

Article

Reporting distress and quality of life of patients with diabetes mellitus in primary and secondary care in Greece

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ABSTRACT

Background and aim This study constitutes an initial attempt at elucidating the relationship between quality of life (QoL), health status and psychological distress in patients with diabetes mellitus (DM) in Greece, by comparing patients with DM registered at a rural primary healthcare centre (PHCC) and those attending a diabetes outpatient clinic (DOC) at an urban hospital.

Methods Cross-sectional study. Participants were consecutive, consenting patients with a known history of type 2 DM (T2DM), currently registered at either of the two centres. All patients were administered the Short Form-36 version 2 (SF-36 v2) and the Problem Areas In Diabetes (PAID) questionnaire, and information in relation to socio-demographic data and clinical characteristics were also obtained.

Results Patients with DM had a lower QoL over all domains when compared with general population normative data. In addition, mean scores for the SF-36 v2 Physical Component Summary

(PCS) and Mental Component Summary (MCS) and six subscales of the SF-36 v2 demonstrated significant differences between the two participating centres ($P < 0.0001$). The mean PAID score was 19.18 (± 15.58) for patients from the PHCC, versus 40.19 (± 17.36) for the DOC ($P < 0.0001$). Lower scores on the MCS of the SF-36 v2, and higher scores on PAID in patients with T2 DM were related to major co-morbidities, insulin use and duration of DM.

Conclusions Patients with T2 DM from the urban DOC had significantly higher levels of distress and consequently lower levels of QoL compared with patients from the rural PHCC. The findings from this study may have important implications with regard to the individualisation of patient care in Greece, and encouragement of patient participation in the treatment process.

Keywords: diabetes mellitus, Greece, mental health, quality of life

Introduction

Diabetes mellitus (DM) is one of the most psychologically challenging chronic illnesses, which demands many lifestyle changes, poses life-threatening complications, and requires education, awareness and constant compliance with treatment on the part of the patient.^{1,2} The assessment of health-related quality of life (QoL) in patients with DM is an important additional consideration to the traditional measures of laboratory values or mortality and morbidity.² As QoL represents the effect of DM, as perceived by the patient, it has also been characterised as the ultimate goal of all healthcare interventions.¹

Diabetes-related emotional distress is an important element that may influence adherence to self-care, glycaemic control and risk of complications.³ During recent years there has been increasing appreciation of the need to estimate the degree to which DM affects QoL (e.g. mental, physical, social and occupational functioning) and enhances the psychological distress of the patient,^{4,5} but this subject has received little attention in Greece. In general, psychosocial determinants of chronic illness have not gained the consideration that they need in the field of clinical practice and research in general practice/family medicine. Thus, while it is recognised that psychosocial factors may have an impact on QoL, it is still unknown to what extent traditional life in rural areas affects the QoL of people with a chronic illness. Several studies focusing on QoL among patients with DM have been published.⁶⁻¹² The results from these studies differ and are difficult to compare, for example due to variations in the populations studied and the instruments that were used to measure QoL.

In Greece, care of patients with DM is provided through primary healthcare settings, and via diabetes outpatient clinics or private practices.¹³ Modern primary care and general practice in Greece arose from the development of the national healthcare system, inaugurated in the 1980s. As such, at the present time it is not as highly developed as Northern European national healthcare systems, with dense networks of primary care settings, located in rural regions. However, the role of general practitioners in the management of diabetes is essential. Thus, understanding this deficit is an important step toward implementing interventions that might have the potential to improve the QoL and quality of care for patients with DM in everyday practice.¹³

The current study reports on the psychological burden of distress caused by DM in primary and secondary care patient populations in Greece, and discusses factors that affect the QoL of patients with DM in this part of the Mediterranean.

Methods

Setting

Patients registered at Stylida primary healthcare centre (PHCC) in Greece (rural population) and at the diabetes outpatient clinic (DOC) of the Diabetes Centre of Tzaneio hospital, Piraeus, Greece (urban population) were invited to participate in the study. The health centre of Stylida is located in the region of Phthiotida, in central Greece and covers the coastal town of Stylida and the neighbouring villages. Tzaneio general hospital operates within the metropolitan area of Athens, in Piraeus, which is the principal port and the second-largest city of Greece.

The study population consisted of patients with a known history of type 2 DM (T2 DM), at various disease stages, who were attending the centre of their area more than four times per year. DM diagnosis was based on current diagnostic criteria, established by the World Health Organization (WHO).¹⁴ The patients were considered eligible for participation if they were mentally lucid and able to read and write Greek. Patients were excluded from the study if they were illiterate, if they had cognitive disorders and if they had severe disability and mobility problems, to the degree that they were not able to complete the patient-assessed questionnaires. They were examined by the first author, and given the questionnaires during an ordinary consultation at the centres.

Concerning the PHCC, all patients with T2 DM who met the inclusion criteria and were treated regularly from December 2006, were consecutively assessed for inclusion in the study. Similarly, for the DOC centre, all patients with T2 DM who met the inclusion criteria were consecutively evaluated for participation. For the PHCC a total of 203 patients (95% of those initially enrolled) and for the DOC a total of 201 (97% of those initially enrolled) met the criteria and completed the study.

All participants underwent a thorough physical examination, and blood samples were collected for the measurement of clinical parameters. An electronic filing system, using FileMaker Pro Advanced 9 was created and the following data concerning each individual patient were recorded: age, sex, body mass index (BMI), duration of diabetes, type of current treatment, metabolic levels (haemoglobin A_{1c} (HbA_{1c}), fasting glucose and blood lipids) and diabetic complications. We also recorded general disease data such as hypertension, cardiovascular and non-vascular co-morbidity and pharmacological treatment. The follow-up of the patients was performed according to American Diabetes Association (ADA) guidelines for diabetes.¹⁵

Patient-reported measures

All participants with T2 DM completed two validated questionnaires: the generic instrument Short Form-36 version 2 (SF-36 v2), and the disease-specific Problem Areas In Diabetes (PAID) scale. No data were missing.

The SF-36 v2 consists of 36 questions assessing eight conceptual domains: physical functioning, role limitations due to physical health, bodily pain, general health perceptions, vitality, social functioning, role limitations due to emotional problems and mental health. This questionnaire has been translated and validated into Greek,¹⁶ and was used after obtaining permission. For each dimension, item scores are coded, summed, and transformed to a scale from 0 (worst health) to 100 (best health). The SF-36 v2 establishes two summary measures: the Physical Component Summary (PCS) and the Mental Component Summary (MCS), which are calculated according to standard methodology.¹⁷⁻²¹ Normative data of a large nationwide sample of adults (upon total US population) are available for comparisons. Strong evidence of the instruments' reliability and validity exists,¹⁷⁻¹⁹ and it is the most thoroughly tested and accepted measure in many countries.

PAID is a 20-item questionnaire that measures diabetes-specific emotional distress, including a wide range of feelings related to living with DM and its treatment.²²⁻²⁴ Each item is rated on a six-point Likert scale, reflecting the degree to which the item is perceived as currently problematic.²⁴ The total scale score reflects the overall level of diabetes-related emotional distress. Use of the six-response PAID provided the opportunity to directly compare PAID item responses with previously published PAID research.^{24,25} PAID has been translated and culturally adapted using international standards,²⁶ and again was used after permission had been obtained.

Before applying the study protocol, authorisation by the scientific board of both health institutions was obtained. All patients willing to participate completed an informed consent form, and all responses were anonymous.

Statistical analysis

For continuous variables, results are presented as mean \pm standard deviation (SD). Differences in continuous parameters between the two groups were calculated by the Student's *t* test. To evaluate differences in proportions between groups, the chi-square test or Fisher's exact test was applied. A difference in mean values among groups was conducted by

one-way analysis of variance (ANOVA), with Bonferroni's test for *post hoc* analysis of multiple comparisons, or with Kruskal-Wallis one-way analysis of variance for non-normally distributed continuous variables.

To answer the research question, contributing factors for the explanation of QoL were explored, based on a linear regression analysis. To this end, we used three models of linear regression analysis, where the dependent variables in the first two regression models were the two summary measures of SF-36 (the PCS in the first model and the MCS in the second), while in the third model the dependent variable was the PAID total score. Independent variables were selected based on a holistic view of diabetic patients' life in which biomedical, psychological as well as social factors have their influence. Co-linearity control included checking variable inflation factors, which had to be below 10.

As normative data from the general US population are available for comparison, the total SF-36 score of participating patients was compared with appropriate US population data.

All analyses were conducted using SPSS version 15.0 (SPSS Inc, Chicago, IL). A *P* value of less than 0.05 was considered significant.

Results

Patients' characteristics

The study population included 203 patients from the PHCC and 201 patients from the DOC. The mean age of the participants was 69.97 ± 8.68 years for patients from the PHCC and 65.07 ± 9.40 years ($P < 0.0001$) for patients from the DOC. The baseline clinical characteristics of the study participants from both centres are described in Table 1. The mean self-reported duration of diabetes for patients from the PHCC was 10.45 years (± 5.8) versus 11.60 (± 7.63) for participants from the DOC ($P = 0.091$).

QoL and diabetes-related emotional distress

When comparing the study sample with the US normal population data, patients with DM had a lower QoL over all domains at baseline. The mean scores for the PCS and MCS scales were 49.81 and 47.80 respectively for patients from the PHCC, versus 46.46 and 38.30 for the DOC patients, demonstrating significant differences between the two centres ($P < 0.0001$). Table 2 illustrates the total analysis of

Table 1 Patients' clinical characteristics

	Mean value and SD for PHCC	Mean value and SD for DOC	<i>P</i> value
Age (years)	69.97 (\pm 8.68)	65.07 (\pm 9.40)	<0.0001
Duration of DM (years)	10.45 (\pm 5.8)	11.60 (\pm 7.63)	0.091
HbA _{1c}	7.09 (\pm 0.6)	7.04 (\pm 1.1)	0.554
Fasting glucose	166.20 (\pm 49.34)	158.70 (\pm 52.19)	0.138
High-density lipoprotein	44.34 (\pm 10.57)	46.09 (\pm 10.59)	0.098
Low-density lipoprotein	156.12 (\pm 87.22)	137.38 (\pm 98.98)	0.210
Triglycerides	155.71 (\pm 65.88)	146.19 (\pm 75.96)	0.179
BMI (kg/m ²)	29.23 (\pm 3.94)	28.96 (\pm 4.53)	0.519

Table 2 Analysis of SF-36 v2 results

SF-36 v2 conceptual domain	Mean value and SD for PHCC	Mean value and SD for DOC	<i>P</i> value
Physical functioning	76.18 (25.04)	68.30 (24.15)	0.001
Role limitations due to physical health	78.29 (24.62)	68.22 (28.5)	<0.0001
Bodily pain	75.27 (24.50)	67.09 (26.8)	0.001
Role limitations due to emotional problems	81.65 (23.23)	68.20 (27.79)	<0.0001
General health perceptions	64.60 (26.65)	41.03 (21.79)	<0.0001
Vitality	71.30 (22.70)	54.04 (28.04)	<0.0001
Social functioning	77.64 (23.06)	63.05 (24.02)	<0.001
Mental health	65.41 (19.83)	46.61 (23.63)	<0.001

SF-36 v2 results. Specifically, patients from the DOC had lower MCS-36 ($P < 0.001$) and PCS-36 scores ($P < 0.001$) compared with those of the PHCC.

The mean PAID score was 19.18 (\pm 15.58) for patients from the PHCC, compared to 40.19 (\pm 17.36) for the DOC ($P < 0.0001$), indicative of higher levels of distress in the DOC group.

Relationships with HbA_{1c}

No statistically significant difference was found between the means of the most-recently obtained HbA_{1c} measurement for the respondents of the two centres. When HbA_{1c} was treated as a continuous variable, the QoL measures revealed a statistically significant relationship between mental wellbeing and high levels of QoL in both centres. Glycaemic control was a significant predictor of

PAID, PCS-36 and MCS-36 scores in all of the regression models.

After HbA_{1c} levels were dichotomised into two groups (HbA_{1c} <7 and >7) in both centres, glycemic control was again indicated as a predictor of scores on the PAID and MCS-36, which both reflect the psychological burden of DM.

Relationships with co-morbidity and treatment therapy

Scores on the MCS of the SF-36 v2, and on PAID, were related to major co-morbidities, insulin use and duration of DM. Increasing number of medications, and insulin use equally affected the scores of the two QoL measures.

When MCS was treated as a continuous variable, duration of diabetes, co-morbidity and type of

treatment were predictive independent variables for mental health-related QoL, including better social and emotional functioning, mental health, and overall wellbeing. Table 3 shows the correlations between MCS scores and patients' characteristics, while Figure 1 demonstrates the relationships between treatment type and the estimated marginal means of MCS score. Similarly Table 4 demonstrates the correlations between PCS scores and patients' characteristics

Higher PAID scores were significantly associated with diabetes duration, treatment type, and co-morbidity, but not with age of the patients or presence of cardiovascular disease. Co-morbidity appeared to be the strongest contributor to the explained variance of PAID with an $\exp \beta = 0.359$ ($P < 0.0001$). Treatment contributed significantly with an $\exp \beta = 0.262$ ($P < 0.0001$). Table 5 shows the correlations between PAID scores and patients' characteristics.

Table 3 Regression analyses between MCS and patient characteristics

Dependent variable	Independent variable	Standardized β coefficient	P-value
Primary healthcare Centre			
MCS	Age	0.081	0.253
	DM duration	-0.280	<0.0001
	HbA1c	-0.251	<0.0001
	Co-morbidity	-0.370	<0.0001
	Cardiovascular disease	-0.175	0.013
	Insulin treatment	-0.250	<0.0001
	Treatment	-0.227	0.001
Diabetes outpatient clinic			
MCS	Age	0.040	0.570
	DM duration	-0.266	<0.0001
	HbA1c	-0.176	0.013
	Co-morbidity	-0.328	<0.0001
	Cardiovascular disease	0.089	0.207
	Treatment	-0.298	<0.0001
	Insulin treatment	-0.291	<0.0001

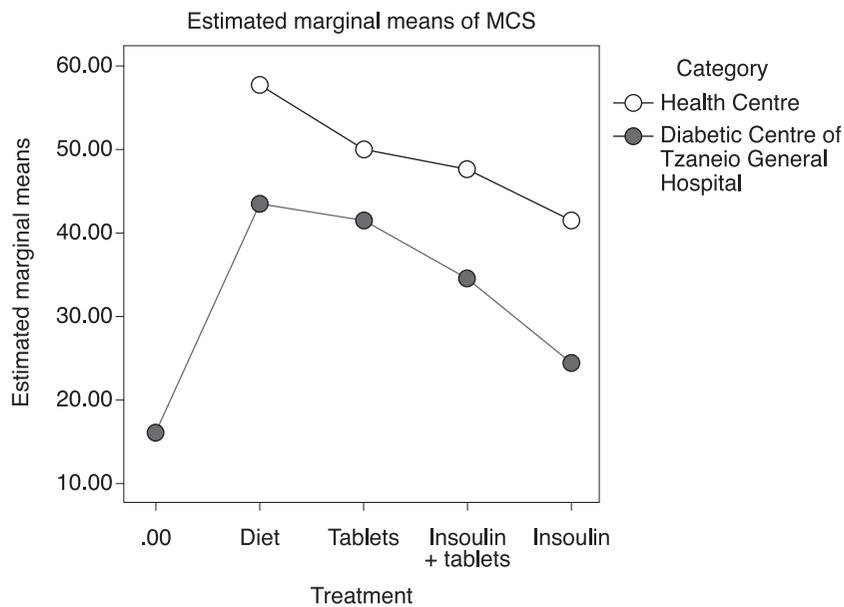


Figure 1 Estimated marginal means of MCS Score in relation to treatment type

Table 4 Regression analyses between PCS and patient characteristics

Dependent variable	Independent variable	Standardized β coefficient	P-value
Primary healthcare centre			
PCS	Age	-0.093	0.189
	DM duration	-0.209	0.003
	HbA _{1c}	-0.321	<0.0001
	Co-morbidity	-0.524	<0.0001
	Cardiovascular disease	-0.164	0.019
	Treatment	-0.176	0.012
	Insulin treatment	-0.156	0.018
Diabetes outpatient clinic			
PCS	Age	-0.021	0.773
	DM duration	-0.258	<0.0001
	HbA _{1c}	-0.146	0.039
	Co-morbidity	-0.437	<0.0001
	Cardiovascular disease	-0.142	0.045
	Treatment	-0.354	<0.0001
	Insulin treatment	-0.242	0.001

Table 5 Regression analyses between PAID scores and patient characteristics

Dependent variable	Independent variable	Standardised β coefficient	P value
Primary healthcare centre			
PAID	Age	0.070	0.326
	DM duration	0.248	<0.0001
	HbA _{1c}	0.183	0.009
	Co-morbidity	0.437	<0.0001
	Cardiovascular disease	0.150	0.033
	Treatment	0.300	<0.0001
	Insulin treatment	0.329	<0.0001
Diabetes outpatient clinic			
PAID	Age	0.086	0.229
	DM duration	0.279	<0.0001
	HbA _{1c}	0.243	0.001
	Co-morbidity	0.373	<0.0001
	Cardiovascular disease	0.104	0.140
	Treatment	0.245	<0.0001
	Insulin treatment	0.053	0.461

Discussion

In recent years there has been a growing appreciation of the patient's perspective on health, disease and medical treatments.²⁷ QoL evaluation should be a fundamental element in the process of providing high-quality health care in patients with diabetes.

This study constitutes an initial attempt to investigate QoL in patients with T2 DM within a primary care setting, in addition to patients utilising a secondary healthcare service in Greece, with a focus on clinical, mental and psychosocial factors that affect QoL.

The main findings

Focus on the research into diabetes-related emotional distress and QoL elucidates a definite association between diabetes and mental wellbeing. When comparing T2 DM patients with data available from the US general population, it was demonstrated that DM patients have significantly impaired QoL. Our study revealed that patients with T2 DM who seek care from the urban DOC compared with patients from a rural primary care unit had consistently worse scores on all SF-36 mental health subscales including MCS and PCS scores. We found that levels of distress were significantly higher for patients treated with insulin compared with those treated with oral medication and diet, for patients with cardiovascular and non-vascular co-morbidity and for those with a long duration of diabetes. These findings are in accordance with reports from other recent studies.^{28,29}

Additionally, the current study highlighted statistically significant differences between the two populations on PAID scores, indicating that the participants from the PHCC experienced less distress and psychological burden than the patients attending the DOC. Furthermore, the mean PAID score proved to be significantly lower for patients from the PHCC in comparison with those in studies conducted in US populations,^{22,30} indicating better QoL and less diabetes-related distress for those patients. Studies investigating such issues within the developing primary care system in Greece are somewhat limited, thus this finding could be of significant value and an indicator for further comparative research.

PAID items that extracted low scores in our study were similar to the items that had received low scores elsewhere,^{22,31} indicating that similar aspects of living with diabetes are perceived as stressful among people with diabetes in different geographic areas.

Strengths and limitations of the study

It is our view, that strengths of the study include the high response rate of the participants and the equal number of patients from both centres, which afforded maximisation of the reliability of the study. In addition, the detailed electronic database, which was used to assess consultation content, and the use of a combination of generic and disease-specific instruments are thought to have contributed to the effectiveness of the study. The use of multiple measures increases confidence in the results, reduces the likelihood of measurement errors, and assists in the accomplishment of a comprehensive investigation of QoL.²⁷

However, the study was not without limitations. The PHCC sample was located in a rural region, and

as such there may have been some effect of rural traditions on the lower levels of distress experienced by this group, which it was not possible to investigate within this study. Likewise, patients travelling from rural regions to attend diabetes services at the DOC were excluded from the study, which did not allow us to perform a within-group comparison between rural and urban patients. It is currently unknown to what extent differences between primary and secondary care outpatient experiences could have an additional impact on patients' levels of distress and QoL. This issue has not been extensively studied in Greece, although preliminary evidence suggests that differences between urban and rural clinical settings concerning the care of patients with diabetes might not be as significant as in other countries.¹³ However, a potential selection bias between the samples of the two participating centres with regard to physicians' ability to cope with patients' QoL and distress may have had an impact on the study's results.

Implications

The findings of this study have several important implications. First, the differences between groups observed in this study concerning emotional distress and type of treatment highlight the importance of the appropriateness and individualisation of treatment type. This information could prove useful to general practitioners in terms of encouraging patient participation in the treatment decision process, and with respect to enhancing treatment satisfaction. This, in turn, may positively affect patient-physician communication and treatment compliance. These factors underline the importance of patient empowerment, and indicate areas where the therapeutic intervention should be focused, especially when GPs are invited to manage chronically ill patients.

Secondly, the findings of this study may help clinicians in Greece to better assess factors associated with mental health in people with T2 DM. The recognition and specification of important modifiable factors that can either cause or maintain diabetes-related emotional distress are crucial for patients and healthcare providers. Future research is needed to further elucidate these factors.

In addition, the revealed difference in QoL and in diabetes-related emotional distress between the two centres supports the value and utility of QoL instruments as suggested by other researchers.^{27,32} Information acquired from such measures allows doctors to understand the way patients perceive their health status, preferences and expectations, and can facilitate the recognition of physical or psychological

problems that might otherwise be overlooked. Special attention should be given to patients with T2 DM and high co-morbidity, as revealed from this study.

Furthermore, our results reveal the necessity of paying attention to the effect of different life domains, such as mental health, social functioning, family status or marital intimacy on QoL. Finally, the key role of general practitioners and primary care in delivering effective healthcare services to patients with T2 DM, particularly in countries where primary care is still developing, should be reconsidered, although further research is needed to document differences between primary and secondary care.

Conclusions

This study, which focused on a rural primary care setting, and an urban diabetes outpatient centre, highlights deficits in QoL and draws attention to distress encountered by people with diabetes attending different diabetes services. Furthermore, it implies to an extent that living in rural areas may determine better QoL and less distress, although additional research is required in order to establish the possible effects of place of residence on the QoL and levels of distress of people with diabetes in Greece.

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CONFLICTS OF INTEREST

None.

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