



## Low Literacy Is Associated with Increased Risk of Hospitalization and Death Among Individuals with Heart Failure

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**BACKGROUND:** Low literacy increases the risk for many adverse health outcomes, but the relationship between literacy and adverse outcomes in heart failure (HF) has not been well studied.

**METHODS:** We studied a cohort of ambulatory patients with symptomatic HF (NYHA Class II-IV within the past 6 months) who were enrolled in a randomized controlled trial of self-care training recruited from internal medicine and cardiology clinics at four academic medical centers in the US. The primary outcome was combined all-cause hospitalization or death, with a secondary outcome of hospitalization for HF. Outcomes were assessed through blinded interviews and subsequent chart reviews, with adjudication of cause by a panel of masked assessors. Literacy was measured using the short Test of Functional Health Literacy in Adults. We used negative binomial regression to examine whether the incidence of the primary and secondary outcomes differed according to literacy.

**RESULTS:** Of the 595 study participants, 37 % had low literacy. Mean age was 61, 31 % were NYHA class III/IV at baseline, 16 % were Latino, and 38 % were African-American. Those with low literacy were older, had a higher NYHA class, and were more likely to be Latino (all  $p < 0.001$ ). Adjusting for site only, participants with low literacy had an incidence rate ratio (IRR) of 1.39 (95 % CI: 0.99, 1.94) for all-cause hospitalization or death and 1.36 (1.11, 1.66) for HF-related hospitalization. After adjusting for demographic, clinical, and self-management factors, the IRRs were 1.31 (1.06, 1.63) for all-cause hospitalization and death and 1.46 (1.20, 1.78) for HF-related hospitalization.

**CONCLUSIONS:** Low literacy increased the risk of hospitalization for ambulatory patients with heart

failure. Interventions designed to mitigate literacy-related disparities in outcomes are warranted.

**KEY WORDS:** heart failure; outcomes; literacy.

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### INTRODUCTION

Clear communication between health care providers and their patients is essential for patients to make good medical decisions, to receive effective instructions on how to take care of their illness, and to achieve desired health outcomes.<sup>1</sup> Literacy, the ability to read and process information, is essential for being able to take advantage of communication.<sup>2</sup> Prior studies have shown that low literacy skills increase the risk for many adverse health outcomes, such as more emergency department (ED) visits, hospitalizations, and deaths.<sup>1,3–5</sup> Two groups of researchers systematically reviewed studies on low literacy and health outcomes published from 1980 to 2003<sup>6</sup> and from 2003 to 2011<sup>4</sup> and also concluded that low literacy was associated with several adverse health outcomes, including increased hospitalization and increased mortality.

Heart failure (HF) is a serious chronic illness.<sup>7,8</sup> In the US, 5,800,000 have HF, approximately 670,000 new cases are diagnosed each year, and about 300,000 die as a result of HF per year.<sup>7,9</sup> HF is associated with substantial morbidity and mortality, poor quality of life (QOL), and frequent hospitalizations.<sup>10</sup> Improving HF self-management is a challenging but promising approach to improving outcomes.<sup>11</sup> Inadequate literacy may be a particularly important barrier to good HF

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self-management.<sup>1</sup> Adequate literacy enhances the patient's access to learning how to self-manage their condition at home (i.e., take their medication, follow a low-sodium diet, and monitor their daily weight and symptoms).<sup>1</sup> Inadequate literacy is associated with low health knowledge, which may lead to less effective use of self-management behaviors.<sup>3,4</sup>

Low or inadequate literacy is common among patients with HF, ranging from 27 % to 54 %.<sup>1,12</sup> Patients with HF were more likely to have low literacy compared with those without HF.<sup>12</sup> However, there is limited research examining the impact of low literacy on hospitalization and death in the HF population.<sup>1</sup> To our knowledge, only one study has reported that HF patients with adequate literacy had fewer HF-related hospitalizations than those with low literacy.<sup>13</sup> However, the participants in this study were recruited from one site, and the sample size was relatively small ( $n=192$ ). Accordingly, the purpose of this study was to examine the relationship between literacy and hospitalization and death in a diverse cohort of 595 adults with HF recruited from four sites in three different states (North Carolina, Illinois, and California) who were participating in a randomized trial of HF self-care.

## METHODS

### Study Design

We performed a prospective cohort study of participants in a four-site randomized controlled trial (RCT) comparing different levels of self-care training (single session vs. multisession). In this study, we explored the relationship between literacy and adverse outcomes in patients with HF.

### Sample and Setting

Detailed eligibility criteria, recruitment methods, and data collection processes have been published previously as in the main results of the trial.<sup>6,14</sup> Briefly, we studied a cohort of ambulatory patients with HF who were recruited from internal medicine and cardiology clinics at four academic medical centers: University of North Carolina (UNC) at Chapel Hill; Feinberg School of Medicine, Northwestern University; University of California, San Francisco-San Francisco General Hospital; and Olive View-University of California at Los Angeles Medical Center. To be eligible, a patient had to have a clinical diagnosis of heart failure and at least one of the following confirmatory tests: (1) left ventricular hypertrophy on an ECG or echocardiogram, (2) ejection fraction <50 %, (3) pulmonary edema on chest radiograph, or (4) elevated B-type natriuretic peptide. Participants were recruited from 2007 to 2009. Participants were eligible for inclusion if they had a

diagnosis of HF, New York Heart Association (NYHA) class II–IV symptoms in the past 6 months, current use of a loop diuretic medication, and an absence of cognitive impairment.

### Procedure

The Institutional Review Boards of all sites approved the study. Patient eligibility was assessed by a trained research assistant (RA) through chart review. The RA then approached potential participants at regular outpatient appointments. He or she explained study requirements to the potential participants and obtained informed written consent. All participants were interviewed at baseline to collect data on demographic and clinical variables and to complete baseline questionnaires. After the baseline assessment, participants were randomly allocated to a single session group that received a 40-min in-person self-care training; those in the multisession group received the same initial training and then ongoing phone-based support. Outcome data were collected for 12 months for each participant.

### Measurement

**Literacy.** Literacy was measured using the short Test of Functional Health Literacy in Adults (S-TOFHLA).<sup>15</sup> We categorized patient scores into the 3 S-TOFHLA categories of literacy typically used in research: inadequate, marginal, and adequate literacy. Because usually only a very small group of individuals have marginal literacy and it is likely not adequate for HF self-management, we collapsed the inadequate and marginal into one group that we label "low literacy."<sup>14,15</sup> As a result, we used a two-category variable for literacy, low and adequate, for all analyses.

**Outcomes.** The primary outcome was combined all-cause hospitalization or death. The secondary outcome was hospitalization for HF. A detailed description of our outcome measures has been published elsewhere.<sup>6,14,16</sup> In short, data on hospitalization or death were assessed through telephone interviews at 1, 6, and 12 months by the UNC Survey Research Unit. We obtained initial hospitalizations from patient interview and requested hospital medical records for the full study period from any hospitals in which the patient reported having had a hospital admission. Whether a hospitalization was HF-related was determined by masked assessors of a three-member adjudication committee. All outcome assessment was blinded to patient literacy status.

**Covariates.** To characterize participants and obtain data on potential confounding variables, we collected information

concerning the following demographics, clinical variables, HF-related symptoms, and self-management skills.

**Demographic Variables.** Age, race/ethnicity, preferred language, gender, income level, education level, and insurance were collected from the patient interview.

**Clinical Variables.** HF-related symptoms,<sup>17</sup> New York Heart Association (NYHA) class, systolic dysfunction (ejection fraction <45 %), systolic and diastolic blood pressure (BP), creatinine level, presence of diabetes, hypertension, history of cardiovascular disease (CVD), depressive symptoms, smoking status, and HF medication prescriptions (such as use of beta-blocker) were collected from patient interview and medical record review. Depressive symptoms were measured using the Patient Health Questionnaire.<sup>18,19</sup>

**Heart Failure-Related Symptoms.** HF-related symptoms were measured using a seven-item Heart Failure Symptom Scale (HFSS).<sup>17</sup> The HFSS was adapted from the Minnesota Living with Heart Failure Questionnaire rated on a scale from 0 (no effect) to 5 (very much); scores were transformed to a 100-point scale with 100 representing the least symptoms. The HFSS is a validated instrument that consists of seven questions and is transformed to a 100-point scale with 100 representing the best symptom profile. In our previous report, a difference of 14 points on a 0–100 scale is roughly equivalent to a change in one level of NYHA classification.<sup>20</sup>

**Self-Management Skills.** Self-management skills were defined as HF general knowledge, salt knowledge, self-efficacy, and self-care behaviors that patients with HF need in order to self-manage their HF condition. HF general knowledge, salt knowledge, and self-care behaviors were measured using an adapted version of the Improving Chronic Illness Care Evaluation telephone survey.<sup>17</sup> HF general knowledge questions included general HF knowledge, such as the definition of HF, with a total score ranging 0–8. Salt knowledge questions (including whether specific foods contain a lot of salt) had a total score ranging 0–10. Self-care behaviors included weight monitoring, following a low salt diet, and exercising. Participants' self-efficacy was assessed using a ten-item self-efficacy scale to measure their perceived confidence in managing their HF symptoms and performing self-care behaviors. More details related to measurement of self-management skills can be found in our previously published paper.<sup>21</sup>

## Data Management and Analysis

All data analyses were performed using Stata 12 (College Station, TX). Data analysis began with a

descriptive examination of all variables, including frequency distributions, percents, means, and standard deviations, as appropriate to the level of measurement of the variables.

We initially compared the differences in demographic and clinical factors between adequate literacy and low literacy participants using chi-square and t-tests. We then compared differences in the incidence rates of the primary and secondary outcomes between literacy groups using negative binomial regression. We first used negative binomial regression to examine whether the incidence of the primary and secondary outcomes differed according to literacy, controlling for site. Any variables that were significantly different between low/adequate literacy groups or might influence outcomes were adjusted for in the analyses. As such, we further adjusted for demographic (age, race/ethnicity, gender, education level, subjective socioeconomic status, and insurance) and clinical variables [New York Heart Association functional status, systolic dysfunction, systolic blood pressure, hypertension, diabetes, atrial fibrillation, history of CVD (myocardial infarction or angina), use of beta-blocker, and HF-related symptoms] in the model (partially adjusted). Finally, we repeated the analysis adding self-management skills (HF general knowledge, salt knowledge, self-efficacy, and self-care behaviors) to the model (fully adjusted). In addition, we also controlled for intervention status in alternate analyses to see how it affected the observed relationships.

## RESULTS

### Patient Characteristics

All participants in the trial with no missing data from literacy, hospitalization and death, or covariates (595 of 605 total participants) were included in this analysis (Table 1). The mean age was 61±13 years. Fifty-eight percent had systolic dysfunction, 31 % were NYHA class III/IV at baseline, 52 % were male, 38 % were white, 39 % African American, and 16 % Hispanic.

### Characteristics Comparison Between Participants who had Adequate and Low Literacy

Thirty-seven percent of participants (220 of 595) had low literacy at baseline. Compared to participants who had adequate literacy, those with low literacy were older, were more likely to be Latino, less likely to use English as their first language, to have less than 12 years of education, and to be insured by Medicare and/or

Table 1. Demographic, Clinical, and Behavioral Characteristics of Participants (N=595)

	Overall Sample	Low literacy	Adequate literacy	P
	N (%) or mean ± SD	N (%) or mean ± SD	N (%) or mean ± SD	
Size	595	220 (37)	375 (63)	
Demographics				
Literacy (TOFHLA)	24.2±12.3	9.8±7.5	32.7±3.7	P<0.001
Site				P<0.001
UNC	212 (36)	68 (31)	144 (38)	
NU	161 (27)	22 (10)	139 (37)	
UCSF	148 (25)	87 (40)	61 (16)	
UCLA	74 (12)	43 (20)	31 (8)	
Age	60.6±13.1	64.1±12.3	58.6±13.1	P<0.001
Race/ethnicity				P<0.001
White NH	229 (38)	42 (19)	187 (50)	
Hispanic	96 (16)	67 (30)	29 (8)	
African American	231 (39)	94 (43)	137 (37)	
Other	39 (7)	17 (8)	22 (6)	
Gender: male	309 (52)	122 (55)	187 (50)	P=0.188
Subjective socioeconomic status	4.8±2.5	3.8±2.3	5.4±2.4	P<0.001
Income level, \$				P<0.001
<15,000	302 (51)	152 (69)	150 (40)	
15,000–24,999	89 (15)	31 (14)	58 (15)	
25,000–40,000	65 (11)	15 (7)	50 (13)	
>40,000	124 (21)	16 (7)	108 (29)	
Education level				P<0.001
<12th grade	158 (27)	112 (51)	46 (12)	
High school	175 (29)	72 (33)	103 (27)	
Some college	137 (23)	22 (10)	115 (31)	
College graduate or greater	125 (21)	14 (6)	111 (30)	
Insurance				P<0.001
Medicare and/or Medicaid	441 (74)	189 (86)	252 (67)	
Private	77 (13)	6 (3)	71 (19)	
Uninsured	77 (13)	25 (11)	52 (14)	
Clinical characteristics				
HFSS	60.8±22.0	55.4±20.5	64.0±22.2	P<0.001
NYHA Class				P=0.001
I	113 (19)	31 (14)	82 (22)	
II	297 (50)	100 (45)	197 (53)	
III	118 (20)	54 (25)	64 (17)	
IV	67 (11)	35 (16)	32 (9)	
Systolic dysfunction: ejection fraction <0.45	348 (58)	125 (57)	223 (59)	P=0.527
Systolic BP (mmHg)	124.9±22.7	129.8±21.9	122.1±22.7	P<0.001
Diastolic BP (mmHg)	71.3±12.9	70.7±13.4	71.6±12.6	P=0.404
Body mass index	33.2±8.9	33.3±8.8	33.1±8.9	P=0.833
Creatinine level	1.3±0.5	1.3±0.6	1.3±0.5	P=0.922
Diabetes	286 (48)	120 (55)	166 (44)	P=0.015
Hypertension	505 (85)	211 (96)	294 (78)	P<0.001
Atrial fibrillation	285 (48)	121 (55)	164 (44)	P=0.008
Previous MI or angina	226 (38)	104 (47)	122 (33)	P<0.001
Chronic kidney disease	249 (42)	98 (45)	151 (40)	P=0.320
PHQ Score	7.4±5.4	7.9±5.2	7.2±5.5	P=0.156
Depressed PHQ≥10	194 (33)	81 (37)	113 (30)	P=0.102
Current smoker	95 (16)	29 (13)	66 (18)	P=0.156
Medication history				
Ejection fraction <0.45 ACE-I	386 (65)	143 (65)	243 (65)	P=0.778
ARB	118 (20)	47 (21)	71 (19)	P=0.473
ACE-I or ARB	490 (82)	183 (83)	307 (82)	P=0.685
Beta blocker	485 (82)	175 (80)	310 (83)	P=0.344
Spirolactone	165 (27)	47 (21)	118 (31)	P=0.006
Knowledge and behavioral factors				
HF general knowledge	6.1±1.8	5.5±1.9	6.6±1.6	P<0.001
Salt knowledge	7.5±1.5	7.0±1.8	7.8±1.3	P<0.001
Self-efficacy	78.3±14.4	73.7±15.5	81.0±13.0	P<0.001
Self-care behaviors	4.6±2.0	3.9±1.9	5.0±2.0	P<0.001

HF heart failure; HFSS heart failure symptoms; NYHA New York Heart Association functional classification  
SD standard deviation

Medicaid. People with low literacy were less likely to take aldosterone and more likely to: be categorized as NYHA class III/IV; have more HF-related symptoms; report lower socioeconomic status; have history of

diabetes, hypertension, atrial fibrillation, or previous myocardial infarction or angina; and have higher systolic blood pressure. In addition, low literacy participants had lower scores on HF general knowledge, salt

knowledge, self-efficacy, and performed fewer self-care behaviors (See Table 1).

## Literacy and Outcomes

During the follow-up period, there were 436 all-cause events (410 hospitalizations, 16 deaths, and 10 hospitalizations ending in death) and 169 HF-related hospitalizations. Participants with low literacy had a slightly higher annual rate of all-cause events (173 events, 0.79/person-year) than those with adequate literacy (263 events, rate of 0.70/person-year). Participants with low literacy had an incidence rate ratio (IRR) of 1.43 (95 % CI: 1.00–2.05) for all-cause hospitalization or death and 1.42 (95 % CI: 1.11–1.83) for HF-related hospitalization.

After adjusting for site, low literacy participants had an IRR of 1.39 (95 % CI: 0.99–1.94) for all-cause hospitalization or death and 1.36 (95 % CI: 1.11–1.66) for HF-related hospitalization. When adding demographic and clinical factors to the model, the partially adjusted IRR for all-cause hospitalization and death was 1.31 (95 % CI: 1.11–1.53) and for HF-related hospitalization was 1.44 (95 % CI: 1.15–1.82). When we repeated the analysis adding self-management skills to the model, the fully adjusted IRR for all-cause hospitalization and death was 1.31 (95 % CI: 1.06–1.63) and for HF-related hospitalization was 1.46 (95 % CI: 1.20–1.78) (Table 2). When intervention status was considered to be a confounder and added into the model, we found no effect on the observed relationships. This is not surprising because randomization was stratified by literacy.

## DISCUSSION

In this study, literacy measured at baseline predicted hospitalizations over 1 year in participants with HF.

Participants with low literacy had a higher rate of events compared with those with adequate literacy before and after adjusting for site, demographic, clinical, and self-management skills. Our finding is consistent with prior investigators' findings that adults who had low literacy had a higher risk of events (hospitalizations or death) compared to those with adequate literacy.<sup>3,4</sup>

Our study extends our understanding of the relationship between literacy and adverse outcomes in heart failure specifically. Two previous studies have examined this relationship. In one single-site study, low literacy was associated with worse outcomes (i.e., hospitalization for HF exacerbation) among 192 patients with HF.<sup>13</sup> Patients with adequate literacy had fewer HF-related hospitalizations than those with low literacy (IRR=0.34).<sup>13</sup> In a second among patients with diabetes, the prevalence of low literacy was nearly twice as high among those with concurrent HF compared with those without HF (27 % vs. 15 %,  $p<0.001$ ) even after controlling for sociodemographic factors.<sup>12</sup> Our multi-site trial enrolled a large and diverse sample of patients, including Latinos, and found similar results, although the magnitude of effect was smaller.

Our findings help identify potential reasons for suboptimal self-care performance. Heart failure requires many self-care skills, such as following a low sodium diet, adhering to medication, engaging in regular physical activity, and monitoring daily weight/symptoms.<sup>11</sup> Low literacy makes obtaining these skills and engaging in these behaviors more difficult.<sup>1</sup> In one study,<sup>22</sup> two thirds of patients with HF reported receiving information or advice from their health care provider about how to care for themselves to avoid complications; however, a majority of them (86 %) did not understand the instructions. Additionally, many of the patients did not realize the importance of daily weighing, the risk of alcohol use, and recommended fluid intake. Patients need to receive understandable information in order to perform effective self-care. Without understanding,

Table 2. All-Cause and Heart Failure-Related Hospitalization

	Low literacy (n=220)				
	N	Incidence rate/year	Adjusted for site incidence rate ratio	Partially adjusted incidence rate ratio <sup>†</sup>	Fully adjusted incidence rate ratio <sup>††</sup>
All-cause hospitalizations or death	595	1.43 (1.00–2.05)	1.39 (0.99,1.94)	1.31** (1.11, 1.53)	1.31* (1.06,1.63)
HF-related hospitalizations	595	1.42 (1.11–1.83)	1.36** (1.11,1.66)	1.44** (1.15, 1.82)	1.46*** (1.20,1.78)

\*Significant at 5 %

\*\*Significant at 1 %

\*\*\*Significant at 0.1 %

<sup>†</sup>Adjusted for site, age, gender, ethnicity, education level, subjective socioeconomic status, insurance, systolic blood pressure, systolic dysfunction, New York Heart Association (NYHA), diabetes, hypertension, atrial fibrillation, history of CVD [myocardial infarction (MI) or angina], beta-blocker use, and HF symptoms

<sup>††</sup>Adjusted for site, age, gender, ethnicity, education level, subjective socioeconomic status, insurance, systolic blood pressure, systolic dysfunction, NYHA, diabetes, hypertension, atrial fibrillation, history of CVD (MI or angina), beta-blocker use, and HF symptoms, HF general knowledge, salt knowledge, self-efficacy, and self-care behaviors  
HF heart failure

absorbing, and retaining the health information, it is not surprising that adherence to the self-care recommendations in patients with HF is poor.<sup>22</sup>

We also found that patients with low literacy had lower scores on HF general knowledge, salt knowledge, self-efficacy, and self-care behaviors.<sup>20,23</sup> When these factors were adjusted in the multivariate model, patients with low literacy still had higher incidence of all-cause and HF-related hospitalizations, suggesting that the observed relationship between literacy and outcomes cannot be explained by knowledge, self-efficacy, and self-behaviors, at least as we have measured them. This finding may be a result of the fact that literacy is a marker for other, unexplained factors, that affect outcomes. Or, it could reflect inadequate measurement of knowledge and behaviors in our study. Indeed, adequate measurement of knowledge and self-management behaviors is difficult and additional efforts to develop reliable and valid measures could improve research in this area.

In addition to knowledge and self-care behaviors, researchers have reported that differences in rehospitalizations may be related to differences in socioeconomic and clinical factors, such as age,<sup>21,22</sup> ethnicity,<sup>23–30</sup> insurance,<sup>31</sup> access to care,<sup>21,22</sup> the prevalence of comorbid conditions,<sup>23,28</sup> effectiveness of the treatment,<sup>23,28</sup> and depression.<sup>23</sup> In our study, we found that participants with low literacy were older and more likely to be Latino; they were less likely to use English as their first language, to have less than 12 years of education, to have Medicare and/or Medicaid, and to report lower socioeconomic status. These participants had more HF-related symptoms and were more likely to have histories of diabetes, hypertension, atrial fibrillation, and CVD. These data are consistent with data from prior studies on factors related to literacy.<sup>31</sup> However, when we adjusted for these factors in our models, the estimates of effect did not change. Nevertheless, due to the possibility of unmeasured confounding factors, we cannot conclude definitively that low literacy directly affects heart failure outcomes.

Intervention studies on literacy in the HF population have showed that patients with low literacy benefit more<sup>14,32</sup> or at least the same<sup>33</sup> from educational counseling on self-care training compared with those with higher literacy levels. More specifically, interventions have improved HF-related knowledge,<sup>32</sup> HF self-efficacy,<sup>32</sup> and self-care behaviors (i.e., better medication adherence<sup>33</sup> and more likely to monitor daily weights<sup>32</sup>), reduced health care utilization (ED visits and hospitalizations),<sup>14,32,33</sup> death,<sup>14,32</sup> medical costs,<sup>33</sup> and also increased patient satisfaction.<sup>33</sup> The findings of these studies give some evidence that this type of intervention can mitigate literacy-related disparities. These studies also provide some evidence that insufficient self-management is a reason why people with low literacy have worse outcomes.

Our study has several limitations. First, Spanish-speaking participants were enrolled only at the two California sites, which confounds studying the effects of site and language. Second, our participants were relatively younger than HF patients in general. The difference might have resulted from recruiting participants in the ambulatory care settings and not the hospital settings. Third, we obtained hospitalizations from patient interview and requested hospital medical records for the full study period from any hospitals in which the patient reported having had a hospital admission. It is possible that participants might forget their hospital admissions or hospitals might not send us the requested records. However, we have no reason to believe that recall or missing records would be different by literacy level. Finally, although this was a multicenter study conducted in several hospitals in three diverse states in the US, the findings may not be generalizable to other health systems in other countries.

## CONCLUSION

Low literacy was associated with higher risk of hospitalizations for ambulatory patients with HF. Based on the results of this study, and of others, it is important for clinicians to consider patients' literacy as a risk factor for worse health outcomes. Interventions designed to mitigate literacy-related disparities in outcomes are warranted.

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**Conflict of Interest:** *The authors declare that they do not have a conflict of interest.*

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