

Impact of Diabetes Screening on Quality of Life

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OBJECTIVE— Diagnosis of a chronic illness can have a negative impact on patients' perception of their well-being ("labeling" effect). We sought to determine the effects of a new diagnosis of diabetes, discovered by systematic screening, on patients' health-related quality of life (HRQoL) 1 year after diagnosis.

RESEARCH DESIGN AND METHODS— We performed diabetes screening at the Durham Veterans Affairs Medical Center of 1,253 outpatients, aged 45–64 years, who did not report having diabetes. Our initial screen was a serum HbA_{1c} measurement. All subjects with HbA_{1c} \geq 6.0% were invited for follow-up measurement of blood pressure and fasting plasma glucose. A case of unrecognized diabetes was defined as HbA_{1c} \geq 7.0% or fasting plasma glucose \geq 7 mmol/dl. HRQoL was measured by Medical Outcomes Study Short Form 36 (SF-36) for all patients at baseline and 1 year after enrollment. Linear multivariable models were used to determine the independent effect of the new diagnosis of diabetes on HRQoL.

RESULTS— Mean SF-36 Physical Component Score (PCS) for all patients was 36.2, and mean Mental Component Score (MCS) was 49.6. A total of 56 patients (4.5%) were found to have diabetes at screening. Patients found to have diabetes at screening had mean PCS of 35.6, which was not different from a mean PCS of 36.3 for those patients found not to have diabetes ($P = 0.67$). After adjusting for baseline PCS values, PCS 1 year after screening was similar for patients with and without diabetes found at screening ($P = 0.95$). Similarly, patients found to have diabetes at screening had mean MCS of 48.8; those found not to have diabetes had MCS of 49.6 ($P = 0.70$). After adjusting for baseline MCS values, MCS 1 year after screening was also similar between the two groups ($P = 0.77$).

CONCLUSIONS— For patients with a new diagnosis of diabetes discovered through systematic screening, HRQoL is similar to patients found not to have diabetes. Furthermore, HRQoL scores remain stable over the year after screening. This suggests that screening for diabetes has minimal, if any, "labeling" effect with respect to HRQoL.

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The effects of systematic disease screening may either improve or worsen short-term health-related quality of life (HRQoL). Systematic but targeted screening of asymptomatic patients may identify patients with a disease that has vague but disabling symptoms.

Subsequent treatment may lead to rapid improvement in HRQoL, to the degree that the patients' perception of ill-being was attributable to the unrecognized disease, as has been described in screening for hypothyroidism (1–3). However, the experience of being identified with a

chronic disease may itself lead to a decline in HRQoL. This phenomenon, sometimes called "labeling," has been demonstrated in the case of mass screening for abdominal aortic aneurysm (4) and may exist as well in screening for hypertension (5–7).

Studies that measure HRQoL in patients with established diabetes show lower HRQoL for patients with diabetes than for patients without. Most studies assessing the aspects of diabetes associated with lower HRQoL have shown that HRQoL depends on severity of complications and comorbidity (8–10). However, these studies are performed in patients already diagnosed with diabetes and, therefore, beyond the point at which either initial treatment or labeling might affect their HRQoL. Early in its course, diabetes is considered a disease of vague symptoms. It is therefore reasonable to consider the possibility that identification and treatment of unrecognized diabetes might rapidly improve HRQoL. Similarly, it is also reasonable to consider that the diagnosis of diabetes might cause a labeling effect. No published studies have addressed these issues in the context of asymptomatic screening for diabetes.

We had two objectives in this study. First, we sought to measure possible differences in HRQoL associated with unrecognized diabetes. Second, we sought to determine whether the change in HRQoL over the first year after diagnosis is different for patients found to have diabetes at screening than for those not to have diabetes, that is, to determine whether screening for diabetes and the associated new diagnosis of diabetes show any "labeling" effect regarding HRQoL.

RESEARCH DESIGN AND METHODS

Patients

We identified all patients aged 45–64 years who had kept an outpatient visit at the Durham Veterans Affairs Medical Center (DVAMC) between October 1996 and March 1999. We sent all these patients a one-page questionnaire that asked whether the patient had diabetes and whether we could contact them by tele-

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Abbreviations: DVAMC, Durham Veterans Affairs Medical Center; HRQoL, health-related quality of life; MCS, Mental Component Score; PCS, Physical Component Score; SF-36, Medical Outcomes Study Short Form 36; VA, Veterans Administration.

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

phone for a research study. Respondents denying knowledge of diabetes or “high blood glucose” and agreeing to be telephoned were contacted by telephone and scheduled for enrollment into the study at their next visit to the DVAMC.

Diabetes screening protocol

The study and enrollment strategy were approved by the Institutional Review Board of the DVAMC. Before enrollment, we obtained written informed consent from all subjects. At the initial visit, we once again asked about diabetes and excluded patients who said they had diabetes. We also excluded patients who had had a prescription filled at the DVAMC pharmacy for a hypoglycemic medication, had a short life expectancy (incurable cancer, heart or lung disease requiring oxygen), or had no easy access to a telephone.

We obtained HbA_{1c} measurements on all subjects. All subjects with HbA_{1c} $\geq 6.0\%$ were invited back for follow-up fasting plasma glucose measurement. Diabetes was defined as HbA_{1c} $\geq 7.0\%$ or fasting plasma glucose ≥ 7 mmol/l (126 mg/dl). Although screening and diagnosis of diabetes by means of HbA_{1c} is not standard, the approach was used for two reasons. First, the convenience of performing a nonfasting test allowed rapid enrollment of patients into the study. Second, the nonfasting test mimics a reasonable strategy that might be used by a medical center to perform mass screening of patients, whether or not they are fasting. At the conservative diagnostic cut point that we chose for further evaluation (HbA_{1c} = 6.0%, 2 SDs above mean and the upper limit of normal on our machine) and in a screening population, the sensitivity of HbA_{1c} for the diagnosis of diabetes is 75–93% (11,12).

Outcome measures and covariates

At enrollment, we obtained multiple demographic and questionnaire measures. Comorbidity and medical illnesses were assessed using the Kaplan-Feinstein comorbidity index for patients with diabetes (12), modified for use in patient interview format. This instrument categorizes both individual disease and overall comorbidity as being absent, mild, moderate, or severe. We assessed exercise by using the Framingham Physical Activity Index, a valid measure of exercise that predicts cardiovascular morbidity (13). The index

is a continuous measure, but because of grossly nonnormal distribution, we divided patients into higher and lower physical activity groups by dividing patients at the median activity level.

We measured HRQoL with the Medical Outcomes Study Short Form 36 (SF-36) questionnaire (14,15). Briefly, the SF-36 is a 36-item questionnaire developed and validated in a cohort of medical outpatients. The Physical Component Scale (PCS) and Mental Component Scale (MCS) are established SF-36 scales that measure HRQoL attributable to physical and mental health, respectively (16). Both scales are normalized to a population mean of 50 and SD of 10.

We chose the SF-36 for three primary reasons. First, we were unable to choose a diabetes-specific measure of HRQoL, as there was no unifying disease for our entire population. Second, the SF-36 has outstanding discrimination in Veterans Administration (VA) populations (17–19), in that it has a near-normal distribution for VA patients with no aggregation of scores near either end of the scale. More sensitive global health status measures are designed for a healthier population than VA patients, and responses among VA users tend to cluster near the bottom of the scale, leaving less room for changes potentially caused by external events (20). Third, because of its extensive use, the magnitude of changes in the SF-36 can be easily clinically interpreted. The smallest clinically important change in PCS is ~ 2 points (21,22), roughly equivalent to the difference in quality of life between healthy populations and populations with hypertension.

Analysis

The sample size goal of $n = 1,255$ was chosen to provide narrow CIs around the prevalence of unrecognized diabetes in the target population. We defined the prevalence of unrecognized diabetes as the proportion of new cases identified in the sample. Descriptive statistics were computed. Unadjusted comparisons between patients with and without diabetes were performed using Student's *t* tests for continuous variables and χ^2 for categorical variables. Multivariable analysis for baseline SF-36 data was performed using traditional linear regression. Multivariable analysis for follow-up SF-36 data was performed using ANCOVA. All multivariable models were performed with both

Table 1—Baseline demographic and clinical characteristics of study patients (N = 1,253).

Demographic characteristics	
Age	55 (6)
Sex (% male)	94
Race	
White	69
African-American	29
Other	2
Clinical characteristics	
Comorbidity (Kaplan-Feinstein scale)	
None	5
Mild	61
Moderate	21
Severe	13
Weight >120% of ideal	60
Quality of life	
SF-36 Physical Component Score	36 (12)
SF-36 Mental Component Score	50 (14)

*Data are mean (SD) or %.

case deletion and multiple imputation methods for handling missing data (23). Results for the two approaches showed no important differences, and data from the case deletion models are presented. All analyses were performed using the SAS analysis system (SAS Institute, Cary, NC).

RESULTS

Patients

We mailed letters to 11,145 patients, and 4,994 (45%) subjects responded. Of these, 1,085 subjects (22%) reported having diabetes, and 529 surveys (11%) were incomplete or otherwise ineligible; therefore, a total of 3,380 subjects were eligible for the study. We contacted 1,452 (43% of eligible respondents) before reaching our target sample size of 1,255 enrolled patients. Two subjects were later found to have known they had diabetes and were excluded, for a total of 1,253 patients.

The baseline demographic and clinical characteristics of the patients are described in Table 1. A total of $\sim 29\%$ of subjects described their race as African-American, and 60% were $>120\%$ of their ideal body weight. Comorbid illness was common, with only 5% having no comorbid illness and 34% having moderate or severe comorbid illness. Mean baseline SF-36 PCS and MCS were 36.2 and 49.6, respectively.

Table 2—Quality of life for patients with and without diabetes discovered at screening (N = 1,253).

	Patients without diabetes, baseline (N = 1,177)	Patients with diabetes, baseline (N = 56)
Physical Component Scale	36.3 (12.2)	35.6 (10.9)
Mental Component Scale	49.6 (14.0)	48.8 (14.1)
	Patients without diabetes, 1 year (N = 1,056)	Patients with diabetes, 1 year (N = 53)
Physical Component Scale	35.2 (11.8)	34.6 (10.9)
Mental Component Scale	48.2 (14.3)	48.0 (14.6)

Data are means (SD). No differences, neither between patients with and without diabetes nor between baseline and 1 year later, were significant at $P < 0.05$.

Treatment of patients with diabetes

We performed medical record review for 54 of the 56 patients found to have diabetes at screening (two records could not be retrieved). Of the 54, 21 (39%) received some form of pharmacotherapy, 13 (24%) had lifestyle modification only, and 20 (37%) had no evidence of any treatment plan for their diabetes. There was no change in physical activity for these patients over the year of follow-up, and physical activity was not different between patients diagnosed with diabetes and those found not to have diabetes either at baseline or at follow-up. For the 39 patients for whom HbA_{1c} was performed within 4 months of the follow-up date, the mean baseline HbA_{1c} was 6.9 and the follow-up was 6.7 ($P = 0.16$).

HRQoL in patients with and without diabetes

Table 2 shows the PCS and MCS values for patients found to have diabetes and

patients found not to have diabetes at screening. Compared with subjects without unrecognized diabetes, subjects with unrecognized diabetes at baseline had clinically and statistically insignificantly lower PCS (35.6 vs. 36.3, $P = 0.67$) and MCS (48.8 vs. 49.6, $P = 0.70$). Patients with and without diabetes both experienced ~1-point decrease in both PCS and MCS over the year of follow-up. Therefore, after 1 year of follow-up, the difference between patients with and without previously unrecognized diabetes was both clinically minimal and statistically insignificant for both PCS (34.6 vs. 35.2, $P = 0.68$) and MCS (48.0 vs. 48.2, $P = 0.94$).

Multivariable modeling

To ascertain that the lack of difference between patients with and without diabetes was not attributable to confounding by predictors of HRQoL, we performed multivariable analyses adjusted for all known

predictors of HRQoL measured in our study. Independent predictors of baseline and 1-year PCS and MCS are shown in Table 3. Most importantly, the diagnosis of diabetes at screening was not independently associated with either PCS or MCS. This was true both at baseline and, after adjusting for baseline values, for 1-year follow-up PCS and MCS.

As expected, comorbid illness was associated with lower PCS, both at baseline and 1 year later, indicating that severity of comorbid illness is the major predictor both of physical HRQoL and of imminent change in HRQoL. Higher baseline PCS scores were also statistically associated with higher physical activity, and this association was clinically significant (i.e., >2-point change in PCS). Older age was statistically significantly associated with increased PCS, but the PCS changes attributable to age were not of a clinically relevant magnitude. Older age and increased physical activity were statistically associated with an increase in MCS both at baseline and at 1-year follow-up. Baseline MCS changes attributable to age and activity were of a clinically relevant magnitude, but the associations with follow-up MCS were not of a clinically important magnitude. Neither race nor sex were independently associated with baseline or follow-up PCS or MCS.

CONCLUSIONS— We measured HRQoL in a large sample of VA outpatients who received systematic screening for diabetes. Our patients had the same poor physical HRQoL and relatively nor-

Table 3—Characteristics independently associated with quality of life before and 1 year after screening for diabetes.

Characteristic	Baseline PCS	Follow-up PCS	Baseline MCS	Follow-up MCS
Demographics				
Age (10-year increase)	1.5 (0.3, 2.6)*	0.3 (−0.5, 1.1)	5.1 (3.7, 6.5)*	2.0 (0.9, 3.0)*
Non-white race	1.3 (−2.7, 0.1)	0.9 (−1.9, 0.1)	0.2 (−1.9, 1.4)	−0.1 (−1.1, 1.3)
Female sex	2.1 (−0.7, 4.8)	0.5 (−1.4, 2.5)	1.7 (−1.7, 5.0)	1.7 (−0.7, 4.0)
Comorbidity				
No comorbidity	Reference	Reference	Reference	Reference
Mild comorbidity	−11.6 (−14.6, −8.5)*	−3.8 (−6.0, −1.6)*	−0.3 (−4.1, 3.3)	−1.2 (−3.8, 1.4)
Moderate comorbidity	−13.1 (−16.4, −9.8)*	−4.3 (−6.6, −1.9)*	−0.3 (−4.3, 3.6)	−0.6 (−3.4, 2.2)
Severe comorbidity	−15.2 (−18.7, −11.7)*	−4.4 (−6.9, −1.9)*	−3.1 (−7.2, 1.1)	−1.2 (−4.2, 1.7)
Exercise level	6.7 (5.4, 8.0)*	−0.6 (−2.8, 1.6)	5.7 (4.2, 7.2)*	1.5 (0.4, 2.6)*
Quality of life, affect				
Baseline PCS	NA	0.70 (0.66, 0.74)*	Not included	Not included
Baseline MCS	Not included	Not included	NA	0.75 (0.71, 0.79)*
Screened (+) for diabetes	0.4 (−2.6, 3.5)	−0.1 (−2.1, 2.0)	0.5 (−4.2, 3.1)	−0.4 (−2.9, 2.2)

Data are regression parameter estimates for association with PCS or MCS, with 95% CIs for that parameter estimate in parentheses. * $P < 0.05$

mal mental HRQoL usually associated with patients at VA medical centers (17,24). In this sample, we found no association between unrecognized diabetes and HRQoL assessed by a well-validated health status measure. This finding is in agreement with most published studies in diabetes and HRQoL. Other studies have shown that HRQoL in patients with diabetes is predominantly related to the prevalence of complications and comorbid illness (8–10). In this study of diabetes screening, in which patients are diagnosed with diabetes earlier in the course of their disease, most patients will not have complications. Therefore, we observe that in our sample, comorbidity is the primary determinant of HRQoL.

Additionally, 1 year after screening, there was no discernible HRQoL difference between patients with diabetes at screening and those who did not have diabetes. Therefore, the diagnosis of diabetes does not impact significantly on HRQoL 1 year after diagnosis. These findings hold true for both physical and mental HRQoL. The implications of our 1-year follow-up findings are twofold. First, the diagnosis and treatment of diabetes discovered at opportunistic screening, followed by informing the patient and provider of this diagnosis, does not seem to make a noticeable positive impact on HRQoL as measured by our global health status measure. This is not surprising, because complications and comorbidities are the primary determinant of HRQoL in patients with diabetes, and complications are unlikely to develop within 1 year of the early diagnosis of diabetes.

Second, if there is any adverse effect of being labeled with the diagnosis of diabetes, this effect is either short-lived or is not reflected in our measure of HRQoL. This does not preclude the presence of a labeling phenomenon in diabetes screening, because global health status is only one dimension of what might be referred to as “labeling.” Other factors, such as anxiety and depression, may factor into each patient’s response to the diagnosis of diabetes. However, to the extent that major or even mild anxiety or depression is usually correlated with measurable deficits in global health status (25–28), our data suggest that the impact of other dimensions of labeling is likely to be relatively modest in diabetes screening.

A relatively small number of patients

with diabetes were discovered at screening in this study. However, the association between diabetes and both baseline and follow-up HRQoL was so minimal that 95% CIs excluded any changes in HRQoL related to the presence of diabetes greater than 2–3 points on the PCS or MCS scale. Using Cohen’s standardized effect size (22), which is an effective way of estimating minimally clinically important differences in HRQoL measures (21), 2.0–2.5 points is a reasonable estimate of the smallest clinically important difference in either PCS or MCS. Therefore, the 95% CIs in Table 3 reflect a study large enough to exclude all but a very small clinically significant difference in HRQoL attributable to diabetes screening.

It is also unlikely that any negative effect on HRQoL of being diagnosed with diabetes was obscured by a subsequent therapeutic effect of diabetes treatment. Physical activity, which is the only element of diabetes treatment known to have a positive effect on SF-36 scores and the only potential treatment associated with PCS in our sample, was not different between patients with and without diabetes and did not change between baseline and follow-up. Many patients were not even treated for diabetes, and HbA_{1c} was essentially unchanged among our patients with diabetes. These low treatment rates more likely reflect a form of clinical inertia (29) to the new diagnosis of diabetes, both in patient self-perception and in physician treatment choice.

Our study has limitations. The sample is a convenience sample, recruited based in part on willingness to participate in the study, and may not generalize to VA outpatients. We do not know whether comorbidity or quality of life was different between responders and nonresponders to our initial survey. Additionally, VA medical center patients both in our study and otherwise have very poor physical HRQoL (17,24), and the impact of diabetes diagnosis and treatment on healthier (non-VA) patients may be larger. Finally, global health status measures such as the SF-36 may not be sensitive to small changes in HRQoL (30); therefore, other measures might detect these changes (20). However, because no common disease links our entire population, no disease-specific measure could be used in this study.

Neither the absence of labeling nor the absence of early HRQoL improve-

ments addresses the central issue of diabetes screening, which is long-term prevention of complications and the cost at which that prevention is achieved (31,32). However, our data suggest that the potential for labeling is not an important barrier to diabetes screening. Our data also suggest that early HRQoL changes might not have to be considered in the complex calculations that underlie the decision to undertake or not undertake mass screening for diabetes.

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