

Health-Related Quality of Life and Treatment Satisfaction in Dutch Patients With Type 2 Diabetes

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of type 2 diabetes patients in eight European countries (3,4).

RESEARCH DESIGN AND METHODS

The CODE-2 study

The CODE-2 study was performed to provide comprehensive data on costs and quality of life and involved 7,635 patients in eight European countries. Full details have been presented by Jonsson et al. (3).

A sample of Dutch type 2 diabetes patients, recruited by a representative sample of 29 Dutch general practitioners, completed questionnaires regarding quality of life and treatment satisfaction. Information regarding medical costs was also collected and has already been reported (5). The general practitioners, randomly selected from a computerized database, identified all type 2 diabetic patients in their practice ($n = 1,371$).

HRQOL measurement

To measure HRQOL we used the Euroqol 5-D instrument (6). The Euroqol 5-D is a widely used and validated generic instrument that has five dimensions: mobility, self care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has three levels: no limitations, some limitations, and severe limitations. As a result, there are 243 possible sets of values for the Euroqol 5-D (i.e., 3^5). All of these possible health states have been valued by the general public in the U.K. using the so-called York A-1 tariff, by means of a large-scale time trade-off study (7). These "valuations" of the health states represent utility values, an indication of their level of desirability or undesirability. The set of possible values has a range of -0.549 to 1, where 1 indicates perfect health, 0 indicates death, and -0.549 indicates the worst possible health state that is viewed by the general public as considerably worse than death. The utility values found in the U.K. study have since been validated for the Netherlands (8). The valuations of patients' health states are

OBJECTIVE — To estimate the health-related quality of life (HRQOL) and treatment satisfaction for patients with type 2 diabetes in the Netherlands and to examine which patient characteristics are associated with quality of life and treatment satisfaction.

RESEARCH DESIGN AND METHODS — For a sample of 1,348 type 2 diabetes patients, recruited by 29 general practitioners, we collected data regarding HRQOL. This study was performed as part of a larger European study (Cost of Diabetes in Europe – Type 2 [CODE-2]). We used a generic instrument (Euroqol 5D) to measure HRQOL. Treatment satisfaction was assessed using the Diabetes Treatment Satisfaction Questionnaire.

RESULTS — Patients without complications had an HRQOL (0.74) only slightly lower than similarly aged persons in the general population. Insulin therapy, obesity, and complications were associated with a lower HRQOL, independent of age and sex. Although higher fasting blood glucose and HbA_{1c} levels were negatively associated with HRQOL, these factors were not significant after adjustment for other factors using multivariate analysis. Overall treatment satisfaction was very high. Younger patients, patients using insulin, and patients with higher HbA_{1c} levels were less satisfied with the treatment than other patients.

CONCLUSIONS — Obesity and the presence of complications are important determinants of HRQOL in patients with type 2 diabetes.

Diabetes Care 25:458–463, 2002

Type 2 diabetes is a chronic disease that affects a patient's general health and well-being in various ways. For example, severe dietary restriction and daily self-administration of oral medications or insulin may adversely affect an individual's health-related quality of life (HRQOL). In addition, the long-term complications of diabetes, such as nephropathy, neuropathy, heart disease, and stroke, with their considerable impact on health, may also have a negative effect on

quality of life, as shown in the U.K. Prospective Diabetes Study (UKPDS) study and a recent review (1,2).

The aim of this study was to determine the HRQOL and treatment satisfaction for patients with type 2 diabetes in the Netherlands and to examine which patient characteristics are associated with quality of life and treatment satisfaction. This study was initiated as part of the Cost of Diabetes in Europe – Type 2 (CODE-2) study, a large study

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Received for publication 20 July 2001 and accepted in revised form 7 November 2001.

Abbreviations: CODE-2, Cost of Diabetes in Europe – Type 2; DTSQ, Diabetes Treatment Satisfaction Questionnaire; HRQOL, health-related quality of life; VAS, visual analog scale.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

henceforth referred to as EQ5D utility scores.

In addition, the patients were asked to describe their overall actual health state using the Euroqol visual analog scale (VAS), where 0 represents the worst imaginable health state and 1 indicates perfect health.

Treatment satisfaction

To assess treatment satisfaction, we used the Diabetes Treatment Satisfaction Questionnaire (DTSQ), consisting of six questions (satisfaction with current treatment, treatment convenience, treatment flexibility, understanding of diabetes, satisfied with treatment continuation, recommending treatment to other diabetic patients), each with seven possible answers (9). When combined, the degree of satisfaction is expressed in a summary score with a range of 0–36, where a higher score indicates greater satisfaction.

Statistical analyses

HRQOL in patient subgroups was compared using the EQ5D utility scores and the Euroqol VAS scores. The following characteristics were studied: sex, age, duration of diabetes, type of therapy (diet, oral glucose-lowering drugs, insulin), presence of complications, fasting blood glucose, HbA_{1c}, hypertension, obesity, hyperlipidemia, and microalbuminuria. Complications were categorized in two ways: 1) presence/absence of any complication; 2) four mutually exclusive categories of no complication, microvascular complications only, macrovascular complications only, and both microvascular and macrovascular complications. The CODE-2 study protocol used the following categorization algorithms. Microvascular complications were defined as foot ulcer, amputation, blindness, photocoagulation or vitrectomy, dialysis, renal transplant, retinopathy, neuropathy, manifest nephropathy, and microalbuminuria. Macrovascular complications were defined as myocardial infarction, angina, heart failure, cardiac surgery (coronary artery bypass grafting, percutaneous transluminal angioplasty), stroke, transient ischemic attack, and peripheral vascular disease. For our analyses, we did not consider amputation as evidence of microvascular complications.

Multivariate analysis using ordinary least-squares linear regression was used to establish which patient characteristics

were associated with quality of life after adjustment for other characteristics. Both stepwise and best-subsets analyses were used to create the final statistical models, and a *P* value of 0.05 provided a guideline for inclusion into the model. Correlation between the EQ5D utility scores and the Euroqol VAS scores was examined using Pearson and Spearman correlation coefficients. Associations between patient characteristics and each of the five EQ5D dimensions were analyzed using univariate analysis (Mann-Whitney *U* test, Kruskal-Wallis test, and Kendall's τ test, where appropriate) and stepwise binary and ordinal logistic regression analysis.

Factors associated with treatment satisfaction were also studied using linear regression analysis.

As a supplement to these analyses, we applied multilevel modeling to take into account the fact that the data collected originated from patients seen by 29 general practitioners (10). In this analysis, the general practitioner status is included as a random effect, and patient characteristics are included as fixed effects. This type of analysis has previously been used in diabetes research (11).

Correlations between the EQ5D utility scores, Euroqol VAS scores, and DTSQ scores were examined using both the Pearson and Spearman correlation methods.

RESULTS

Patients

Of the 1,371 patients recruited for the study, 1,348 Dutch type 2 diabetes patients completed questionnaires regarding quality of life and treatment satisfaction. In total, 1,224 questionnaires (91%) contained a completed Euroqol VAS score, and 1,136 (84%) contained complete information on the EQ5D. The average age in this population was 64.9 years, and half of the patients were women (50.2%). Approximately two-thirds of the patients used oral glucose-lowering drugs; treatment of the remaining patients was evenly divided between diet/exercise and insulin therapy. Almost half of the patients had no complications, 22% only microvascular complications, 15% only macrovascular complications, and 16% had both types of complications.

HRQOL using EQ5D utility scores

Diabetic patients reported an average EQ5D utility score of 0.74 (SD 0.27), which is only slightly lower than the scores seen in individuals of similar age in the general population (U.K. population: 60–69 years of age; women 0.81, men 0.78) (Table 1) (12). Women, older patients, and patients with a longer duration of diabetes reported a lower HRQOL than other patients. Both insulin therapy and presence of complications were associated with a lower quality of life. Patients without complications reported the highest HRQOL, whereas patients with both microvascular and macrovascular complications reported the lowest HRQOL (i.e., -0.191 units lower). Patients with only microvascular complications and patients with only macrovascular complications reported an HRQOL between these two extremes. Obesity was associated with a lower utility score (-0.07 units). Higher fasting blood glucose and HbA_{1c} levels were associated with a lower utility score, although the association seen for HbA_{1c} was more pronounced (a decrease of 0.02 Euroqol units per increase in HbA_{1c} by 1%) (Table 2).

Multivariate analysis resulted in a model containing age, female sex, obesity, insulin therapy, microvascular complications only, macrovascular complications only, and both microvascular and macrovascular complications (Table 2). Multilevel modeling showed that only 1.6% of the variance in EQ5D utility scores was seen at the general practitioner level and 98.4% was seen at the patient level. The differences between the model based on linear regression and the model based on multilevel modeling were insubstantial.

HRQOL using Euroqol VAS scores

The average Euroqol VAS score was 0.68 (SD 0.18) (Table 1). Quality of life decreased slightly with age, and women reported a lower quality of life than men. Patients treated with insulin reported a lower quality of life than patients using oral therapy, whereas patients treated with diet showed a better quality of life. Obesity and complications were associated with a lower quality of life. The final model using the VAS score as the outcome included insulin therapy (coefficient -0.072 ; 95% CI -0.101 , -0.042 ; $P < 0.001$), microvascular complications only (coefficient -0.051 ; 95% CI -0.078 , -0.024 ; $P < 0.001$), macrovascular com-

Table 1—Quality of life as reported by type 2 diabetic patients

	EQ5D utility score (n = 1136)	Euroqol VAS score (n = 1,224)
Overall	0.74 (0.27)	0.68 (0.18)
Sex		
Female	0.70 (0.28)	0.67 (0.18)
Male	0.79 (0.25)	0.70 (0.18)
Age		
<50 years	0.79 (0.26)	0.69 (0.19)
50–59 years	0.75 (0.26)	0.69 (0.18)
60–69 years	0.78 (0.25)	0.70 (0.18)
≥70 years	0.70 (0.28)	0.67 (0.18)
Duration of diabetes		
<5 years	0.77 (0.25)	0.70 (0.17)
5–10 years	0.73 (0.29)	0.67 (0.19)
≥10 years	0.70 (0.29)	0.66 (0.18)
Treatment		
Diet and exercise only	0.79 (0.26)	0.73 (0.17)
Oral therapy only	0.76 (0.25)	0.69 (0.17)
Insulin only or combined	0.63 (0.30)	0.61 (0.20)
Complications		
No complications	0.81 (0.23)	0.72 (0.16)
Only microvascular complications	0.72 (0.28)	0.67 (0.18)
Only macrovascular complications	0.73 (0.27)	0.66 (0.17)
Microvascular and macrovascular complications	0.61 (0.31)	0.62 (0.20)
Obesity	0.70 (0.28)	0.66 (0.19)
No obesity	0.77 (0.26)	0.69 (0.17)

Data are means (SD). Note: microvascular complications were defined as foot ulcer, blindness, photocoagulation or vitrectomy, dialysis, renal transplant, retinopathy, neuropathy, manifest nephropathy, and microalbuminuria. Macrovascular complications were defined as myocardial infarction, angina, heart failure, cardiac surgery (coronary artery bypass grafting, percutaneous transluminal angioplasty), stroke, transient ischemic attack, and peripheral vascular disease.

only (coefficient -0.065 ; 95% CI -0.096 , -0.034 ; $P < 0.001$), both microvascular and macrovascular complications (coefficient -0.085 ; 95% CI -0.116 , -0.054 ; $P < 0.001$), and obesity (coefficient -0.034 ; 95% CI -0.056 , -0.004 ; $P = 0.004$).

Association between EQ5D utility and Euroqol VAS scores

The EQ5D utility and Euroqol VAS scores correlated well (Pearson coefficient 0.633 , $P < 0.001$; Spearman coefficient 0.639 , $P < 0.001$), although a low or high score on one scale did not necessarily mean a low or high score on the other scale. In fact, many patients with a relatively low EQ5D utility score had a tendency to report a moderate Euroqol VAS score. The relationships regarding age, sex, use of insulin, obesity, and the presence of complications were similar for the two quality-of-life measures (Table 1).

Decomposition of EQ5D quality-of-life scores

The frequency of problems varied between the EQ5D dimensions, where problems with mobility and pain were frequent and problems with self-care were less frequent.

Women always reported limitations more often than men (Table 3). Although older age was usually associated with a greater frequency of problems, younger patients reported problems with anxiety/depression more often than older patients. In most cases, patients without complications were less likely to report problems than other patients, with the exception of anxiety/depression, which was reported slightly less frequently by patients with macrovascular complications than by patients without complications. Patients with both microvascular and macrovascular complications reported problems more often than other patients.

Ordinal logistic regression analysis

was used to create five models, one for each dimension, to determine which patient characteristics were associated with problems in these dimensions (Table 4). Although the composition varied somewhat between models, several patient characteristics appeared in at least two of the five models. Hyperlipidemia was selected in three of the models. Using the classification index as an indicator of the discriminative ability of the model, the models for mobility and self-care performed better than the other models.

Treatment satisfaction

Complete DTSQ scores were available for 1,162 patients. Given the maximum possible score of 36, satisfaction was high (mean 31.3 , SD 5.8); 50% of patients scored 33 or higher. For five of the six subscales, 60% of patients rated the highest degree of satisfaction. In the subscale of understanding of diabetes, 40% of patients scored 33 or higher.

Using multivariate analysis, age (coefficient 0.061 ; 95% CI 0.024 , 0.098 ; $P = 0.001$), insulin therapy (coefficient -1.353 ; 95% CI -2.596 , -0.110 ; $P = 0.033$), and HbA_{1c} level (coefficient -0.444 ; 95% CI -0.684 , -0.205 ; $P < 0.001$) were associated with treatment satisfaction, suggesting that younger patients, patients on insulin therapy, and patients with higher HbA_{1c} levels were less satisfied with the treatment than other patients. Presence of complications was associated with lower satisfaction on univariate analysis but was not associated after adjustment for age, insulin therapy, and HbA_{1c} level.

The correlation between treatment satisfaction and HRQOL was modest (Pearson correlation: EQ5D utility $+0.28$, Euroqol VAS $+0.33$) although statistically significant ($P < 0.001$).

CONCLUSIONS— In a study of Dutch type 2 diabetic patients, we found that older age, female sex, insulin therapy, presence of complications, and obesity were associated with a lower HRQOL. These results correspond remarkably well with the findings reported by Rubin and Peyrot, who systematically analyzed all recent literature on diabetes and quality of life (2). Studies using established generic quality-of-life measures such as the Short Form 36 (SF36), Short Form 20 (SF20), the Nottingham Health Profile (NHP), and the Sickness Impact Profile (SIP) have

Table 2—Relationship between patient characteristics and HRQOL (EQ5D utility scores)

	Univariate analyses		Multivariate analyses	
	Coefficient	P	Coefficient	P
Age (per year)	−0.003	0.0001	−0.002	0.0139
Female sex	−0.087	0.0001	−0.083	0.0001
Duration since diagnosis (per year)	−0.006	0.0001		
Treatment type (three categories)				
Diet versus oral	0.026	0.2397		
Insulin versus oral	−0.134	0.0001		
Insulin therapy	−0.139	0.0001	−0.077	0.0009
Presence of any complications	−0.114	0.0001		
Per complication category				
Microvascular only	−0.085	0.0001	−0.068	0.0015
Macrovascular only	−0.075	0.0026	−0.077	0.0017
Microvascular and macrovascular	−0.191	0.0001	−0.169	0.0001
Hypertension	−0.011	0.4773		
Obesity (if BMI >30 kg/m ²)	−0.067	0.0001	−0.044	0.0153
Hyperlipidemia	0.013	0.4712		
Microalbuminuria	−0.012	0.6349		
Blood glucose (per mmol/l)	−0.004	0.0669		
HbA _{1c} (per percentage unit)	−0.019	0.0014		
Model intercept			0.986	0.0001
Adjusted <i>r</i> square				0.1166 (df = 959)

also reported the quality of life of diabetes patients to be lower than the average population of the same age and that quality of

life decreases with age, presence of complications, and use of insulin (2). Regarding the association between the duration

since diagnosis of diabetes and quality of life, Rubin and Peyrot reported mixed results. In our study, duration of diabetes

Table 3—Frequency of problems according to the five Euroqol 5D subscales seen in different patient groups

Patient group	Mobility	Self-care	Usual activities	Pain/discomfort	Anxiety/depression
All patients	47	11	37	53	29
Sex	(<0.0001)	(<0.0001)	(<0.0001)	(<0.0001)	(<0.0001)
Female	55	14	44	58	35
Male	38	9	30	47	23
Age categories†	(<0.0001)	(<0.0001)	(0.0004)	(0.6548)	(0.0564)
<50 years	24	5	34	48	38
50–59 years	40	6	39	57	33
60–69 years	40	8	28	51	27
≥70 years	63	19	44	53	27
Duration since diagnosis†	(<0.0001)	(0.0614)	(0.0125)	(0.0335)	(0.4186)
<5 years	24	5	34	48	38
5–10 years	40	6	39	57	33
≥10 years	63	19	44	53	27
Treatment categories‡	(<0.0001)	(0.0048)	(<0.0001)	(<0.0001)	(0.0016)
Diet/exercise	30	10	27	44	27
Oral medication	46	10	34	51	27
Treatment insulin	67	19	61	69	41
Complication categories‡	(<0.0001)	(<0.0001)	(<0.0001)	(<0.0001)	(<0.0001)
No complications	32	7	27	46	27
Only microvascular	53	9	41	57	35
Only macrovascular	53	13	42	58	19
Microvascular and macrovascular	75	26	55	64	40

Data are percentages of patients with at least some problem (*P* values shown in parentheses) (*n* = 1136). Statistical tests: *Mann-Whitney *U* test; †Kendall τ test; ‡Kruskal-Wallis test.

Table 4—Factors associated with problems according to the five Euroqol 5D subscales

	Mobility	Self-care	Usual activities	Pain/discomfort	Anxiety/depression
Age (per year)	1.04 (1.03, 1.06) (<i><.001</i>)	1.05 (1.03, 1.08)	—	—	—
Female sex	1.92 (1.37, 2.70) (<i><.001</i>)	—	1.75 (1.26, 2.43) (<i><.001</i>)	1.82 (1.35, 2.44) (<i><.001</i>)	1.74 (1.25, 2.42) (.001)
Insulin therapy	2.69 (1.43, 5.08) (.002)	—	3.49 (2.02, 6.03) (<i><.001</i>)	—	—
Microvascular complications only	1.73 (1.13, 2.66) (.012)	—	1.70 (1.11, 2.59) (.015)	—	—
Macrovascular complications only	2.38 (1.49, 3.80) (<i><.001</i>)	—	2.23 (1.41, 3.51) (<i><.001</i>)	1.68 (1.12, 2.53) (.012)	0.43 (0.25, 0.76) (.004)
Microvascular and macrovascular complications	6.41 (3.53, 11.65) (<i><.001</i>)	5.00 (2.72, 9.20) (<i><.001</i>)	3.22 (1.96, 5.28) (<i><.001</i>)	1.66 (1.05, 2.63) (.029)	2.00 (1.26, 3.19) (.004)
Obesity	1.84 (1.27, 2.66) (.001)	2.40 (1.39, 4.16) (.002)	1.53 (1.08, 2.16) (.018)	1.58 (1.14, 2.17) (.006)	—
Hyperlipidemia	0.65 (0.45, 0.94) (.021)	0.22 (0.10, 0.49) (<i><.001</i>)	0.64 (0.45, 0.91) (.014)	—	—
Classification index	0.72	0.78	0.67	0.61	0.62

Data are odds ratio, 95% CI, and *P*, based on models created using multiple logistic regression (*n* = 1,136).

was not associated with quality of life after adjustment for other patient characteristics. In addition, we found that obesity was associated with a lower quality of life, even after adjustment for other patient characteristics, consistent with the overall European findings of the CODE-2 study (13).

The relationship seen between the EQ5D utility scores and the Euroqol VAS scores reflects a frequently observed pattern. Namely, severe health states are valued as being less severe by patients in those states than by the general public (14).

When individual EQ5D dimensions were analyzed, we found results similar to those seen using the overall EQ5D utility score, although we found some unexpected associations. For example, anxiety/depression was more often reported by younger patients than by older patients. One possible explanation is that the prospect of future disease progression is especially distressing for younger patients. In a study involving the general public, anxiety/depression was the only dimension in which frequency of prob-

lems first increased across age categories and then decreased (15). Another more general explanation for this phenomenon is that older individuals are able to attribute their health problems to aging and are therefore better able to accept their conditions (16). We also found that patients with only macrovascular complications have a lower frequency of anxiety/depression than patients with no complications. We do not have similar data with which to compare this finding.

It has been questioned whether the EQ5D instrument is sensitive enough to detect clinically relevant differences in quality of life between patient groups (17). Bradley recently noted that the use of an instrument such as the EQ5D can only help to identify large differences in HRQOL (18). In our study, patients with only microvascular complications had a lower HRQOL than patients with no complications, even after adjustment for other factors. Although concerns might be raised about the consideration of foot ulcers as a type of microvascular complication given their often mixed pathophysiology (i.e., neuropathy and

ischemia), the presence of other forms of neuropathy was, in fact, more associated with a lower HRQOL than the presence of an ulcer.

One important reason for using the EQ5D instrument to measure HRQOL was the ability to transform the utility scores into quality-adjusted life years for use in economic evaluations of new therapies. The shorter completion time (1 min) compared with other generic instruments was also a consideration. Although the EQ5D instrument showed differences in quality of life among diabetic patients in whom differences were expected to be found, this should not be taken to mean that the sensitivity of the EQ5D is comparable to that of a diabetes-specific instrument. Numerous study objectives exist for which a diabetes-specific instrument is more appropriate. For example, the detection of any negative psychological effects of a more effective therapy must be considered.

Regarding treatment satisfaction, the low correlation between treatment satisfaction and HRQOL found in this study indicates that treatment satisfaction and

HRQOL are two fairly distinct phenomena. This finding also corresponds with research indicating that in a general practitioner's setting, patient satisfaction depends first and foremost on the physician's attitude toward the patient and the degree of communication (19). The lack of an association between the presence of complications and the level of treatment satisfaction has been noted by others (20).

Because of the relationships found in this study as well as in other studies, it is reasonable to conclude that any efforts to avoid or postpone obesity, insulin use, and development of complications will enhance HRQOL and thereby improve healthy life expectancy. A similar analysis of the relationship between clinical parameters and costs shows a set of determinants very similar to those seen for quality of life (5). Consequently, if preventive and/or therapeutic interventions could postpone or prevent obesity, insulin use, and complications, costs could potentially be mitigated and substantial health effects could be obtained. In this endeavor, it would be necessary to examine the cost-effectiveness of such interventions, taking into consideration the costs of these interventions, the expected compliance, and the amount and timing of future health effects in a systematic manner.

Acknowledgments—Financial support for this study was received from SmithKline Beecham Pharma (U.K. and the Netherlands).

We thank Jan van Busschbach, Joseph McDonnell, and two anonymous reviewers for their constructive comments and suggestions. We would also like to acknowledge the efforts of Ronald Jansen, Nienke Feenstra, Gerda

Schutter, and Dirk Aelvoet in the Dutch CODE-2 study.

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