

Health related Quality of Life of male type2 diabetes: A case control study

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Abstract: Objectives: To measure the Health Related quality of Life (HRQoL) in male type2 diabetic patients and identifying the variation of HRQoL with the socioeconomic factors. **Materials and Methods:** This matched case control study was conducted in Abha, Aseer Region on 106 diabetic patients and 106 non diabetic patients. Data was collected using an interviewer-administered questionnaire. The health related quality of life of participants in the four weeks prior to assessment was measured by using the SF-36 questionnaire. **Results:** The mean age of cases and controls was 57.60 ± 11.3 years and 57.62 ± 11.5 years respectively. Compared to the controls, the participants in the case were highly educated, less unemployed and had higher monthly income. Mean scores of Quality of life with respect to physical functioning, role limited due to physical health, role limited due to emotional problem, energy and vitality and psychological domains were significantly poor among cases compared to controls. Age and low level of education are significantly negatively affecting all domains of quality of life among cases. **Conclusion:** Diabetes mellitus has considerable negative impact on the HRQoL. Quality of life of patients is an essential factor that affects diabetic management and therefore, the ultimate diabetic care should involve the assessment of HRQoL in any modality used to treat diabetic patients. Understanding the effect of diabetes on QOL is important for day to day clinical management and also for public health policy initiatives in order to improve the QOL of diabetic patients.

[Alsamghan AS. **Health related Quality of Life of male type2 diabetes: A case control study.** *Life Sci J* 2016;13(4):54-61]. ISSN: 1097-8135 (Print) / ISSN: 2372-613X (Online). <http://www.lifesciencesite.com>. 6. doi:[10.7537/marslsj13041606](https://doi.org/10.7537/marslsj13041606).

Keywords: Health Related quality of Life (HRQoL), type2 diabetic patients, SF-36 questionnaire

1. Introduction

The World Health Organization (WHO) and International Diabetes Federation (IDF) have projected that the number of diabetes cases will increase to 366 million by 2030.^{1,2} Diabetes mellitus (DM) is associated with multiple medical complications that decrease the Health-Related Quality of life (HRQoL) and contribute to suboptimal physical and mental functioning and earlier mortality.^{3,4} The incidence of type 2 diabetes mellitus is becoming a global challenge with all the negative repercussions in term of morbidity and mortality.³ The international Diabetes Federation (IDF) has projected that type II diabetes mellitus represents the fourth leading cause of global death.² Type II diabetes mellitus appears to be a silent epidemic in many parts of the world. Diabetes mellitus is triggered by multiple factors, which lead to chronic complications such as blindness, amputation, neuropathy, nephropathy, and cardiovascular of individuals, and society which in turn, create undue burden to public health.⁴⁻⁶

There is evidence to suggest that diabetes is highly prevalent among the diverse ethnicity living in the Middle East⁷⁻⁹. In the Arabian Gulf, studies have reported that nearly 17% of adults in the United Arab Emirates,¹⁰ 15% of Kuwaitis,¹¹ and 14% of Saudis¹² suffer from type 2 diabetes mellitus.

Studies from many parts of the world suggest that patients with diabetes have a lower QoL than people with no chronic illness.^{13,14} The duration and type of diabetes are related to QoL. Intensive diabetes therapy is shown to improve glycemic levels, which are associated with better QoL.¹⁵ Complications resulting from diabetes are the most important diabetes-specific determinants of QoL.¹⁶ Better diabetes QoL is associated with better levels of social support, self-efficacy, exercises, education level, income, and with the absence of complications.¹⁷ There is also evidence to suggest that patients' QoL and treatment satisfaction improved after good glycemic control and greater perceived flexibility in leisure time activities and diet^{18, 19} which in turn suggest the importance of QoL as prevention and prognostic indicators.

Despite many epidemiological studies and clinical impressionistic observation, there are limited studies that examine the quality of people with type2 diabetes in Aseer, Southern Region of Saudi Arabia. This study aim to measure the HRQoL in type2 diabetes in comparison to non-diabetic subjects and identifying the variation of HRQoL by their socioeconomic factors. It is expected that this study would shed light on preventive measures, planning intervention, which, in turn would help improve HRQoL of people with diabetes type 2.

2. Materials and Methods

This age and nationality matched case control study was conducted in Abha diabetic center and chronic disease clinics in five primary health centers in Abha City, Aseer Region. Data was collected from January to June 2015. Abha, the capital city of Aseer province in Southwestern Saudi Arabia, is situated at 2500 m (7200 ft) above sea level in the fertile mountains of the south west.

Cases were the type2 diabetics and controls were the patients without diabetes. Ratio of case and control was 1: 1. A total of 212 was the sample size, of them 106 was cases and 106 were control. The sample size was calculated by using the formula for difference in means, the accepted type 1 error was 0.05, the accepted power was 80% and the expected differences between groups was 5 and standard deviation was 13.

The cases (patients with diabetes type2) were selected during their routine visit to the outpatient clinics and controls were selected from those taking health care for other diseases in the same centers. The inclusion criteria were patients older or equal to 35 years, having type 2 diabetes mellitus, at least one visit last three months. Exclusion criteria for both cases and controls included having chronic diseases such as heart failure, chronic lung disease, diabetic foot or limb amputation and age more than 75 years. Abha diabetic clinic and five primary health care centers were selected by simple random sampling. Both cases and controls were selected purposively and conveniently.

Data was collected using an interviewer-administered questionnaire containing two parts. The first part containing socio demographic and disease related check list. The second part was the Arabic version of the SF-36 questionnaire. The demographic parameters were age, marital status, education, occupation, monthly income. The patients were classified as high income if their monthly income was >10,000 Saudi Arabian Riyal (SAR), monthly income SAR >5,000 to 10,000 were classified as middle income and monthly income SAR ≤5,000 were considered as poor monthly income.

Disease related information noted were: duration of diabetes, age at onset of diabetes, use of anti-diabetic drugs, obesity (BMI>30), Hypertension (Hypertension was defined as elevated systolic (≥ 140 mm Hg) or diastolic (≥ 90 mm Hg). Complications of diabetes included ischemic heart disease, peripheral vascular disease, cerebrovascular accident, neuropathies (diagnosed on clinical findings), diabetic nephropathy was diagnosed by the nephrologists (the presence of microalbuminuria which defined as, the presence of microalbuminuria ≥ 30 to 299 mg/24 hours urine collection sample or the presence of macro albuminuria ≥ 300 mg/24 hours urine collection

sample). These data were noted from the patient's medical records.

The health related quality of life experience of participants in the four weeks prior to assessment was measured by using the SF-36 questionnaire.²¹ The SF-36 is a well-known generic HRQoL instrument that was developed initially in the United States of America. Its reliability and validity has been approved in multiple populations in several studies.²² These 36 items were adapted from longer instruments completed by patients participating in the Medical Outcomes Study, an observational study of variations in physician practice styles and patient outcomes in different systems of health care delivery.²³

The SF-36 has gained popularity because of its ease of administration, acceptability, and psychometric performance.²⁴ The questionnaire itself consists of thirty-six questions measuring eight domains of health, namely, "physical functioning," "role limitation due to physical" health problems, "bodily pain," "general health," "energy and vitality," "social functioning," "mental health," and "role limitations due to emotional problems". Scores range from 0 to 100 for each domain with higher scores indicating a better HRQOL.

The SF-36 Health Survey items and scales were constructed using the Likert method of summated ratings. Answers to each question were scored. These scores were then summed to produce raw scale scores for each health concept which were then transformed to a 0 to 100 scale with higher scores indicating better HRQOL.

Each item was assumed to have a linear relationship with the score for its domain. The eight scales of the SF-36 questionnaire have been shown to have high internal consistency (Cronbach's Alpha 0.76–0.86). Content validity (the extent to which SF-36 comprehensively measured health status) and criterion validity (the extent to which SF-36 correlated with existing measures of health) were established during this developmental stage. The SF-36 health assessment questionnaire has been reported as valid and reliable in normal populations as well as diabetes patient groups.^{25, 26} In addition, Arabic version of the questionnaire has been reported as valid and reliable.²⁷

The questionnaire was administered by nine trained female medical students of Level12 from College of Medicine in King Khalid university, who received two days training on the purpose of study, method of interview and data collection. Interviews were conducted in a separate room in order to maintain privacy and confidentiality. Informed consent was taken from all subjects in compliance with the principles of the 1996 amendment to the Declaration of Helsinki. The study was approved by the Research Ethical Committee of the King Khalid University.

Statistical Analyses

Data analysis was done with SPSS version 17 (SPSS Inc., Chicago, IL, USA)–Comparison between quality of life score in case and control was done by *t* Test. One way analysis of variance (ANOVA) was performed to compare of quality of life score in education, occupation, monthly income. Tukey *post hoc* test was conducted to look at differences among the groups. *P* value of <0.05 was considered to be statistically significant.

3. Results

Socioeconomic characteristics of Cases and Control

The socioeconomic characteristics of the study participants are shown in Table 1. The mean age of cases and controls was 57.60 ± 11.3 years and 57.62 ± 11.5 years respectively with a range of 35 to 75 years. As regards to socioeconomic factors, statistically significant difference was observed in education and income and occupation between cases and controls. Compared to the controls, the participants in the case were highly educated ($p < 0.001$) and had higher monthly income ($p = 0.002$). More participants were unemployed or retired among controls (67.0%) than cases (52.8%). Compared to the controls, 35.9% cases were in government jobs while none of the control group worked in government job ($p < 0.001$).

Table 2 represents the disease profile of diabetic patients. Mean age of onset of diabetes was 46 ± 11.0 years and the mean duration of diabetes was $13.36 \pm$

9.22 years. About 52.8% % of the total diabetic patients had at least one major complication of diabetes. The most prevalent complication was retinopathy (34.0%) followed by peripheral vascular disease (17.9%), coronary artery disease (17.0%) and neuropathy (13.2). More than one third (35.8%) of the diabetes patients were hypertensive and 81.0% diabetes patients were either overweight or obese. Majority of diabetics were either on oral hypoglycemic agents alone or a combination of oral hypoglycemic agents and insulin for the control of their diabetes. Only 15.7% used insulin alone to control diabetes.

Health related Quality of Life (HRQoL) and association with socioeconomic characteristics

Table 3 presents the scores of the HRQoL domains among the cases and controls. Mean scores of Quality of life with respect to physical functioning, role limited due to physical health, role limited due to emotional problem, energy and vitality and psychological domains were significantly low among cases compared to controls while no significant difference was observed in mean scores of domain of social functioning, pain and general health. Mean scores of HRQoL in the domains related to physical functioning (58.11 vs. 78.94, $p < 0.001$), role limited due to physical health (52.02 vs 77.67, $p < 0.001$), role limited due to emotional problem (64.44 vs. 82.84, $p = 0.002$) were very low in cases compare to control.

Table 1: Socioeconomic characteristics of the cases and controls

Characteristics	Case (Diabetic patient) n=106	Control (Non-diabetic patient) n=106	p-value
Age			
< 50 years	22 (20.8%)	26 (24.5%)	Ns
50-60 years	42 (39.6%)	36 (34.0%)	
> 60 years	42 (39.6%)	44 (41.5%)	
Education			<0.001
Primary	39 (36.8%)	15 (14.2%)	
Intermediate	20 (18.9%)	35 (33.0%)	
High school	18(17.0%)	56 (52.8%)	
Bachelor & Master	29 (27.3%)	xxxx	
Occupation			<0.001
Unemployed& Retired	56 (52.8%)	71 (67.0%)	
Business	12 (11.3%)	35 (33.0%)	
Government service	38 (35.9%)	xxxx	
Monthly income			0.002
≤ 5000 SR	26 (24.5%)	51 (48.1%)	
> 5000-10000SR	42 (39.6%)	31 (29.2%)	
> 10000 SR	38 (35.9%)	24 (22.7%)	

Mean age of cases= 57.60 ± 11.3 . Mean age of control = 57.62 ± 11.5

Table 2: Disease profile of the diabetes patients

Disease profile	Frequency	Percentage
Complications present	56	52.8
Hypertension	38	35.8
Retinopathy	36	34.0
Peripheral vascular disease	19	17.9
Coronary artery disease	18	17.0
Neuropathy	14	13.2
Stroke	11	10.4
Nephropathy	10	9.4
Overweight and Obesity	86	81.0
Medication use for diabetes		
Pills	45	42.5
Pills & Insulin	40	37.7
Insulin	16	15.7
Diet only	05	4.7

Table 3: Comparison of Health related Quality of Life (HRQoL) domains in case and control

QOL domains	Case mean±SD	Control mean±SD	p
Physical functioning	58.11±21.21	78.94±25.37	<0.001
Role limited due to physical health	52.02±45.95	77.67±39.12	<0.001
Role limited due to emotional problem	64.44±44.05	82.84±37.59	0.002
Energy and vitality	50.30±15.11	61.89±16.13	<0.001
Mental health	63.49±13.43	68.93±12.18	0.002
Social functioning	82.90±27.29	83.96±19.42	0.745
Pain	79.36±24.80	84.22±20.78	0.124
General health	67.92±20.05	70.80±24.20	0.691

Comparison of the socioeconomic data (age, level of education, income, and occupation) and domains of HRQOL were analyzed and significant difference was observed only with age and level of education in domains of quality of life score. Correlation between the age and score of HRQOL domains in cases and controls is given in Table 4. Age

is significantly negatively correlated with the all domains of quality of life while in control only mental health is significantly negatively correlated with age ($p=0.003$). Correlation showed that with increasing age, quality of life scores decreased in all domains of HRQOL in case of diabetic patients.

Table 4: Correlation between HRQoL scores and Age

HRQOL	Case		Control	
	(Correlation coefficient = r)	p	(Correlation coefficient = r)	p
Physical functioning	-0.562	<0.001	-.113	0.250
Role limited due to physical health	-0.387	<0.001	-.174	0.079
Role limited due to emotional problem	-.322	<0.001	0.133	0.181
Energy and vitality	-0.652	<0.001	0.092	0.350
Mental health	-.225	0.025	-.284	0.003
Social functioning	-.207	0.033	-0.041	0.679
Pain	-.210	0.031	-0.013	0.896
General health	-.236	0.015	-0.023	0.819

Comparison between the level of education and HRQoL subscales showed that cases had significantly poorer HRQoL in Physical functioning (<0.001), Role limited due to physical health (<0.001), Role limited due to emotional problem (<0.001), Energy and

vitality (<0.001) and mental health(0.002) scales compared with Control (Table 5). Post hoc tests revealed that this significant difference was due to cases that had primary level of education (Table 5).

Table 5: Comparison of HRQOL in cases and controls by level of education

QOL domains	Educational level						p-value
	Case			Control			
	Primary Mean±SD	Intermediate Mean±SD	≥High school Mean±SD	Primary Mean±SD	Intermediate Mean±SD	≥High school Mean±SD	
Physical functioning	49.59±21.1	56.00±21.4	65.85±19.1	65.00±28.6	84.28±22.6	78.48±25.1	<0.001
Role limited due to physical health	33.11±31.1	56.25±46.5	67.34±42.5	46.66±33.2	87.14±30.5	77.27±43.3	<0.001
Role limited due to emotional problem	51.35±40.2	68.25±40.6	71.01±40.2	60.00±41.2	81.00±40.6	75.00±40.3	<0.001
Energy and vitality	42.83±13.3	52.00±13.6	56.00±14.7	58.33±14.1	67.42±13.7	58.62±14.7	<0.001
Mental health	58.78±9.6	67.05±11.3	66.08±15.6	66.94±11.0	68.48±12.9	71.33±12.7	0.002
Social functioning	78.37±28.9	80.62±32.8	78.37±23.0	76.66±25.8	86.07±18.4	84.26±18.4	0.384
Pain	75.07±24.2	75.25±25.7	83.77±25.0	76.50±24.5	88.14±18.2	83.87±20.8	0.127
General health	63.11±19.6	68.00±21.1	72.02±19.8	70.33±16.2	69.43±16.4	69.83±16.2	0.365

4. Discussion

As diabetes is reaching epidemic proportion in Saudi Arabia with its related social, psychological and financial consequences, it is important to understand the overall quality of life in these patients. Quality of life is an important aspect in diabetes, because poor quality of life leads to diminished self-care, which in turn leads to increase risks for complications and exacerbation of diabetes.²⁸ It is very important for medical and clinical disciplines to examine the quality of life and find opportunities to improve it. This study is the first of its kind in Aseer Region to assess the HRQOL in male diabetic patients and identify its relation with socioeconomic factors.

The characteristics of the current study population such as age, education and occupations and income do not differ greatly from what is reported in other studies in Saudi Arabia.^{20, 29, 30}

The complications found in the diabetic patients of the present study are also similar to what is typically reported in the medical literature. The complications found in this study reflect the lifestyle of this diabetic population. Undeniably, an improper lifestyle leads to poor metabolic control, which is known to be an important risk factors for the occurrence of complications and there by effect of quality of life.^{31,32} It is obvious that improving the lifestyles in the diabetic population is imperative to improve the quality of their lives.

The current study showed that the patients of diabetes type2 (cases) have a significantly lower QOL scores for physical functioning, role limit due to physical health, limit due to emotional health, energy and vitality, and mental health compared to matched control group which are in accordance with other studies regardless of the questionnaire used.^{20,29,33,34} One might argue that poor quality of life compare to control may be due to complications of diabetes mellitus or numerous problems which diabetic patients encounter. However it has been repeatedly and

consistently stated that diabetes has detrimental effects on QOL and impair all dimensions of health, even in patients without major complications.^{35,36,37}

As regard to relationship between HRQoL subscales and age, the current study demonstrated a significant negative correlation between age and all subscales of HRQOL compared to control which is in accordance with some previous studies.^{20,29,38-42} This is an expected finding because of increasing physical and emotional restrictions in aging patients. However some other studies done by Hanninen J et al⁴³ and Aghakoochak A et al⁴⁴ showed no significant association between age and HRQoL. It has been discussed that if elderly have satisfactory living conditions, increasing age may not result in deterioration of their quality of life.^{45,46} Thus, the efforts should be made to delay or limit the impact of age on the body in order to give higher quality to the life of the aging population.

Many previous studies^{20,47,48} have consistently observed an association between low education level and low HRQoL. In accordance with these studies the present study also found that diabetes patients with low level of education had poor HRQoL compare with their counterparts. HRQOL refers to the physical, psychological, and social domains of health that are influenced by a person's experiences, beliefs, expectations, and perceptions.²⁸ According to Lasheras⁴⁹, lower educational level is associated with unhappiness, poor social relationships, poor self-assessed health among the people. Education is an important indicator that may directly or indirectly influence HRQoL through its association with higher social class and economic status.⁵⁰

The present study has limitation. This study did not include some relevant data of controls such as morbidities, obesity and hypertension etc. Thus affect of these factors could not be examined and compared with HRQoL between cases and controls. Despite these limitations, this study has implications. This

study is the first of its kind in Aseer Region, providing a picture of the prevailing situation of HRQoL of diabetic patients and identifies its relation with socioeconomic factors.

Conclusion

The result of this study indicates that the HRQoL of type 2 male diabetic patients was significantly lower than that of matched control group. It may be concluded from this study that diabetes mellitus has considerable negative impact on the HRQoL. Higher age and low level of education negatively affect the HRQoL. Quality of life of patients is an essential factor that affects diabetic management and therefore, the ultimate diabetic care should involve the assessment of HRQoL in any modality used to treat diabetic patients.

Diabetes is a lifelong disease requiring patients to continuously self-manage their disease to maintain HRQoL. To improve their quality of life, mass educational and training programs aimed at counseling diabetic patients about all aspects of diabetes care have to be initiated.

Understanding the effect of diabetes on QOL is important for day-to-day clinical management and also for public health policy initiatives in order to improve the QOL. This approach may delay early disability and increase the life expectancy in diabetic population.

Acknowledgments

We acknowledge with gratitude the support of the directors of the Diabetic clinic and Primary Health care Centers in Abha. Thank to medical students who were involved in data collection. Appreciation is also extended to all participants. Finally, the author is sincerely thankful to Professor Shamsun Nahar, PhD, Professor of Community Medicine, Department of Family and Community Medicine, King Khalid University, Abha, Saudi Arabia for data analysis and editing the manuscript.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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3/16/2016