The Evaluation of Two Measures of Quality of Life in Patients With Type I and Type II Diabetes

ALAN M. JACOBSON, MD
JACQUELINE A. SAMSON, PHD
MARY DE GROOT, EDM

OBJECTIVE — To examine the effects of type I and type II diabetes on patient perceptions of their quality of life and compare the psychometric properties of a generic versus a diabetes-specific quality of life measure.

RESEARCH DESIGN AND METHODS — Consecutive outpatients (n = 240) from a large multispecialty diabetes clinic were studied on a single occasion using two measures of quality of life—Diabetes Quality of Life Measure (DQOL) and the Medical Outcome Study Health Survey 36-Item Short Form (SF-36). No interventions were performed. This study examines three issues: *1*) the reliability (internal consistency) of the two measures; 2) the relationship between the DQOL and SF-36 scales; and 3) the influence of clinical patient characteristics, such as number and severity of diabetes complications, on quality of life. Examination of this issue provides information about the construct validity of the two quality of life measures.

RESULTS — The estimates of internal consistency (Cronbach's alpha) for the DQOL and SF-36 subscales ranged from 0.47 to 0.97. These values were very similar to the published findings from previous studies. The subscales of the two measures were variably correlated with one another (range of correlations: −0.003 to 0.60), indicating that the areas of functioning addressed by the DQOL and SF-36 overlapped only to a modest degree. Examination of the relationship of demographic factors to the DQOL measures suggests that they are not generally confounded by factors such as education, sex, or duration of diabetes. Health-related quality of life is affected by the marital status of both type I and type II diabetic patients, with separated and divorced individuals generally experiencing lower levels of quality of life. The quality of life measures were sensitive to clinical characteristics, such as frequency and severity of complications. Even after factors such as marital status and, among type II diabetic patients, type of treatment, patients' severity of diabetes complications was a significant predictor of both the diabetes-related and the more broad-based measure of quality of life. For type II diabetic patients, insulin treatment was associated with lower levels of satisfaction with diabetes and greater impact of diabetes on quality of life.

CONCLUSIONS — This study provides evidence for the reliability and validity of two measures of quality of life. The two measures examine quality of life from different but complimentary perspectives. The DQOL seems more sensitive to lifestyle issues and contains special questions and worry scales oriented toward younger patients, whereas the SF-36 provides more information about functional health status. Thus, the measures may be used usefully in combination in studies of both type I and type II diabetic patients.

From the Mental Health Unit of the Joslin Diabetes Center, Boston; McLean Hospital, Belmont; and the Department of Psychiatry, Harvard Medical School, Cambridge, Massachusetts.

Address correspondence and reprint requests to Alan M. Jacobson, MD, Joslin Diabetes Center, One Joslin Place, Boston, MA 02215.

Received for publication 3 February 1993 and accepted in revised form 4 November 1993.

DQOL, Diabetes Quality of Life Measure; SF-36, 36-Item Short Form; DCCT, Diabetes Control and Complications Trial; ANOVA, analysis of variance; OHA, oral hypoglycemic agent.

There is increasing recognition that the impact of chronic illnesses and their treatments must be assessed in terms of their influences on quality of life in addition to more traditional measures of medical outcome, such as morbidity and mortality (1). Consequently, investigators have begun developing measures that address patient perceptions of their health-related well-being (2,3). Two strategies for quality of life evaluation have been described: measures that address illness-specific issues and measures that may be used across a wide spectrum of conditions. The rationale for each approach has been described previously (4,5).

Type I and type II diabetes are typical of chronic illnesses that can influence quality of life because the treatments are burdensome and the complications can be debilitating and life-threatening. Yet, relatively little is known about the effects of these related disorders on patient quality of life. A few previous studies suggest patients with diabetes experience a decrease in their quality of life (6–9) compared with healthy individuals and that well-being decreases as complications become more severe (9). However, these studies have important limitations. For example, the Medical Outcomes Study (6), which evaluated a generic measure of quality of life, did not distinguish between the types of diabetes under study and did not examine the effects of complications or type of treatment. Moreover, no studies have compared quality of life findings in diabetic patients using both illness-specific and generic measures. Such comparisons would increase our understanding of the psychometric properties and the clinical utility of these alternative approaches to quality of life assessment among diabetic patients.

We now present findings about the effects of type I and type II diabetes on quality of life using two measures currently used by investigators in clinical studies: the Diabetes Quality of Life Measure (DQOL) (5) and the Medical Out-

come Study Health Survey 36-Item Short Form (SF-36) (6). This study extends prior research by its comparison of two measures to quality of life assessment. Furthermore, it provides new information about the psychometric properties of these two increasingly used measures in heterogeneous and well-defined clinical samples.

RESEARCH DESIGN AND METHODS

— Consecutive patients from the outpatient department of the Joslin Diabetes Center in Boston were identified. All patients with a diagnosis of type I or type II diabetes (10) who were ≥18 years of age and not currently pregnant (to avoid the confounding psychological effects of pregnancy) were contacted by letter. Patients were not excluded on the basis of having diabetes complications. Of the patients who were approached, 88% (n = 240) agreed to participate. These patients filled out questionnaires at the time of an appointment in the outpatient department. At this visit, informed consent was obtained in writing.

The DQOL was designed for use in the Diabetes Control and Complications Trial (DCCT) (5). Initial evaluations in a sample of patients with type I diabetes who had demographic characteristics similar to those of patients randomized into the trial indicated favorable internal consistency and test-retest reliability. The findings from that study showed the DQOL scales were correlated moderately with measures of general well-being, emotional status, and adjustment to illness, thereby providing initial information about the construct validity of the measure (5).

The DQOL has 46 core items rated by the respondent on a 5-point Likert-type scale that ranges from 1 to 5. A score of 1 represents no impact or worries and always satisfied. A score of 5 represents always affected, worried, or never satisfied. When first developed, the DQOL scores were presented as the total of the items of each scale divided by the number of items rated. Thus, a low score indicated good quality of life. However, different investigators (5,9,11) have presented their results using various methods of scoring (9,11,12), suggesting to us that the original approach was not user-friendly. In this study, we used an alternative method of scoring based on the method used in scoring the SF-36 (6,9). Using this method, DQOL scores were arithmetically transformed to a 100-point scale (100 reflects the highest possible quality of life score and 0 the lowest possible quality of life). This scoring approach is described in detail elsewhere (13).

Some DQOL items may not be applicable for certain subjects. This is particularly relevant for the worry scales, because they were developed especially for use in younger patient samples. This study included older adults who were expected to rate some items as not applicable; therefore we only included scale data for any subject if they completed 12 of the 15 satisfaction items, 16 of the 20 impact items, 2 of the 4 diabetes worry items, or 5 of the 7 social/vocational worry items. As a consequence, the number of patients that comprise the data set for each DQOL subscale varies (e.g., n = 228 for the satisfaction scale; n = 217 for the impact scale; n = 219 for the diabetes worry scale; and n = 61 for the social worry scale).

The Medical Outcome Study Health Survey SF-36 (14,15) assesses six domains of functional health status: *1*) physical functioning, 2) effect of physical illness on role functioning, 3) perception of general health, 4) effect of illness on social functioning, 5) discomfort because of pain, and *6*) mental health. Because psychiatric symptom and structured psychiatric interview measures were being collected in another phase of the study, we excluded the mental health subscale of the SF-36 and only evaluated the other five SF-36 subscales. Different versions of this measure have been studied in a variety of outpatient settings with diverse patient populations, including individuals with human immunodeficiency virus infection (16,17) and other chronic illnesses such as arthritis, heart disease, and diabetes (6). These studies indicate favorable psychometric properties including the internal consistency and construct validity of the subscales (6,16,17).

Diabetes complications were identified from a review of patient medical records by a research assistant who was unaware of patient responses to the questionnaires. A second, blinded, research assistant also reviewed the records, and a consensus meeting with a clinician was held where differences in ratings were resolved. For each patient, we noted the presence or absence of all current diabetes-related complications as well as other current medical conditions listed in the record. Two different methods of rating diabetes-related complications were used.

1. A Diabetes Severity Index score was given to the patient based on the medical information given in the chart. The severity of complications experienced by each patient was rated on a 4-point scale where 1 represents no complications present and 4 represents very serious complications present. This method, therefore, allowed for a rating of 4 based on a single serious complication (e.g., severe painful neuropathy or diabetic proliferative retinopathy causing severe vision impairment). The reliability of the scoring procedure was evaluated on a sample of 60 patients. Two research assistants separately rated the medical records. Their scores were compared using the intraclass correlation statistic (F = 0.92; $P \leq$ 0.0001).
2. A number of categories of the complications index were based on the presence/absence of three diabetes complications: *1*) proliferative retinopathy, 2) symptomatic neuropathy, and 3) nephropathy requiring treatment. This approach provided a rating of 0 to 3 complications present. We did not perform a for-

Table 1—*Social and demographic characteristics of patients by diabetes type*

	Type I diabetes	Type II diabetes
n	111	129
Age (years)	44 ± 16	60 ± 12*
Sex *n* (%)		
Male	52 (47)	66 (51)
Female	59 (53)	63 (49)
Marital status *n* (%)		
Married	70 (63)	89 (69)†
Separated/divorced	10 (9)	7 (5.5)
Single	27 (24)	17 (13)
Widowed	4 (4)	16 (12)
Education *n* (%)		
≤High school	25 (22.5)	54 (42)‡
>High school	86 (77.5)	75 (58)
Duration of diabetes (years)	18.8 ± 11.5	12 ± 8*
Type of treatment *n* (%)		
Insulin	111 (100)	68 (53)§
OHA	—	49 (38)
Diet only	—	10 (9)
Diabetes complications *n* (%)		
Retinopathy		
Yes	26 (23.4)	13 (10.1)‖
No	85 (76.6)	116 (89.9)
Neuropathy		
Yes	39 (35.1)	63 (48.8)¶
No	72 (64.9)	66 (51.2)
Nephropathy		
Yes	8 (7.2)	3 (2.3)#
No	103 (92.8)	125 (97.2)

Data are means ± SE unless otherwise noted. * Student's *t* test, $P < 0.0001$. † χ^2, $x = 10.99$, df = 3, $P \leq 0.01$. ‡ χ^2, $x = 10.1$, df = 1, $P \leq 0.001$. § χ^2, $x = 64.7$, df = 2, $P \leq 0.0001$. ‖ χ^2, $x = 7.8$, df = 1, $P \leq 0.005$. ¶ χ^2, $x = 4.6$, df = 1, $P \leq 0.03$. # χ^2, $x = 3.2$, df = 1, P = NS.

mal test of the reliability of the two independent raters on this variable. However, we found that the information on complications required changing in <10 cases at the consensus conference.

The results from these two methods of assessing complications were highly correlated ($r = 0.72$; $P \leq 0.0001$).

Our objective in assessing diabetes complications from medical records was to use them as a marker of disease severity and thereby provide external validation of the quality of life scales. We present data from both methods for comparative purposes.

Statistical analysis

The internal consistency of quality of life subscales was assessed using Cronbach's alpha. We also evaluated the internal consistency of the overall or total DQOL score. Using Pearson correlations, we then examined the relationships among the subscales of the DQOL and SF-36. For patients with type II diabetes, we examined the influence of treatment type using one-way analysis of variance (ANOVA) (diet alone, oral hypoglycemic agents [OHA], insulin injection) on quality of life. We also studied the effect of social-demographic variables on the quality of life measures. In this instance, we anticipated that some demographic variables would be associated with quality of life (marital state, age, and duration of diabetes), whereas others would not be linked to quality of life (sex and education level). Finally, we used hierarchical multiple regression analyses to model the unique effects of complications on quality of life, after accounting for relevant demographic variables, and treatment type among type II patients.

RESULTS

Characteristics of the patients

As expected, patients with type II diabetes were older (Table 1). They were also more likely to be widowed, less likely to be single, divorced, or to have received post–high school education. On average, they had shorter durations of diabetes at the time of study. Of the patients with type II diabetes, just >50% used insulin. Type II patients were less likely to have complications.

Type II diabetic patients reported a significantly better quality of life than type I patients on the DQOL and on the physical functioning and social functioning subscales of the SF-36. For example, the total DQOL score for type I patients was 67 (12.9) vs. 75 (12.2) for type II patients. Because of the demographic and clinical differences between patients with type I and type II diabetes, we performed a series of hierarchical regression analyses in which diabetes type was entered into the model predicting each of the quality of life outcomes after age, marital status, education, illness duration, and severity of complications. We found that patients with type II diabetes still reported less impact of diabetes ($P < 0.01$), fewer diabetes worries ($P < 0.02$), and better perceived social functioning on the SF-36 ($P < 0.01$). The groups were not differentiated in terms of physical functioning, role functioning because of physical status, pain, general health perceptions, or diabetes satisfaction or social worries.

Reliability of the DQOL and SF-36 subscales

We computed the reliability coefficients (Cronbach alpha) for the subscales of both quality of life measures for the two diabetes groups separately. The Cron-

Table 2—*Pearson correlations of DQOL and SF-36 scales for type I and type II diabetic patients*

	SF-36									
	Type I diabetes					Type II diabetes				
	Physical functioning	Social functioning	Role physical functioning	Pain score	General health score	Physical functioning	Social functioning	Role physical functioning	Pain score	General health score
DQOL										
Total	0.38*	0.56*	0.51*	0.33†	0.60*	0.35*	0.34*	0.40*	0.38*	0.43*
Impact	0.37*	0.59*	0.49*	0.30†	0.58*	0.35*	0.32†	0.34*	0.39*	0.41*
Satisfaction	0.30†	0.43*	0.44*	0.28†	0.50*	0.33†	0.37*	0.42*	0.36*	0.42*
Diabetes worry	0.12	0.34†	0.26†	0.16	0.44*	0.08	0.19	0.26†	0.19	0.23
Social worry	0.21	0.46†	0.31	0.13	0.31	0.001	0.05	0.17	−0.003	0.17

* $P \leq 0.0001$. † $P < 0.01$.

bach alpha coefficients ranged from 0.47 to 0.87 on the DQOL subscales and from 0.78 to 0.91 on the SF-36 subscales. Except for the lower alpha levels for the DQOL diabetes worry subscale (alpha = 0.47 and 0.49) among type I and type II patients, respectively, these reliability coefficients were very similar to those reported previously for the two measures (5,6,14,16–17).

Relationships between the DQOL and SF-36 subscales

The subscales of the DQOL and SF-36 were modestly related to one another (Table 2). The magnitude of the correlations, although not reaching statistical significance, was generally larger among the type I patients than among the type II patients. Compared with the satisfaction and impact subscales, the diabetes and social worry subscales of the DQOL were typically less strongly correlated with the SF-36 subscales. Among the SF-36 subscales, the pain and physical functioning subscales were the least strongly correlated with the subscales of the DQOL.

Influence of demographic factors on quality of life

In general, the quality of life measures were not influenced by characteristics such as sex or education level. Age appeared to have limited influence on quality of life. Among type I patients, older individuals reported worse physical functioning ($r = -0.47$, $P < 0.0001$), but no age effects emerged in relationship to other SF-36 scales or to any diabetes-related quality of life scales. Among type II patients, physical functioning deteriorated with age ($r = -0.21$, $P < 0.05$), and overall diabetes-specific quality of life also deteriorated with age ($r = 0.34$, $P < 0.05$). No other age effects were detected. The pattern of relationships between marital status and quality of life suggested that separated or divorced individuals generally experienced worse quality of life than those who were single or married. Duration of diabetes did not influence quality of life ratings on either measure across both type I and type II patient groups.

Treatment and quality of life

In patients with type II diabetes, treatment influenced diabetes-related quality of life, with patients on insulin reporting the lowest levels of satisfaction ($F = 3.96$; $df = [2,222]$; $P < 0.05$) and greatest impact ($F = 14.84$; $df = [2,221]$; $P < 0.0001$) in comparison with those on OHA or diet alone. One interesting exception was found. Patients on OHA worried more about their future with diabetes than patients on diet alone or those already taking insulin ($F = 5.55$, $df = [2,210]$; $P < 0.05$). Only one SF-36 scale distinguished patients receiving different treatments: the general health perception scale of the SF-36 revealed better quality of life for patients on diet treatment alone ($F = 3.57$, $df = [2,230]$; $P < 0.05$).

Diabetes complications and quality of life

To examine the relationship between diabetes and quality of life, we compared patients with different frequency and severity of the major diabetes complications. Specifically, we performed hierarchical regression analyses including demographic factors that, as shown previously, affect quality of life scores (age and marital status) and, among type II patients, treatment. These factors were entered into the model first followed by either frequency or severity of complications (Tables 3 and 4). All SF-36 scales were predicted by severity of diabetes complications and among type I patients by number of complications. Among type II patients, the number of complications was a weak predictor of functional health status as indexed by the SF-36 scales. Note that type II patients had fewer complications than type I patients. Indeed, only one type II patient had three complications. Therefore, for these analyses, categories two and three were combined. A

Table 3—*Hierarchical regression analyses examining the effect of number of complications on quality of life*

	Model 1 R^2	Change in R^2	F_{obs} test
DQOL			
Type 1 diabetes			
Total	0.01	0.16	10.20*
Impact	0.02	0.09	5.86†
Satisfaction	0.04	0.24	18.06*
Diabetes worry	0.002	0.002	0.09
Social worry	0.06	0.11	1.81
Type II diabetes			
Total	0.32	0.06	2.73
Impact	0.29	0.04	2.09
Satisfaction	0.17	0.09	4.42†
Diabetes worry	0.08	0.04	1.32
Social worry	0.14	0.37	3.08
SF-36			
Type 1 diabetes			
Physical functioning	0.28	0.15	14.73*
Social functioning	0.09	0.11	7.34‡
Role physical functioning	0.05	0.19	13.54*
Pain	0.09	0.09	5.86†
General health	0.08	0.18	12.74*
Type II diabetes			
Physical functioning	0.36	0.006	0.31
Social functioning	0.06	0.04	1.50
Role physical functioning	0.15	0.25	14.13*
Pain	0.29	0.01	0.52
General health	0.03	0.006	0.22

Model 1 includes age and marital status for patients with type I diabetes and age, marital status, and treatment type for patients with type II diabetes. Change in R^2 occurs when the number of complications score is added to model 1. *F* test and significance level is indicated for change in variance when the complications variable is added to the model. * $P \leq 0.005$. † $P \leq 0.05$. ‡ $P \leq 0.01$.

similar pattern of findings was found in examining the DQOL with the total score, satisfaction, and impact scales consistently sensitive to severity of complications and less consistently responding to number of complications. As noted in prior analyses of treatment type, the diabetes worry and social worry scales respond differently than the impact and satisfaction scales, showing little systematic variations with severity or frequency of complications.

The cumulative effect of increasing numbers of complications on quality of life among type I patients is presented in Figs. 1 and 2. Using ANOVA, significant main effects were seen for the total DQOL, the DQOL impact and satisfaction scales, and all SF-36 scales. Post-hoc tests revealed that the effects on the DQOL were determined largely by differences between patients with zero to two complications versus those with three complications. Post-hoc tests showed a more complex effect of complications on SF-36 scales than seen for the DQOL.

CONCLUSIONS— This study provides information about quality of life and its assessment among patients with type I and type II diabetes. Several conclusions can be drawn from this study: The subscales of the DQOL and the total DQOL score generally demonstrate favorable degrees of internal consistency in type I and type II diabetic patients. Thus, our results confirm prior findings regarding internal consistency of the DQOL scales, but in a somewhat older and far more heterogeneous sample of type I patients attending an outpatient diabetes clinic. Furthermore, this study presents, for the first time, data on the internal consistency of the DQOL in patients with type II diabetes, with findings very similar to those from type I patients.

Unlike the initial sample (5), which was chosen to match the demographic entry criteria of the DCCT (e.g., 13–39 years of age, duration of illness 1–15 years, no clinically evident complications) (18), many of the patients we studied had clinically identified and symptomatic complications of diabetes. This difference could have accounted for the relatively low level of internal consistency reported for the diabetes worry scale.

The DQOL appeared sensitive to external criteria of disease severity (e.g., the severity of complications) with the total, satisfaction, and impact scores shown to deteriorate as the severity of complications increased. Furthermore, among type II patients, taking insulin also was associated with lower patient satisfaction and a greater impact of diabetes. Thus, the impact and satisfaction scales of the DQOL also appeared sensitive to the lifestyle effects of different diabetes treatments.

The worry scales appeared less sensitive to differences in severity of complications. In addition, among type II patients, the kind of treatment was associated with diabetes-related worries in a complex way. These treatment group comparisons suggest that future worries about diabetes are greater in patients who are on OHA compared with those not yet required to start medications or already receiving insulin. Thus, worries about the future of diabetes are possibly stimulated by the start of a pharmacological treatment but recede once the anticipated injections begin. This could reflect anticipa-

Table 4—*Hierarchical regression analyses examining the effect of diabetes severity on quality of life*

	Model 1 R^2	Change in R^2	F_{obs} test
DQOL			
Type 1 diabetes			
Total	0.03	0.17	21.60*
Impact	0.005	0.16	19.74*
Satisfaction	0.09	0.14	18.17*
Diabetes worry	0.003	0.05	5.54†
Social worry	0.17	0.03	1.28
Type II diabetes			
Total	0.13	0.05	7.19‡
Impact	0.08	0.09	12.21*
Satisfaction	0.14	0.05	6.55†
Diabetes worry	0.04	0.009	1.05
Social worry	0.26	0.002	0.05
SF-36			
Type 1 diabetes			
Physical functioning	0.27	0.18	33.08*
Social functioning	0.03	0.09	10.59*
Role physical functioning	0.07	0.11	14.00*
Pain	0.09	0.10	12.97*
General health	0.06	0.21	29.14*
Type II diabetes			
Physical functioning	0.10	0.05	7.12‡
Social functioning	0.007	0.03	43.42*
Role physical functioning	0.02	0.05	6.43†
Pain	0.02	0.05	6.96‡
General health	0.03	0.12	16.50*

Model 1 includes age and marital status for patients with type I diabetes and age, marital status, and treatment type for patients with type II diabetes. Change in R^2 occurs when Diabetes Severity Index score is added to Model 1. F test and significance level is indicated for change in variance when the complications variable is added to the model. * $P \leq 0.005$. † $P \leq 0.05$. ‡ $P \leq 0.01$.

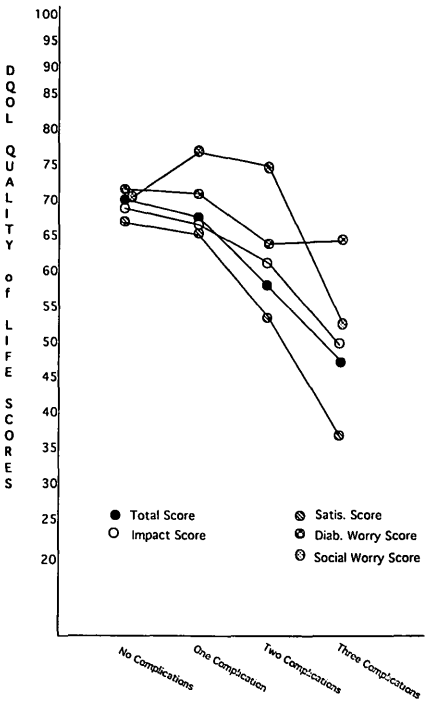

Figure 1—*DQOL scores for type I patients by number of complications. Results of one-way ANOVA with post-hoc tests comparing pair-wise means at the* $P < 0.05$ *level. Total score:* $F = 7$; $P < 0.0002$; *0, 1, 2 > 3 complications. Impact score:* $F = 6.2$; $P < 0.007$; *0, 1, 2 > 3. Satisfaction score:* $F = 6.8$; $P < 0.003$; *0, 1, 2 > 3. Diabetes worry score:* $F = 1.89$; $P = NS$. *Social worry score:* $F = 1.28$; $P = NS$.

tory anxiety triggered by a treatment that signifies to the patient that he or she has an illness that necessitates medication as opposed to diet regulation. Of course, patients were not assigned to different treatments, so these associations must be interpreted cautiously.

As suggested previously (19), assessing future worries may be especially useful among adolescent patients with diabetes before the onset of long-term complications. Indeed, the worry scales were incorporated in the DQOL (5) because of recognition that worry about the future might increase in young patients exposed to an intensive treatment regimen (i.e., the experimental treatment condition of the DCCT) (20). Because the items were selected with adolescents in mind, the scales are less appropriate to concerns of adults and elderly patients. This is especially true for the social-vocational worry scale. Thus patients with type II diabetes rated frequently some of the social-vocational worry items as not applicable. Consequently, our conclusions about the social-vocational scale in particular must be tempered by the small number of patients who rated at least five items as applicable to them.

Different versions of the Medical Outcome Study Health Survey have been used in patients with a wide variety of illnesses and backgrounds. However, data regarding its psychometric properties among diabetic patients has been derived primarily from one large ambulatory care survey that evaluated individuals whose type was not identified or used in the data analyses (6). Furthermore, important clinical characteristics, such as severity of complications, have not been addressed. Thus, available data on its use in diabetic patients is based on samples of patients with known sociodemographic characteristics but who were not well described with regard to complications. Findings from our study provide information about the SF-36 in well-characterized samples of type I and type II patients.

Our study has shown that the SF-36 scales exhibit favorable internal

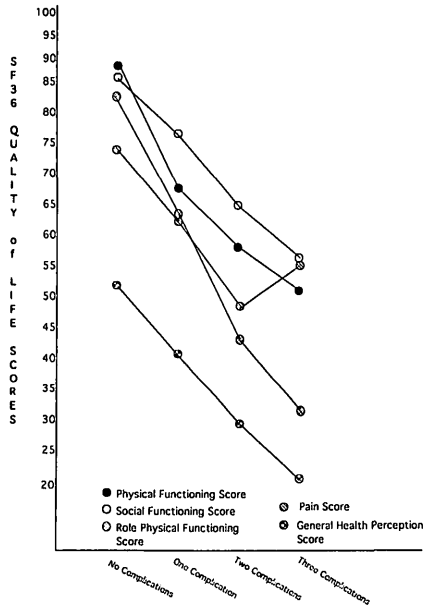

Figure 2—*Medical Outcome Study Health Survey SF-36 scores for type I patients by number of diabetes complications. Results of one-way ANOVA with post-hoc tests comparing pair-wise means at the* $P < 0.05$ *level. Physical functioning score:* $F = 14.7$; $P < 0.0001$; $0 > 1, 2, 3$ *complications. Social functioning score:* $F = 4.5$; $P < 0.006$; $0 > 3$. *Role-physical functioning score:* $F = 7.8$; $P < 0.0001$; $0 > 2, 3$. *Pain score:* $F = 7.5$; $P < 0.0001$; $0 > 2$. *General health score:* $F = 11.3$; $P < 0.0001$; $0 > 2, 3$; $1 > 3$.

consistency in patients with both type I and type II diabetes. The validity of the SF-36 was supported by the size and direction of relationships with clinical characteristics of the patients. As shown with the DQOL, quality of life was found to be lower among patients with more severe diabetes complications. Indeed, the effect of even one complication led to a decrease on the physical function scale of the SF-36. Patients with one complication did not report less satisfaction or greater impact on the DQOL when compared with patients without any complications. These findings also indicate that the SF-36 is less sensitive than the DQOL to lifestyle issues; e.g., the effects of diet, OHA, or insulin treatment. Note that a prior study also suggested that the DQOL was sensitive to lifestyle effects, whereas a generic quality of life measure was not (12). On the other hand, the SF-36 appears more sensitive to changes in the number and severity of complications. The differences in the sensitivity of the DQOL, compared with the SF-36, probably reflects differences in item content with more DQOL items evaluating treatment and life experiences. Almost all SF-36 items report physical function effects. Thus, the DQOL may be especially useful for detecting quality of life effects where changes in morbidity may not be detectable, whereas the SF-36 may be a more sensitive indicator of changes in physical state.

The size of the correlations of the SF-36 subscales with the DQOL subscales demonstrates that these two approaches to measuring quality of life overlap but are not redundant. Because each method can offer different information and may be differentially sensitive to clinically relevant issues, a strategy of incorporating both may be useful. This is consistent with prior suggestions for assessing qualities of life with multiple instruments that measure generic and illness-specific issues (1,4,5). Where the primary goal is comparing the results of a particular study with those conducted on different illness populations, generic measures such as the SF-36 are particularly valuable. Furthermore, preference indexes, such as the quality of well-being scale (2), provide a single score that can be used in the calculations of quality of life adjusted years. These indexes provide utility ratings that can be used in economic analyses of the effect of treatment. If the goal of quality of life assessment includes careful delineation of illness-specific problems, a method such as the DQOL is better suited.

Little is known about the level of satisfaction, impact, or frequency of functioning that could be considered as representing good or poor quality of life. As data are gathered from typical samples, such as in this study, we can derive normative data that provide a basis for drawing such conclusions. For example, using findings from this study and a prior study of younger healthier type I patients (5), we should anticipate that patients with type I diabetes without complications or other impairing conditions will typically rate themselves on the DQOL as generally satisfied or only slightly impacted (a rating of about 2.0 on the original scale and a rating of 70–75 on the 100-point scale). The presence of three complications, as suggested by this study, is associated with 20–25 point lower total DQOL scores. Similarly, a recent study of type I patients undergoing a kidney only or a combined kidney-pancreas transplant (12) suggests these adults perceive their quality of life before transplant at similar levels to our type I sample with triopathy (DQOL total score of ~50).

In summary, this study presents the first comparison between two increasingly used measures of quality of life in heterogeneous samples of patients with type I and type II diabetes. These findings support the favorable psychometric properties of the DQOL and SF-36 and expand our understanding of their validity. Furthermore, these data underline ways that the two measures complement one another.

Acknowledgments— This study was supported in part by a donation from Herbert Graetz and National Institues of Health Grants AM-27845 and DK-42315–02.

References

1. Croog S, Levine S, Tecta M, Brown B, Bulpitt C, Jenkins C, Klerman G, Williams G: The effects of antihypertensive therapy on the quality of life. *N Engl J Med* 314:1657–64, 1986
2. Bush JM, Kaplan RM: Health-related quality of life measurement. *Health Psychol* 1:61–80, 1982
3. Bergner M, Bobbitt RA, Carter WB, Gibson BS: The sickness impact profile: development and final revision of a health status measure. *Med Care* 19:787–805, 1981
4. Guyatt G, Bombardier C, Tugwell P: Mea-

suring disease-specific quality of life in clinical trials. *Can Med Assoc J* 134:889–95, 1986
5. DCCT Research Group: Reliability and validity of a diabetes quality of life measure for the Diabetes Control and Complications Trial (DCCT). *Diabetes Care* 11: 725–32, 1988
6. Stewart AL, Greenfield S, Hays RD, Wells K, Rogers WH, Berry SD, McGlynn EA, Ware JE: Functional status and well-being of patients with chronic conditions. *JAMA* 262:907–13, 1989
7. Nerenz DR, Repasky DP, Whitehouse FW, Kahkonen DM: Ongoing assessment of health status in patients with diabetes mellitus. *Med Care* 30:112–23, 1992
8. Mayou R, Bryant B, Turner R: Quality of life in non-insulin-dependent diabetes and a comparison with insulin-dependent diabetes. *J Psychosom Res* 34:1–11, 1990
9. Lloyd CE, Matthews KA, Wing RR, Orchard TJ: Psychosocial factors and complications of IDDM. *Diabetes Care* 15: 166–72, 1992
10. Bennett P: Classification and diagnosis of diabetes mellitus and impaired glucose tolerance. In *Textbook of Diabetes*. Pickup J, Williams G, Eds. Oxford, England, Blackwell, 1991, p. 37–46
11. Selam JL, Micossi P, Dunn FL, Nathan DM, Implantable Insulin Pump Trial Study Group: Clinical trial of programmable implantable insulin pump for type I diabetes. *Diabetes Care* 15:877–84, 1992
12. Nathan DM, Fogel H, Norman D, Russell PS, Tolkoff-Rubin N, Delmonico FL, Auchincloss H, Camuso J, Cosimi AB: Long-term metabolic and quality of life results with pancreatic/renal transplantation in insulin-dependent diabetes mellitus. *Transplantation* 52:85–91, 1991
13. Jacobson AM, DCCT Research Group: The diabetes quality of life measure. In *Handbook of Psychology and Diabetes*. Bradley C, Ed. In press
14. Ware JH, Sherbourne CD: The MOS 36-Item Short Form Health Survey (SF-36). I. Conceptual framework and item selection. *Med Care* 30:473–83, 1992
15. International Resource Center (IRC) for Health Care Assessment: *How to Score the MOS 36-Item Short-Form Health Survey (SF-36)*. Boston, New England Medical Center Hospitals, 1991
16. Wachtel T, Piette J, Mor V, Stein M, Fleishman J, Carpenter C: Quality of life in persons with human immunodeficiency virus infection: measurement by the medical outcomes study instrument. *Ann Intern Med* 116:129–67, 1992
17. Wu AW, Rubin HR, Mathews WC, Ware JE, Brysk LT, Hardy WD, Bozzette SA, Spector SA, Richman DD: A health status questionnaire using 30 items from the Medical Outcomes Study: preliminary validation in persons with early HIV infection. *Med Care* 29:786–98, 1991
18. DCCT Research Group: Diabetes Control and Complications Trial (DCCT): design and methodological considerations for the feasibility phase. *Diabetes* 35:530–45, 1986
19. Kramer J, Jacobson AM, Ryan C, Murphy W, the DCCT Research Group: Psychological aspects of the Diabetes Complications and Control Trial. In *The Technology of Diabetes Care*. Bradley C, Christie M, Eds. London, Wiley. In press