Assessment of quality of life in type II diabetic patients using the modified diabetes quality of life (MDQoL)-17 questionnaire

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Diabetic complications, comorbidities, and cost of treatment affect the quality of life (QoL) of an individual. The QoL assessment is considered an important measure of outcome in chronic disease management. The objective of our study was to assess the quality of life in Type II diabetes mellitus patients with and without complications using the modified diabetes quality of life (MDQoL)-17. A prospective descriptive study was conducted over 6 months, after taking ethical committee approval. As per the inclusion criteria from medicine wards of tertiary care hospital, 250 patients were selected. Demographic characteristics were documented in the data collection form and the patients were administered with the MDQoL questionnaire in different languages. The data was analyzed using IBM SPSS version 20. Majority of the patients were male (64.4%). The average age of the study population was 60.34 ± 12.04 years. Most of the patients had a diabetes history of more than 10 years and HbA1c > 8%. The average QoL score was 65.47 ± 15.07. Majority of the diabetic patients had the QoL score between 70 and 50. Patients without complication had a better QoL. As the number of complications increased, there was a decrease in the QoL. The presence of comorbidity also decreased the QoL. There was a statistically significant correlation with various parameters such as age, duration of diabetes history, HbA1c, number of complications and type of complication verses QoL of diabetic patients ($p < 0.05$). The overall QoL in diabetic patients is reduced. Thus, proper management and strict glycemic control is necessary to prevent progression and occurrence of complications to maintain a better QoL in diabetes patients.

Keywords: Quality of Life. Diabetes complications/prevention and control. Diabetes Mellitus. Surveys and Questionnaires/utilization.

INTRODUCTION

The quality of life (QoL) in general is decreased in diabetic patients regardless of the gender. The patients with complications of diabetes mellitus suffer from a variety of lifestyle problems. In the end, it affects the renal system by causing nephropathy, vision loss, heart problems, erectile dysfunction, and peripheral neuropathies affecting the QoL. In one cohort study, it was found that there was an improvement in mental QoL more than physical QoL when there was a tight glycemic control (Lau, Qureshi, Scott, 2004). Rubin *et al.* (1999) stated in their study that the patients suffering from diabetes had a poor quality of life than the patients without any disease, but had somewhat higher QoL than the patients with the majority of other chronic illness. The mere presence of diabetes can reduce the quantity and quality of any relationship, family life, and hindrance in traveling and increase in economic burden (Polonsky, 2000). Education on self-control had more impact on controlling the condition and improving the quality of life as shown by one meta-analysis (Gerstein *et al.*, 2011).

According to the result of International Diabetes Federation (2015), there are 415 million people worldwide suffering from diabetes and 78.3 million are from South East Asia. India is the second largest worldwide with diabetes population, after China (International Diabetes Federation, 2015). Diabetes has become increasingly prevalent and demands better care and control. The quality

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of life assessment is considered an important measure of outcome in long-term illness and management. General quality of life assessment tools used for diseases are Short Form 36 (SF-36 Health Survey), a Rand-36 measure of health-related quality of life, and The Euro QoL (EQ) (Acharya *et al.*, 2014). Tools for measuring the quality of life are Problem areas in diabetes (PAID), Diabetes Treatment Satisfaction Questionnaire (DTSQ), Appraisal Diabetes Scale (ADS) (Acharya *et al.*, 2014), and Medical Outcomes Study (MOS) is also used for diabetic patients. The MOS instrument includes physical, social, role functioning scales to capture behavioral dysfunction due to health problems. Measuring different areas of quality of life requires various domains, specifically for example, physical, psychological, social, and functioning aspects (Stewart *et al.*, 1989). From an analytical point of view, the quality of life assessment has been used to give a reference norm, better prognosis, signal change in the patient's perspective.

The studies on QoL help in the evaluation of the psychological functioning of a patient, identification of specific shortcomings, and the needs of patients at different stages of the disease. They also help in comparing the impact of different treatment regimens on a patient's well-being and satisfaction (Snoek, 2000). These results from the study of QoL can help a clinicians' ability to predict, treatment response, and survival time in certain contexts (Acharya *et al.*, 2014). Such comparative studies have equipped the clinicians with important information to support clinical decision-making, taking both biomedical and psychosocial aspects into consideration (Snoek, 2000).

Most health care providers focus on medically related outcomes only when assessing the efficacy of their intervention, thus for a better outcome it is important to extend the assessment of the effect on physical, emotional, social and economic wellbeing that is, the quality of life.

Diabetes is a chronic illness therefore there is a need for assessing the QoL 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 (Power, 2008).

The QoL 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 well-being (Rubin, 2000). Routine assessment of QoL as a part of clinical practice has the potential to improve communication between the patient and the health care provider, identify frequently overlooked problems, assess the problems, and evaluate the effect of therapeutic efforts at the individual patient's level (Acharya *et al.*, 2014).

In our study, we have used MDQoL-17 questionnaire developed by Acharya *et al.* (2014). It contains 17 diabetic specific questions and 8 concepts for physical, social functioning, role limitations due to personal and emotional problems, psychological impact, energy/fatigue, bodily pain, and general health perceptions. This was used to assess the QoL in Type II diabetes mellitus patients with and without complications and get a better understanding of the patients' perspective regarding the disease and impact of disease on their QoL.

METHODOLOGY

This prospective descriptive study was conducted in the General Medicine units of Tertiary care hospital in South India, after obtaining Ethical Committee approval from the Institutional Ethics committee. The study was done for a total duration of six months. During the study period, 250 patients were recruited with Type II diabetes based on the following inclusion and exclusion criteria. The selected patients were administered with the MDQoL-17 questionnaire and recorded the demographics information in the data collection form after obtaining their consent.

Acharya *et al.* (2014) developed and validated the MDQoL-17 questionnaire in the year 2010 in the local South Indian languages - Kannada and English. It consists of 17 questions that comprise seven domains, which include physical functioning, role limitations due to physical health problems, role limitations due to personal or emotional problems, emotional well-being, social functioning, energy/fatigue, and general health perceptions. All the contents are scored so that a high score depicts a more favorable health state. The possible scores are 0-100, 0 being the minimum and 100 being the maximum score Scores represent the percentage of total possible score achieved. The various domains, number of items in each domain, and item numbers that come in that particular domain and their scores are shown in Tables I and II.

Data were analyzed using IBM SPSS statistics 20 software for various demographic parameters such as gender, age group, duration of diabetic history, the number of diabetic drugs prescribed, the prescription pattern of diabetic drugs, laboratory tests on admission and the time taken for interview and the QoL.

The QoL score of MDQoL-17 was expressed as a percentage of the total QoL Score for ease of comparison and analysis. Those patients with a QoL score of more than 70 had a better QoL, those with a QoL score of 50-70 had a moderate QoL, and those with less than 50 had a poor QoL.

Descriptive statistics was used to express various demographic parameters. For the comparison of the QoL

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Score and covariates, demographics, diabetic related complaints, comorbidities, diabetes with and without complications etc. unpaired 'T' test (also known as independent 'T' test) was applied for comparing the mean of two groups and for comparing the means of three of more groups the one way ANOVA test was applied. P value <0.05, was considered significant.

TABLE I - MDQoL-17 Domains and item numbers

Domains	Number of Items	Item Numbers
Physical functioning	3	4,5,6
Role limitations due to physical health	1	7
Role limitations due to emotional	2	11,12
Energy Fatigue	1	17
Emotional well being	3	8,9,10
Social functioning	4	13,14,15,16
General Health	3	1,2,3

RESULTS

As per the study criteria, the 250 diabetic patients admitted were included and the majority of them were male members as shown in Table III.

Among the 250 patients, 16 (6.4%) patients were in the age group of less than 40 years, 142(56.8%) were in the age group of 40-65 years, and 89(35.6%) were falling under the age group of more than 65years. The mean age of patients was found to be 60.34±12.04 years.

We observed that out of 190 patients, 27 (14.2%) had the history of diabetes less than 1year, 30(15.8%) had a history of 1-5 years, 57(30%) of 6-10 years, and 76 (40%) of more than 10 years.

Patients 155(62%) were hospitalized for less than 10 days, 67 (26.8%) for 10-20 days, and 22(8.8%) for more than 20 days. The mean duration of hospitalization in the diabetic patients was found 11.07±.8.55 days.

Out of 250 patients, 116 (46.4%) had health insurance and 134 (53.6%) did not have any health insurance. Patients were prescribed with 1 to 4 medications for diabetes treatment; the majority of the patients were on monotherapy (Table III).

There were 94 (37.6%) patients being treated with insulin monotherapy, 80 (32%) were on oral hypoglycemic agents, and 62 (24.8%) were taking a combination of insulin and oral hypoglycemic agents.

Among the diabetic patients, many had other comorbidities present, such as hypertension (HTN), kidney disease, liver disease, and other diseases as shown in Table III. Various tests were performed to determine the glycemic control, fasting blood sugar (FBS), glycosylated hemoglobin (HbA1c), and the body mass index (BMI) at the time of admission. Details are shown in Table III.

On analysis of MDQoL-17 questionnaires, the average QoL score was 65.47±15.07. The number of patients under a different range of QoL score is represented in Table IV.

The correlation between the QoL score and the number of diabetic complications is described in Table V. Eighty-seven patients had various types of complications; retinopathy, nephropathy, neuropathy, diabetic foot, Ischemic Heart Disease (IHD) and ketoacidosis. The patients with diabetic neuropathy had the least QoL score (53.99±16.39) and the patient with diabetic retinopathy had a better QoL score (65.20±18.16) compared to other complications (Table V).

The QoL in comparison to the demographic characteristics of the patient showed that there was no significant difference in the QoL scores between male and female. As the age increased the QoL decreased, patients less than 40 years had a better QoL while those more than 65 years had comparatively a poor QoL.

The patients without comorbid condition had a better QoL than the patients with comorbidity. The QoL in different types of cormorbidity is described in Table V. QoL in patients with a diabetes history of less than 1 year was better and as the duration increased the QoL decreased, those with more than 10-year diabetic history had a lower QoL. QoL score for a patient hospitalized

TABLE II - Response category and scores of MDQoL-17

Item Number	Response category and Scores
1,2,7,13	1→100,2→75,3→50,4→25,5→0
3	1→0,2→25,3→50,4→75,5→100
4,5,6	1→0,2→50,3→100
8,9,10,11,12,14,15,16	1→0,2→20,3→40,4→60,5→80,6→100
17	1→100,2→80,3→60,4→40,5→20,6→0

TABLE III - Demographics of Diabetes patient

S.No		Category	Number of patients (%)
1	Gender N=250	Male	161(64%)
		Female	89 (36%)
2	Fating Blood Sugar (mg/dl) N= 142	Less than 110	36 (25.4%)
		110-126	8 (5.6%)
		More than 126	98 (69%)
3	HbA1c (%) N=168	4-7	38 (22.6%)
		7-8	28 (14.3%)
		More than 8	106 (63.1%)
4	BMI (Kg/m^2) N=130	≤18.4	9 (6.9%)
		18.5-22.9	32 (24.6%)
		23-24.9	18 (13.8%)
		≥25	71 (54.6%)
5	Comorbidity	HTN	124 (49.6%)
		Kidney Disease	46 (18.4%)
		Liver Disease	12 (4.8%)
6	DM with and without Complication	DM Without Complication	163 (65.2%)
		DM+1 complication	65 (26%)
		DM+2 complication	13 (5.2%)
		DM+3 complication	7 (2.8%)
		DM+4 complication	2 (0.8%)
7	Types of Diabetic Complication	Retinopathy	22 (25.3%)
		Nephropathy	24 (27.6%)
		Neuropathy	14 (16.1%)
		Diabetic foot	17 (19.5%)
		IHD	39 (44.8%)
		Ketoacidosis	5 (5.7%)
8	Number of diabetic drugs prescribed N=250	One	134 (53.6%)
		Two	61 (24.4%)
		Three	38 (15.2%)
		Four	3 (1.2%)

TABLE IV - Assessment of QoL of diabetic patients

QoL Score	No. of patients (%) N=250
Less than 50	40(16%)
50-70	106(42.4%)
More than 70	103(41.2%)

less than 10days was better than for patient hospitalized for more than 20day, as the duration of hospitalization increased the QoL decreased.

Patients prescribed with a combination of insulin and OHA had a better QoL than patients on monotherapy of only insulin or OHA. Patients on OHA monotherapy had a slightly Better QoL than those on insulin monotherapy. Diabetic patients without Complications had a better QoL in comparison to those with complications, and the minimum QoL score was in patients having diabetes with three complications.

The QoL for patients with health insurance was slightly better compared to those without health insurance. The patients with a BMI of less than or equal to 18.4kg/m^2 had higher QoL score than the others and those with BMI of 18.5-22.9 had the lowest QoL score. The patients with HbA1c between 4% - 7% had a lower QoL in contrast to those with an HbA1c of more than 8% who had a better QoL score. The details of correlation of QoL score with various demographics characteristics of diabetic patients are represented in Table V.

The QoL of diabetic patients was assessed with respect to diabetes-related complaints, it was found that fatigue, sleep disturbances, polyuria, problems in work life, decreased energy levels, hypoglycemic symptoms, tingling sensation/numbness, problems in social life, difficulty in walking, swelling in limbs, pain in limbs, and delayed wound healing statistically significantly effect on QoL, reduces the QoL scores. However, weight change and blurred vision did not have a statistically significant difference in the QoL score. The detailed summary of the result is given in Table VI.

DISCUSSION

The present study is aimed at assessing the QoL in Diabetic patients in a tertiary care hospital where 250 patients were admitted. We found that the patients with diabetes had generally a negative impact on the QoL (65.47±15.07). This is supported by the studies done by Gautam *et al.* (2009) and Anumol *et al.* (2014) both concluded that diabetes had an adverse effect on the QOL of the patient.

The majority of the study subjects were males 161 (64.4%) and this was similar to the observation from the study carried out by Eljedi *et al.* (2006) in which the majority of the patients were males.

The mean age of diabetic patients was found to be 60.34±12.04 years and Ali et al. (2013) made a similar observation in their study and reported the mean age 59.65±12.3 years. Majority of the patients (n=142) were

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TABLE V - Correlation of QoL with various demographics characteristics of diabetic patients

S.no	Covariate factors		QOL scores (Mean ± S.D)	p values
1	Gender	Male	65.71±16.08	0.713
		Female	65.02±13.15	
2	Age (years)	Less than 40	71.47±14.16	0.024
		40-65	66.83±14.86	
		More than 65	62.38±15.16	
3	Comorbidity	Present	64.37±14.75	0.179
		Absent	67.09±15.55	
4	Type of Comorbidity	HTN	64.39±14.56	>0.05
		Kidney disease	62.12±15.03	
		Liver disease	63.24±16.81	
5	Duration of Illness (years)	<1	75.93±10.93	0.004
		1-5	68.15±16.34	
		6-10	65.56±15.33	
		>10	63.88±14.18	
6	Length of stay in hospital (days)	<10	66.49±15.53	0.370
		10-20	64.40±14.79	
		>20	62.27±13.73	
7	Patients diabetic Medication	Insulin	63.95±15.97	0.279
		OHA	65.92±14.92	
		Insulin+ OHA	67.89±14.08	
8	Health insurance status	Present	66.69±15.28	0.238
		Absent	64.42±14.88	
9	Diabetes with and without Complication	DM without complications	66.80±14.51	>0.05
		DM+1 complications	64.87±14.66	>0.05
		DM+2 complications	60.59±20.16	>0.05
		DM+3 complications	50.04±14.29	0.031
		DM+4 complications	62.94±16.63	>0.05
10	Type of Diabetic Copmlication	Retinopathy	65.20±18.16	0.931
		Nephropathy	58.24±16.94	0.013
		Neuropathy	53.99±16.39	0.003
		Diabetic foot	63.34±15.94	0.547
		IHD	63.88±15.10	0.476
		Ketoacidosis	58.65±10.24	0.308
11	BMI (kg/M^2)	≤18.4	70.46±11.76	0.572
		18.5-22.9	65.73±14.52	
		23-24.9	66.08±12.28	
		≥25	69.29±14.68	
12	HbA1c (%)	4-7	59.05±18.06	0.025
		7-8	67.59±13.81	
		>8	66.49±13.89	

P< 0.05, was considered statistical significant

TABLE VI - Assessment of QoL based on the diabetes related complaints

S.no	Diabetes related complains		QOL scores (Mean ± S.D)	p values
1	Fatigue	Present (n=189)	62.47±14.70	<0.0001
		Absent (n=60)	74.90±12.14	
2	Sleep disturbances	Present(n=104)	61.52±13.90	<0.0001
		Absent(n=146)	68.30±15.29	
3	Polyurea	Present (n=84)	61.72±17.01	0.005
		Absent (n=165)	67.37±13.65	
4	Weight change	No change(n=91)	66.47±14.07	0.126
		Loss (n=119)	63.61±16.31	
		Gain(n=39)	68.82±12.77	
5	Problems in work life	Yes(n=134)	60.79±14.51	<0.0001
		No(115)	70.92±13.89	
6	Decreased Energy Levels	Yes (n=180)	61.63±14.40	<0.0001
		No (n=69)	75.48±11.91	
7	Hypoglycemic symptoms	Present (n=109)	60.36±15.25	<0.0001
		Absent (n=140)	69.45±13.72	
8	Tingling sensation/Numbness	Present (n=132)	60.64±14.88	<0.0001
		Absent (n=117)	70.92±13.38	
9	Blurred vision	Present (n=103)	63.33±14.87	0.059
		Absent (n=146)	66.98±15.08	
10	Problems in social life	Present (n=53)	56.41±17.47	<0.0001
		Absent (n=196)	67.92±13.39	
11	Difficulty in walking	Present (n=169)	60.81±14.07	<0.0001
		Absent (n=80)	75.30±12.71	
12	Swelling of limbs	Present (n=90)	61.44±14.77	0.001
		Absent (n=159)	67.75±14.80	
13	Pain in limbs	Present (n=140)	60.91±14.87	<0.0001
		Absent (n=109)	71.32±13.25	
14	Delayed wound healing	Yes (n=73)	59.66±16.25	<0.0001
		No (n=176)	67.88±13.90	

P< 0.05, was considered statistical significant

in the age group between 40-65 years as observed in a study of global prevalence in diabetes by Wild *at al.* (2004) which stated that in the developing countries, majority of the people with diabetes are in the age range of 45-65 years. King *et al.* (1998) made a similar observation in their study. We also observe as the age increases there is a significant decrease in the QoL score (p= 0.024). Ali *et al.* (2013) and Glasgow *et al.* (1997) made a similar observation in a study, where an increase in age decreased the QoL in diabetes patients.

In our study, majority of diabetic patients had a history more than 10 years, their QoL score was poor compared to those with a history of less than 10 years, and Shirish, Priya, and Ahsan (2011) made a similar observation in their study. We observed in the study that as the duration of history increased there was a significant decrease in the QoL (p=0.004).

The QoL score for the patients on combination therapy with insulin and OHA was better than the patients on monotherapy do with only insulin or OHA. These may be attributed to the fact that using combination therapy of insulin and OHA gives a better glycemic control. The studies by Hermanns *et al.* (2015) and Yki-Järvinen (2001) both reported that the combination of insulin with OHA

had a better glycemic control, less adverse effect and better outcome in type 2 diabetic patients.

The subjects with Health insurance had a better Quality of life than those without insurance, these can be attributed to regular checkup, and the insurance company covers medication adherence as the cost.

The patients with a BMI of <18.4 Kg/m² had a better QoL than the patients with a BMI >25 kg/m², but there is no statistically significant difference in the QoL scores, previously the studies independently looking at the association between obesity and Qol have clearly indicated that the obesity impairs the QoL (Kolotkin, Meter, Williams, 2001). A study in from Stanford also showed that among diabetics, the presence of obesity significantly impaired QoL (Hlatky, et al., 2010).

Patients with HbA1c 7-8% had a better QoL life (67.59±13.81) compared to the patients with HbA1c levels between 4-7% and more than 8%. A study by Stanetić et al. (2012) reported the similar result that the poor QoL was observed in the patients with poor glycemic control and levels of HbA1c >8.1%. It also stated that the better QoL was found in patients with HbA1c level between 7.1 -8.0%.

The QoL decreased in the presence of comorbidity, and Jiménez-Garcia et al. (2008) made the similar observation in their study that reported comorbidities as a predictor of poor QoL. There was no statically significant difference in the score as seen in a study by Shirish, Priya, Ahsan (2011) and Jiménez-Garcia et al. (2008). We also observed that the most predominant Comorbidity was hypertension [124(49.6%)] and followed by chronic renal failure [46(18.4%)] in diabetic patients. Similar results were seen in the studies by Gautam et al. (2009), Wexler et al. (2006) and Spasić et al. (2014) in diabetes patients the most frequent comorbidity was hypertension. In a study by Acharya et al. (2016), it was reported that more than 50% of the total diabetes patients had hypertension and the similar observation is reported in our study.

The diabetic patients without complications had a better QoL compared to the patients with diabetic complications, and as the number of complications increased the QoL score decreased. The most commonly observed diabetic complication was IHD [39(44.8%)] and the other complications were retinopathy [22(25.3%)], nephropathy [24(27.6%)], neuropathy [14(16.1%)]. Similar observations were seen in a survey and chart review that was conducted to assess the health-related quality of life among 2285 Type II diabetes people in Canada. The study results showed that the most prevalent diabetic complications were coronary artery disease (16%), retinopathy (15%), cerebrovascular accidents (9%), neuropathy (9%), peripheral vascular disease (7%), and nephropathy (6%). The study concluded that the people with diabetes experience significant impairment in their health-related quality of life; the presence of diabetic complications significantly affects some health-related quality of life of Type II diabetes mellitus patients (Thommasen, Zhang, 2006). Our study showed a statistically significant decrease in QoL (53.99±16.39) in the patients with neuropathy (P=0.003). It was also observed that among the diabetic complications the patients with neuropathy had the least QoL score, which is similar to the study by Benbow et al. (1998) who reported that neuropathy impairs the QoL. The patients with nephropathy had a lower QoL (58.24±16.94) and there was a statistically significant difference in the QoL scores (P=0.013) compared to the patients without complications, and it is supported by a study by Lauro et al. (2005) who reported that the patients with diabetic nephropathy showed deterioration in the QoL.

Diabetic related complaints fatigue, sleep disturbances, polyurea, problems in work life, decreased energy levels, hypoglycemic symptoms, tingling sensation/numbness, problems in social life, difficulty in walking, swelling in limbs, pain in limbs and delayed wound healing significantly reduce the QoL scores (P<0.001). Benbow et al. (1998) reported the similar observation where the patients complaining of fatigue and pain in limb had poor QoL.

The limitations we encountered were failure to obtain an equal number of patients with different complications, without diabetic complications for better comparison of outcome, and the short duration of the study period.

CONCLUSION

In conclusion, the study was carried out to evaluate the QoL in Type II diabetic patients with and without complications. Among the 250 Diabetic patients enrolled, the majority of them were male, the mean age of diabetic patients was 60.34±12.04 years, and majority had a history of diabetes for more than 10 years. Most of the patients [106(42.4%)] had a moderate QoL score between 50 and 70. There are various factors such as age of the patient, duration of history of diabetes, and HbA1c significantly reduce the QoL of diabetic patients (p<0.05). The presence of complication and comorbidity had an adverse effect on the QoL of diabetic patients, as the number of complications increased the QoL decreased and hypertension was the predominant comorbid condition.

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Overall patients with Type II diabetes have a negative impact on their quality of life with or without complications. It also shows that diabetes affects various domains such as physical functioning, emotional well-being, social functioning, economical status, and general health in a patient's life, thereby affecting the QoL. Hence, it is recommended for patients to have an adequate and strict glycemic control enabling them to maintain their quality of life, preventing disease progression and diabetic complications.

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