

## Research Article

# Health-related quality of life and factors affecting it in type-2 diabetic nephropathy patients: a cross sectional observational study

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## ABSTRACT

**Background:** Diabetes is known to worsen the health related quality of life (HRQoL). The aim of the study was to analyze a comprehensive set of potential determinants of HRQoL in a sample of patients suffering from diabetic nephropathy.

**Method:** 60 patients were enrolled and divided into different groups on the basis of stage of diabetic nephropathy. HRQoL was evaluated using generic and disease- specific questionnaires. Generic instrument included SF-36 and diseases-specific instruments used were D-39 (Diabetes-39) and ADS (appraisal diabetes scale). The scores of these questionnaires were analyzed for their association with various demographic factors.

**Results:** It was observed that quality of life deteriorated with the progression of diabetic nephropathy. On the basis of SF-36 score HRQoL was found to be dependent on, age, HbA1c level, presence of positive family history of diabetes and alcohol consumption. On the other hand D-39 scores showed significant association between HRQoL and various demographic factors such as gender, blood pressure, alcoholic consumption and blood sugar levels. According to ADS scores, HRQoL showed association with alcohol consumption and blood sugar levels.

**Discussion:** HRQoL is associated with multiple factors but high linkage is demonstrated by socio-demographic factors and diabetic complications. A patient centred approach should be helpful to prevent deterioration of HRQoL and thus will decrease the burden of diabetes. A regular checkup and early detection of diabetic nephropathy and its management could further delay the decline in quality of life of these patients.

**Keywords:** Health related quality of life, Appraisal diabetes scale, Diabetes 39 questionnaire, Diabetic nephropathy, Short form -36 questionnaire (SF-36)

## INTRODUCTION

Globally, Type 2 diabetes (T2DM) is one of the most frequent chronic disease. T2DM is a growing cause of disability and premature death, mainly through cardiovascular diseases and other chronic complications. Various studies indicate that diabetic patients are more likely to develop micro as well as macro vascular complications. Diabetic nephropathy (DN) is one of the major micro vascular complications of diabetes which can result in end stage renal disease (ESRD).<sup>1</sup>

Diabetes strongly affects QoL (Quality of Life) and mental health of patients.<sup>2-4</sup> An increase in diabetic complications and mortality is observed with decline in QoL.<sup>5</sup> Therefore, HRQoL (Health Related Quality of Life) constitutes the most important objective in DM (Diabetes Mellitus) control program and a multidisciplinary disease management program for patients with poorly controlled type 2 diabetes can improve both glycemic control and HR-QoL.<sup>6</sup> Recently, HRQoL has become an interesting issue in evaluating research.<sup>7</sup> It focuses on the emotional well-being of

patients and helps to predict disease outcome.<sup>8,9</sup> Different approaches can be followed to evaluate HRQoL.

The costs to individuals and for health care are enormous. Thus any measure that could reduce the burden of diabetes is of immense importance socially and economically. Keeping this background in view, a study was undertaken to analyze a comprehensive set of potential determinants of HRQoL in patients of diabetic nephropathy using various HRQoL instruments. In this study generic and disease-specific questionnaires were utilized to evaluate HRQoL. Generic HRQoL questionnaires (SF-36) are useful scales for measuring the specific impact of the disease itself on patient's well-being. These scales measure patient's physical, emotional and mental functions, social concepts and health perceptions, general life satisfactions, activity, sleep and pain.<sup>10,11</sup> Disease-specific instruments include aspects of health considered by patients or clinicians to be of greatest importance (D-39, ADS).

## METHODS

A cross sectional observational study was carried out on the patients attending an endocrine clinic of tertiary care hospital. The study was approved by institutional ethics committee and was performed in accordance with the principles of Declaration of Helsinki and the code of Good Clinical Practices. A written informed consent was obtained from each patient after full explanation about the study prior to enrolment. 65 patients were screened, out of which 5 were excluded due to non-fulfillment of inclusion criteria. Remaining 60 patients were divided into 3 groups, each group consisting of 20 patients as described below:

**Group 1:** Type 2 diabetic patients without diabetic nephropathy.

**Group 2:** Type 2 diabetic nephropathy patients (30-300mg/d of albumin excretion).

**Group 3:** Type 2 diabetic nephropathy patients (>300mg/d of albumin excretion and serum creatinine >1.4mg/dL).

### Inclusion criteria

- Type-2 Diabetes Mellitus patients without diabetic nephropathy (Group 1).
- Type-2 Diabetic nephropathy patients (Groups 2 and 3).
- Age 35 to 80 years.
- Able to give written informed consent.
- Able to comply with study protocol.

### Exclusion criteria

- Patients with Type-1 Diabetes Mellitus.
- Pregnancy and lactation.

- Unable or unwilling to give informed consent.
- Patients suffering from end stage renal disease.

Demographic characteristics (age, gender, duration of diabetes, family history, history of alcohol intake, smoking, dietary control, physical activity and literacy) of the patients were recorded. Clinical and laboratory evaluation of subjects included assessment of Body Mass Index (BMI), Blood Pressure, Fasting Plasma Glucose, Glycated Haemoglobin (HbA1c) levels and Kidney function tests. All patients were subjected to SF- 36, D-39 and ADS Questionnaires to assess their quality of life. The SF- 36 measures the physical and mental health of the patients in the form of physical components summary and mental components summary. On the other hand D-39 measures six parameters: energy and mobility, diabetes control, anxiety and worry, social burden, sexual functioning and diabetes medication, whereas, ADS assesses an individual's thoughts about coping with diabetes. All questions of the questionnaires were explained to the patients in local language during a personal interview.

Statistics Continuous variables were expressed as mean  $\pm$  standard error by applying one way

ANOVA. All the data were analyzed using SPSS (Statistical Program for Social Sciences, version 17 for windows, 2007, SPSS Inc. Chicago, Illinois, USA) and chi-square test was applied with Yates correction to assess the association between QoL, diabetic nephropathy and different parameters.

## RESULTS

Of the total number of diabetic nephropathy patients included in the study, 71.7% patients were between 51-65 years, 16.6 % had the ageless than 50 years and 11.7% of the patients were more than 65 years. 60% of the subjects were females. Majority of enrolled patients were literate (61.7%) and remaining (38.3%) were illiterate. 61.6% of patients had BMI greater than 24.9 and they fell into the category of obese patients and 43.3% patients experienced high blood pressure. 78.3% of the patients were non-alcoholic and 93.3% were non-smokers. 78.3% patients followed a strict diet plan to keep a good control on their blood sugar levels while remaining 21.7% did not maintain the diet control, as reported by the patients themselves. 55% patients regularly indulged themselves in one or the other physical activity.

There was no significant difference in age ( $p=0.801$ ), body Mass Index ( $p=0.331$ ), hemoglobin levels (Hb) ( $p=0.199$ ), systolic ( $p=0.331$ ) and diastolic blood pressure ( $p=0.998$ ) of patients amongst group 1, group 2 and group 3. Factors that differed significantly among the three groups were duration of diabetes ( $p=0.006$ ), HbA1c ( $p=0.000$ ) and fasting glucose levels ( $p=0.001$ ). Renal parameters i.e. Serum creatinine ( $p=0.01$ ) and Blood urea nitrogen ( $p=0.01$ ) levels differed significantly in different

stages of DN as observed among these three groups (Table 1).

**Table 1: Clinical characteristics of the subjects.**

Variables	Group 1	Group 2	Group 3	p-value
Age (Years)	50.85±2.30	50.5±2.00	48.8±2.50	0.801
Systolic B.P.(mmHg)	139.1±5.07	142.1±5.50	140.35±3.83	0.331
Diastolic B.P.(mmHg)	84.65±1.90	84.6±2.32	84.4±1.99	0.998
Duration of diabetes (Years)	4.8±1.038 <sup>‡</sup>	10.9±1.63 <sup>†</sup>	7.3±1.124	0.006*
Hb (g/dl)	9.54±0.29	9.74±0.30	9.01±0.28	0.199
HbA1c (%)	6.42±0.23 <sup>‡,§</sup>	7.86±0.49 <sup>†,§</sup>	9.74±0.43 <sup>†,‡</sup>	0.001*
BMI (kg/m <sup>2</sup> )	26.29±1.39	29.1±1.61	27.16±0.98	0.331
Fasting glucose level (mg/dL)	148.25±8.88 <sup>‡,§</sup>	178.2±3.92 <sup>†,§</sup>	212.9±11.76 <sup>†,‡</sup>	0.001*
Serum creatinine (mg/dL)	0.99±0.1 <sup>§</sup>	1.01±0.1 <sup>§</sup>	3.37±0.4 <sup>†,‡</sup>	0.01*
Blood Urea (mmol/L)	28.85±2.7 <sup>§</sup>	29.5±2.1 <sup>§</sup>	70.2 ±3.6 <sup>†,‡</sup>	0.01*

Values are expressed as mean±SEM. Statistical analysis was done by one way ANOVA, <sup>†</sup>p<0.05vs Group 1; <sup>‡</sup> p < 0.05vs Group 2; <sup>§</sup>p<0.05vs Group 3,\*highly significant (p<0.05).

Quality of life differed significantly between groups as the values of SF-36 showed significant difference (p = 0.000). Similarly, significant difference was observed in D-39 scores (p=0.000) which illustrated that quality of

life differed amongst various groups. Also, significant difference was prominent in ADS scores (p=0.000) between the groups. These values indicate that with the progression of diabetic nephropathy the HRQoL deteriorated (Table 2).

**Table 2: Quality of life scores using SF-36, D-39 and ADS questionnaires.**

Questionnaire		Group			Chi-Square	p-value
		Group 1	Group 2	Group 3		
SF-36	<20	0(0)	1(5.6)	17(94.4)	35.82	0.000*
	21-54	3(13)	17(73.9)	3(13)		
	>54	17(89.5)	2(10.5)	0(0)		
D-39	100-170	16(64)	9(36)	0(0)	15.84	0.000*
	>170	4(11.4)	11(31.4)	20(57.1)		
ADS	≤20	18(60)	10(33.3)	2(6.7)	16.87	0.000*
	>20	2(6.7)	10(33.3)	18(60)		

\*p<0.05 -statistically significant, SF-36 scoring: <20 - worst; 21-54 - poor; >54 - good quality of life, D-39 scoring: 100-170 - good; >170 - poor quality of life, ADS scoring: ≤20 - good quality of life; >20 - poor quality of life.

Evaluation of HRQoL by SF-36 score, indicated that, 41.7% females and 12.5% males experienced poor quality of life (<20) however, quality of life was found to have no significant association with the gender (p=0.054). None of the alcoholics exhibited good quality of life (SF score >54), whereas 40.4% of non-alcoholics had better quality of life. Thus it was observed that quality of life significantly deteriorated in patients with alcohol use (P<0.034). SF-36 scores differed significantly in accordance with age (p=0.013). 70% of the patients falling in the age less than 50 years showed good quality of life while 23.3% of patients falling in age group of 51-65 years and 28.6% of the patients in age group of more than 65 years exhibited poor quality of life. Thus with advancement of age quality of life deteriorated. It was found that family history of diabetes is also significantly

related to the QoL as observed by comparing the SF-36 scores (p=0.015). 44.8% of patients having good blood sugar control (HbA1c ≤7) depicted good quality of life as compared to patients who had HbA1c >7. SF-36 score was, therefore, strongly associated with HbA1c (p=0.034) (Table 3).

It was observed that D-39 score was significantly associated with five factors: blood pressure (p=0.042), alcohol consumption (p=0.012), HbA1c (p= 0.002), fasting plasma glucose levels (p= 0.025) and gender (p=0.017). 73.1% patients suffering from high blood pressure experienced poor quality of life (P=0.042). 92.3% of the alcoholics experienced poor quality of life as compared to non-alcoholics. 62.1% of the patients having good blood sugar control (HbA1c ≤7) displayed good

quality of life as compared to patients who had HbA1c >7 (p=0.002). 66.7% of patients maintaining fasting plasma glucose levels near to normal ( $\leq 130$ mg/dl) depicted better quality of life as compared to patients who have higher (>

130 mg/dl) fasting plasma glucose levels (p=0.025). All female patients were observed to have poor quality of life as compared to male patients (p=0.017) (Table 4).

**Table 3: Association of SF-36 with different variables.**

Variables		SF36 SCORE			Chi-square	p- value
		<20 n(%)	21-54 n(%)	>54 n (%)		
Gender	Male	3 (12.5)	10 (41.7)	11 (45.8)	3.71	0.054
	Female	15 (41.7)	13 (36.1)	8 (22.2)		
Alcohol Consumption	Drinkers	7 (53.8)	6 (46.2)	0 (0)	4.49	0.034*
	Non-drinkers	11 (23.4)	17 (36.2)	19 (40.4)		
Age	30-50	2 (20)	1 (10)	7 (70)	6.16	0.013*
	51-64	15 (34.9)	18 (41.9)	10 (23.3)		
	>64	1 (14.3)	4 (57.1)	2(28.6)		
Family History of Diabetes	Absent	11 (34.4)	7 (21.9)	14 (43.8)	8.44	0.015*
	Present	7 (25)	16 (57.1)	5(17.9)		
HbA1c	$\leq 7$	4 (13.8)	12 (41.4)	13 (44.8)	4.49	0.034*
	>7	14 (45.2)	11 (35.5)	6 (19.4)		

\*Value of p<0.05 was considered as significant, \*\*SF-36 scoring :<20 - worst quality of life; 21-54 - poor quality of life; >54 - good quality of life.

**Table 4: Association of d-39 with different variables.**

Variables		D-39 score		Chi-square	p-value
		100-170 n (%)	>170 n (%)		
Blood pressure	Normal	18 (52.9)	16 (47.1)	4.103	0.042*
	High	7 (26.9)	19 (73.1)		
Alcohol consumption	Drinkers	1 (7.7)	12 (92.3)	6.19	0.012*
	Non-drinkers	24 (51.1)	23 (48.9)		
HbA1c	$\leq 7$	18 (62.1)	11(37.9)	9.61	0.002*
	>7	7 (22.6)	24 (77.4)		
Fasting plasma glucose level	$\leq 130$	10 (66.7)	5 (33.3)	5.14	0.025*
	>130	15 (33.3)	30 (66.7)		
Gender	Male	5 (20.8)	19 (79.2)	5.68	0.017*
	Female	0 (.0)	36 (100.0)		

\*Value of p<0.05 was considered as significant; \*\*D-39 scoring: 100-170 – good quality of life; >170 – poor quality of life.

**Table 5: Association of ADS with different variables.**

Variables		ADS score <sup>†</sup>		Chi-square	p- value
		$\leq 20$ n (%)	>20 n (%)		
Alcohol consumption	Drinkers	2 (15.4)	11 (84.6)	6.28	0.012*
	Non-drinkers	28 (59.6)	19 (40.4)		
HbA1c	$\leq 7$	19 (65.5)	10 (34.5)	5.406	0.020*
	>7	11 (35.5)	20 (64.5)		

\*Value of p<0.05 was considered as significant.,<sup>†</sup>ADS scoring :  $\leq 20$  – good quality of life; >20 – poor quality of life.

ADS score for HRQoL was significantly associated with two factors, HbA1c (p=0.020) and alcohol consumption (p=0.012). 66.7% of the patients having good blood sugar

control (HbA1c  $\leq 7$ ) displayed good quality of life. 84.6% of alcoholics experienced poor quality of life as compared TO NON-alcoholics (P=0.005) (Table 5).

Furthermore factors such as smoking, dietary control, physical activity and literacy did not show any statistically significant correlation with HRQoL in diabetic nephropathy patients.

## DISCUSSION

T2DM has become one of the pivotal conditions in terms of morbidity and mortality and the prevalence of diabetes mellitus has been increasing worldwide over recent years.<sup>12</sup> T2DM has rapidly become a global health problem due to rapidly mounting population growth, aging, urbanization and increasing prevalence of obesity and physical inactivity.<sup>13</sup> Diabetic nephropathy is a clinical syndrome characterized by interminable albuminuria, an inexorable decline in GFR (Glomerular Filtration Rate) and raised blood pressure.<sup>14</sup> DN affects the kidney in various stages. In the initial stage of DN there is low level of albumin (micro albuminuria) in the urine referred to as incipient nephropathy. With the progress of disease, urine albumin levels increase leading to development of overt nephropathy (albumin excretion more than 300 mg per 24 hours).<sup>15</sup>

Major diabetic complications are associated with poor HRQoL.<sup>13</sup> With the progression of diabetic nephropathy HRQoL declines as observed with the help of different instruments used for assessing HRQoL in this study (SF-36, D-39 and ADS). Similar results have been reported that depicted the deterioration of HRQoL with advancement of diabetic nephropathy.<sup>16</sup> Majority of patients suffering from DN were found to be anemic. This can be linked to decreased production of erythropoietin involved in erythropoiesis as a result of diabetic nephropathy.<sup>17</sup>

Numerous demographic and psychosocial factors such as age, gender, alcohol consumption, control on blood sugar level, fatigue and psychological stress have been found to influence quality of life (QoL).<sup>18</sup> In this study, it was noted that age had a negative effect on patient's Quality of life. Younger patients had higher physical and social function scores while older patients had lower levels of SF-36 scores. These results are similar to many previous observations.<sup>19-21</sup> Men are found to be more satisfied with their diabetes treatment than women and exhibit better SF-36 and D-39 scores as compared to women.<sup>22-26</sup> In the present study generic instrument SF- 36 found that gender had no significant association with HRQoL, however, with the use of disease specific instrument D-39, similar to previous studies,<sup>27</sup> it was found that HRQoL was poorer for females as compared to males. This may be due to more psychosocial, hormonal and emotional concerns in case of women. Present and previous studies reveal that improvement in HbA1c is strongly associated with improvement in HRQoL.<sup>28</sup> Thus good control on blood sugar levels can enhance the QoL of diabetic patients with nephropathy.

In this study, association of family history of diabetes with SF-36 scores revealed that patients having a family history of diabetes experienced poor quality of life as compared to patients who do not have any family history of diabetes. Although it is unclear which genetic determinants are important in the pathogenesis of DN, but epidemiological data and family studies show that inherited factors are likely to be imperative in the pathogenesis of the condition.<sup>29</sup> There is a strong correlation between degree of hypertension and the rate of progression of overt diabetic nephropathy. Much evidence indicates that the lowering of blood pressure reduces risk of micro and macro vascular complications.<sup>30</sup> In this study, an increase in blood pressure and alcohol consumption were found to be associated with impairment of HRQoL. Although physical activity and diet control had not shown any significant association with the HRQoL results but it is quite possible that the patients were reluctant to admit to the fact that they fail to keep control on their diet and exercise regularly.

The present study has been conducted to assess the impact of progression of diabetic nephropathy on HRQoL of diabetic patients. Though a negative impact on HRQoL has emerged with the progression of diabetic nephropathy in the current assessment, however further studies with large sample size are warranted to sustain the outcomes of this study.

These results of the study suggest that the clinician should be watchful of the potential Quality of life determinants for DN patients, following its diagnosis and management. Many studies have demonstrated that when health related quality of life (HRQOL) is properly measured in individuals with type 2 diabetes and the results are incorporated into healthcare management, improvements in the health status of the person occurs.<sup>31</sup> Thus, a regular checkup and early detection of diabetic nephropathy could delay the decline in quality of life of patients. This is significant because improved diabetes management reduces the incidence of type 2 diabetes complications.<sup>32</sup> Conversely, when issues affecting a person's quality of life are not addressed and the incidence of complications increases, an individual's perceived quality of life is further impacted on negatively, additionally confounding attempts to ameliorate disease progression.<sup>31,33</sup>

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