

Effects of diabetes mellitus on health-related quality of life at a tertiary hospital in South Africa: A cross-sectional study

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Background. Diabetes mellitus (DM) is a chronic metabolic disease that potentially causes debilitating and life-threatening complications, demands a lifestyle change, and has important implications with regard to wellbeing and health-related quality of life (HRQOL).

Objectives. To: (i) determine the HRQOL of a sample of patients with type 2 diabetes; (ii) describe the demographics (age, gender, and smoking and alcohol use) of the population studied; (iii) document the following parameters, which are important in determining the control and severity of type 2 diabetes: (a) glycosylated haemoglobin (HbA_{1c}), (b) total amount of insulin required per day (if on insulin therapy), (c) body mass index (BMI), and (d) exercise compliance; (iv) determine whether there was an association between any or all of the above parameters and the HRQOL of these patients; and (v) determine whether coexisting diseases (hypertension (HT) and dyslipidaemia) were present, and compare HRQOL between diabetic patients with and without these diseases.

Methods. This was a cross-sectional and descriptive study of 200 patients attending the diabetes clinic at Helen Joseph Hospital, Johannesburg, South Africa. HRQOL assessments were made using the Diabetes 39 (D-39) questionnaire, which patients filled in once consent had been obtained and if they fulfilled the inclusion criteria. Patients' questionnaire forms were then analysed with regard to their demographics (age and gender), exercise regimen, smoking and alcohol history, employment status, living arrangements, age of diagnosis of DM, and concurrent use of antihypertensive and cholesterol-lowering drugs. The patients' files were analysed and various clinical parameters were noted (HbA1c) lipogram, BMI, number of insulin units used per day, and whether any antihypertensive and/or lipidlowering drugs were used).

Results. There was an association between HRQOL and HbA_{1c}, and between HRQOL and HT and dyslipidaemia.

Conclusions. No association was found between HRQOL and other clinical parameters, namely number of insulin units used per day, exercise, BMI, lipogram and the use of oral hypoglycaemic agents. Demographic parameters (age, gender, age at diagnosis, employment status and living arrangements) were also shown to have no impact on HRQOL. We found no association between HRQOL in patients who consumed alcohol and smoked cigarettes and in those who did not.

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Quality of life (QOL) is described as a multidimensional construct incorporating an individual's subjective perception of physical, emotional, and social wellbeing, including both a cognitive and an emotional component.[1] Health-related QOL (HRQOL) is increasingly being recognised as an important outcome of health, representing the ultimate goal of all healthcare interventions. [2] Conventional outcome assessment for diabetes mellitus (DM) relies on laboratory indicators, primarily glycosylated haemoglobin (HbA_{1c}), and complications. [3] However, exclusive reliance on clinical outcomes does not necessarily reflect a patient's perception of his/ her health. Management regimens that require changes in lifestyle and behaviour can influence daily functioning and general wellbeing. HRQOL is therefore increasingly being used as an outcome indicator alongside traditional biomarkers.[3]

Guidelines for the treatment of type 2 DM emphasise that one of the primary objectives is to improve HRQOL. [2] Studies show that HRQOL is associated with the duration of diabetes, age, gender, diabetic complications, comorbid diseases and the severity of the disease itself.[2]

Patients with diabetes, like those with many other chronic diseases, are less concerned with clinical biomarkers such as HbA1c, blood pressure or lipid levels, and more concerned with how the disease will affect their lives in various domains.[4] These domains include physical and social function, emotional and mental health, the burden of the illness and stigma attached to it, and how treatment will impact on their daily life.[4]

There is a dearth of South African (SA)-specific information on HRQOL and diabetes. Country-specific HRQOL information may provide improved insight, and potentially lead to improved management of diabetes. The objective of this study was to better understand the effects of diabetes on HRQOL in an SA tertiary-level hospital setting.

Methods

Ethical approval was received from the Human Research Ethics Committee, University of the Witwatersrand, Johannesburg (protocol no. M120536). This was a clinical audit, cross-sectional in nature, and a descriptive study of consecutive patients attending the diabetes clinic at Helen Joseph Hospital (HJH), a level 3/tertiary state hospital in Johannesburg, over a 3-month period. The study population consisted of 200 patients attending the diabetes clinic at HJH. This sample size was chosen to include all patients who met the inclusion criteria and obtain a fair representation of the population attending

Inclusion criteria. Patients with type 2 DM who had attended the specialist diabetes clinic for ≥6 months.

Exclusion criteria. Patients with type 1 DM or blindness, or from whom informed consent could not be obtained.

Fig. 1 shows the study flow.

Measuring HRQOL in diabetes

Various instruments, generic and disease specific, have been developed to measure HRQOL in diabetes. Generic instruments are designed to investigate aspects of health that are of universal importance, and allow comparisons of HRQOL among different groups of patients. These may be useful for capturing the additional HRQOL deficits associated with comorbid diseases and their respective treatments, such as hypertension (HT), dyslipidaemia and depression, as they incorporate a wider range of dimensions of HRQOL. In contrast, diabetes-specific instruments capture the specific impact that diabetes has on a patient's daily functioning and wellbeing and hence on their QOL, and so could be more sensitive to small clinically important differences. Reviews have shown that the dimensions covered by diabetes-specific instruments vary, but they generally include physical and psychological functioning, fulfilment of the patient's social role, diabetes control and satisfaction with treatment. [2,3]

Among the best-known generic instruments are the Short-Form Health Survey (SF-36) (this is the shortened version of the RAND Corporation's MOS Functioning and Well-being profile), the Quality of Well-being (QWB) scale, its successor, the Quality of Well-being Self-Administered Scale (QWB-SA), and the Euroqol 5D and the COOP/WONCA charts. The Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) is a commonly used generic instrument for diabetes, while the Diabetes-39 (D-39) questionnaire has been demonstrated to have good psychometric properties. [2]

The D-39 questionnaire

The D-39 questionnaire^[5] (Appendix 1) was used in this study. Developed by Boyer and Earp, this is a 39-item instrument that was designed to assess HRQOL in patients with type 1 and type 2 DM. The developers did not give express consideration to face/content validity, but used extensive literature reviews, existing QOL questionnaires and interviews with health professionals and patients with diabetes.^[5] Written permission to use the D-39 questionnaire was obtained from them.

The D-39 questionnaire encompasses measurements of energy and mobility, diabetes control, anxiety and worry, social burden and sexual functioning. Patients are asked how much the quality of their life was affected by

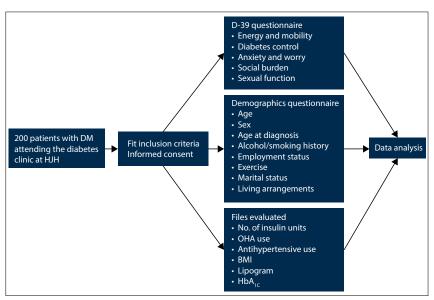


Fig. 1. The study flow.

a wide range of aspects of diabetes illness and its treatment in the past month. Items are administered using seven response categories, ranging from not affected at all (score = 1) to extremely affected (score = 7). The detailed D-39 scoring instructions and further information in this regard are available from the author (reyna.daya13@gmail.com). The reliability of the questionnaire is acceptable, with a Cronbach alpha of 0.81 - 0.93 for all the subscales. The construct validity has been compared with the widely used SF-36 and found to be very satisfactory.

The D-39 questionnaire has been recommended for use in research and clinical settings. The instrument provides evidence for validity and reliability, includes several domains that cover various aspects of QOL, and is therefore applicable to a wide population of patients.^[5] It is one of few diabetes-specific QOL measures that have been shown to be responsive to changes in health status.[5,6] Importantly, it does not impose a definition of QOL upon patients, but instead allows them to respond in the context of their personal conceptualisation of QOL.[5] These attributes make the instrument highly patient-centered, one of the most critical components of any patientassessed QOL measure.[5,6]

The following measurements of the severity and control of diabetes were used in this study:

- Demographics (age, gender)
- Smoking pack-year history (number of cigarettes smoked per day divided by pack of 20 cigarettes multiplied by number of years smoked). Factors such as brand and strength (nicotine and tar content) were not measured.

- Alcohol units consumed per week. The study did not distinguish between types of alcohol consumed (wine, spirits, etc.).
- Number of insulin units used per day.
 The study did not distinguish between the types of insulin used (i.e. rapid- or long-acting insulin) or the number of times a patient injected him/herself (daily or twice-daily regimens).
- Use of antihypertensive or lipid-lowering medication or oral hypoglycaemic agents (OHAs)
- Exercise. Patients were considered to be exercising if they attended a gym/sporting/recreational facility at least three times a week or if they reported doing an exercise routine by themselves for at least 30 minutes, three times a week. This routine must have been followed for at least 1 month. The study did not distinguish between the grades of physical activity.
- Weight was measured using a standard calibrated scale placed on the floor.
 Patients were weighed while standing barefoot and were instructed not to hold onto any form of support.
- Height was measured with a tape measure and recorded to the nearest centimetre.
 The patient was requested to stand barefoot with his/her heels together and touching the wall, with his/her back against a wall.
- Body mass index (BMI) was calculated using Quetelet's formula (weight (kg)/height²) and defined using the World Health Organization (WHO) classification (underweight <20 kg/m²), normal 20 24.9 kg/m², overweight >25 29.9 kg/m², and obese >30 kg/m²).

- Most recent lipid profile
- Latest HbA_{1c} level.

Statistical analysis

All data collected were extrapolated onto an Excel 2010 spreadsheet (Microsoft, USA), and STATISTICA 12 (StatSoft, USA) was used for descriptive statistics (means, medians, modes, standard deviations (SDs) and interquartile ranges (IQRs), where appropriate). In addition to the descriptive statistics, a principal component analysis (PCA) was performed. The PCA allowed for reduction in the number of variables for analysis and subsequently for the variables explaining the largest amount of variance to be analysed in the context of the objectives of the study.

Data were checked for normality (normal distribution), but normality is often not achieved in social studies. In order to mitigate against this, data were bootstrapped 100 000 times to ensure that sufficient variance existed in the data and that the results obtained could be interpreted confidently.

To assess whether there were factors influencing QOL, associations between variables were analysed using Pearson's correlation coefficient. It is important to note that the associations should not to be interpreted as causal factors.

Continuous data were presented as median values with IQRs, and categorical data were described using proportions. Student's t-test for unpaired data was performed to compare medians between groups when the data were normally distributed, and the Mann-Whitney test was used when the data were not normally distributed. Fisher's exact test was used to compare categorical variables between groups. A *p*-value of <0.05 was considered significant.

Results

Data were collected from 220 patients. Twenty patients were excluded from the study owing to an incompletely filled-in questionnaire (n=14) or lack of data recorded in the file (n=6). Ten patients were approached but refused to participate in the study. Table 1 shows the demographic profile of the patients analysed.

Diabetes control

Khanna et al.[7] report that on a transformed scale of 0 - 100, a score closer to 0 indicates a better QOL and a score closer to 100 a worse QOL. The mean score for diabetes control in our study was 43.65.

Anxiety and worry

The mean score for anxiety and worry in our study was 53.77 (mean for males 51.58, mean for females 55.42). Nineteen patients had a score of 71.43 (the mode, or most frequently observed score) (range 7.14 - 235.71)

Social burden

Possible scores for social burden ranged from 7.14 to 92.86. The mean score in our study was 32.76 (mean for males 30.66, mean for females 34.34). The mode was 7.14, with 22 patients having this score.

Sexual function

The total mean score in our study was 51.76 (mean for females 45.66, mean for males 59.86). The mode was 7.14, with 35 patients having this score (range 2.38 - 92.86).

Energy and mobility

The total mean score in our study was 43.65 (mean for females was 46.66 and for males 39.63). The mode was 36.90, with 12 patients having this score (range 7.14 - 92.86).

Overall ratings

The five aspects of QOL in the D-39 questionnaire all affect HRQOL and are set out in Table 2.

| Parameter | Results |
|-----------------------------------|---------------|
| Total patients, N | 200 |
| Gender, <i>n</i> (%) | |
| Males | 86 (43.0) |
| Females | 114 (57.0) |
| Age (yr) | |
| Mean (SD), median (range) | 55.89 (12.52) |
| | 58 (30 - 82) |
| Males, mean (SD) | 53.29 (12.73) |
| Females, mean (SD) | 57.85 (12.04) |
| Age distribution (years), n (%) | |
| 30 - 40 | 27 (13.5) |
| 41 - 50 | 41 (20.5) |
| 51 - 60 | 55 (27.5) |
| ≥61 | 77 (38.5) |
| Age at diagnosis (years) | |
| Mean (SD), median (range) | 42.19 (10.74) |
| | 40 (18 - 72) |
| Males, mean (SD) | 41.34 (10.81) |
| Females, mean (SD) | 42.82 (10.69) |
| Employment status, n (%) | |
| Employed | 49 (24.5) |
| Unemployed | 151 (75.5) |
| Living arrangements, n (%) | |
| Live alone | 26 (13.0) |
| Live with others | 174 (87.0) |
| Cigarette smoking, n (%) | |
| Cigarette use (pack-years) | 61 (30.5) |
| 0.1 - 10 | 32 (16.0) |
| 10.1 - 20 | 17 (8.5) |
| 20.1 - 40 | 9 (4.5) |
| >40.1 | 3 (1.5) |
| No cigarette use | 139 (69.5) |
| Alcohol consumption, <i>n</i> (%) | |
| Consume alcohol | 31 (15.5) |
| 1 - 5 units per week | 28 (14.0) |
| 5.1 - 10 units per week | 3 (1.5) |
| No alcohol consumed | 169 (84.5) |
| OHAs with insulin use, n (%) | |
| Metformin | 130 (65.0) |
| Sulphonylurea | 176 (88.0) |
| Exercise, n (%) | , |
| Regular exercise | 106 (53.0) |
| No exercise | 94 (47.0) |
| | Continued |

Table 1. (continued) Demographic and cohort characteristics of the study subjects

| Parameter | Results |
|--|-------------|
| Insulin used/not used, and no. of units used per day, <i>n</i> (%) | |
| Insulin used | 199 (99.5) |
| 0.1 - 40 | 63 (31.7) |
| 40.1 - 80 | 89 (44.7) |
| 80.1 - 120 | 25 (12.6) |
| 120.1 - 160 | 3 (1.5) |
| 160.1 - 20 | 4 (2.0) |
| No insulin use | 1 (0.5) |
| Coexisting diseases, n (%) | 1 (0.0) |
| HT | 148 (74.0) |
| Dyslipidaemia | 140 (70.0) |
| HT + dyslipidaemia | 128 (64.0) |
| HbA _{1c} (%), <i>n</i> (%) | 120 (01.0) |
| ≤7 | 28 (14.0) |
| 7.1 - 7.9 | 28 (14.0) |
| 8 - 8.9 | 23 (11.5) |
| 9 - 9.9 | 41 (20.5) |
| ≥ 10 | 80 (40.0) |
| Total cholesterol (mmol/L), <i>n</i> (%) | 00 (10.0) |
| ≤4.5 (target level) | 113 (56.5) |
| 4.6 - 4.9 | 22 (11.0) |
| 5.0 - 6.0 | 42 (21.0) |
| 6.1 - 7.0 | 15 (7.5) |
| ≥7.1 | 8 (4.0) |
| Triglyceride (mmol/L), <i>n</i> (%) | 0 (1.0) |
| ≤1.7 (target level) | 123 (61.5) |
| 1.8 - 2.5 | 38 (19.0) |
| 2.6 - 3.5 | 23 (11.5) |
| 3.6 - 4.5 | 11 (5.5) |
| ≥ 4.6 | 5 (2.5) |
| HDL (mmol/L), <i>n</i> (%) | 3 (2.3) |
| ≤1.2 (target level) | 128 (64.0) |
| 1.3 - 2.0 | 60 (30.0) |
| 2.1 - 3.0 | 8 (4.0) |
| 3.1 - 4.0 | 1 (0.5) |
| ≥4.1 | 3 (1.5) |
| LDL (mmol/L), n (%) | 0 (1.0) |
| ≤1.8 (target level) | 48 (24) |
| 1.9 - 2.5 | 65 (32.5) |
| 2.6 - 3.5 | 54 (27.0) |
| 3.6 - 4.5 | 19 (9.5) |
| ≥4.6 | 9 (4.5) |
| Blank | 5 (2.5) |
| | |
| | Continued . |

Table 1. (continued) Demographic and cohort characteristics of the study subjects

| or the stady subjects | |
|---|-------------|
| Parameter | Results |
| BMI, n (%) | |
| Underweight (<20 kg/m²) | 5 (2.5) |
| Normal (20 - 24.9 kg/m²) | 31 (15.5) |
| Overweight (>25 - 29.9 kg/m²) | 41 (20.5) |
| Obese (>30 kg/m²) | 123 (61.5)* |
| HDL = high-density lipoprotein; LDL = low-density lipoprotein. *Of these, 60.2% (n =74) were female and 39.8% (n =49) male. | |

While Table 2 indicates the HRQOL factors, further examination of the factors that individuals perceive as influencing QOL was done using a PCA (Table 3). The results show that sexual function, anxiety and worry and diabetes control are the main factors that influence HRQOL. PCA 1, representing the psychological component of HRQOL, was most influenced by sexual function, anxiety and worry, and social burden, while PCA 2, representing the physical effects of the diabetes, was influenced by diabetes control, and energy and mobility. Table 3 indicates that sexual function accounts for the most variation in the dataset of all the constructs that measure QOL. Significant associations between HRQOL and the parameters investigated are set out in Table 4.

Discussion

Our results indicate that a greater number of females than males responded to the questionnaire. While this does not mean that females are more susceptible to DM, respondent bias may be a possible explanation for the greater number of female respondents (n=114 v. 86). While the gender distribution may reflect the male/ female ratio of patients attending the diabetes clinic, analysing demographics was not the objective of the study, although it may prove to be a fruitful area for further research focusing specifically on gender. With this in mind, we did note interesting gender differences that may support earlier research conducted by authors such as Rubin and Peyrot,[1] who reported that HRQOL is better among diabetic men than among diabetic women.

We found a mean HRQOL score of 216.98 for males and 223.78 for females. These scores indicate that females with DM may have a reduced QOL compared with males. Rubin and Peyrot^[1] reported that males are more satisfied with their diabetes treatment regimen than women, and missed fewer days of work and fewer leisure activities as a result of DM. Furthermore, it has been reported that men with diabetes report less disease impact and greater treatment satisfaction than women.[8] These results are consistent with a study conducted in the Netherlands, which found that women with DM had significantly lower HRQOL scores than men. [9] The differences were explained as being due to gender differences in levels of obesity. The present study supports these results, as females were found to be more obese than males, and therefore supports the view that obesity may affect HRQOL and have an adverse impact on females.

There have been differing reports on age as a factor affecting diabetic patients' QOL. Brown et al.[10] and Rubin and Peyrot[1] reported that age has no effect on QOL, but Redekop et al.[9] reported that it may have a negative effect. They attributed this to older people having lower levels of energy, physical activity and social functioning. Our results, however, indicated that there is no association between age and HRQOL. This finding is consistent with those of Brown et al.[10] and Rubin and Peyrot.[1] While we could not find an explanation

| Table 2. Linear transformed ratings | | | | | | | |
|-------------------------------------|---------------------|-------------------|------------------|--------------------|---------------------------|--|--|
| | Diabetes control | Anxiety and worry | Social burden | Sexual function | Energy and mobility | | |
| Mean total | 43.65 | 53.77 | 32.76 | 51.76 | 38.91 | | |
| Mean male | 39.63 | 51.58 | 30.66 | 59.86 | 35.2 | | |
| Mean female | 46.66 | 55.42 | 34.34 | 45.66 | 41.71 | | |

| Table 3. Principal component analysis | | | | |
|---------------------------------------|-------|-------|--|--|
| | PCA 1 | PCA 2 | | |
| Sexual function | 0.71 | -0.69 | | |
| Anxiety and worry | 0.53 | 0.47 | | |
| Social burden | 0.30 | 0.29 | | |
| Diabetes control | 0.27 | 0.38 | | |
| Energy and mobility | 0.19 | 0.24 | | |

| | HRQOL | High BP | High cholesterol | Diabetes control | Anxiety/ worry | Social burden | Sexual function | Energy/ mobility | HBA |
|--|----------|------------------------|---------------------|------------------|-------------------|------------------|-----------------|---------------------|-----|
| HRQOL | 1 | | | | | | | | |
| High BP | -0.232** | 1 | | | | | | | |
| High cholesterol | -0.301** | 0.607** | 1 | | | | | | |
| Diabetes control | 0.745** | -0.174^{*} | -0.306** | 1 | | | | | |
| Anxiety/worry | 0.781** | -0.064 | -0.171* | 0.603** | 1 | | | | |
| Social burden | 0.728** | -0.076 | -0.191** | 0.573** | 0.469** | 1 | | | |
| Sexual function | 0.667** | -0.187** | -0.167* | 0.186** | 0.344** | 0.270** | 1 | | |
| Energy/mobility | 0.606** | -0.362** | -0.294** | 0.532** | 0.296** | 0.464** | 0.167* | 1 | |
| HBA _{1c} | -0.155* | 0.069 | 0.041 | -0.166* | -0.045 | -0.214** | -0.082 | -0.086 | 1 |
| BP = blood pressure. *Significant at the 0.05 leve **Significant at the 0.01 lev | | gnificant at any p-val | ue. | | | | | | |

for this in the literature, it may indicate that while physical health does decline with age, older people are not necessarily physically incapacitated and unenergetic.

The literature also reports conflicting findings on the relationship between duration of DM and HRQOL. The duration of DM has been reported to be associated with a decreased HRQOL.[11] A possible reason for this could be that the longer a patient has DM, the more complications may develop, thus worsening QOL. Rubin and Peyrot^[1] and Redekop et al.^[9] found no association between duration of DM and HRQOL, which is supported by the present study. No explanation for this could be found in the literature. A possible reason could be that the duration of DM does not necessarily correlate with good control, experience with treatment or level of complications, so not necessarily impacting on QOL.

The never-ending demands on the patient with diabetes, such as watching one's diet, exercising regularly, monitoring blood glucose levels, and scheduling and planning life around one's treatment, affects QOL in patients with both type 1 and type 2 DM.[1] It could be assumed that in addition to improving glucose control and reducing diabetes-related complications, improved adherence to a treatment regimen would lead to improved HRQOL, but some studies indicate that engaging in selfmanagement behaviour has a negative effect on QOL. $^{[12,13]}$ Watkins etal.[13] have suggested that dietary adherence may negatively affect QOL by increasing the level of perceived diabetes-related burden. People affected by DM are often restricted with regard to the amount, type and timing of food consumed (e.g. having to be aware of the glycaemic index of foods, eating mandatory meals at certain times, waiting for insulin to take effect before eating meals, etc.). These restrictions may negatively affect an individual's QOL and their interaction with people around them, in their social lives and in the workplace.[13]

The present study found an association between a diabetic patient's HRQOL and diabetes control as measured by HbA_{1c}. The reasons are probably multifactorial, ranging from dietary restrictions to being deterred from engaging in social events and the time and commitment required to achieve good glycaemic and weight control.

Connel et al.[11] reported an association between socioeconomic status (income and level of education) and HRQOL. We used employment to indicate socioeconomic status, but found no association. This may be because employment is not a reliable means of assessing an individual's socioeconomic status (e.g. employment status does not necessarily reflect financial status), so employment status may not have a significant impact on HRQOL. The fact that unemployment rates in SA are extremely high should also be kept in mind.

Exercise is closely related to weight control, which is reported to be an important factor in the management of diabetes. However, our results indicate that only half of the study population reported exercising regularly. This may be related to age (median 58 years), with older age being associated with a progressively more sedentary lifestyle, worsening the problem of DM and general HRQOL. Furthermore, physical strength decreases as an individual ages, and this may also be compounded by diabetes-related complications. Patients often do not perceive exercise as having a potential positive impact on QOL, which is further evidenced by the lack of an association between HRQOL and exercise.

Fal et al.[14] reported that BMI affects QOL. However, results from the present study provide no evidence for an association between the two, and indicate that while BMI and therefore weight may be significant in some specific medical conditions, they have no impact on DM. While being overweight may be linked to QOL, patients do not perceive it to be significant with specific reference to DM.

DM and HT appear to comparably impair HRQOL.[15] We found an association between HRQOL and concomitant HT and dyslipidaemia. DM and HT have comparable adverse effects on HRQOL.[15]

According to the American Diabetes Association, sexual dysfunction is one of the most common complications of DM and also one of the most underdiagnosed. Diabetic men are three times as likely as non-diabetic men to develop erectile dysfunction (ED). The cause is often multifactorial, but most commonly reflects endothelial dysfunction and autonomic neuropathy. [16] Studies have shown that sexual dysfunction, ED in particular, negatively affects QOL. The Exploratory Comprehensive Evaluation of Erectile Dysfunction study reported that among patients in the general population presenting to a urologist, ED negatively affected both general QOL and HRQOL.[16]

According to the Canadian Diabetes Association, little is known about the relationship between DM and anxiety. [17] The prevalence of anxiety disorders seems to higher in patients with diabetes (14%) than in the general population (3 - 4%). As many as 40% of diabetic patients have at least some anxiety symptoms. [17] Fear of hypoglycaemia is common in patients with DM, and while it may not affect HRQOL per se (e.g. it has little impact on pain or mobility), it can affect aspects of more general QOL (e.g. independence, ability to work or perform household duties, enjoyment of leisure activities). Sheu et al.[18] found that hypoglycaemic symptoms were associated with reduced QOL, as well as increased anxiety and worry, in diabetic patients treated with OHAs.[18] The present study found an association between anxiety and worry and HRQOL in patients with type 2 diabetes, whether they were treated with insulin alone or with OHAs.

The effects of lifestyle interventions in type 2 DM are relatively well described in the literature. [6,19,20] It has been noted that many such strategies can reduce the complications of type 2 DM. Lifestyle modification in relation to loss of weight, changing eating habits, cessation of cigarette smoking, reducing alcohol consumption and increasing physical exercise can play a major role in preventing complications related to DM. Although there has been substantial work on developing behavioural strategies to aid these lifestyle modifications, they are not easy to implement or to maintain on a long-term basis. Our study found no association between HRQOL and whether individuals drank alcohol and smoked cigarettes or not. However, although religious belief was not included in the questionnaire, our respondents included a substantial number of Muslims, who do not drink alcohol for religious reasons.

Clinicians need to keep a wide range of factors in mind when creating a treatment regimen for patients with DM. It is important to consider how DM affects each patient's QOL, but resource constraints in the public sector make it a challenge to solve these problems. Psychological factors such as mental and physical strain need to be considered, together with costs associated with healthcare visits, days spent away from work, and loss of independence. Managing DM holistically by attempting to improve the psychological aspect of the patient's disease as well as controlling blood glucose levels, blood pressure and cholesterol levels may lead to better HRQOL.

Study limitations

Global inferences are limited by the study design, duration and sample size and the fact that the study cohort represented a small group of patients, with poorly controlled blood glucose levels. Another limitation is that it was a non-random sample, conducted at a specialist diabetic clinic.

Conclusions

The results show an association between HbA1c and HRQOL. Furthermore, there was an association between HRQOL and HT and dyslipidaemia. No association was found between HRQOL and other clinical parameters, namely number of insulin units used per day, exercise, BMI, lipogram and the use of OHAs. Demographic parameters (age, gender, age at diagnosis, employment status and living arrangements) were also shown to have no impact on HRQOL in this study. Whether an individual consumed alcohol or smoked cigarettes did not affect his/her HRQOL.

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Appendix 1. The D-39 questionnaire

Quality of Life Survey

A person's quality of life is affected by many things. These things might include health, the opportunity for recreation and vacations, friends and family, and a job. This questionnaire is designed to help us learn about what affects the quality of life of people with diabetes.

Below are questions about <u>your</u> quality of life. For each factor listed, we ask you to place an "X" on the line to show whether that factor affects your quality of life "extremely," "not at all," or some place in the middle. An example is shown in the box below. For example, if you thought "having an automobile" affected your quality of life to some extent, but not extremely, you might mark the line as shown.

| DURING THE PAST MONTH, HOW MUCH WAS THE QUALITY OF YOUR LIFE AFFECTED BY: | | | | | |
|---|--|--|--|--|--|
| having an automobile | | | | | |
| 12_3_45_X_67 | | | | | |
| Not Affected Extremely | | | | | |
| At all Affected | | | | | |
| | | | | | |
| DURING THE PAST MONTH, HOW MUCH WAS THE QUALITY OF YOUR LIFE AFFECTED BY: | | | | | |
| | | | | | |
| 1. Your diabetes medication schedule | | | | | |
| 1234567 | | | | | |
| Not Affected Extremely At all Affected | | | | | |
| At all Affected | | | | | |
| 2. Worries about money matters | | | | | |
| 1 2 3 4 5 6 7 | | | | | |
| Not Affected Extremely | | | | | |
| At all Affected | | | | | |
| | | | | | |
| 3. Limited energy levels | | | | | |
| 12_3_4_5_67 | | | | | |
| Not Affected Extremely | | | | | |
| At all Affected | | | | | |
| | | | | | |
| 4. Following your doctor's prescribed treatment plan for diabetes | | | | | |
| 12_3_4_5_6_7 | | | | | |
| Not Affected Extremely | | | | | |
| At all Affected | | | | | |
| 5. Food restrictions required to control your diabetes | | | | | |
| 1 2 3 4 5 6 7 | | | | | |
| Not Affected Extremely | | | | | |
| At all Affected | | | | | |
| 7.1100000 | | | | | |
| 6. Concerns about your future | | | | | |
| 1234567 | | | | | |
| Not Affected Extremely | | | | | |
| At all Affected | | | | | |
| | | | | | |

| 7. Other health problems besides diabetes | |
|---|-------------|
| 12345_ | _67 |
| Not Affected | Extremely |
| At all | Affected |
| | |
| 8. Stress or pressure in your life | |
| 12_3_4_5_ | 6 7 |
| Not Affected | |
| | Extremely |
| At all | Affected |
| | |
| Feelings of weakness | |
| 12345_ | 67 |
| Not Affected | Extremely |
| At all | Affected |
| / te dii | Allected |
| 10. Dootsietiene en heur femuer een welle | |
| 10. Restrictions on how far you can walk | 6 7 |
| 12345_ | |
| Not Affected | Extremely |
| At all | Affected |
| | |
| 11. Exercise requirements | |
| 1 2 3 4 5 | 6 7 |
| Not Affected | |
| | • |
| At all | Affected |
| | |
| 12. Loss or blurring of your vision | |
| 12345_ | _67 |
| Not Affected | Extremely |
| At all | Affected |
| | |
| 13. Not being able to do what you want | |
| 1 2 3 4 5 | 6 7 |
| Not Affected | |
| | Extremely |
| At all | Affected |
| | |
| 14. Having diabetes | |
| 12345_ | _67 |
| Not Affected | Extremely |
| At all | Affected |
| | |
| 15. Losing control of your sugar levels | |
| 1 2 3 4 5 | 6 7 |
| | |
| Not Affected | Extremely |
| At all | Affected |
| | |
| 16. Other illnesses besides diabetes | |
| 12345_ | _67 |
| Not Affected | Extremely |
| At all | Affected |
| / te uil | Allected |

| Not Affected | | Extremely | | |
|--------------------------------|-----------------|----------------------|-------|--|
| At all | | Affected | | |
| 18. The time required to cont | rol vour diabet | tes | | |
| | 345_ | | | |
| Not Affected | | Extremely | | |
| At all | | Affected | | |
| 10. The restrictions your dish | stac places on | your family and frie | an de | |
| 19. The restrictions your diab | | | mus | |
| Not Affected | _345_ | | | |
| | | Extremely | | |
| At all | | Affected | | |
| 20. Being embarrassed becau | se you have di | abetes | | |
| | _345_ | 67 | | |
| Not Affected | | Extremely | | |
| At all | | Affected | | |
| 21. Diabetes interfering with | our sex life | | | |
| | _345_ | 67 | | |
| Not Affected | | Extremely | | |
| At all | | Affected | | |
| 22. Feeling blue or depressed | | | | |
| - | 3 4 5 | 6 7 | | |
| Not Affected | | , Extremely | | |
| At all | | Affected | | |
| 23. Problems with sexual fund | tioning | | | |
| | 3 4 5 | 6 7 | | |
| Not Affected | 55 | o, Extremely | | |
| At all | | Affected | | |
| Atali | | Affected | | |
| 24. Getting your diabetes wel | | | | |
| | _345_ | | | |
| Not Affected | | Extremely | | |
| At all | | Affected | | |
| 25. Complications from your o | liabetes | | | |
| 12 | _345_ | 67 | | |
| Not Affected | | Extremely | | |
| At all | | Affected | | |
| 26. Doing things that your fan | nily or friends | don't do | | |
| | , _345_ | | | |
| Not Affected | | Extremely | | |
| At all | | Affected | | |

| | Keeping a record of your sugar levels 1 2 3 4 5 | 67 |
|------------------|--|--------------------------------|
| | Not Affected | Extremely |
| | At all | Affected |
| | | |
| 28. | The need to eat at regular intervals | 6 7 |
| | 12_345 | |
| | Not Affected | Extremely |
| | At all | Affected |
| 29. | Not being able to do housework or other j | obs around the house |
| | 12345 | _67 |
| | Not Affected | Extremely |
| | At all | Affected |
| 30. | A decreased interest in sex | |
| | 1 2 3 4 5 | 6 7 |
| | Not Affected | Extremely |
| | At all | Affected |
| 21 | Having your schedule center around diabe | otes |
| JI. | 1 2 3 4 5 | |
| | 12343 Not Affected | Extremely |
| | At all | Affected |
| | At all | Affected |
| 32. | Needing to rest often | |
| | 12345 | _67 |
| | Not Affected | Extremely |
| | At all | Affected |
| 33. | Problems in climbing steps | |
| | | 6 7 |
| | Not Affected | Extremely |
| | At all | Affected |
| 21 | Having trouble caring for yourself (dressin | a bathing or using the tailet) |
| J 4 . | 1 2 3 4 5 | |
| | 12343 Not Affected | Extremely |
| | At all | Affected |
| | At all | Allecteu |
| 35. | Restless sleep | |
| | | _67 |
| | Not Affected | Extremely |
| | At all | Affected |
| 36. | Walking more slowly than others | |
| | 12_345 | _67 |
| | Not Affected | Extremely |
| | | |

| Being labeled a diab | etic | | |
|--|--------------------|------------------------------|----------------------------------|
| 1_ | 234 | 567 | |
| Not Affecte | ed . | Extremely | |
| At all | | Affected | |
| | | | |
| 38. Having diabetes inte | rfere with your fa | amily life | |
| 1_ | 234 | 567 | |
| Not Affecte | ed . | Extremely | |
| At all | | Affected | |
| | | | |
| 39. Diabetes in general | | | |
| 1_ | 234 | 567 | |
| Not Affecte | ed . | Extremely | |
| At all | | Affected | |
| | | | |
| | | | |
| OVERALL RATINGS | | | |
| | | | of your overall quality of life. |
| 1_ | 234 | 567 | |
| Not Affecte | ed . | Extremely | |
| At all | | Affected | |
| 2 Places place on "V" | an tha lina halaw | to about bout sources was th | sink wave diabatas is |
| | | to show how severe you th | link your diabetes is. |
| - | 234 | | |
| Not Affecte | ! d | Extremely | |
| At all | | Affected | |
| | | | |