Assessment of quality of life in type 2 diabetes mellitus patients using World Health Organization quality of life-BREF questionnaire and appraisal of diabetes scale - a cross-sectional study

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ABSTRACT

Diabetes is a chronic metabolic disorder that disturbs the quality of life (QOL) of patients. Therefore, evaluation of diabetes-related QOL could be a key outcome measure for its management. This study assessed the QOL in type 2 diabetes mellitus (T2DM) patients using the World Health Organization (WHO) quality of life (QOL)-BREF questionnaire and disease-specific appraisal of diabetes scale (ADS). In this cross-sectional study, 520 T2DM patients were included. Patients' demographic data, clinical information was collected through interviews, and the WHOQOL-BREF instrument and ADS were used for the QOL of patients. Statistical analysis was performed by using R software (Version 3.6.0). The mean ADS scores were lower in controlled diabetic subjects (18.50±3.08) and higher in uncontrolled diabetic subjects (19.29±2.73) ($P<0.05$). For WHOQOL-BREF, the mean scores for all the domains (overall general health, physical, psychological, social, and environmental) were significantly higher in controlled diabetic subjects ($P<0.001$). In addition, the age, duration of diabetes, associated comorbidities, treatment, and HbA1c level of patients showed a highly significant correlation with WHOQOL-BREF ($P<0.001$). Diabetic patients had poor-to-average QOL. Therefore, public health measures and education of diabetic patients are essential to create more awareness for improving the QOL of T2DM.

Introduction

Diabetes mellitus (DM) causes secondary pathophysiological changes due to associated metabolic dysregulation resulting in tremendous pressure on the quality of life (QOL) of the diabetic individual. Individuals with type 2 DM (T2DM) are at 2-4 times greater risk for coronary heart disease, which is the 9th major cause of death.[1] Globally, around 1 adult among 11 have DM, and 90% of them have T2DM. The epicenter for this rapidly emerging T2DM global epidemic is Asia, with China and India topping the list.[2] India had 62.4 million cases of T2DM in 2011. It is estimated that by 2030, India will have 100 million people with diabetes.[2]

QOL is a broad concept. In a complex way, it is affected by an individual's psychological state, physical health, social relationships, personal beliefs, level of independence, and relationship with their environment.[3] The evaluation of QOL is considered an important outcome measure for the management of chronic diseases.[4] The mental status and psychosocial behavior of diabetic patients affect their self-care behavior leading to impaired QOL and the risk of developing long-term complications.[3]

It is obligatory to use generic, disease-specific, and situation-specific instruments to evaluate patient-assessed outcomes (QOL) for diabetes.[5] The World Health Organization quality of life-BREF (WHOQOL-BREF) is one such generic instrument,[4] designed to measure the health aspects that are universally essential and can be used for comparing healthy populations or two different groups of pa-

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Key words: Quality of life; diabetes mellitus; questionnaires; comorbidity; World Health Organization.

Contributions: SP, literature search, experimental studies, data acquisition, statistical analysis, manuscript preparation; SKP, manuscript editing and review; SP, YP, definition of intellectual content, clinical studies, data analysis; YP, SKP, study design; SP, YP, SKP, study concept and guarantors.

Conflict of interests: the authors declare no potential conflict of interests.

Received for publication: 10 December 2020.
Revision received: 10 May 2021.
Accepted for publication: 10 May 2021.

Licensee PAGEPress, Italy
Italian Journal of Medicine 2021; 15:164-169
doi:10.4081/itjm.2021.1444

tients.[4] The appraisal of diabetes scale (ADS) is a disease-specific instrument that can make such generic instruments more responsive to health changes.[6] Together, these instruments help in a more accurate and detailed assessment of patient-related concerns and are essential endpoints in studies designed to measure changes in QOL.[7]

Several studies have been performed on the QOL in T2DM from developed and developing countries and have shown that poor QOL leads to worsening glycemic control, increased hospital visits, poor sleep, and restricted social life.[8-10] Due to the increased incidence of T2DM in India, it becomes essential to measure the QOL for improved care and control.[11] Thus, the purpose of this study was to assess the QOL in T2DM patients using the WHOQOL-BREF questionnaire and disease-specific ADS.

Materials and Methods

Study design

With the institutional ethics committee's approval (Approval number- KIMSDU/IEC/03/2017), this cross-sectional study was conducted at a tertiary care hospital in Karad (Maharashtra) for 19 months (December 2017-June 2019). Informed consent was obtained from all the patients included in the study. The sample size was calculated by using the standard formula, by considering the prevalence of poor (dissatisfied lifestyle/low scores) QOL in T2DM as 39%.[12,13]

Selection criteria

Five hundred and twenty patients of either sex, diagnosed with T2DM, aged 31-90 years, and on drug therapy for at least 1 month were included in the study. Patients with type 1 DM, gestational DM, newly diagnosed diabetes, and patients not willing to participate were excluded from the study.

Data collection

A structured questionnaire was used to collect the socio-demographic information (age, sex, marital status, religion, education, occupation, family type, total members in the family, monthly income and monthly per capita income, social habits, food habits, exercise habits, and BG Prasad class status),[14,15] anthropometric measurements (height, weight, and body mass index [BMI]) along with diabetes-related information such as family history, past medical history, duration of diabetes, whether undergoing treatment, disease symptoms, postprandial glucose (PPBG) level, fasting blood glucose (FBG) level, and glycosylated hemoglobin level (HbA1c) needed by the study.

Patients with HbA1c <7% were considered controlled diabetics, while patients with HbA1c >7% were considered uncontrolled diabetics. WHOQOL-BREF questionnaire[4] was used to assess the QoL, and ADS questionnaire[6] was used to assess the status of diabetes. WHOQOL-BREF questionnaire is a 26-item generic questionnaire assessing the individual's perception towards their culture and value system and their personal goal, standards, and concerns. All the items were classified in five domains: global-overall general health (two items), physical (seven items), psychological (six items), social relationships (three items), and environment (8 items) and were scored on a five-point Likert scale and a low score indicating poor QOL. ADS questionnaire is a seven-item diabetes-specific scale addressing the patient's perception towards their feeling and attitudes about diabetes. This questionnaire consists of uncertainty due to diabetes, anticipated future deterioration, distress caused by diabetes, control over diabetes, and effect of diabetes on life goals scored on a five-point Likert scale and a low score indicating good QOL.

Statistical analysis

Statistical analysis was performed by using R software (Version. 3.6.0). Data were recorded in Microsoft Excel and expressed as mean±standard deviation with frequency and percentage. Qualitative variables were analyzed using the Chi-square test of independence, and the unpaired '*t*' test was used to test the difference between the two groups. Data were considered statistically significant when $P \leq 0.05$.

Results

This study was carried out on 520 T2DM patients. Table 1 presents the socio-demographic data of all the patients. The majority of the patients were in the age group of 51-60 years with male predominance (male: female=1:0.9). Most of the patients was married, belonged to Class III economic class, and was from a joint family, which implied more responsibilities leading to more stress, which could be one of the risk factors for T2DM (Table 1).

Most of the male patients were middle-aged and doing business, while the majority of the female patients were housewives and had reached old age. The BMI data revealed that 40.9% of the subjects had their BMI within the normal range (18.5-22.9 kg/m^2). In addition, most patients of either gender had completed either primary or secondary school, passing out stipulating low education level (Table 2).

The clinical profile of most patients indicated a family history of diabetes, stipulating that the genetic profile could be a major risk factor. Most patients had diabetes from 0 to 10 years of age. Polyuria was noted

to be the most common symptom indicative of uncontrolled bladder activity in diabetic patients. Furthermore, as diabetes results in comorbidities, the majority of the patients showed multiple comorbidities along with hypertension. Although oral hypoglycemic agents were most used for treatment, some patients were using both insulins and oral hypoglycemic agents. Although fasting and postprandial blood glucose levels were mostly under control, most patients had their hemoglobin A1c levels above the normal range due to diabetes (Table 3).

The age, duration of diabetes, associated comorbidities, treatment, and HbA1c level of patients showed a highly significant correlation with QOL, assessed by WHOQOL-BREF (P<0.001). However, no significant correlation was observed between the BMI of patients and WHOQOL-BREF (P>0.05) (Table 4).

Table 1. Socio-demographic characteristics of the patients.

Socio-demographics	Patients No. (%)
Age range (years)	
31-40	12 (2.3)
41-50	79 (15.2)
51-60	198 (38.1)
61-70	188 (36.2)
71-80	37 (7.1)
81-90	6 (1.2)
Sex	
Male	264 (50.76)
Female	256 (49.24)
Marital status	
Married	389 (74.8)
Widowed/widower	123 (23.7)
Unmarried/divorced	8 (1.5)
Type of family	
Nuclear	172 (34.23)
Joint	348 (66.92)
Religion	
Hindu	343 (65.96)
Muslim	94 (18.07)
Christian	64 (12.3)
Others	19 (3.65)
B.G Prasad class status (economic class)	
Class I	20 (3.8)
Class II	114 (21.9)
Class III	226 (43.5)
Class IV	136 (26.2)
Class V	24 (4.6)
Do not know	221 (42.50)
Diet pattern	
Vegetarian	280 (53.8)
Non-vegetarian	59 (11.3)
Both veg and non-veg	181 (34.8)
Frequency of exercise	
Regular	347 (66.7)
Occasional	65 (12.5)
No exercise	108 (20.8)

No (%), number (percentage).

The mean ADS score was 19.03±2.87 (range: 12-28). A significant difference in the ADS scores (P<0.05) was observed between controlled and uncontrolled diabetes, suggesting that patients' QOL was more affected in uncontrolled diabetes than in controlled diabetes. All the 5 domains of WHOQOL-BREF also showed a highly significant difference between controlled and uncontrolled diabetics (P<0.001), with physical, psychological, and environmental health of patients with uncontrolled diabetes being affected the most (Table 5).

Discussion

In terms of psychological and social well-being and physical health, diabetes can have a profound effect on the QOL. Of all the chronic diseases, it is one of the most psychologically demanding diseases, with psychosocial factors associated with almost every aspect and treatment.[16] Resolution of symptoms should not be the only goal of treatment; rather, it now necessitates a holistic approach targeting the overall improvement of QOL.[16] Hence, we assessed the QOL in T2DM patients using the WHOQOL-BREF questionnaire and ADS.

The socio-demographic characteristics like age, male predominance, marital and economic status, diet

Table 2. Gender distribution of patients based on socio-demographic variables.

Socio-demographic variables	Gender No=520		Total No (%)
	Male No (%)	Female No (%)	
Age range (years)			
31-40	6 (2.3)	6 (2.3)	12 (2.3)
41-50	50 (18.9)	29 (11.3)	79 (15.2)
51-60	95 (36.0)	103 (40.2)	198 (38.1)
61-70	84 (31.8)	104 (40.6)	188 (36.2)
71-80	25 (9.5)	12 (4.7)	37 (7.1)
81-90	4 (1.5)	2 (0.8)	6 (1.2)
Education			
Illiterate	29 (11.0)	79 (30.9)	108 (20.8)
Primary	67 (25.4)	88 (34.4)	155 (29.8)
Secondary	84 (31.8)	70 (27.3)	154 (29.6)
12th grade	60 (22.7)	11 (4.3)	71 (13.7)
Graduation	24 (9.1)	8 (3.1)	32 (6.2)
Occupation			
Housewife	-	235 (91.8)	235 (45.2)
Govt. employee	7 (2.7)	2 (0.8)	9 (1.7)
Private employee	27 (10.2)	12 (4.7)	39 (7.5)
Business	117 (44.3)	2 (0.8)	119 (22.7)
Others	113 (42.8)	5 (2.0)	118 (22.7)
BMI (kg/m^2)			
<18.4	4 (1.51)	7 (2.73)	11 (2.11)
18.5-22.9	107 (40.53)	106 (41.41)	213 (40.96)
23-24.9	76 (28.78)	67 (26.17)	143 (27.5)
≥25	77 (29.16)	76 (29.68)	153 (29.42)

No (%), number (percentage); BMI, body mass index.

pattern, and duration of the exercise of patients in the present study are consistent with previous studies on diabetes in India.[17,18] The male predominance indicates that the number of male patients visiting the outpatient clinics is still higher than females in India as the latter give less importance to their health. Furthermore, the frequency of regular exercise among patients indicated increased awareness among them regarding the importance of exercise in controlling diabetes.

In the present study, most of the females had low educational status as compared to men. Furthermore, most of the male patients were middle-aged and employed in businesses while the majority of the female patients were housewives and had reached old age,

Table 3. Clinical variables of type 2 diabetes mellitus patients.

Clinical variables	No (%)
Family history of diabetes	
Yes	186 (35.76)
No	113 (21.73)
Don't know	221 (42.5%)
Symptoms	
Polyuria	172 (33.1)
Polydipsia	49 (9.4)
Polyphagia	56 (10.8)
>One symptom	150 (28.8)
All three	15 (2.9)
Asymptomatic	78 (15)
Associated diseases	
Hypertension	115 (22.1)
Ischemic heart disease	05 (0.96)
Cerebrovascular accident	0
Retinopathy	23 (4.42)
Neuropathy	28 (5.38)
Nephropathy	01 (0.19)
Others	26 (5)
Multiple co-morbidities	262 (50.38)
None	60 (11.53)
Duration of diabetes (years)	
0-5	162 (31.2)
6-10	165 (31.7)
11-15	101 (19.4)
>15	92 (17.7)
Treatment	
Oral hypoglycemic agents	225 (43.3)
Insulin	18 (3.5)
Both	195 (37.5)
No treatment	82 (15.8)
FBG level (mg/dL)	
<126	293 (56.3)
>126 mg/dL	227 (43.7)
PPBG level (mg/dL)	
<180	337 (64.8)
>180	183 (35.2)
HbA1c level (%)	
<7	169 (32.5)
>7	351 (67.5)

FBG, fasting blood glucose; HbA1c, hemoglobin A1c; N (%), number (percentage); PPBG, postprandial blood glucose.

demonstrating that the chances of getting T2DM in females increased on reaching old age. This result agreed with Anumol *et al*.,[17] who found that more than half of the females with T2DM had a low education level and were housewives.[17] Low educational status is associated with low health status as it possibly limits resources and information on environmental exposures and healthy behaviors.

Most of the patients in the present study had a family history of diabetes, like the study conducted by Patel *et al*.[13] Patients with a family history of diabetes have an 80% greater risk of developing diabetes. Furthermore, the postprandial glucose metabolism in Asian people is strongly associated with the family history-related incidence of diabetes.[18] Polyuria was the most frequently occurring symptom among diabetic patients, as reported in the literature.[18] It occurs as a result of osmotic diuresis due to high glucose levels than excreted in the urine. Passively, the water follows the glucose concentration resulting in abnormally high urine output.

In the present study, patients had multiple comorbidities, with hypertension being the most commonly occurring comorbidity. Although the majority of the patients received oral hypoglycemic agents, many used both insulin and oral hypoglycemic agents. Although fasting and postprandial blood glucose levels were under control in many patients, most of them had their hemoglobin A1c levels above the normal range due to diabetes. Similar observations were made by Patel *et al*.[13]

Several factors have been identified as predictors of T2DM-related QOL. Age, duration of diabetes, associated comorbidities, treatment, and HbA1c level of patients significantly affected the QOL as patients aged ≥60 with 6-10 years of diabetes, multiple comorbidities, oral hypoglycemic medication, and uncontrolled diabetes (HbA1c level ≥7 mmol/mol) had very poor and poor QOL. This is consistent with Somappa *et al*.'s study in which[19] patients with HbA1c level ≥7 mmol/mol (uncontrolled diabetes) showed poor QOL.[19] These findings demonstrate that HbA1c levels are essential predictors of QOL among people with diabetes, and it is crucial to maintain these levels to control T2DM for improved QOL.

The mean ADS score of patients with uncontrolled diabetes was higher than that of patients with controlled diabetes. This is consistent with the findings of Patel *et al*., who reported that the mean ADS score was 19.9±3.4.[13] Furthermore, the overall WHOQOL-BREF score concerning all its five domains was significantly low for uncontrolled than controlled diabetes patients in the present study. This is in accordance with a study from UAE,[9] in which the physical and social domains scored high among controlled diabetics. The reason may be that, like Indians, the UAE people also enjoy strong family connections and social

relationships. However, the findings of a study from Nigeria were in contrast with our study's results as it reported higher QOL scores in the social domain and lower scores in physical, environmental, and psychological domains than our study.[20] The observed difference in some of the domains could be due to socio-cultural factors, despite Nigeria being a developing country like India.

Our study showed a significant difference for major domains in QOL instruments and depicted poorer QOL in uncontrolled diabetics than controlled diabetics. Considering it as an important finding of our study, we suggest the effectiveness of both the instruments in evaluating the impact of disease control on the QOL of diabetic patients.

Our study has its limitations. It was a single-centered study in India and included patients from lower socioeconomic classes and only T2DM. Therefore, the study's findings may not be generalized for all Indian patients and both types of diabetes. Future studies are recommended to evaluate the effect of therapeutic interventions on the QOL of diabetic patients. Hence, a future prospective study should be undertaken with follow-up visits to observe the impact.

Table 4. Association of QOL with age, duration of diabetes, associated comorbidities, treatment, HBA1c, and BMI.

Variables	WHOQOL-BREF (No=520) No (%)				P-value*
	Very poor	Poor	Average	Good	
Age (years)					
≤60	42 (8.07)	20 (3.84)	144 (27.69)	38 (7.30)	<0.001*
≥60	44 (8.46)	92 (17.69)	127 (24.42)	13 (2.5)	
Duration of diabetes (years)					
0-5	29 (5.57)	14 (2.69)	90 (17.30)	29 (5.57)	<0.001*
6-10	31 (5.96)	24 (4.61)	92 (17.69)	18 (3.46)	
11-15	15 (2.88)	16 (3.07)	66 (12.69)	4 (0.76)	
>15	11 (2.11)	58 (11.15)	23 (4.42)	0 (0)	
Associated comorbidities					
Single co-morbidity	33 (6.34)	35 (6.73)	100 (19.23)	34 (6.53)	<0.001*
Multiple co-morbidities	45 (8.65)	71 (13.65)	132 (25.38)	10 (1.92)	
None	8 (1.53)	6 (1.15)	39 (7.52)	7 (1.34)	
Treatment					
Oral hypoglycemic agents	31(5.96)	68 (13.07)	97 (18.65)	29 (5.57)	<0.001*
Insulin	2 (0.38)	4 (0.76)	11 (2.11)	1 (0.19)	
Both	39 (7.5)	23 (4.42)	116 (22.30)	17 (3.26)	
None	14 (2.69)	17 (3.26)	47 (9.03)	4 (0.76)	
HbA1c (mmol/mol)					
<7 (controlled diabetes)	0 (0)	27 (5.19)	114 (21.92)	28 (5.38)	<0.001*
≥7 (uncontrolled diabetes)	86 (16.53)	85 (16.34)	157 (30.19)	23 (4.42)	
BMI (kg/m^2)					
<18.4	2 (0.38)	1 (0.19)	6 (1.15)	2 (0.38)	0.1885
18.5-22.9	40 (7.69)	43 (8.26)	108 (20.76)	22 (4.23)	
23-24.9	16 (3.07)	39 (7.52)	70 (13.46)	18 (3.46)	
>25	28 (5.38)	29 (5.57)	87 (16.73)	9 (1.73)	

BMI, body-mass index; C, Chi-square test of independence; HbA1c, hemoglobin A1c; mmol/mol, millimoles per mole; N (%), number (percentage); WHOQOL-BREF, World Health Organization Quality of Life-BREF. *Highly significant.

Table 5. Difference between QOL in controlled and uncontrolled diabetes in terms of ADS and WHOQOL-BREF domains.

Domain	For all scores (mean±SD)	Controlled diabetes (mean±SD)	Uncontrolled diabetes (mean±SD)	P-value°
ADS (scores)				
ADS	19.03±2.87	18.50±3.08	19.29±2.73	0.003
WHOQOL-BREF (scores)				
Overall General Health	5.4±1.23	6.0±1.13	5.1±1.18	<0.001*
Physical	17.8±4.64	19.35±5.08	17.14±4.23	<0.001*
Psychological	16.4±2.88	17.3±3.31	15.9±2.53	<0.001*
Social	7.4±1.17	7.91±1.22	7.17±1.07	<0.001*
Environmental	23.4±5.8	24.6±4.52	22.83±6.26	<0.001*

ADS, Appraisal of Diabetes Scale; SD, standard deviation; WHOQOL-BREF, World Health Organization Quality of Life BREF; °unpaired 't' test. *Highly significant.

Conclusions

The QOL was more impaired in uncontrolled diabetics in comparison to controlled diabetics in T2DM. Both the instruments, *i.e*., generic WHOQOL-BREF and disease-specific ADS, were significantly correlated with uncontrolled diabetes being affected the most. They were reliable and effective in measuring the QOL in T2DM. Age, duration of diabetes, associated comorbidities, treatment, and HbA1c level of patients were important predictors of QOL as they significantly affected the QOL of T2DM patients.

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