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Low Literacy is associated with Uncontrolled Blood Pressure in Primary Care Patients with Hypertension and Heart Disease

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Abstract

Objectives—Evaluate the association between low literacy and uncontrolled blood pressure (BP) and their associations with medication adherence.

Methods—Cross-sectional study of 423 urban, primary care patients with hypertension and coronary disease. The relationship between low literacy (Rapid Estimate of Adult Literacy in Medicine 44) and uncontrolled BP (140/90 mmHg, 130/80 mmHg for patients with diabetes) was evaluated by crude and adjusted logistic regression. Relationships with self-reported adherence and refill adherence were explored using adjusted linear and logistic regression.

Results—Overall, 192 (45%) subjects had low literacy and 227 (52.9%) had uncontrolled BP. Adjusting for age, gender, race, employment, education, mental status, and self-reported adherence, low literacy was associated with uncontrolled BP (OR 1.75, 95% CI 1.06–2.87). Lower self-reported adherence was associated with uncontrolled BP; the relationship between refill adherence and uncontrolled BP was not statistically significant.

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Dr. McNaughton declares that she has no relevant conflicts of interest. She has served on an advisory board for Cornerstone Therapeutics, Inc.

Dr. Jacobson declares that he has no conflicts of interest.

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We confirm all patient/personal identifiers have been removed or disguised so the patient/person(s) described are not identifiable and cannot be identified through the details of the story

Conclusions—Low literacy is independently associated with uncontrolled BP.

Practice Implications—Awareness of the relationships among patient literacy, BP control, and medication adherence may guide healthcare providers as they communicate with patients.

Keywords

hypertension control; literacy; medication adherence; blood pressure control

1. INTRODUCTION

Hypertension affects nearly 1 billion individuals worldwide, including more than 77 million adults in the United States,(1) and it is one of the most important modifiable risk factors for heart failure and coronary, renal, and cerebrovascular disease.(2–5) In the United States, only 50.1% of adults with hypertension have controlled blood pressure, and only 73.5% of adults with hypertension are prescribed antihypertensive medication.(1) The proportion of patients who take their cardiovascular medications as prescribed varies by population and measurement methods(6–9)

Low literacy skills are common in the health care setting,(10–14) are associated with worse health outcomes,(15) and are costly,(16) accounting for up to 5% of health care costs annually.(17) Literacy is thought to be a key component of the skill set needed for successful medication adherence, disease self-management, and hypertension control. However, physicians are often unaware of their patients literacy skills,(18–20) which in the healthcare setting may be measured with research tools such as the Rapid Estimate of Adult Literacy in Medicine (REALM)(21) or short Test of Functional Health Literacy in Adults (sTOFHLA).(22)

Low literacy is associated with less knowledge about hypertension(23, 24). Few studies have evaluated the relationship between literacy and blood pressure control, and these findings have been equivocal(24–26) or paradoxically found that higher literacy is associated with higher systolic blood pressure.(27)

The mechanism by which literacy impacts outcomes such as blood pressure is not well understood but may be related to adherence to antihypertensive medications.(28, 29) Literacy measured by the sTOFHLA has been related to cardiovascular medication adherence in the Medicare population(30) but not among Veterans in a primary care clinic when measured by the REALM.(31) Evidence for the connection between adherence to blood pressure medications and blood pressure control has been difficult to identify clearly in general clinic populations.(6, 32)

The primary goal of this study was to examine the relationship between literacy and blood pressure control, hypothesizing that low literacy is associated with uncontrolled blood pressure. We also hypothesized that medication adherence is important mediator in the relationship between literacy and blood pressure control and tested this using measures of both self-reported and refill adherence.

2. METHODS

Research design and setting

We conducted a cross-sectional analysis of patients enrolled in the randomized controlled trial, Improving Medication Adherence through Graphically Enhanced Interventions in Coronary Heart Disease (IMAGE-CHD), which was designed to evaluate the impact of refill reminder postcards and illustrated medication schedules on medication adherence. Detailed inclusion criteria and a description of the trial and its results are published elsewhere.(33) The clinical study and this analysis were approved by the local institutional review boards.

Participants

Briefly, over one year, participants were recruited into the IMAGE-CHD study from an inner city primary care clinic in Atlanta, Georgia, USA. Enrollment efforts targeted patients with coronary heart disease, who were eligible for inclusion if they regularly filled their prescriptions in the health system pharmacy and reported an intention to continue doing so. Patients were excluded if they routinely received caregiver assistance with medication management, used a medication chart similar to the IMAGE-CHD educational intervention, (34) had corrected visual acuity worse than 20/60, were unable to communicate in English, had no telephone or mailing address, were in police custody, or had an illness that was thought to limit effective involvement in the study (psychiatric illnesses such as schizophrenia, bipolar disorder, or schizoaffective disorder; delirium or severe dementia; or other severe illnesses). Patients meeting eligibility criteria who also had a diagnosis of during the enrollment clinic visit were included in this analysis.

Study procedures and measures

On the day of enrollment in the IMAGE-CHD study, a trained interviewer conducted a face-to-face interview that included measures of cognitive function (Mini-Mental Status Exam [MMSE]),(35) literacy (REALM),(21, 36) and self-reported adherence (Adherence to Refills and Medications Scale [ARMS]).(37)

The REALM has been validated as a measure of literacy in the healthcare setting.(21, 36) Subjects read 66 medical terms out loud, and the number of correctly pronounced words is summed to generate a score between 0 and 66. In order to focus on patients at highest risk for communication barriers, literacy was evaluated as a dichotomous variable: a REALM score of 0–44 was used to define low literacy, or a reading level at or below 6th grade; REALM >44 was used to indicate marginal or adequate literacy.(21, 25, 36, 38)

The ARMS assesses medication adherence by asking patients about their medication taking and refill behaviors under differing sets of circumstances and was developed and validated in the primary care setting.(37) Each of the 12-items is on a 4-point scale, with a possible range of 12–48; higher scores indicate lower adherence. The ARMS was included as a continuous variable.

Medication refill adherence was calculated retrospectively for the 6-month period prior to the date of enrollment using the cumulative medication gap (CMG).(30, 39) The CMG

represents the proportion of days in which medication was not available and is calculated from pharmacy refill records. Values range from 0 (perfect refill adherence) to 1 (zero refill adherence), with a lower CMG indicating higher medication refill adherence. The CMG was included as a continuous variable.

Uncontrolled blood pressure

The primary outcome of interest was uncontrolled blood pressure, a dichotomous variable taking comorbid conditions into account. Uncontrolled blood pressure was defined as 140/90 mmHg for patients without diabetes and 130/80 mmHg for patients with diabetes. (40) Blood pressure measurements for this study were abstracted from patients medical charts, where they had been recorded by the patients treating physicians during the delivery of clinical care on the day of enrollment. Only a single blood pressure measurement was recorded. These values were obtained manually by the physician, using an appropriate-sized cuff while the patient was seated. If a physician-obtained blood pressure was not available in the chart for that day (<20% of cases), the value obtained at clinic check-in by the nurse was recorded. Clinical measures of blood pressure were chosen because these thresholds are used to make clinical decisions and initiate lifestyle modification, drug initiation, and drug titration.(40, 41)

Covariates

Based on prior literature suggesting these factors may confound the relationship between literacy and blood pressure control, we planned *a priori* to adjust for age, gender, and race. (42, 43) Due to concerns for confounding based on education, socioeconomic status, and mental status, we also planned to include these as covariates. Education was included as a continuous measure of the total number of years of school completed. Mental status was measured by the MMSE, which is a survey of 30 questions used to evaluate level of cognition; higher scores indicate better cognitive status. Employment was based on patient self-report and was categorized as unemployed, employed full-time, employed part-time, and retired/disabled.

Analysis

Descriptive statistics are reported as means and standard deviations (SD), medians and interquartile ranges (IQR), or frequencies and percentages. Demographics stratified by literacy level were compared using Fishers exact test or Wilcoxons rank sum test, as appropriate.

To evaluate the relationship between low literacy and blood pressure control, we performed unadjusted and adjusted logistic regression. In all multivariable models, we adjusted for age, gender, race, years of education, employment status, and MMSE score. In two separate models, to examine the influence of self-reported and refill adherence, we then included adjustment for the ARMS (continuous) or CMG (continuous), respectively. The contributions of these measures of medication adherence were assessed using a likelihood ratio test, where $P < 0.05$ was considered statistically significant.

Planned exploratory linear regression models then evaluated the relationship between literacy (continuous) and medication adherence (continuous) using the ARMS and the CMG as outcome variables, adjusting for age, gender, race, years of education, employment, and mental status based on prior work and the proposed causal pathway between literacy and BP control.(28, 44, 45) Exploratory logistic regression models next assessed the relationship between medication adherence (continuous) and uncontrolled blood pressure using the ARMS and the CMG as independent variables, adjusting for age, gender, race, education, employment, and mental status. Because of the exploratory nature of this analysis, no adjustment for Type I error was made. All analyses were performed using Stata/IC 11.2 (Copyright © 2009, College Station, TX, USA).

3. RESULTS

Of the 435 patients enrolled in the IMAGE-CHD study, 423 subjects with coronary heart disease had hypertension and a blood pressure recorded during the enrollment clinic visit (Figure 1). Clinical characteristics of these patients are listed in Table 1, stratified by literacy level. Overall, 237 (56%) participants were female, 387 (92%) were African American (non-Hispanic), and 195 (46%) had diabetes. One hundred ninety two (45%) had low literacy, or a reading level at or below 6th grade, as measured by the REALM. The CMG for the 6 months prior to enrollment in the study was missing for 22 of the 423 subjects; otherwise, there were no missing data.

Subjects with low literacy were more likely to be older, male, and African American. They also completed fewer years of schooling and had lower MMSE scores. Subjects with low literacy reported higher medication adherence as measured by the ARMS scale, while the CMG measure of refill adherence did not differ by literacy level.

Blood pressure measurements and proportion of subjects with controlled blood pressure are listed in Table 2. A total of 78 (41%) subjects with low literacy and 118 (51%) patients with marginal or adequate literacy had controlled hypertension, respectively.

Results of the analysis evaluating the relationship between literacy and blood pressure control are listed in Table 3. Model 1 shows that the unadjusted OR of having uncontrolled blood pressure was 1.53 (95% confidence interval [CI] 1.04–2.25) for subjects with low literacy compared to patients with marginal or adequate literacy. This relationship did not change substantially after adjustment for age, gender, race, education, employment status, and mental status (Model 2: OR 1.68, 95% CI 1.03–2.76); and after additional adjustment for either self-reported medication adherence (Model 3: OR 1.75, 95% CI 1.06–2.87) or medication refill adherence (Model 4: OR 1.53, 95% CI 0.92–2.55). Models 3 and 4 also demonstrated that while self-reported adherence (ARMS) contributed significantly as a predictor of blood pressure control ($p=0.045$), medication refill adherence (CMG) did not.

Table 4 shows the relationship between low literacy and self-reported (Model 5) or refill adherence (Model 6), after adjusting for age, gender, race, education, employment, and mental status. Higher literacy was associated with *lower* self-reported medication adherence, or a higher ARMS score (beta coefficient 0.03, 95% CI 0.006–0.06, per point increase in the

ARMS score). There was no evident association between literacy and CMG (beta coefficient -0.009 , 95% CI -0.02 – 0.003 per 0.10 increment change in CMG).

DISCUSSION AND CONCLUSIONS

4.1 DISCUSSION

In this study of 423 patients with hypertension and coronary artery disease in an urban primary care clinic, low literacy was associated with higher odds of uncontrolled blood pressure in crude and adjusted analyses (Tables 2 and 3). Lower medication adherence measured by the ARMS was also independently associated with increased odds of uncontrolled blood pressure. Refill adherence was not significantly associated with odds of uncontrolled BP (Table 3). Unexpectedly, we found that low literacy was associated with higher self-reported medication adherence (Tables 1 and 4); there was no evident association between low literacy and refill adherence. This analysis expands upon existing published work, strengthening the evidence for a relationship between literacy and BP control. This highlights the need for awareness of health literacy in order to achieve controlled BP.

Prior conceptual frameworks tying literacy to BP control have theorized that this relationship functions in part through adherence to medication. (28, 46) We found that literacy and self-reported adherence were each related to BP control. However, the association between literacy and BP control did not change appreciably when we adjusted for adherence, whether by self-report or refill data, suggesting that adherence did not mediate this relationship. The relationship between literacy and BP control may be related to factors beyond medication adherence, including lifestyle factors, social support, and the ability to navigate the healthcare system effectively, though this requires further study. Whether therapeutic intensity and prescribing behavior are influenced by patient literacy is not known.

Despite prior work establishing the link between literacy and disease outcomes in diabetes, heart failure, asthma, and HIV (47–56), the association of literacy with BP control has not been consistent. (25–27) Powers et al. (2008) found that the relationship between patient literacy measured by the REALM and systolic blood pressure varied by model of healthcare delivery. (25) Rothman et al. (2004) found that in a study of a comprehensive disease management program, improvement in systolic blood pressure did not vary by literacy status, as measured by REALM, (26) although patients with low literacy were more likely to achieve glycemic control. Willens et al. (2013) found that higher patient-reported literacy was associated with higher blood pressure in an insured clinic population. (27)

The relationship between literacy and adherence has also been inconsistent in prior work. Chew et al. (2004) found that low literacy was associated with lower adherence to preoperative instructions, (57) and Kalichman et al. (1999) showed that low literacy was associated with decreased adherence to HIV medication adherence in one study. (58) In contrast, Gazmararian et al. (2006) found that low literacy was significantly associated with refill adherence in unadjusted, but not in adjusted, analyses, (30) while Paasche-Orlow et al. (2006) found that lower literacy was associated with increased adherence to antiretroviral therapy (29). McDermott et al. (1997) posit that because adherence to placebo has been

associated with reduced morbidity and mortality, some outcomes attributed to adherence may in fact be due to other behaviors highly correlated with medication adherence.(59) Residual confounding related to diet and exercise(60) may also impact the relationship between adherence and disease control.

While the ARMS was validated in our patient population,(37) it relies on patient self-report of their medication refill behaviors. The CMG relies on having accurate and complete pharmacy and prescription information and assumes that the correlation between refilling medications and taking them is high. Because our findings suggest that the ARMS and CMG measure different aspects of medication adherence, we computed their Spearman rank order correlation coefficient and kappa after dichotomization to indicate non-adherence (ARMS>15 and CMG>0.20). This revealed only weak correlation, with a Spearman correlation coefficient of 0.34 (95% CI 0.25 to 0.42), and very little agreement beyond chance, with a kappa of 0.20 (95% CI 0.10 to 0.30). While this was not the original goal of our investigation, these findings suggest that more refined measures of medication adherence may be necessary to determine whether it is a truly an important mediator between literacy and BP control.

This is a cross-sectional study using the baseline data from a randomized study of an intervention to improve medication adherence. This analysis was designed to address the relationship between literacy and BP control, but it was not the primary aim of the parent clinical trial. Other limitations are present. Given lack of temporality, this study evaluates associations, not causation. Blood pressure control was determined using a single manual measure,(61) the usual level of data that guides clinical practices such as drug titration. Insurance status and income were not collected as part of this study, although patients were recruited from a single urban clinic and low-income and uninsured patients paid only \$2 per month for each medication at the time of this study. In an effort to control for potential residual confounding, we included employment status as a covariate in adjusted models.

Our findings raise several questions: If medication adherence is not a significant mediator between the relationship of literacy and blood pressure control, how may literacy impact blood pressure control? Does lack of evident association between medication adherence and blood pressure control result from lack of a relationship, difficulty measuring adherence, or multiple determinants of blood pressure control? Given that self-management skills are different for patients with heart failure, diabetes, pulmonary disease, and hypertension, it is also possible that the relationships among literacy, disease control, and adherence may vary by disease. Patients with hypertension are encouraged to lose weight, exercise, and reduce salt intake, which often requires the ability to read, understand, and to act based on the content of nutrition labels.(40) Patients also are encouraged to periodically measure blood pressure at home, record them in diary form, and then communicate with their health care providers regarding these readings. Additional research is needed to understand the mechanisms by which literacy and medication adherence interact to impact blood pressure.

4.2 CONCLUSION

Our study adds to the current body of knowledge on literacy and hypertension, with findings from a high-risk group of inner-city primary care patients in whom low literacy was

associated with increased odds of uncontrolled blood pressure, independent of education, race, employment status, age, and mental status. We did not find evidence for mediation of the relationship between literacy and BP control by either self-reported medication adherence or medication refill adherence.

4.3 PRACTICE IMPLICATIONS

To better inform interventions aimed at achieving and maintaining controlled blood pressure, future work is needed to explore additional mechanisms by which literacy may be related to blood pressure control and to develop more objective and reliable measures of medication adherence. Improved awareness of the relationships among patient literacy, BP control, and medication adherence may guide healthcare providers as they communicate with patients.

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Figure 1.

Study flow and patient selection for analysis

Abbreviations: IMAGE-CHD Study, Improving Medication Adherence through Graphically Enhanced Interventions in Coronary Heart Disease; Rx, prescription

Table 1

Clinical characteristics of the study cohort (n=423)

	Patients Included in Analysis (n = 423)	Low Literacy* (n = 192)	Marginal or Adequate Literacy (n = 231)	p[†]
Age, median (IQR)	64 (56–71)	66 (59–73)	62 (54–69)	<0.001
Female, no. (%)	237 (56)	97 (51)	140 (61)	0.04
African American, no. (%)	387 (91)	189 (97)	204 (87)	<0.001
Employment status				
Unemployed, no. (%)	65 (15)	24 (13)	42 (18)	0.18
Full-time, no. (%)	9 (2)	3 (2)	6 (3)	0.52
Part-time, no. (%)	22 (5)	12 (6)	10 (4)	0.39
Retired, disabled, no. (%)	327 (77)	153 (80)	174 (75)	0.3
Years of schooling completed, median (IQR)	12 (9–12)	10 (7–12)	12 (11–14)	<0.001
MMSE, median (IQR)	25 (22–27)	22 (21–25)	26 (24–28)	<0.001
Number of antihypertensive medications, median (IQR)	3 (2–4)	3 (2–4)	3 (2–4)	0.88
ARMS, mean (SD)	16 (4)	16 (4)	17 (4)	0.03
CMG, median (IQR)	0.19 (0.09–0.33)	0.19 (0.9–0.35)	0.18 (0.09–0.31)	0.41

Abbreviations: IQR, interquartile range; SD, standard deviation; MMSE, Mini-Mental Status Exam; ARMS, Adherence to Refills and Medications scale; CMG, cumulative medication gap

* Low literacy, defined as REALM 44

[†] Comparing low literacy and marginal/adequate literacy

Table 2

Mean blood pressure and blood pressure control by level of literacy

	Low Literacy	Marginal or Adequate Literacy	
	(n = 192)	(n = 231)	P
SBP mmHg, mean (SD)	138 (21)	134 (21)	0.05
DBP mmHg, mean (SD)	75 (13)	75 (12)	0.98
Blood pressure controlled, No. (%)	78 (41)	118 (51)	0.04

Abbreviations: SBP, systolic blood pressure; SD, standard deviation; DBP, diastolic blood pressure

Table 3

Factors associated with uncontrolled blood pressure

	Model 1* OR (95% CI)	Model 2† OR (95% CI)	Model 3‡ OR (95% CI)	Model 4§ OR (95% CI)
Low literacy //	1.53 (1.04–2.25)	1.68 (1.03–2.76)	1.75 (1.06–2.87)	1.53 (0.92–2.55)
ARMS	--	--	1.05 (1.00–1.11)	--
CMG	--	--	--	1.44 (0.46–4.47)
Age	--	1.01 (0.99–1.04)	1.02 (1.00–1.04)	1.02 (0.99–1.04)
Female	--	1.12 (0.75–1.70)	1.14 (0.75–1.71)	1.07 (0.71–1.63)
African American	--	0.83 (0.40–1.72)	0.84 (0.41–1.74)	0.71 (0.34–1.49)
Employment status	--	1.56 (0.87–2.81)	1.51 (0.84–2.73)	1.44 (0.79–2.65)
Education	--	1.04 (0.96–1.12)	1.04 (0.96–1.12)	1.03 (0.95–1.11)
MMSE	--	1.01 (0.93–1.09)	1.01 (0.93–1.09)	1.00 (0.92–1.08)

Abbreviations: ARMS, Adherence to Refills and Medications scale; CMG, cumulative medication gap; MMSE, Mini-Mental Status Exam; REALM, Rapid Estimate of Adult Literacy in Medicine; OR odds ratio

* Unadjusted logistic regression of low literacy and uncontrolled blood pressure

† Logistic regression adjusted for age, gender, race, education, employment status, and MMSE score

‡ Logistic regression including ARMS (continuous), also adjusted for age, gender, race, education, employment status, MMSE score

§ Logistic regression including CMG (continuous), also adjusted for age, gender, race, education, employment status, MMSE score, and CMG

// Low literacy defined as REALM 44

Table 4

Association of literacy with medication adherence, as measured by the ARMS and CMG

	Model 5 [*] beta coefficients (95% CI) [†] : <u>ARMS</u>	Model 6 [‡] beta coefficients (95% CI) [§] : <u>CMG</u>
REALM	0.03 (0.006–0.06)	–0.009 (–0.02 to 0.003)
Age	–0.11 (–0.15 to –0.07)	–0.04 (–0.06 to –0.02)
Female	–0.35 (–1.15 to 0.46)	0.10 (–0.26 to 0.49)
African American	–0.12 (–1.51 to 1.27)	0.34 (–0.04 to 0.11)
Employment status	0.72 (–0.39 to 1.83)	0.59 (0.06 to 1.11)
Education	–0.08 (–0.23 to 0.08)	0.04 (–0.04 to 0.11)
MMSE	–0.12 (–0.28 to 0.04)	–0.02 (0.09 to 0.06)

Abbreviations: ARMS, Adherence to Refills and Medications scale; CMG, cumulative medication gap; REALM, Rapid Estimate of Adult Literacy in Medicine; MMSE, Mini-Mental Status Exam

* Analysis with ARMS as continuous outcome variable (higher ARMS indicates lower adherence), REALM as continuous variable (higher REALM indicates higher literacy) in linear regression adjusted for age, gender, race, education, employment status, and MMSE score

[†] Per point increase in the aRMS score

[‡] Analysis with CMG as outcome variable, REALM as continuous variable, and linear regression adjusted for age, gender, race, education, employment status, and MMSE score

[§] Per 0.10 increment in CMG