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Disease-specific quality-of-life measures as predictors of mortality in individuals living with type 2 diabetes☆,☆☆

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Abstract

Objective: The aim of this study was to examine whether disease-specific quality-of-life measures are independent predictors of mortality in patients with type 2 diabetes. **Methods:** A cohort of 420 patients with type 2 diabetes was recruited from the outpatient clinic of a medical center. At baseline, the disease-specific measure of the Diabetes Impact Measurement Scales (DIMS) and clinical and biological marker variables were measured. The DIMS domains included symptoms, diabetes-related morale, social role fulfillment, and well-being. Complications consisted of stroke, heart disease, visual impairment, amputations, kidney disease, cognitive impairment, and incontinence. Mortality data were collected from the national mortality register using personal identification numbers. Multivariate Cox proportional hazards models were used. **Results:** The overall mortality rate was 10.9%. The DIMS scales of symptoms and well-being and the total score were significantly associated with mortality, independent of age, gender, glucose control, and complications. When the scales of the DIMS were simultaneously considered, only symptom and social role fulfillment of the DIMS exerted a significant effect on mortality. Patients in the categories of the second and third quartiles (worse status) had significantly increased risk compared with those in the category of the fourth quartile (best status) [for the symptom scale: RR=13.10, 95% confidence interval (CI)=2.75–62.50 and RR=5.49, 95% CI=1.50–20.09, respectively; for the social role fulfillment scale: RR=6.18, 95% CI=1.10–34.87 and RR=6.53, 95% CI=1.40–30.57, respectively]. **Conclusion:** Our data suggest that the unique contribution of health-related quality of life to mortality was independent of objective health measures, such as glucose control and complications.

Keywords: Type 2 diabetes; Diabetes Impact Measurement Scales; Health-related quality of life; Prognosis; Survival

☆ Competing interests: The authors declare that they have no competing interests.

☆☆ Authors' contributions: C.C.L. and T.C.L. designed the study and drafted the manuscript. C.S.L., C.C.C., and C.I.L. carried out the study and participated in coordination and evaluation of data. Y.D.L. contributed to the study with knowledge on field study and helped draft the manuscript. T.C.L. and C.I.L. carried out the data organization and performed the statistical analysis. All authors read and approved the final manuscript.

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Introduction

The medical world has recognized the importance of the centrality of the patient point of view in monitoring the quality of medical care outcomes. Health-related quality of life (HRQOL) focuses on the impact of a perceived health state on the ability to live a fulfilling life [1], for people living with diabetes can be influenced by a complex diabetes treatment regimen that includes dietary behavior, exercise, medication, glucose monitoring, and safety and preventive measures. Patients frequently feel that their lives are negatively affected due to diabetes, partly because they have to integrate and coordinate the various components of the treatment regimen into their normal life activities [2]. On the contrary, as the disease progresses, the effect of diabetic complications and the resultant risk of adverse drug experiences would have an impact on the medical outcomes of these patients [3]. To maximize quality of life for people with diabetes is to attempt to strike a balance between an individual patient's needs and desires and the imperatives of disease management.

A growing body of research shows that self-perceptions of health are linked to mortality, even when more "objective" health measures, such as morbidity [4,5], social support [5], and health behaviors [6], are controlled. A great value of the self-assessment of health lies in these findings. The unique contribution of health perceptions to mortality is substantial for both the general population [7–10] and individuals with adult-onset diabetes [11]. These studies used a single indicator measuring the self-assessment of health, and some of them used a wide range of psychosocial and well-being measures. Prior studies exploring the relationship between HRQOL and mortality have focused on patients with asthma or chronic obstructive pulmonary disease [12,13], congestive heart failure [14], coronary heart disease [15,16], kidney disease [17], or advanced age [18]. Two recent studies reported a significant association between HRQOL and mortality using generic instruments to measure HRQOL focusing on patients with diabetes [19,20]. For a population with a specific disease, a disease-specific instrument should be more capable of detecting subtle improvements in health resulting from treatment, while a generic instrument is more applicable when measuring the complete spectrum of function, disability, and disease that is relevant to quality of life. To our knowledge, none of the previous studies examined the effects of disease-specific quality-of-life measures on mortality in patients with type 2 diabetes. The objective of the present study was to examine the effects of disease-specific quality-of-life measures on mortality in a Taiwanese outpatient-based sample with type 2 diabetes.

Methods

Study subjects

During the period of 1998–2000, a diabetes HRQOL study consisting of 510 outpatients with type 2 diabetes recruited from the China Medical University Hospital was conducted. Outpatients with a diagnosis of diabetes mellitus (*International Classification of Diseases, Ninth Revision, Clinical Modification*, abbreviated as ICD-9-CM, code 250) were included in this study. Predominantly, subjects received oral hypoglycemic agents as treatment. Those who agreed to participate signed consent forms and were interviewed by our trained interviewers during their outpatient visits. The subjects' mean age was 62.98 years, with a standard deviation of 9.95 years, and 67.25% of them were female. Information regarding hemoglobin A_1C, blood glucose levels before and after meals, creatinine, urine protein, electrocardiogram readings, conduction deficit, and brain computed tomography were abstracted from hospital records.

HRQOL measures

The Diabetes Impact Measurement Scales (DIMS) is a measure of HRQOL in patients living with type I and type II diabetes. The scale was developed after a literature review. The DIMS consists of 44 items measuring four domains: symptoms (17 items, such as excessive thirst, muscular strength and endurance, blurring of vision, etc.), well-being (11 items, such as anxious or worried, feeling that you were good at doing the most important things you do, etc.), diabetes-related morale (patient's attitude toward managing the disease; 11 items, such as feeling personally in charge of managing your diabetes, feeling optimistic about your diabetes, etc.), and social role fulfillment (5 items, such as have you functioned well, not limited by your health, in your usual occupation, have you participated in and enjoyed family life, etc.). The scale requires 15–20 min to complete. Items are scored according to the selected response, with high values representing less severe or less frequent symptoms, greater morale, greater social role fulfillment, and greater well-being. Item responses were simply summed. The processes used in the translation of the Chinese version of the DIMS have been reported [21]. Validation of the DIMS in our baseline survey suggests that the Chinese DIMS is a reliable and valid instrument and is appropriate in clinical settings for Chinese with diabetes. Pearson's correlation coefficients ranged from moderate to high for test–retest coefficients: symptoms, 0.55; morale, 0.78; social role fulfillment, 0.76; well-being, 0.79; and total score, 0.92. Estimates of the internal consistency of the DIMS scales using Cronbach's α coefficients ranged from a low of 0.61 to a high of 0.86 across scales. With the use of external group validation, the scales for well-being, social role fulfillment, and total score revealed that the DIMS has a greater ability than the other scales to discriminate between individuals with good glucose control and those with poorer glucose control.

Vital status ascertainment of all patients through December 2005 was determined via yearly linkage with the

National Death Index (1998–2005) using gender, identification number, and date of birth. The precise date of death, along with the date of entry, was used to calculate the event time. Those who did not die were defined as censored, and data were censored on December 31, 2005.

Diabetes status at baseline

Baseline diabetes status was determined by the information abstracted from hospital records within 4 months of each subject's entry date. The information consisted of a physical examination by a clinic physician, a blood sample by venipuncture from an antecubital vein, and measurement of the blood pressure. Individuals with signs and symptoms of cardiac or peripheral neuropathic abnormalities, an exercise or resting electrocardiogram (EKG), and echocardiogram were evaluated.

Blood chemistry analyses were performed in the clinical laboratory of the China Medical University Hospital by a biochemical autoanalyzer (LX-20, Beckman Coulter, Brea, CA, USA). Glucose control was measured by hemoglobin A_1C (glycosylated hemoglobin) using boronate affinity and high-performance liquid chromatography (reference range=4.6%–6.5%). The inter- and intra-assay coefficients of variation for hemoglobin A_1C were 2.91% for a normal level, 1.79% for an intermediate level, and 1.09% for a high level. Urinary creatinine (Jaffe's kinetic method) and albumin (colorimetyl BCP) were also measured on the autoanalyzer. The inter-assay precision coefficient of variation was <3.0% for both creatinine and albumin concentrations. The lowest detection limits were <10 mg/dL for urinary creatinine and <1 g/dL for albumin. Blood pressure measurements were obtained using mercury manometers. Duration of diabetes was defined as the time interval between the time point of first diagnosis and the time point of being recruited.

The EKG readings (Cardiovit AT10, Schiller, Switzerland) determined ischemic change. Ischemic change was defined as EKG readings of an abnormal ST-T wave (or non-specific ST-T change); elevation or depression of the isoelectric segment following ventricular depolarization and preceding ventricular repolarization, measured from the end of the QRS complex to the beginning of the T wave; left ventricular hypertrophy with strain, manifesting primarily as an increase in voltage (height of R wave) in those EKG leads that reflect left ventricular potentials; suspected ischemia; old myocardial infarction (code 412.00 from ICD-9), with a negative Q wave in those EKG leads; and acute myocardial infarction (code 410.90 from ICD-9), with a negative Q wave and S-T segment elevation in those leads.

Neuropathy was determined by conduction deficit, which was measured by Nerve Conduction Velocity (Viking Select, Nicolet, USA). Patients were defined as having diabetic peripheral neuropathy if they had paresthesia or hypesthesia in all four limbs or in the lower extremities; if they had neurological abnormalities, including an abnormal Achilles reflex and the absence of a sense of vibration in the lower extremities; or if their motor-nerve conduction velocity in the tibial nerve ranged between 30 and 48 m/s or their sensory-nerve conduction velocity in the median nerve (in the distal area) ranged between 35 and 55 m/s. Retinopathy was evaluated by a fundus check-up by a physician. Skin ulcer was also determined by physician check-up.

Statistical analysis

To assess the association of the DIMS, we used Cox proportional hazards models to estimate the relative risk of mortality. First, we calculated the quartiles of the DIMS and used them as cutoff points. Then, we evaluated the crude risk of mortality separately for each scale, using Cox proportional hazards models, and then added age, gender, glucose control, and complication (retinopathy, neuropathy, nephropathy, skin ulcer, and ischemic change). Second, we used the continuous variables of the DIMS scales to test linear trends. Finally, we examined the association of the DIMS scales simultaneously to mortality. The PHREG of SAS 8.02 was used to fit the proportional hazards models.

Table 1
Distributions of age, gender, complications, glucose control, and comorbidity in the study sample

Variables	*n* (%)
Age (years)	
<50	49 (13.0)
50–60	85 (22.6)
60–70	144 (38.3)
>70	98 (26.1)
Gender	
Male	131 (31.8)
Female	281 (68.2)
Good glucose control	
Hemoglobin $A_1C \leq 7$	198 (52.1)
Duration (years)	
<1	42 (12.9)
1–5	83 (25.5)
5–10	79 (24.3)
10–15	54 (16.6)
>15	67 (20.6)
Complications	248 (60.2)
Retinopathy	
Yes	35 (8.5)
Neuropathy	
Yes	51 (12.5)
Nephropathy	
Yes	64 (15.5)
Skin ulcer	
Yes	1 (0.2)
Ischemic change	
Yes	193 (46.8)

Table 2
ICD-9 codes and observed number of deaths from the main causes of death

Cause of death	ICD-9 codes	*n* (%)
All causes		84 (100.0)
Septicemia	038	2 (2.4)
Malignant neoplasms	140–208	13 (15.5)
Diabetes	250	27 (32.1)
Cardiovascular	390–459	20 (23.8)
Heart disease	410–428	11 (13.1)
Cerebrovascular	430–438	9 (10.7)
Gastrointestinal	520–579	14 (16.7)
Chronic liver disease and cirrhosis	571	6 (7.1)
Other gastrointestinal causes	531, 578	10 (11.9)
Respiratory	493	1 (1.2)
	584	1 (1.2)
Renal failure	586	3 (3.6)
Shock and respiratory failure	785–800	6 (7.1)
Injury	928	1 (1.2)

Results

From August 1998 to March 2000, 510 patients were enrolled in the study. Since a personal identification number was needed to link with the National Death Index, those who did not provide a personal identification number or had missing information on the DIMS were excluded (*n*=90). The characteristics of 412 patients are shown in Table 1. Most of the study subjects were between 60 and 70 years old (38.3%), and the group was predominantly female (68.2%). We documented 44 all-cause deaths (10.7%) during 16,748 person-months (15,760 for survivors and 988 for deceased participants) of follow-up from 1998 to 2005. The main causes of death were diabetes, cardiovascular diseases, gastrointestinal diseases, and malignant neoplasms, which accounted for 27.3%, 20.5%, 15.9%, and 13.6%, respectively (Table 2).

Symptoms, well-being, diabetes-related morale, social role fulfillment, and total score of the DIMS were categorized into four categories based on their quartiles. Symptoms, diabetes-related morale, social role fulfillment, and total score were significant predictors of mortality (Table 3). After adjustment, they remained significant predictors. Compared with patients whose symptom scores were greater than 45, those whose symptom scores were 34–38 and 38–45 had RRs of 2.63 [95% confidence interval (CI)=1.18–5.85] and 2.46 (95% CI=1.16–5.21), respectively; compared with patients whose diabetes-related morale scores were greater than 33, those whose diabetes-related morale scores were 24–33 had an RR of 2.18 (95% CI=1.06–4.47); compared with patients whose social role fulfillment scores were greater than 13, those whose social role fulfillment scores were 8–13 had an RR of 2.79 (95% CI=1.20–6.44); and compared with patients whose total scores were greater than 116, those whose total scores were 90–116 had an RR of 4.41 (95% CI=2.04–9.5).

To examine further the independent relationship between DIMS scales and mortality, we performed a multivariate proportional hazards model by simultaneously including four scales of the DIMS (Table 4). Symptoms and social role fulfillment were significant independent predictors of mortality. Compared with patients whose symptom scores were greater than 45, those whose symptom scores were 34–38 and 38–45 had RRs of 13.10 (95% CI=2.75–62.5) and 5.49 (95% CI=1.50–20.09), respectively. Compared with patients whose social role fulfillment scores were greater

Table 3
Crude and adjusted relative risks of 5-year mortality for four scales and total score of the DIMS among individuals living with type 2 diabetes

	Crude		Adjusted[a]	
Variable	RR (95% CI)	*P* for trend	RR (95% CI)	*P* for trend
Symptoms (>45 as reference)		.50		.17
≤34.5	1.41 (0.44–4.51)		2.35 (0.60–9.21)	
34.5–38	3.75 (1.41–9.97)		5.57 (1.67–18.53)	
38–45	3.44 (1.33–8.87)		4.17 (1.32–13.14)	
Well-being (27> as reference)		.84		.57
≤21	1.00 (0.43–2.32)		1.39 (0.52–3.70)	
21–23	1.16 (0.45–3.01)		1.30 (0.43–3.97)	
23–27	1.33 (0.58–3.07)		1.38 (0.50–3.77)	
Diabetes-related morale (>33 as reference)		.12		.36
≤20	0.59 (0.19–1.83)		0.89 (0.23–3.41)	
20–24	1.29 (0.46–3.62)		1.23 (0.32–4.73)	
24–33	3.36 (1.51–7.50)		4.27 (1.58–11.50)	
Social role fulfillment (>13 as reference)		.60		.71
≤4	1.54 (0.43–5.55)		3.12 (0.59–16.53)	
4–8	2.81 (0.87–9.12)		4.96 (1.02–24.15)	
8–13	7.18 (2.48–20.77)		10.35 (2.37–45.07)	
Total score (>116 as reference)		.24		.83
≤82	0.96 (0.29–3.21)		2.17 (0.46–10.19)	
82–90	1.26 (0.38–4.20)		2.98 (0.68–12.96)	
90–116	5.79 (2.38–14.05)		10.03 (2.92–34.47)	

[a] Adjusted for age, gender, glucose control, and complications.

Table 4
Multivariate relative risks of 5-year mortality for four scales of the DIMS among individuals living with type 2 diabetes

Variable	Adjusted RR [a] (95% CI)	*P* for trend
Scores of the DIMS		
Symptoms (>45 as reference)		.23
≤34	5.42 (0.99–29.69)	
34–38	13.10 (2.75–62.50)	
38–45	5.49 (1.50–20.09)	
Well-being (>27 as reference)		.60
≤21	0.67 (0.21–2.15)	
21–23	0.88 (0.23–3.34)	
23–27	0.67 (0.22–2.08)	
Diabetes-related morale (>33 as reference)		.03
≤20	0.21 (0.04–1.19)	
20–24	0.32 (0.06–1.64)	
24–33	2.37 (0.71–7.91)	
Social role fulfillment (>13 as reference)		.43
≤4	3.30 (0.48–22.50)	
4–8	6.18 (1.10–34.87)	
8–13	6.53 (1.40–30.57)	

[a] Adjusted for age, gender, glucose control, and complications.

than 13, those whose social role fulfillment scores were 4–8 and 8–13 had RRs of 6.18 (95% CI=1.10–34.87) and 6.53 (95% CI=1.40–30.57), respectively.

Discussion

This study shows that disease-specific quality-of-life measures strongly predicted mortality in a cohort of persons living with type 2 diabetes. After adjustment for age, gender, glucose control, and complication status, the groups with the lowest quality-of-life quartile had a 417% to 1035% higher risk of death than the reference group.

We observed that the effects of symptom and social role fulfillment scales on mortality are independent from glucose control and complication because we had adjusted for the effects of glucose control and complication. There are two non-biological possibilities that could explain the associations between the scales of social role fulfillment and symptom and mortality. First, these two scales are more reliable and therefore predict outcome more readily. Second, the content of these two subscales predicts better outcome (i.e., a content-based explanation).

There are two possible explanations for the association between the social role fulfillment scale and mortality. One possibility is that if one's social role fulfillment does not meet one's expectation that would be related to low self-efficacy and high hopelessness [22], the neurological system might become stimulated, calling for the release of various chemicals that compromise the immune system and leave the individual more susceptible to opportunistic disease or cancer [23]. The other possibility is that the conceptual definition of this scale reflects the level of life control. Thus, this predictive value of the social role fulfillment scale could be caused by a delay in taking health-protective and health-maintaining actions due to the lack of control in the patient's life. However, the current study was not up to the task of explaining these observed relationships.

Two studies using generic measures explored the relationship between HRQOL and mortality [19,20]. The effect of quality-of-life measures on mortality among persons with diabetes was persistent despite extensive disease severity controls. The findings of our study further provide evidence that disease-specific quality-of-life measures add finer-graded information about health related to survival. The predictive power of these measures confirms the importance of the centrality of the patient point of view—that is, what people say about themselves to health professionals—in monitoring the quality of medical care outcomes.

A number of limitations should be noted in interpreting the results of this study. Those living with type 2 diabetes in this study were recruited during their office visits and had relatively better glucose control. The predictive ability of the DIMS might be less in a population living with type 2 diabetes representing a more severe spectrum of disease. This might limit the generalizability of the results but should not affect the internal validity. In addition, there exists the possibility of a DIMS measurement error. This kind of measurement error might be random or differential. If such a measurement error is independent of mortality (i.e., due to random error), the biased results in the effect may be toward the null, a lesser threat to validity. If the errors are not independent of mortality (i.e., differential error), the bias will result in an exaggeration or underestimation of an effect. However, there is no strong likelihood for assuming that the measurement error of the DIMS is differential; thus, the possibility of measurement error jeopardizing the validity of our results should be small.

In conclusion, HRQOL provides additional clinical information regarding disease course and outcome that is not captured by traditional indexes of clinical status. Scales of DIMS were strong predictors of mortality among persons living with diabetes, and their predictive power was only slightly explained by age, gender, glucose control, and complication. When DIMS scales were simultaneously considered, only symptom and social role fulfillment scales exerted an independent effect on mortality. The results show the clinical importance of the HRQOL and may facilitate interpretation by health care professions.

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