected to have poor glycemic control and more complications, hence worse quality of life, and these variable correlations between age and HRQOL could be explained by different sample size and variable representation of age groups in these studies.

The level of education is another predictor found to influence all domains of HRQOL in this study. Those with secondary and higher levels of education and diabetes were found to have better QOL than those with primary education or lower; which is consistent with previous studies from Eastern Province, Saudi Arabia (25) and Oman (32).

The present study reported a statistically significant correlation between HRQOL and duration of diabetes. The shorter the duration of diabetes, the better the HRQOL. Those with duration more than 10 years appeared to have the worse quality of life in almost all health related domains. Many previous studies reported similar findings (17-20). Longer duration of diabetes is usually linked with the presence of comorbid vascular diseases and appearance of diabetes complications. In the current study, two-thirds of the participants have comorbid hypertension. They reported no significant differences in DASS index; even though they have significantly higher levels of HgbA1c. However, the presence of hypertension significantly

affects all domains of HRQOL. Similarly; Zhang et al in a Chinese study involving type 2 diabetics reported over 80% comorbid hypertension and reduced HRQoL (34). Evidence suggested a link between hypertension and cardiovascular mortality in patients with T2DM. Previous studies have reported a lower HRQoL among diabetes patients with complications (16,21,22,25). The present study also reported that HRQoL is significantly lower among diabetes patients with complications. Multilevel regression analysis confirmed diabetes complications as an independent risk factor for all domains of quality of life. The burden of diabetes complications could be explained by poor glycemic control, physical dysfunction, extension of treatment time, multiple treatment methods, hospitalization and mental health deterioration.

The association of insulin therapy with quality of life was debatable in previous studies. Changes of insulin therapy reported to improve glycemic control in Japanese patients with type 2 diabetes mellitus without adversely affecting QOL (35). Better rating on all domains of QOL have been reported by Home, Philip, et al (36) and Al Hayek, et al. (16), due to the beneficial effect of adding insulin such as lower risk of diabetic complications and better glycemic control. Even so, multivariate regression analysis revealed no significant association between type of type of treatment and HRQOL. Contrarily, other researchers reported lower QOL with insulin therapy, due to adverse effects such as fear of weight gain and the increased risk of hypoglycemia (25). In the current study, diabetes patients who were treated with hypoglycemic agents, insulin or a combination of both had higher risk of lower HRQOL when the program diet-exercise was not involved in the treatment. However, such a risk was significantly reduced in all domains of QOL when a diet-exercise program was added to the hypoglycemic agents. Addition of a diet-exercise program to combined hypoglycemic and insulin therapy significantly improved physical functioning. No improvement in rating of QOL subscales were observed with insulin therapy alone or when a program of diet-exercise was added to it, indicating no beneficial effect of insulin on quality of life.
In the current study, it was found that obesity, severe obesity and morbid obesity DM2 patients had a significantly high risk of lower HRQL for all subclasses except Social relation. DASS subscales for mental health were also adversely affected. Multilevel regression analysis indicated an independent significant impact on physical functioning. In keeping with this, negative influence of BMI had been reported in previous studies done in Egypt, Mexico and Poland (37-39). Obesity impaired physical functioning and increased risk of cardiovascular mortality.

In the current study, diabetes patients who reported current smoking have a surprisingly significant higher level of HRQOL for all subclasses except social relation domain compared to those who never smoke. Multilevel regression analysis indicated smoking as a parameter, which also has an effect on the HRQOL of diabetes patients in the subclass Physical Health. Nevertheless, the cause-effect link between smoking and quality of life in diabetes patients cannot be established with certainty because of other well-known confounding risk factors. Furthermore, the effect of smoking on glycemic control and quality of life in people with diabetes is poorly studied with often confusing results (40). However, current guidelines highlight the importance of smoking abstinence for patients with diabetes to achieve a better quality of life and to delay the onset and progression of diabetes complications. Large quantitative and more qualitative studies are needed to establish the cause-effect link between smoking and quality of life in diabetes patients.

The present study had several strong points. WHOQOL-BREF questionnaire used in this study permitted extensive and broad assessment of all subscales of quality of life. The study elicited the predictors that have an independent significant effect on HRQOL such as gender, age, level of education and diabetes complications. Furthermore, the study raised the association of smoking and quality of life in diabetes patients and suggested further studies for new evidence. However, the study had several limitations; being cross sectional it precluded true causation. The study was confined to the southern province of Saudi Arabia, and this limited generalization of the results. Other limitations were the small sample size and adjustment of confounders such as stress, diet and physical function that may affect quality of life.

Conclusion

Mental health and quality of life were significantly impaired in diabetes patients. Females had the worse quality of life and mental health compared with the males. Gender, age category, education, duration of diabetes, hypertension, complication of diabetes and BMI were the most important predictors of HRQOL. Healthy diet and exercising when combined with hypoglycemic and insulin therapy greatly improve HRQOL and mental health among diabetes patients. Scales that are based on a broad definition of health such as the WHOQOL-BREF are appropriate for use in the primary care setting and can enhance patient management and care.

Ethics approval and consent to participate
The bioethics standards and guidelines of the Kingdom of Saudi Arabia were contemplated while conducting this study. Participants were informed that they had the right to withdraw from the study at any time, their information would be kept anonymous and the data collected would only be used for scientific purposes. Written informed consent was obtained from each participant after explaining the purpose of the study. In addition, permission was obtained from the administration of all primary health care centers, from where participants were recruited, before data collection. Finally, the Standing Committee provided ethical approval for this study for Scientific Research Ethics-Ministry of Health, (Ref. no: Form #06).

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