Association of Health Literacy With Diabetes Outcomes

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Context Health literacy is a measure of patients' ability to read, comprehend, and act on medical instructions. Poor health literacy is common among racial and ethnic minorities, elderly persons, and patients with chronic conditions, particularly in public-sector settings. Little is known about the extent to which health literacy affects clinical health outcomes.

Objectives To examine the association between health literacy and diabetes outcomes among patients with type 2 diabetes.

Design, Setting, and Participants Cross-sectional observational study of 408 English- and Spanish-speaking patients who were older than 30 years and had type 2 diabetes identified from the clinical database of 2 primary care clinics of a university-affiliated public hospital in San Francisco, Calif. Participants were enrolled and completed questionnaires between June and December 2000. We assessed patients' health literacy by using the short-form Test of Functional Health Literacy in Adults (s-TOFHLA) in English or Spanish

Main Outcome Measures Most recent hemoglobin A_{1c} (HbA_{1c}) level. Patients were classified as having tight glycemic control if their HbA_{1c} was in the lowest quartile and poor control if it was in the highest quartile. We also measured the presence of self-reported diabetes complications.

Results After adjusting for patients' sociodemographic characteristics, depressive symptoms, social support, treatment regimen, and years with diabetes, for each 1-point decrement in s-TOFHLA score, the HbA_{1c} value increased by 0.02 ($P=.02$). Patients with inadequate health literacy were less likely than patients with adequate health literacy to achieve tight glycemic control ($HbA_{1c} \leq 7.2\%$; adjusted odds ratio [OR], 0.57; 95% confidence interval [CI], 0.32-1.00; $P=.05$) and were more likely to have poor glycemic control ($HbA_{1c} \geq 9.5\%$; adjusted OR, 2.03; 95% CI, 1.11-3.73; $P=.02$) and to report having retinopathy (adjusted OR, 2.33; 95% CI, 1.19-4.57; $P=.01$).

Conclusions Among primary care patients with type 2 diabetes, inadequate health literacy is independently associated with worse glycemic control and higher rates of retinopathy. Inadequate health literacy may contribute to the disproportionate burden of diabetes-related problems among disadvantaged populations. Efforts should focus on developing and evaluating interventions to improve diabetes outcomes among patients with inadequate health literacy.

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HEALTH LITERACY IS A CONSTELLATION of skills, including the ability to perform basic reading and numerical tasks required to function in the health care environment.[1] Patients with poor health literacy levels have difficulties that range from reading labels on a pill bottle and interpreting blood sugar values or dosing schedules to comprehending appointment slips, educational brochures, or informed-consent documents. Patients with poor health literacy not only have limitations in reading but also may have difficulties processing oral communication and conceptualizing risk.[2,3] In the context of a health care system in which scientific advances and market forces place greater technical and self-management demands on patients, poor health literacy may be a particularly important barrier to chronic-disease care.

Poor health literacy is more common among patients who have low educational attainment and among immigrants, older patients, and racial and ethnic minorities.[1] Research has shown that poor health literacy is most prevalent in public hospitals but is also common among the elderly in private-sector settings. A recent study of Medicare managed care enrollees demonstrated that more than one third had poor health literacy.[4] Poor health literacy is common among patients with chronic medical conditions, such as type 2 diabetes, asthma, AIDS (acquired immunodeficiency syndrome), and hypertension.[5-9]

A growing body of research demonstrates that poor health literacy is independently associated with poor self-

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rated health[10] and higher use of services.[11,12] A study among patients with hypertension and diabetes demonstrated a nonstatistically significant relationship between inadequate health literacy and poor blood pressure and glycemic control, although the study was not powered to detect a difference.[8] Although it is unclear to what extent health literacy is merely associated with or causally related to outcomes, there are reasons to believe that poor health literacy may directly contribute to poor outcomes. Patients with poor health literacy have greater difficulties naming their medications and describing their indications,[13] more frequently hold health beliefs that interfere with adherence,[7] and are more likely to have poor understanding of their condition and its management.[5,8,9]

Because relatively little is known regarding the impact of poor health literacy on clinical outcomes, we investigated the association between health literacy and diabetes outcomes among patients cared for in the clinics of a public hospital. We selected type 2 diabetes because it is one of the most common diseases in the United States, affecting more than 16 million people and 18% of all people 65 years of age and older.[14] Despite high rates of health care access and use for most patients with type 2 diabetes, outcomes are frequently unsatisfactory for reasons that are often unclear.[15] Isolating the independent contribution of health literacy toward diabetes outcomes may have important clinical implications for the care of individual patients. Since type 2 diabetes disproportionately affects ethnic minorities and those of lower socioeconomic status,[16] understanding the association between health literacy and diabetes outcomes may have strategic implications for the reduction of racial, ethnic, and socioeconomic disparities in diabetes care called for in Healthy People 2010.[17]

METHODS

Setting and Study Participants

The study took place in 2 primary care clinics (a family practice and a general internal medicine clinic) at San Francisco General Hospital, the public hospital of the city and county of San Francisco. Patients in these clinics receive care from University of California, San Francisco, attending faculty and residents. Primary care physicians treat more than 90% of type 2 diabetes patients at San Francisco General Hospital; the remainder receive services exclusively from specialists or from the emergency department sporadically. The primary care clinics have diabetes educators who attempt to consult with every patient for individual sessions. During the study, there was no disease-management system in place.

Potential subjects were identified by querying the hospital system's computerized clinical and administrative database, an enterprise data warehouse. The San Francisco General Hospital database captures laboratory, radiology, billing and use, and demographic information for all patients who used the public health care system of the city and county of San Francisco within 3 years before the start of the study. Patients were eligible if, according to the database, they were older than 30 years, were registered as speaking English or Spanish, and had type 2 diabetes, controlled or uncontrolled, with or without complications (all *International Classification of Diseases, Ninth Revision [ICD-9]* codes of 250._0 or 250._2). Participants had to have had a database-recorded visit with a primary care physician in 1 of the clinics in the prior 12 months and at least 1 additional visit to the same physician within the prior 6 months. We excluded patients with any documented billing diagnosis of end-stage renal disease, psychotic disorder, dementia, or blindness (conditions that may interfere with accurate health literacy measurement).[18]

To ensure that our database-generated list of patients accurately reflected eligibility criteria, we also provided primary care physicians (n=89) with a list of eligible patients generated from the database and asked them to indicate additional patients meeting criteria for exclusion.

Between June and December 2000, bilingual research assistants attempted to enroll all eligible patients who attended a clinic appointment. Patients who stated that they were fluent in English or Spanish were asked to participate in a study of patient-physician communication and diabetes care and were offered $5.00 for their participation. Written consent, oral consent, or both were obtained from patients before enrollment. To facilitate comprehension of the study and consent process, the consent form was written at a fifth-grade level; in addition, research assistants read an abbreviated version to all patients.

Patients who agreed to participate first had their visual acuity tested with a pocket vision screener (Rosenbaum, Granham-Field Surgical Co Inc, New York, NY); patients with corrected vision of 20/50 or worse were excluded. Patients were then administered an abbreviated version of the short-form Test of Functional Health Literacy in Adults (s-TOFHLA, 14-point font),[19] a reliable and validated instrument used to assess a patient's health literacy level.[18] Research assistants also orally administered a questionnaire regarding demographic information (race/ethnicity, income, and education), health-related habits (current alcohol, tobacco, and illicit drug use), social support, depressive symptoms, current diabetes treatment (use of diet, oral hypoglycemic agents, and insulin), receipt of diabetes education, length of time with diagnosed diabetes, and the presence of diabetes complications. The protocol was approved by the Human Subjects Committee of the University of California, San Francisco.

Measures

To measure health literacy, we used the abbreviated form of the s-TOFHLA, Spanish or English version.[19] The abbreviated s-TOFHLA is a 36-item timed reading comprehension test that uses the modified Cloze procedure[20]; every fifth to seventh word in a passage is omitted, and 4 multiple-choice options are provided. The abbreviated s-TOFHLA

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contains 2 health care passages, the first selected from instructions for preparation for an upper gastrointestinal tract radiograph series (Gunning-Fog Index readability grade 4.3[21]) and the second from the patient's "Rights and Responsibilities" section of a Medicaid application (Gunning-Fog Index readability grade 10.4). The abbreviated s-TOFHLA is scored on a scale of 0 to 36. Using established convention, we categorized patients as having inadequate health literacy if the s-TOFHLA score was 0 to 16, marginal health literacy if it was 17 to 22, and adequate health literacy if it was 23 to 36. Patients with inadequate health literacy often misread simple materials, such as prescription bottles, appointment slips, or nutrition labels; patients with marginal health literacy frequently have trouble with more complex materials, such as an educational brochure or informed-consent document.[22]

Because social support and depression may affect patients' glycemic control,[23] we assessed both domains in the patient interview. We measured diabetes-related social support by using 8 questions adapted from the Diabetes Care Profile[24] social-support scale that asks patients to rate the extent to which family or friends support their diabetes self-care. We measured depressive symptoms by using the Center for Epidemiologic Studies Depression Scale-10,[25] a 10-item questionnaire that has been used extensively in type 2 diabetes research[23] and asks patients how frequently they have had symptoms of depression in the prior month. We measured diabetes-related conditions by asking patients whether they had ever been told by a physician that they had a condition considered to be a complication of diabetes, including retinopathy (diabetic eye disease), nephropathy (kidney disease or protein in the urine), lower extremity amputation (amputation of a toe, foot, part of a leg, or entire leg), ischemic heart disease (blocked arteries in the heart, angina, or heart attack), or cerebrovascular disease (stroke).[26] Most questions in the patient survey had been translated into Spanish. For those that we modified or that had never been translated, we performed translation and back-translated until we attained concordance in meaning between English and Spanish versions.

We obtained patients' most current hemoglobin A_{1c} (HbA_{1c}) values by querying the San Francisco General Hospital database for data preceding the interview. The San Francisco General Hospital clinical laboratory is a University of California, San Francisco–administered facility that uses ion-exchange chromatography (HPLC: Diastat Hemoglobin A_{1c} program, BioRad Laboratories, Hercules, Calif) to measure HbA_{1c} (normal range, 4.9%-6.7%). To validate patients' self-report of diabetes complications, we queried the database for billing diagnoses corresponding to diabetic retinopathy (*ICD-9* codes 250.50, 250.52, 362.01, 362.02, and 362.89). We reasoned that a billing diagnosis of retinopathy would be the most accurate means to validate self-reported diabetes complications, given the regularity with which retinopathy screening is carried out and the consistency with which an accompanying billing diagnosis is entered. In contrast, a billing diagnosis of stroke, for example, would likely be recorded only if the event occurred within the 3-year span of the San Francisco General Hospital database. We also obtained patients' insurance information and the name of their primary care physician from the database.

Statistical Analysis

To determine the contribution of health literacy to glycemic control across the entire range of s-TOFHLA scores, we analyzed health literacy as a continuous variable. To correct for the nonnormal distribution of HbA_{1c} data, we used the log transformation of the HbA_{1c} data. Regression analysis was used to measure the association between s-TOFHLA score and HbA_{1c} after other potentially confounding patient characteristics were controlled. We included any variables that were significant at $P<.20$ in bivariate analysis and also included variables that we had hypothesized would affect glycemic control. Specifically, we performed multivariate linear regression, controlling for differences in patients' characteristics, including age, race/ethnicity, sex, education, language, insurance, depressive symptoms, social support, diabetes education, treatment regimen, and diabetes duration. To facilitate interpretation of these results, all displayed coefficients reflect non–log-transformed (raw) HbA_{1c} values. To address the theoretical concern that low s-TOFHLA scores may result from undetected cognitive problems in patients with high HbA_{1c} or higher rates of diabetes complications, we repeated the analysis after excluding patients with self-reported stroke.

Because patients are often categorized clinically by their degree of glycemic control, we created cutoffs to define tight control and poor control according to the 25th and 75th percentiles of HbA_{1c} distribution for the study sample. These cutoffs were the same for the raw HbA_{1c} and log-transformed HbA_{1c} data. Logistic regression was used to assess the independent effect of health literacy level on the extent of patients' glycemic control after adjustment for the same potential confounders. We also used multivariate regression models to determine the independent effect of health literacy on the risk of diabetes complications (present vs absent) but adjusted for additional clinical predictors known to be related to the outcome.[27] We included a term for hypertension (obtained by querying the San Francisco General Hospital database for *ICD-9* codes 401, 401.1, and 401.9) in the model for retinopathy and nephropathy and terms for hypertension and smoking in the model for lower extremity amputation, coronary artery disease, and cerebrovascular disease. The SEs for all model coefficients were adjusted for the clustering of patients within physician by using generalized estimating equations.[28] All statistical analyses were performed with SAS version 8 (SAS Institute Inc, Cary, NC).

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RESULTS

Eight hundred fifty-eight patients were identified by the San Francisco General Hospital clinical database as potentially eligible for the study. Of these, 142 were ineligible because their primary care physicians informed us that the patients were not in their panel (n=10), did not have type 2 diabetes (n=25), did not speak English or Spanish fluently (n=28), had moved out of the area (n=35), had a psychiatric condition, eg, dementia, psychosis, or mental retardation (n=23), or had died (n=1). An additional 20 patients were identified as ineligible by physicians who stated no reason. Of the 716 remaining eligible patients, 261 did not make a primary care visit during the enrollment period. All remaining 455 patients were approached at a clinic appointment. Of these, 36 patients refused to participate. An additional 17 patients were excluded because they were too ill to participate (n=9), were acutely intoxicated (n=2), or had poor visual acuity (≥20/50; n=6). Four hundred thirteen patients completed the questionnaire. For 408 of the 413 patients, at least 1 HbA_{1c} value was available in the San Francisco General Hospital database; these patients composed our study sample. Patients who refused to participate and patients who were not interviewed by virtue of not attending a clinic appointment during the enrollment period were more likely than study subjects to be younger and male but were not different in terms of sex, race/ethnicity, and language.

The study participants were ethnically diverse, had low income and educational attainment, and were predominantly uninsured or publicly insured (**Table 1**). Most patients were treated with oral hypoglycemic agents either alone or with insulin. The mean abbreviated s-TOFHLA score was 21 (range, 0-36). Thirty-eight percent of patients had inadequate health literacy (s-TOFHLA score, 0-16), and 13% had marginal health literacy (s-TOFHLA score, 17-22). Patients with inadequate health literacy were more likely than patients with adequate health literacy (s-TOFHLA, 23-36) to be older, female, nonwhite, and Spanish-speaking, to have Medicare coverage, to have received only some high school education or less, and to have had diabetes longer.

The mean HbA_{1c} for the study population was 8.5%. Ninety-eight percent of HbA_{1c} results were obtained within 1 year of the interview date; median length of time between HbA_{1c} and interview date was 90 days. We found no relationship between HbA_{1c} values and the length of time between the date that HbA_{1c} was obtained and the interview date. **Table 2** shows the bivariate relationships between predictors of glycemic control and patients' most recent HbA_{1c} value, accounting for the clustering of patients within physician. The s-TOFHLA score, education, insurance, years with diabetes, and diabetes treatment regimen were

Table 1. Characteristics of Patients Stratified by Health Literacy Level

Characteristics	Total (N = 408)	Health Literacy Level*: Inadequate (n = 156)	Marginal (n = 54)	Adequate (n = 198)	P Value†
Age, mean (SD), y	58.1 (11.4)	62.7 (10.9)	59.8 (9.8)	54.0 (10.7)	<.001
Sex, No. (%)					
Female	235 (58)	104 (67)	30 (56)	101 (51)	.01
Male	173 (42)	52 (33)	24 (44)	97 (49)	
Race/ethnicity, No. (%)					
Asian	75 (18)	30 (19)	10 (19)	35 (18)	<.001
Black	100 (25)	27 (17)	13 (24)	60 (30)	
Latino	173 (42)	90 (58)	24 (44)	59 (30)	
White	60 (15)	9 (6)	7 (13)	44 (22)	
Education, No. (%)					
Some high school or less	185 (46)	118 (75)	23 (43)	44 (22)	<.001
High school graduate or general equivalency degree	95 (23)	26 (17)	17 (31)	52 (26)	
College graduate/some college	115 (28)	11 (7)	11 (20)	93 (47)	
Graduate degree	13 (3)	1 (1)	3 (6)	9 (5)	
Household income (annual <$20 000), No. (%)	379 (93)	151 (97)	52 (96)	176 (89)	.009
Insurance status, No. (%)					
Uninsured	130 (32)	37 (24)	18 (33)	75 (38)	.004
Medicare	149 (36)	75 (48)	21 (39)	53 (27)	
Medicaid	93 (23)	33 (21)	12 (22)	48 (24)	
Commercial	36 (9)	11 (7)	3 (6)	22 (11)	
Language					
Spanish	148 (36)	84 (54)	21 (39)	43 (22)	<.001
English	260 (64)	72 (46)	33 (61)	155 (78)	
Alcohol intake (>1 drink/wk), No. (%)	60 (15)	15 (10)	8 (15)	37 (19)	.06
Illicit drug use (≥once/mo), No. (%)	27 (7)	2 (1)	5 (9)	20 (10)	.008
Depression score (0-100), mean (SD)	38.5 (22.5)	37.1 (21.0)	39.0 (23.3)	39.5 (23.4)	.58
Social support score (0-100), mean (SD)	64.3 (36.1)	66.0 (34.6)	59.7 (39.0)	64.2 (36.5)	.55
Years with diabetes, mean (SD)	9.5 (8.0)	11.4 (8.7)	10.4 (8.3)	7.7 (6.9)	<.001
Received diabetes education, No. (%)	318 (78)	117 (75)	44 (82)	157 (79)	.50
Treatment regimen, No. (%)					
Diet alone	23 (6)	12 (8)	1 (2)	10 (5)	.10
Oral hypoglycemic alone	223 (54)	76 (49)	33 (61)	114 (57)	
Insulin alone	49 (12)	16 (10)	4 (7)	29 (15)	
Insulin and oral hypoglycemic	113 (28)	52 (33)	16 (30)	45 (23)	
Time between hemoglobin A_{1c}–level test and interview, median (interquartile range), d	90 (111)	91 (113.5)	92 (83)	87 (114)	.80

*For definitions of health literacy level, see the "Methods."
†The χ^2 test was used for categorical variables; analysis of variance, for means of continuous variables; Kruskal-Wallis test, for medians of continuous variables; and Fisher exact test, for illicit drug use.

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Table 2. Relationship Between Patient Characteristics and Hemoglobin A_{1c} Levels

Predictor	Unadjusted		Adjusted*	
	Coefficient†	*P* Value	Coefficient†	*P* Value‡
s-TOFHLA score (0-36)	−0.02	.001	−0.02	.02
Age	−0.006	.91	−0.01	.48
Sex, female	0.19	.27	0.09	.60
Race/ethnicity, nonwhite vs white	0.18	.43	−0.02	.94
Education vs some high school or less				
High school graduate or general equivalency degree	−0.51	.01	−0.34	.05
College graduate/some college	−0.24	.13	0.04	.97
Graduate degree	−0.73	.05	−0.25	.50
Household income (annual <$20 000)§	−0.36	.53	. . .	. . .
Insurance status vs commercial				
Uninsured	−1.03	.01	−0.87	.03
Medicare	−0.93	.02	−0.90	.02
Medicaid	−0.72	.12	−0.71	.11
Language, Spanish vs English	0.22	.09	0.02	.96
Alcohol intake >1 drink/wk§	−0.05	.99	. . .	. . .
Illicit drug use, ≥once/mo§	−0.17	.86	. . .	. . .
Depression score (0-100), mean (per point)	−0.001	.90	−0.004	.30
Social support score (0-100), mean (per point)	0.002	.53	0.0002	.99
Years with diabetes (per year)	0.03	.001	0.02	.13
Receipt of diabetes education (no vs yes)	−0.045	.84	0.05	.79
Treatment regimen vs combination therapy				
Diet alone	−1.64	.001	−1.46	.001
Oral hypoglycemic alone	−0.72	.001	−0.56	.03
Insulin alone	−0.52	.08	−0.52	.10

*Adjusted for age, sex, race, education, insurance, language, social support, diabetes education, depression, treatment regimen, and years with diabetes, and accounting for the clustering of patients within physicians. s-TOFHLA indicates short-form Test of Functional Health Literacy in Adults.
†All coefficients correspond to a change in raw hemoglobin A_{1c} value for unit change of each covariate.
‡*P* values were derived from generalized estimating equations by using the log transformation of hemoglobin A_{1c}.
§Ellipses indicate that data were not significant at $P<.15$ in the univariate analyses and so were not included in the multivariate model.

all associated with HbA_{1c}. After adjustment for age, race/ethnicity, sex, education, language, insurance, depressive symptoms, social support, receipt of diabetes education, treatment regimen, and years with diabetes, only the s-TOFHLA score, insurance status, and treatment regimen were independently associated with HbA_{1c} (Table 2). For each 1-point decrement in s-TOFHLA score, the HbA_{1c} value increased by 0.02 ($P=.02$); the entire 36-point range of the abbreviated s-TOFHLA score accounted for 0.72 percentage point of HbA_{1c} percentage. Repeating the analysis after excluding patients who reported a history of stroke (n=46) did not alter the relationship between s-TOFHLA score and HbA_{1c} (–0.02; $P=.04$). We assessed interactions between significant variables, but none were significant at $P<.05$.

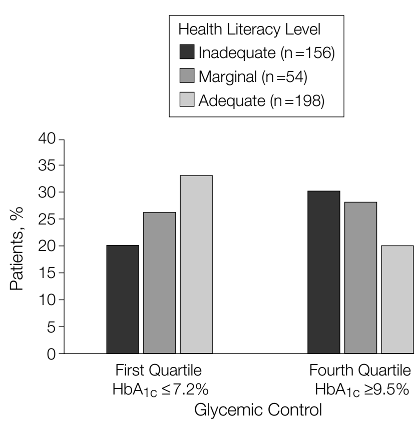
The 25th percentile cut point for HbA_{1c} was 7.2% (tight glycemic control), and the 75th percentile cut point for HbA_{1c} was 9.5% (poor glycemic control). Twenty percent of patients with inadequate health literacy had tight glycemic control, whereas 33% of patients with adequate health literacy had tight glycemic control (FIGURE) (unadjusted odds ratio [OR], 0.51; 95% confidence interval [CI], 0.32-0.79; $P=.003$). Thirty percent of patients with inadequate health literacy had poor glycemic control, whereas 20% of patients with adequate health literacy had poor glycemic control (unadjusted OR, 1.70; 95% CI, 1.09-2.65; $P=.02$). After confounders were adjusted, patients with inadequate health literacy were less likely than patients with adequate health literacy to achieve tight control (adjusted OR, 0.57; 95% CI, 0.32-1.00; $P=.05$) and were more likely than patients with adequate health literacy to have poor control (adjusted OR, 2.03; 95% CI, 1.11-3.73; $P=.02$).

Thirty-six percent of patients with inadequate health literacy and 19% of patients with adequate health literacy reported that they had retinopathy (unadjusted OR, 2.44; 95% CI, 1.50-3.96; $P<.001$). After confounders were adjusted, patients with inadequate health literacy were more likely to report retinopathy (adjusted OR, 2.33; 95% CI, 1.19-4.57; $P=.01$) (TABLE 3). When the analysis was repeated with billing diagnoses of retinopathy instead of self-reported retinopathy, the results were similar (unadjusted OR, 2.68; 95% CI, 1.57-4.60; $P<.001$). The extent of the associations between health literacy and other self-reported diabetes complications, including nephropathy, lower extremity amputation, cerebrovascular disease, and cardiovascular disease, was similar to that of retinopathy but in most cases did not reach statistical significance (Table 3).

COMMENT

Our study demonstrates that, among patients who have type 2 diabetes and access to primary care physicians in public hospital clinics, health literacy was independently associated with glycemic control. Inadequate health literacy was an independent predictor of

Figure. Health Literacy Level and Glycemic Control by Hemoglobin A_{1C} (HbA_{1C}) Quartile



See "Methods" for definition of health literacy levels.

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Table 3. Adjusted Odds of Self-reported Diabetes Complications for Patients With Inadequate vs Adequate Health Literacy*

Complication	Study Subjects With Complication, No.	Odds Ratio (95% Confidence Interval)	P Value
Retinopathy	111	2.33 (1.19-4.57)	.01
Nephropathy	62	1.71 (0.75-3.90)	.20
Lower extremity amputation	27	2.48 (0.74-8.34)	.14
Cerebrovascular disease	46	2.71 (1.06-6.97)	.04
Ischemic heart disease	93	1.73 (0.83-3.60)	.15

*Adjusted for age, sex, race, education, insurance, language, social support, depression, treatment regimen, years with diabetes, and diabetes education, and accounting for clustering of patients within physicians. Hypertension was included in the models for retinopathy and nephropathy; hypertension and smoking were included for all others.

poor glycemic control and was associated with a lower likelihood of achieving tight control. In addition, inadequate health literacy was associated with a higher prevalence of retinopathy and other self-reported complications of diabetes. The results of our study are consistent with those of a smaller study in which a trend of worse control of blood glucose levels with worse health literacy was noted.[8]

The association between health literacy and glycemic control that we observed is significant from a clinical and public health perspective. The proportion of patients with tight glycemic control vs poor control is routinely used as a quality-of-care indicator for diabetes.[29] Glycosylated hemoglobin is an objective clinical end point that has been linked to health care use and costs[30] and disabling and life-threatening conditions.[31,32] Studies have demonstrated that there is a curvilinear relationship between HbA_{1c} and microvascular complications and that a decrease in HbA_{1c} of 1 percentage point (from 9.0% to 8.1%, for example) results in a halving of the risk of retinopathy.[31-33] Consistent with this body of research, our study showed that the worse glycemic control experienced by patients with inadequate health literacy was reflected in a higher prevalence of retinopathy. When compared with patients with adequate health literacy, patients with inadequate health literacy had 2 times the odds of having retinopathy, even after adjustment for patient sociodemographics, diabetes education, treatment regimen, and duration of diabetes.

From the public health perspective, health literacy may represent an important variable explaining the prevalence of poor health outcomes among patients with type 2 diabetes,[15] as well as some of the socioeconomic, racial, and ethnic disparities in diabetes outcomes in the United States.[17,34] A considerable proportion of patients with type 2 diabetes is likely to have poor health literacy. In the United States, nearly 80% of patients with type 2 diabetes have completed only high school or less compared with 40% of the general population.[16] In our sample, 66% of patients with a high school education or less had inadequate or marginal health literacy. Because of its higher prevalence in racial and ethnic minorities,[1] poor health literacy may represent an important variable contributing to high rates of diabetes complications, such as diabetic retinopathy and blindness, end-stage renal disease, and lower extremity amputations among racial and ethnic minorities.[35-40]

Our study has a number of limitations. First, its cross-sectional design did not allow us to ascertain whether inadequate health literacy was causally associated with poor diabetes outcomes. It is possible that health literacy is simply a marker for other factors, such as health-seeking behavior or psychological makeup, or that other factors, such as multiple comorbidities or obesity, represent unmeasured confounders. A recent study among public-hospital patients with type 2 diabetes demonstrated no relationship between medical comorbidities, body mass index, and degree of glycemic control.[41] Although we hypothesized that health literacy predicted diabetes glycemic control, theoretically, our findings could be a result of poor glycemic control or higher rates of complications (such as stroke) leading to lower scores on the s-TOFHLA. In designing our study, we attempted to minimize this possibility by excluding patients who were too ill to participate or had dementia. To further address this concern, we reanalyzed the association between s-TOFHLA score and glycemic control in all study patients, excluding those with a history of stroke, and found the same relationship as in the entire sample. Because our study involved patients receiving ongoing medical care, we cannot determine the degree to which the association between inadequate health literacy and diabetes outcomes was a result of events occurring before or after clinical presentation. Community-based studies have demonstrated that one third to one half of patients with type 2 diabetes are undiagnosed.[42,43] Although our models controlled for self-reported duration of diabetes, it is possible that patients with inadequate health literacy were less likely to recognize signs and symptoms of diabetes, presented to care later, and therefore were more likely to experience diabetes complications.

Our study does not elucidate mechanisms whereby inadequate health literacy may result in worse diabetes outcomes. Diabetes care requires that a host of concepts and skills be conveyed by a team of health care providers and successfully carried out by the patient. The diabetes self-management regimen is one of the most challenging of any for chronic illness. Patients often must perform self-monitoring of blood glucose, manage multiple medications, visit multiple providers, maintain foot hygiene, adhere to diet and meal plans, and engage in an exercise program. Patients also must be able to identify when they are having problems across these functions and effectively problem-solve to divert crises, so diabetes outcomes may be especially sensitive to

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problems in communication, empowerment, and self-management.[44] The determinants of the quality of diabetes care are multiple and complex, with inputs and interactions at the patient, provider, health system, and family and community levels.[45-48] Poor health literacy probably impedes successful communication across many levels. For example, patients with poor health literacy have lower levels of diabetes-related knowledge and are less likely to correctly interpret or act on self-monitoring results even after adjustment for exposure to diabetes education.[8] Providers may fail to successfully transmit the technical skills or behavioral motivation necessary to perform and maintain self-care activities or respond to abnormal results.[49] Health systems may fail to provide tailored, systematic support to patients and clinicians.[50] Although studies have demonstrated the positive impact of diabetes education,[51] in our study standard diabetes education did not eliminate health literacy–related disparities in diabetes outcomes.

Our study has a number of important implications. From the public health standpoint, our findings can inform strategic plans to address the growing diabetes epidemic.[52] To prevent diabetes, reduce its economic burden, and improve the quality of life for all persons who have or are at risk for diabetes,[52] public health messages and health care system interventions should target patients with poor health literacy. For health care professionals, the prevalence of poor health literacy and the strength and consistency of the association between health literacy and diabetes outcomes that we observed should serve as a call to action. Development of strategies to communicate more effectively with patients who have poor health literacy are needed at the patient-clinician level[49,53] and the patient-system level[50,54] and should be based on a deeper understanding of the needs and competencies of patients with poor health literacy. Research to develop effective office-based communication strategies and efforts to more widely apply chronic-disease management programs for patients with poor health literacy should be supported.

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Factual evidence can never "prove" a hypothesis; it can only fail to disprove it, which is what we generally mean when we say, somewhat inexactly, that the hypothesis is "confirmed" by experience.
—Milton Friedman (1912-   )

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