

Influence of Patient Literacy on the Effectiveness of a Primary Care–Based Diabetes Disease Management Program

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APPROXIMATELY 90 MILLION Americans have literacy skills insufficient to function in today's economy and health care settings.¹⁻³ Patients with low literacy can have trouble reading prescriptions and following medical recommendations, poorer knowledge of their disease, and worse clinical outcomes.^{2,4-8} Low literacy is common among patients with diabetes and is associated with poor knowledge about diabetes.^{2,8-12} Although 1 recent cross-sectional study has found that low literacy is associated with poor glycemic control,¹¹ other studies have not.^{8,13}

No published studies have rigorously examined interventions that can mitigate literacy-related disparities in patients with diabetes.¹⁴ We previously conducted a pilot study that suggested that a comprehensive intervention might improve glycemic control for patients with low literacy,¹⁵ but that study lacked a control group. To better examine this issue, we recently completed a randomized controlled trial of a comprehensive disease management

Context Low literacy is an important barrier for patients with diabetes, but interventions to address low literacy have not been well examined.

Objective To examine the role of literacy on the effectiveness of a comprehensive disease management program for patients with diabetes.

Design, Setting, and Participants Analysis of the influence of literacy on glycemic control and systolic blood pressure using data from a randomized controlled trial (conducted from February 2001 through April 2003) of a comprehensive diabetes management program. Participants were 217 patients aged 18 years or older with type 2 diabetes and poor glycemic control (glycosylated hemoglobin [HbA_{1c}] levels $\geq 8.0\%$) and presenting to a US academic general internal medicine practice.

Interventions All communication to patients was individualized and delivered to enhance comprehension among patients with low literacy. Intervention patients received intensive disease management from a multidisciplinary team. Control patients received an initial management session and continued with usual care.

Main Outcome Measures Achievement of goal HbA_{1c} levels and systolic blood pressure at 12-month follow-up for control and intervention patients stratified by literacy status.

Results Complete 12-month data were available for 193 patients (89%). Among patients with low literacy, intervention patients were more likely than control patients to achieve goal HbA_{1c} levels ($\leq 7.0\%$) (42% vs 15%, respectively; adjusted odds ratio [OR], 4.6; 95% confidence interval [CI], 1.3 to 17.2; $P = .02$). Patients with higher literacy had similar odds of achieving goal HbA_{1c} levels regardless of intervention status (24% vs 23%; adjusted OR, 1.0; 95% CI, 0.4 to 2.5; $P = .98$). Improvements in systolic blood pressure were similar by literacy status.

Conclusions Literacy may be an important factor for predicting who will benefit from an intervention for diabetes management. A diabetes disease management program that addresses literacy may be particularly beneficial for patients with low literacy, and increasing access to such a program could help reduce health disparities.

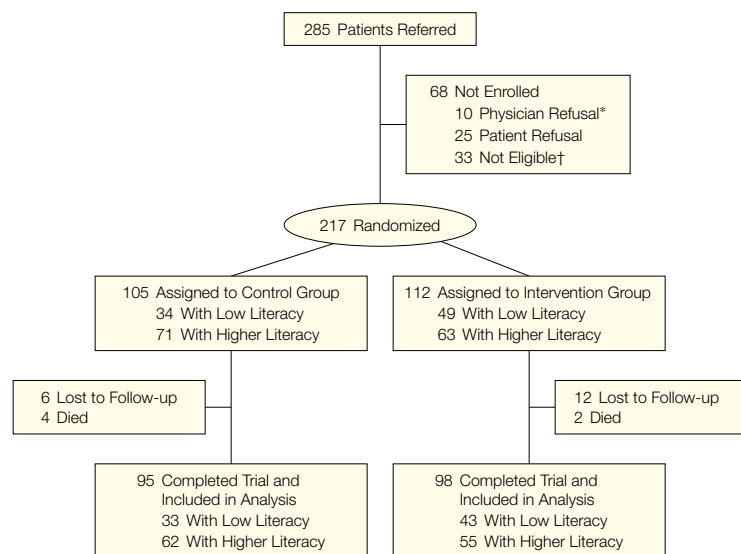
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Figure 1. Study Flow

Low literacy defined as \leq sixth-grade level; higher literacy, as $>$ sixth-grade level.

*Refused to sign consent and participate.

†Due to glycosylated hemoglobin level $<8.07\%$, non-English speaking, or life expectancy <6 months.

program that included strategies to overcome clinician deficits and patient barriers, including low literacy, for patients with diabetes and poor glycemic control. This program successfully improved blood pressure and glycemic control.¹⁶ This article examines how patient literacy influenced the effectiveness of this program.

METHODS

Study Design

The data come from a randomized controlled trial that examined the effect of an intensive diabetes management program (FIGURE 1).¹⁶ The study was conducted in a university general internal medicine practice that serves a wide socioeconomic range of patients. The study was initiated in February 2001 and completed in April 2003. All patients were followed up for 1 year. The University of North Carolina institutional review board approved the study.

Eligible patients included all adults (aged ≥ 18 years) with type 2 diabetes who were followed up for their diabetes care in the general internal medicine practice, had poor glucose control (ie, glycosylated hemoglobin

[HbA_{1c}] levels $\geq 8.0\%$), spoke English, and had a life expectancy greater than 6 months. Primary care clinicians referred eligible patients for possible participation.

After written informed consent and baseline measures were obtained, all patients attended a 1-hour educational session conducted by a clinical pharmacist. The pharmacist provided treatment recommendations about glycemic control and cardiovascular risk reduction to patients' primary care clinicians. After this session, patients were randomized with concealed allocation.

Intervention

Patients in the control group received usual care from their primary care clinician and had no further contact with the disease management team. In the intervention group, usual care was supplemented by intensive diabetes management from 3 clinical pharmacist practitioners and a diabetes care coordinator (DCC). Pharmacists had training in outpatient disease management and 2 were certified diabetes educators. The intervention included (1)

one-to-one educational sessions including counseling and medication management by the pharmacists and the DCC; (2) application of evidence-based treatment algorithms (available at <http://www.med.unc.edu/medicine/edursrc/algorithm.htm>) to help manage glucose and cardiovascular risks by allowing pharmacists to both initiate and titrate blood pressure- and glucose-lowering medications; and (3) strategies to address patient barriers provided by the DCC, including telephone reminders and, when needed, addressing difficulties with transportation, communication, and insurance.

A pharmacist or the DCC contacted intervention patients by telephone or in person every 2 to 4 weeks (more frequently if indicated). The pharmacist and the DCC were aware of patients' literacy status. Communication to patients was individualized using techniques that enhance comprehension among patients with low literacy,¹⁷⁻²⁰ including predominantly verbal education with concrete, simplified explanations of critical behaviors and goals; "teach-back"^{21,22} to assess patient comprehension; and picture-based materials. Main topics, revisited throughout the follow-up period, included treatment goals, identification of hypoglycemic and hyperglycemic symptoms, prevention of long-term complications, and self-care.

Measures

Levels of HbA_{1c} and systolic blood pressure (SBP) were collected at baseline and at 6 and 12 months. Levels of HbA_{1c} were measured by staff at the University of North Carolina Hospital laboratories, who were unaware of patients' study status. Clinic nurses, unaware of study assignment, recorded SBP from automated monitors. Literacy was assessed at enrollment using the Rapid Estimate of Adult Literacy in Medicine.^{23,24} Race was classified by patient self-report, and options were defined by the patient. We measured race because of its role in disparities in diabetes care and in health literacy.^{2,14,25-27}

During the intervention, the disease management team documented process measures for all intervention patients, including time spent in direct contact with the patients (including the initial management session), actions related to patient care (eg, scheduling appointments, education), and medication changes (initiating new medications, titrating current medications).

Statistical Analysis

We performed all analyses using SAS version 8.02 (SAS Institute Inc, Cary, NC). At baseline, we compared patients by intervention status and literacy status using *t* tests or Wilcoxon rank-sum tests for continuous variables and χ^2 tests or the Fisher exact test for categorical variables.

Our primary outcomes were improvement in HbA_{1c} levels and SBP from baseline to 12 months, stratified by literacy status. A priori, we stratified literacy at the sixth-grade level based on research from the scale developers and our own previous research.^{15,28} We performed analysis of covariance, adjusting for baseline values (HbA_{1c} level or SBP). We then conducted multivariable general linear models, adjusting for baseline covariates if there were differences ($P < .20$) between groups or if we believed a priori that variables were clinically relevant. This resulted in the inclusion of age, race, sex, income, insulin status at enrollment, and duration of disease, in addition to baseline HbA_{1c} level or SBP in the multivariable models. We did not include education or insurance status because they were highly correlated with other covariates and were not associated with our outcome. Results were very similar for unadjusted and adjusted analyses; adjusted analyses are presented.

We also examined the effect of the intervention on the proportion of patients who attained recommended goals for HbA_{1c} level ($\leq 7.0\%$) and SBP (≤ 130 mm Hg)²⁹ at 12 months. We first performed χ^2 analyses to obtain crude odds ratios (ORs) of obtaining goal HbA_{1c} levels and SBP at 12 months between

control and intervention groups, stratified by literacy status. We then used logistic regression to adjust for the covariates used in our primary analysis. Interaction between literacy status and treatment assignment was assessed by including the interaction term in the multivariable logistic regression model.

Finally, in an intent-to-treat analysis in which we carried forward baseline or 6-month HbA_{1c} and SBP values for missing outcomes, we found similar results for all analyses. We also examined differences in process measures using Wilcoxon rank-sum tests to compare intervention patients with low and high literacy levels.

Based on a 2-sided significance level of .05 and 80% power, we estimated a

sample size of 107 patients per group to detect a 1% difference in HbA_{1c} level. To detect a 10-mm Hg between-group difference in SBP required 93 patients per group. The study was not powered to detect differences by literacy status.

RESULTS

Follow-up data were available for 193 of 217 enrolled patients (89%) at 12 months (Figure 1). Baseline patient characteristics were similar between the control and intervention groups and reveal a population with low socioeconomic status and poor glycemic control (TABLE 1). More than one third of patients had low literacy (\leq sixth grade). Patients with low literacy were more likely to be older, be African

Table 1. Baseline Patient Characteristics Stratified by Intervention and Literacy

Variable	No. (%)			
	Control (n = 105)		Intervention* (n = 112)	
	Low Literacy† (n = 34)	Higher Literacy (n = 71)	Low Literacy† (n = 49)	Higher Literacy (n = 63)
Demographics				
Age, mean (SD), y	59 (10.4)	56 (10.9)	57 (10.5)	51 (13/1)‡
Women	18 (53)	41 (58)	22 (55)	41 (65)‡
African American	23 (68)	39 (55)	46 (94)	32 (51)‡
Household income \leq \$20000 annually	29 (85)	49 (71)	40 (82)	37 (59)‡
Less than high school education	28 (82)	18 (26)‡	40 (82)	37 (59)‡
Private insurance	3 (9)	25 (35)‡	19 (39)	27 (43)
Medicare	16 (47)	24 (34)	20 (41)	14 (22)‡
Medicaid	11 (32)	14 (20)	9 (18)	9 (14)
Clinical characteristics				
Baseline HbA _{1c} , median (IQR), %	10.6 (9.1-11.3)	9.9 (9.0-11.6)	10.4 (8.8-12.1)	10.5 (9.4-12.2)
Baseline systolic blood pressure, mean (SD), mm Hg	134.2 (18.4)	138.9 (22.3)	144.1 (22.6)	138.9 (21.0)
Body mass index, median (IQR)§	31 (27-37)	33 (30-39)	32 (29-39)	35 (28-42)
Diabetes Knowledge Score, median (IQR)	40 (20-50)	60 (40-70)‡	40 (30-50)	60 (40-80)‡
Duration of diabetes, median (IQR), y	5 (1-10)	6 (2-13)	6 (0.6-13)	5 (2-10)
Newly diagnosed diabetes (≤ 3 mo)	7 (21)	13 (18)	9 (18)	11 (18)
Use of insulin at enrollment	12 (35)	28 (39)	23 (47)	22 (35)
Receiving oral hypoglycemic agent	27 (79)	59 (83)	36 (74)	46 (73)

Abbreviations: HbA_{1c}, glycosylated hemoglobin; IQR, interquartile range.

*For intervention vs control, $P < .05$ for age and private insurance; $P > .05$ for all other comparisons.

†Defined as \leq sixth-grade literacy level on the Rapid Estimate of Adult Literacy in Medicine.

‡ $P < .05$ for comparison between patients with low and higher literacy.

§Calculated as weight in kilograms divided by square of height in meters.

||Range, 0-100.

American, report lower income, and have lower reported educational attainment and less diabetes-specific knowledge. Other clinical characteristics did not differ by literacy status.

HbA_{1c} Levels

Overall, patients in the intervention group had significantly greater improvement in levels of HbA_{1c} (−2.1%) compared with control patients (−1.2%) (adjusted difference, −1.0%; 95% confidence interval [CI], −1.5% to −0.4%; $P = .001$). Among patients with higher literacy (FIGURE 2B), a small, nonsignificant difference between groups in improvement in levels of HbA_{1c} was observed (adjusted difference, −0.5%; 95% CI, −1.4% to 0.3%; $P = .21$). How-

ever, among patients with low literacy (Figure 2A), patients in the intervention group had more improvement in HbA_{1c} levels than did the control patients (adjusted difference, −1.4%; 95% CI, −2.3% to −0.6%; $P < .001$).

Similarly, patients in the intervention group were more likely than were those in the control group to obtain goal HbA_{1c} levels ($\leq 7.0\%$) at 12 months (adjusted OR, 1.9; 95% CI, 1.0 to 3.8; $P = .05$) (TABLE 2). Again, there was no significant treatment effect for patients with higher literacy (adjusted OR, 1.0; 95% CI, 0.4 to 2.5; $P = .98$). However, among patients with low literacy, intervention patients were significantly more likely to obtain goal HbA_{1c} levels than were the control pa-

tients (adjusted OR, 4.6; 95% CI, 1.3 to 17.2; $P = .02$). The P value for interaction between the ORs for the patients with low and higher literacy was significant ($P = .01$), confirming that literacy is an effect modifier for reaching goal levels of HbA_{1c}. No other covariates showed significant interaction.

Blood Pressure

For SBP, overall, intervention patients improved more than control patients (adjusted difference, −7.6 mm Hg; 95% CI, −13.0 to −2.2; $P = .006$). However, differences were comparable for patients with low and higher literacy levels (Figure 2C and 2D). Similarly, patient literacy status did not modify the effect of the intervention on obtaining goal SBP at 12 months (adjusted OR for patients with low literacy, 1.5; 95% CI, 0.5 to 4.6; $P = .44$; adjusted OR for patients with higher literacy, 1.1; 95% CI, 0.5 to 2.3; $P = .89$).

Process Measures

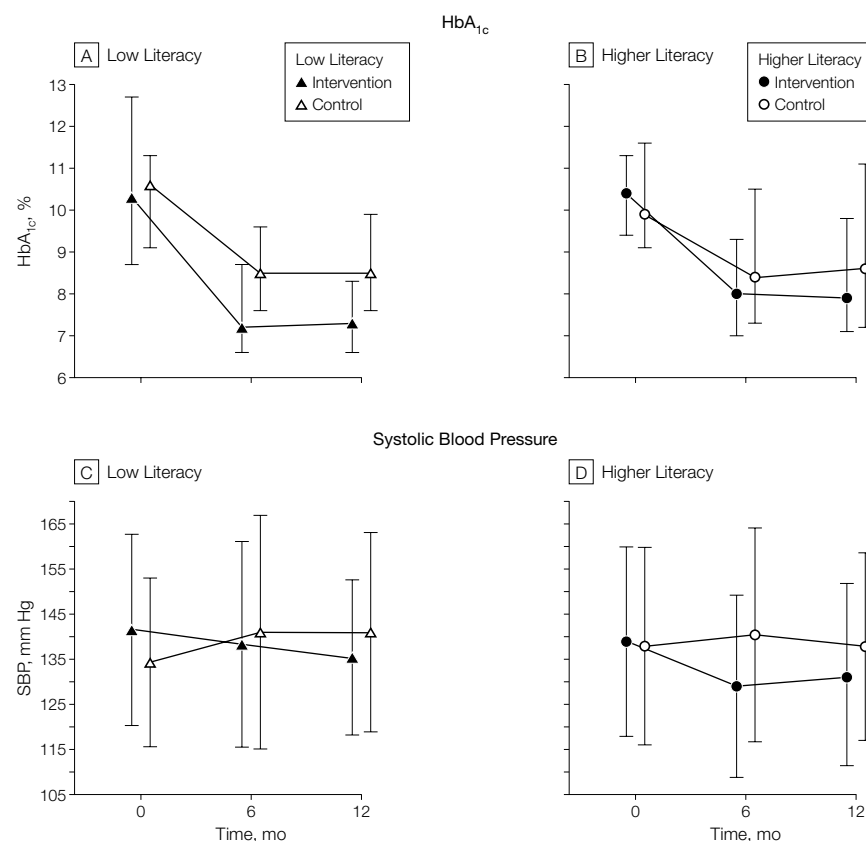
Among intervention patients, there were no differences by literacy status (higher vs low literacy) for frequency of completed actions (30 vs 31, $P = .64$), time spent with patients (364 vs 392 minutes, $P = .28$), or number of medications added (3.6 vs 3.6, $P = .81$) or titrated (5.2 vs 5.3, $P = .53$).

COMMENT

We found that a comprehensive diabetes disease management program benefited patients with low literacy to a greater degree than it did patients with higher literacy. Literacy appears to be an important factor for determining who benefited from this program, even after adjusting for race, income, and clinical status. Our program, with frequent one-to-one patient contact and interventions oriented toward patients with low literacy, may have helped such patients overcome barriers and fully participate in their diabetes management.

Patients with diabetes and low literacy have poor knowledge of their disease^{2,8-12} and may have difficulties learning the advanced self-care skills needed

Figure 2. Improvement in Outcomes by Literacy Status



Adjusted differences at 12 months: A, −1.4 (95% confidence interval [CI], −2.3 to −0.6), $P < .001$; B, −0.5 (95% CI, −1.4 to 0.3), $P = .21$; C, −7.9 (95% CI, −17.7 to 1.9), $P = .11$; and D, −7.1 (95% CI, −14.3 to 0.004), $P = .05$. Differences are adjusted for baseline glycosylated hemoglobin (HbA_{1c}) level or systolic blood pressure (SBP) and for age, race, sex, income, insulin use, and duration of diabetes. Error bars indicate interquartile range (for HbA_{1c}) and standard deviation (for SBP).

Table 2. Odds of Attaining Goal HbA_{1c} Levels ($\leq 7\%$) at 12 Months When Stratified by Literacy Status

Literacy Status	No./Total (%)		Crude OR (95% CI)	P Value	Adjusted OR (95% CI)*	P Value
	Control (n = 95)	Intervention (n = 98)				
Overall	19/95 (20)	31/98 (32)	1.9 (1.0 to 3.6)	.07	1.9 (1.0 to 3.8)	.05
Low	5/33 (15)	18/43 (42)	4.0 (1.3 to 12.5)	.01	4.6 (1.3 to 17.2)	.02
Higher	14/62 (23)	13/55 (24)	1.0 (0.4 to 2.5)	.89	1.0 (0.4 to 2.5)	.98

Abbreviations: CI, confidence interval; OR, odds ratio.

*Adjusted for age, race, sex, income, insulin status at enrollment, duration of disease, and baseline HbA_{1c} level.

to improve glycemic control, particularly in our fast-paced and complex health care system. We believe that the success of our program was at least in part due to our using effective strategies for communicating with patients with low literacy, eg, focusing on selected critical behaviors, decreasing the complexity of information, using concrete examples, limiting the number of topics covered in one session, avoiding jargon, and using “teach back” to ensure comprehension. Previous studies suggest that these strategies may improve patient self-care and outcomes,^{4,17,21,30-32} but to our knowledge ours is the first study to examine differences in effectiveness of diabetes disease management by literacy levels in a randomized trial. Interestingly, we did not observe differential improvement in blood pressure by literacy level. Compared with glucose control, improving blood pressure may be more dependent on providers’ actions than on strong patient self-care skills.

This was a small, single-site study, which may limit generalizability. Our study was not powered to detect differences when stratified by literacy status. The comprehensive nature of our intervention makes it difficult to discern which aspects of our intervention were the most beneficial. One possible explanation for the greater benefit for patients with lower literacy in our program would be that these patients received more time and attention. However, our analysis of process measures suggests otherwise—patients with low and higher literacy had similar amounts of contact (approximately 30 min/patient per month). Furthermore, by enrolling only patients with elevated

levels of HbA_{1c}, it is possible that patients with higher and low literacy have poor glycemic control for differing reasons that we did not measure. For example, perhaps patients with higher literacy were more likely to have poor control because of nonadherence. This could contribute to patients with higher literacy being less responsive to our intervention for lowering levels of HbA_{1c}. Arguing against this possibility is the fact that patients with higher literacy still had significant improvements in blood pressure.

Although many diabetes disease management programs have been able to reduce levels of HbA_{1c} by 1 to 2 percentage points, programs that focus on socially disadvantaged populations have often been less successful.³³⁻³⁶ It is possible that this is partly because these programs did not directly address the problem of low literacy. Our study suggests that literacy is an important factor for influencing who will benefit from a diabetes management intervention. Our disease management program, sensitive to literacy, was able to improve outcomes for patients with both low and higher literacy—and particularly for patients with low literacy. Future studies will need to examine the optimal role of disease management for improving outcomes and addressing disparities for patients with higher and low literacy.

Author Contributions: Dr Rothman had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analyses.

Study concept and design: Rothman, DeWalt, Malone, Bryant, Pignone.

Acquisition of data: Rothman, DeWalt, Malone, Bryant, Crigler, Pignone.

Analysis and interpretation of data: Rothman, DeWalt, Shintani, Weinberger, Pignone.

Drafting of the manuscript: Rothman, DeWalt, Shintani, Weinberger.

Critical revision of the manuscript for important intellectual content: DeWalt, Malone, Bryant, Crigler, Weinberger, Pignone.

Statistical analysis: Rothman, DeWalt, Shintani, Weinberger.

Obtained funding: Malone, Bryant, Pignone.

Administrative, technical, or material support: DeWalt, Malone, Bryant, Crigler.

Study supervision: Rothman, Weinberger, Pignone.

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Where so many hours have been spent in convincing myself that I am right, is there not some reason to fear I may be wrong?

—Jane Austen (1775-1817)