The association of health literacy with adherence and outcomes in moderate-severe asthma

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Background: Low health literacy is associated with poor outcomes in asthma and other diseases, but the mechanisms governing this relationship are not well defined.
Objective: We sought to assess whether literacy is related to subsequent asthma self-management, measured as adherence to inhaled steroids, and asthma outcomes.
Methods: In a prospective longitudinal cohort study, numeric (Asthma Numeracy Questionnaire) and print literacy (Short Test of Functional Health Literacy in Adults) were assessed at baseline in adults with moderate or severe asthma for their impact on subsequent electronically monitored adherence and asthma outcomes (asthma control, asthma-related quality of life, and FEV_1) over 26 weeks, using mixed-effects linear regression models.
Results: A total of 284 adults participated: age, 48 ± 14 years, 71% females, 70% African American, 6% Latino, mean FEV_1 66% ± 19%, 86 (30%) with hospitalizations, and 148 (52%) with emergency department visits for asthma in the prior year. Mean Asthma Numeracy Questionnaire score was 2.3 ± 1.2 (range, 0-4); mean Short Test of Functional Health Literacy in Adults score was 31 ± 8 (range, 0-36). In unadjusted analyses, numeric and print literacy were associated with better adherence ($P = .01$ and $P = .08$, respectively), asthma control ($P = .005$ and $P < .001$, respectively), and quality of life ($P < .001$ and $P < .001$, respectively). After controlling for age, sex, and race/ethnicity, the associations diminished and only quality of life (numeric $P = .03$, print $P = .006$) and asthma control (print $P = .005$) remained significantly associated with literacy. Race/ethnicity, income, and educational attainment were correlated ($P < .001$).
Conclusion: While the relationship between literacy and health is complex, interventions that account for and address the literacy needs of patients may improve asthma outcomes. (J Allergy Clin Immunol 2013;132:321-7.)

Key words: *Health literacy, numeracy, print literacy, asthma, adherence, adults, inner-city asthma, inhaled corticosteroids, asthma-related quality of life, asthma control*

About half of US adults have no more than basic reading and numerical skills, the primary components of literacy.[1] Lack of these skills in turn compromises health literacy, "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions."[2] Low health literacy is associated with poorer health access and outcomes, higher health costs, and less patient satisfaction with health care providers.[2-5] Low health literacy is especially prevalent among those with low socioeconomic status, the elderly, and those whose primary language is not English, reflecting limited educational opportunities. In these same groups, the prevalence of asthma morbidity is high. Limited literacy is thought to contribute to poor health outcomes in part by making self-management difficult. This is pertinent in chronic diseases such as asthma that require relatively complicated self-management regimens and especially for patients with several medical problems. The complexity of insurance plans and health care systems also may pose particular difficulty for those with limited literacy to access health care.[6,7]

In asthma, cross-sectional studies have associated limited reading ability or low print literacy with improper use of inhalers and less disease knowledge.[8] Poor aural literacy skills have also been associated with poorer management.[9] We found that low numeric literacy or numeracy is associated with prior emergency department (ED) visits and hospitalizations for asthma.[10] We also found that adequate numerical skills attenuate the association of minority status with lower asthma-related quality of life

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Abbreviations used
AE: Asthma education
ANQ: Asthma Numeracy Questionnaire
AQOL: Asthma-related quality of life
ED: Emergency department
ICS: Inhaled corticosteroid
PS: Problem-solving
S-TOFHLA: Short Test of Functional Health Literacy in Adults

(AQOL).[11] Together these studies suggest that health literacy influences self-management and subsequent outcomes, but longitudinal studies are needed to better assess potential causal pathways between health literacy and health outcomes.

An important marker of self-management ability for all but the mildest asthma may be adherence to inhaled corticosteroid (ICS) therapy,[12-14] which is universally difficult to achieve.[15-17] Adherence may also be a measure of patient satisfaction with care or trust in the provider[18,19] or the prescribed therapy.[20] Measuring adherence to ICS is difficult; serum levels cannot be measured, and canister weighing or patient and physician report are unreliable.[21-23] Counting prescribed or filled prescriptions does not ensure that medications are taken.[16,24] Although the act of monitoring adherence can change behavior, recording the date and time of use with an electronic monitor is the most accurate method of assessing adherence.[25,26]

This project explores the association of health literacy, measured by print literacy or reading comprehension and asthma-related numeracy, with electronically monitored ICS adherence and asthma outcomes in adults with moderate or severe asthma. We hypothesized that higher health literacy is associated with better adherence and better asthma outcomes.

METHODS
Study design

We conducted a prospective cohort study to examine the association between baseline health literacy skills and subsequent ICS adherence as a reflection of self-management within a large randomized controlled trial. The parent study, Individualized Interventions to Improve Adherence in Asthma (NCT00115323, R01 HL073932), compared an individualized problem-solving (PS) strategy to standard asthma education (AE) in adults with moderate or severe asthma.[27] Electronically monitored adherence was the primary outcome of this 26-week trial; asthma clinical outcomes were other end points. In the parent study, overall no difference emerged in outcomes between randomized groups.[27] About 6 months into recruitment, we added literacy questionnaires to the protocol for all participants for the secondary analysis reported here. Controlling for randomization assignment, we assessed whether adherence and asthma outcomes were associated with health literacy, measured by asthma-related numeracy and reading comprehension or print literacy. We evaluated whether participants would differentially benefit from the PS intervention by literacy level and whether the negative association between low literacy and adherence and asthma outcomes is diminished by the PS intervention. This study was approved by the institutional review boards of the University of Pennsylvania and the Philadelphia Veterans Affairs Medical Center.

Subjects

Participants were English- or Spanish-speaking adults with moderate or severe persistent asthma according to National Heart, Lung, and Blood Institute Expert Panel Report 3 guidelines.[28] Inclusion criteria were designed to identify patients with sufficiently severe and reversible asthma who were likely to benefit from ICS therapy. Specific criteria were (1) age 18 years or older; (2) physician's diagnosis of asthma; (3) prescription for an ICS-containing medication for asthma; and (4) evidence of reversible airflow obstruction defined as an increase of at least (i) 15% and 200 mL in FEV_1 with asthma treatment over the previous 3 years or (ii) 12% in FEV_1 or forced vital capacity and 200 mL in FEV_1 within 30 minutes of 2 to 4 puffs of albuterol by metered-dose inhaler or 2.5 mg by nebulizer. Smokers were included. Patients with severe psychiatric problems such as obvious mania or schizophrenia that would make it impossible to understand or carry out the protocol were excluded. Subjects were not selected by criteria related to literacy or adherence.

Subjects were recruited from practices serving low-income inner-city neighborhoods with high prevalence of asthma morbidity. These included outpatient primary care and asthma specialty practices of the University of Pennsylvania Health System; Woodland Avenue Health Center, a federally qualified health center; the Comprehensive Health Center at Episcopal Hospital; and Philadelphia Veterans Affairs Medical Center. Charts or electronic medical records of participating practices were prescreened for patients with a diagnosis of asthma who were prescribed an ICS. Potential subjects were then approached by telephone or at the time of a clinic visit and asked to sign consent for further screening, which included spirometry using standard procedures.[29] Those satisfying all enrollment criteria were then asked to sign a second informed consent to participate in the 26-week study.

Procedures

Upon enrollment, participants completed questionnaires about their socio-demographics, health literacy, present and past asthma status, and comorbidities. Spirometry was obtained.[29] An electronic monitor was attached to participants' ICS-containing inhaler.[25,30] Participants were informed that the monitor recorded the time and date of inhaler actuation and that data would be downloaded at each of the following study visits. Two weeks later, at visit 2, subjects were randomized according to a computer-generated algorithm in 1:1 ratio to either PS or AE. Subjects met with research coordinators monthly for 4 sessions (visits 2-5) of either PS or AE, which included assessment of asthma control, spirometry, and need for hospitalization or ED visits. Electronic monitor data were downloaded. Subjects then continued to meet monthly with research coordinators for 3 additional months (visits 6-8) so that the research coordinators could download monitor data, obtain spirometry, and collect information on medication use, ED visits, and hospitalizations. No PS or AE occurred at visits 6 to 8. Details of the PS and AE interventions have previously been reported.[27] Participants received $20 for the first visit, $15 for visits 2 to 5, $10 for short visits 6 to 7, and $50 for completing visit 8. The ICS was supplied for subjects without any insurance coverage for an ICS. For subjects with a co-payment, this sum was reimbursed if all visits were completed and medication receipts were submitted.

With the exception of the print literacy questionnaire, all questionnaires were administered by reading the items to the participant while the participant looked at the written questionnaire. For patients whose primary language was Spanish, bilingual research coordinators administered the questionnaires and PS or AE in Spanish. All validated questionnaires were available in English and Spanish; clinic scripts were translated into Spanish by native speakers, translated back into English, and compared with the original English version. In addition, both English and Spanish versions were reviewed independently by other bilingual speakers to be sure the Spanish scripts were equivalent to the English versions.

Outcomes

Adherence to ICS regimen prescribed by participant's physician. Electronic monitors recorded the time and date of ICS actuation.[25,31] Such monitors can record multiple actuations over a short time period and thus can detect medication "dumping."[31] This is in contrast to inhalers with built-in counters, which display doses but cannot capture deliberate multiple actuations of an ICS unaccompanied by inhalation.[31,32]

No commercial monitor was available for a dry powder inhaler containing fluticasone-salmeterol, the most frequently prescribed ICS to subjects during the study period. We used the Diskus Adherence Logger or DAL, the research