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Development and Validation of the High Blood Pressure-Focused Health Literacy Scale

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Abstract

Objective—While the role of health literacy in chronic disease management is well documented, few intervention studies have been reported. A major barrier to designing and implementing such interventions is the lack of valid health literacy tools. This study developed and tested a novel health literacy scale for individuals with high blood pressure (HBP).

Methods—A two-step design process was used: In the construction phase, focus group studies and a literature review were conducted to generate a pool of items. The testing phase involved a psychometric evaluation and pilot-testing of the scale on hypertensive Korean Americans (n=386). The end product was a HBP-health literacy scale (HBP-HLS) with two essential domains, print literacy and functional health literacy.

Results—Psychometric testing indicated that the scale was reliable (Kuder-Richardson-20 coefficient=0.98), valid (content validity index ≥0.8), and significantly correlated with theoretically selected variables (education, r=0.67, p<0.01; HBP knowledge, r= 0.33, p<0.01).

Conclusion—The HBP-HLS demonstrated its utility for evaluating HBP management interventions in the community setting. Practice Implications: Utilizing the HBP-HLS should be considered as a potential tool for improving health literacy and evaluating intervention studies in the context of HBP management.

Keywords

Health literacy; High blood pressure; Validation

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Conflict of Interest
The authors declared no conflict of interest.

1. Introduction

Health literacy, defined as the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions (1), has been shown in a growing number of scientific reports to play a significant role in the management of chronic diseases, such as high blood pressure (HBP). However, only a small number of health literacy-focused intervention studies have been reported in the recent literature (2-4). Previous intervention studies involving individuals with low health literacy have predominantly focused on adjustment of reading levels in written educational materials or incorporating the use of video, audiotapes, or other technology (4-6). Very few clinicians and researchers have attempted to directly influence health literacy levels as a mean of improving the ability to manage chronic diseases (7). The adverse effect of low health literacy is most salient among foreign-born, non-English speakers, and the elderly. In particular, limited health literacy has been found to be a strong predictor of inadequate utilization of health care resources in immigrant populations (8-11). Furthermore, insufficent health literacy has long been identified as a major barrier to successful management of chronic diseases because of its impact on one's self-care skills such as acquiring appropriate knowledge, communication with providers, and adherence to treatment recommendations (12,13).

There are numerous barriers to pursuing potentially fruitful interventions, including a lack of sensitive health literacy measures and strong researcher skepticism about whether adult health literacy can be meaningfully improved through a relatively short-term education intervention. Specifically, most health literacy measures such as the Rapid Estimate of Adult Literacy in Medicine (REALM) and the Test of Functional Health Literacy in Adults (TOFHLA) assess broad and global levels of health literacy rather than disease- or context-specific health literacy (12-17).

A trend towards developing measures that capture health literacy within a specific context has been growing. For example, there are health literacy measures that focus on diabetes management (18, 19), asthma (20), and genetics (21). However, a health literacy measure that is context specific to HBP is not available. The theoretical proposition advancing this trend is compelling. It is argued that a disease- or context-specific health literacy tool may be more useful and immediately relevant when it is applied to a group of people in need of managing a particular chronic illness or condition (22). Furthermore, it can provide clinicians with useful assessments of patients' educational needs and function as an effective evaluation tool for targeted disease-specific interventions. Using disease specific health literacy measurement tools are particularly applicable for patients from recent immigrant populations who have limited English proficiency and who will most likely benefit from both careful assessment and subsequent intervention.

In order to address the urgent challenge of advancing the self-care science for a growing population of people with HBP and limited health literacy such as recent immigrants, we developed a HBP-specific health literacy measure that is sensitive to capturing the intervention effects of health literacy-focused HBP management education and counseling program. This paper reports the development process of the HBP-specific health literacy instrument as well as the initial psychometric properties of the scale using a sample of first generation Korean Americans. Preliminary evidence of its potential utility as an intervention outcome assessment tool is also presented.

2. Methods

A two-step instrumentation design process was employed that began with an exploratory construction phase, followed by a cross-sectional descriptive study.

2.1. Construction phase

2.1.1. Selection of hypertension-specific items—Several methods were used to create a comprehensive pool of relevant words for the scale. First, we searched the relevant literature for current practice guidelines, such as the one published by the 7th Joint National Committee (JNC VII) on the Detection, Evaluation, and Treatment of High Blood Pressure (23); we also searched for educational materials targeting patients with HBP to identify important terminology in the context of HBP care such as common complications and the names of antihypertensive medications. In addition, we used participant observation methodology to explore common clinical encounters experienced by patients with HBP. Specifically, we selected seven clinical settings where patients with HBP often seek care (e.g., primary care office, pharmacy, emergency room, cardiology clinic). At least one patient encounter for each setting was observed by a trained research staff. Recorded field notes from each setting were used to inform the essential terminology needed by patients with HBP. We also ran three focus groups to gain a comprehensive understanding of the health literacy needs in the context of HBP management in the target population. The memberships in those focus groups were Korean-American hypertensive patients with self-reported limited English proficiency. Using these combined methods, we developed a comprehensive pool of relevant words most commonly used in the context of HBP care. Then, a panel of 10 people including Korean American HBP patients, family members, nurses, physicians, a nutritionist and community health workers who have been working in the Korean American community, assessed the face validity of the initial item pool as well as the appropriateness and readability of each item in the pool. Finally, another panel of 10 experts including health care providers and researchers with extensive experience working with hypertensive patient populations were asked to rate, by marking on a paper form, how well each item reflected essential knowledge needed for the chronic management of HBP. As described by Lynn (24), a 4-point Likert scale was used with “1= not relevant” and “4= very relevant.” A content validity index was then derived by calculating the proportion of experts who gave an item a rating of 3 or 4. Based on a statistical formula provided by Lynn (24), 8 out of the 10 experts were required to endorse an item for it to be established as content valid (Kappa >.80, $p<.05$). Using this strategy, a total of 78 words specific to HBP care were retained.

2.1.2. Initial structure of the HBP-Focused Health Literacy Scale—As described earlier, health literacy can be defined as, “The degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions” – a definition that is used by the Institute of Medicine (IOM) (22). The IOM report on Health Literacy further explicates several dimensions of health literacy: oral literacy, print literacy, and functional literacy. Oral literacy refers to speech and speech comprehension. Print literacy refers to the ability to read, write, and understand written language. Functional literacy is the use of literacy in order to perform a particular task.

For clinical utility and feasibility we focused on print literacy and functional literacy. While comprehension of the spoken word (oral literacy) is critically important in health care, there are no established tests to adequately measure it. Secondly, it is argued that the cognitive process necessary for understanding the spoken word and the printed word are deeply intertwined (25). For those reasons, individuals with limited print literacy are likely to also

experience limited oral literacy. Parsing out oral literacy as a distinct concept, while appealing, may be difficult due to its inherent interrelatedness.

The print literacy subscale of the HBP-HLS was modeled on the most common global health literacy scale, the REALM. Our print literacy subscale was composed of 78 items that measured patients' ability to pronounce selected medical terminology related to HBP, its treatment and self-care. As in the REALM, the 78 items were listed in three columns of ascending difficulty (26 items per column). The items were scored as correct/ incorrect, with total possible scores ranging from 0-78.

Functional Health Literacy: In contrast to the situation for print literacy, there are two excellent functional health literacy tools that could be adapted for use for people with HBP: the TOFHLA and the Newest Vital Sign (NVS). Both of which were developed for people with limited literacy (26, 27). We modified the items on these two scales to make them more relevant to hypertensive patients. For example, the original NVS consists of an ice cream nutrition label with six accompanying questions that assess the ability to interpret nutritional information. In the HBP-HLS, we used a nutrition label for ramen (a popular instant noodle among Koreans) instead to make questions more relevant to the context of HBP, since reducing sodium intake is a major self-care skill that people with HBP should have in order to achieve adequate HBP control. For the present study, seven items from TOFHLA and six items from NVS were adapted for our functional health literacy subscale. The items were scored as correct/ incorrect, with total possible scores ranging from 0-13.

Item-reduction process: The initial items were carefully examined in an effort to create a parsimonious, yet psychometrically sound scale. The following criteria were used to examine the items: 1) internal consistency reliability indices; 2) discrimination ability of items, to assess how well the items could distinguish the low-literacy group from high literacy group (items that were too easy or too difficult based on overall distribution scores were removed); and 3) theoretical relevancy and congruency of the items with current HBP care guidelines and practices.

Overall, the 78 items showed a relatively high Kuder-Richardson (KR)-20 coefficient (=0.988), with item-total correlations ranging from 0.41 to 0.87. Items with relatively low item-total correlations, defined as less than 0.30, were nominated for removal. Through this procedure, the total items on the print literacy subscale were reduced to 30. An assessment of the functional literacy subscale indicated that the seven numeracy items adapted from the TOFHLA and the six modified items from the NVS showed excellent internal consistency, with coefficients of 0.88 and 0.89, respectively.

2.2. Testing phase

2.2.1. Sample—Data were obtained from a sample of Korean Americans with HBP who were participating in an ongoing community-based intervention study designed to promote HBP self-care skills. Eligibility for the study was based on the following inclusion criteria: Self-identified as a Korean American aged 60 or older; SBP >140 and/or DBP >90 mmHg or on HBP medication; and written consent to participate in the study. The study employed an experimental study design with two parallel arms, with those in the intervention arm (n=192) receiving a comprehensive, health-literacy focused HBP intervention and the control comparison group (n=194) receiving usual care. We used a cluster randomization using ethnic churches as the unit of random assignment in order to reduce the potential risk of treatment diffusion between participants. Recent literature and our previous studies indicated that a majority of Korean American seniors (85%) attend an ethnic Korean church (29). Considering several important factors such as denominations, urban vs. suburban neighborhoods, the size of membership in each church, and required sample size of 360

Korean American seniors, we selected 22 Korean churches in the Baltimore-Washington metropolitan area.

In the ongoing study from which the current dataset was driven, participants in the intervention group receive a health-literacy focused HBP intervention to improve both HBP knowledge and relevant health literacy skills. The intervention starts with 6 weeks in-class group education (2hours per week), followed by individual telephone counseling from trained bilingual counselors for 24 months. Thus far, data collection up to 12 months has been completed. A total of 440 eligible Korean Americans completed the study questionnaires at baseline. We used the baseline data to test the psychometric properties of the newly developed HBP-HLS and the 12-month follow-up data to evaluate the utility of the HBP-HLS as an outcome assessment tool for an HBP intervention. The final analysis involved 386 participants who completed the 12-month follow-up survey.

2.2.2. Procedure—After obtaining informed consent, trained bilingual research assistants (RAs) conducted face to face interviews with participants. To assess print literacy, we gave the participants a laminated copy of the 30 words that were selected as the most relevant to the context of HBP care (see Appendix A) and asked them to pronounce each word. The bilingual RAs scored answers on an unlaminated copy of the same scale, using (+) for each item correctly pronounced. If the participant took more than 5 seconds on a certain item, they were told to skip that item and proceed to the next word. RAs checked (−) for any word that was either not attempted or was mispronounced. The number of correctly pronounced words (+) was then counted to derive a sum score. To assess functional health literacy, participants were instructed to apply their health literacy knowledge in self care activities such as understanding appointment slips, medication labels and food labels (see Appendix B). While an interviewer was available for clarification of instructions, participants self-administered these 13 items. Most participants spent about 10-15 minutes completing the HBP-HLS.

2.3. Analysis

Descriptive statistics were used to summarize study participants' demographic information and other psychosocial variables. To evaluate the internal consistency and reliability of the health literacy items, KR-20 coefficients were calculated for the health literacy total scores and the two subscales, print literacy and functional health literacy. In addition, item analysis was performed to see if any items showed inter-item correlations (>0.30 or <0.70) or item-total correlations (>0.30). The correlation of health literacy with theoretically driven variables, including education and HBP knowledge, was assessed by Pearson correlation. Independent *t*-tests were conducted to assess the level of health literacy at baseline and 12-months follow-up. Drop-out analyses were executed using independent samples t-tests and chi-square test. Statistical significance was determined at alpha = 0.05.

3. Results

3.1 Demographic Characteristics of the Sample

Sample characteristics are shown in Table 1. Of the 440 participants who completed baseline measures, 69.5% were women. The mean age was 70.9 ± 5.5 years, ranging from 60 years to 89 years. About 66% of the participants reported having a high school education or lower. The Korean Americans in this sample were all first-generation immigrants who had been born in Korea, with a mean length of stay in the United States of 24.2 (± 11.3) years. In terms of medical history, 84.3% of the participants reported being on antihypertensive medication(s), and 52% had a family history of HBP. They had HBP for an average of 9.6 (± 8.8) years, and 45.2% of the participants reported having one or more co-

morbid conditions. There were no significant demographic differences between the intervention and control groups.

3.2 Reliability Testing

Table 2 summarizes the means, standard deviations, and KR-20 reliability coefficients for the print literacy and functional literacy subscales. The KR-20 for the total HBP-HLS was 0.98, indicating high internal consistency. Each subscale also showed high internal consistency, with KR-20=0.98 for the print literacy and 0.93 for the functional literacy subscale, respectively. Furthermore, item analysis revealed item-total correlations for the total HBP-HLS ranging from 0.32 to 0.91, and the item-total correlations of the print literacy and functional literacy ranging from 0.38-0.87 and 0.32-0.91, respectively.

3.3. Validity testing

The validity of this newly developed scale was assessed both qualitatively and quantitatively. The face and content validity of the scale was assessed through a series of focus groups as well as through the use of an expert panel, as described earlier. Based on the rating that experts assigned to each item, a content validity index (CVI) was calculated to assess the degree of agreement. Each of the final 30 items achieved a CVI of >0.80, suggesting strong agreement among the judges, and therefore high content validity.

To empirically assess construct validity, we tested the convergent validity of the print literacy subscale with the functional health literacy subscale, since most of the items on the functional health literacy subscale were adopted from the TOFHLA and NVS. Our results show that the print literacy subscale was positively correlated with the modified TOFHLA (r=0.80), modified NVS (r=0.76), and the total functional health literacy subscale (r=0.82).

We also examined the correlation coefficients between the total scores on the HBP-HLS and theoretically relevant variables, including education, years of stay in the US, and HBP knowledge. The HBP-HLS showed a significant positive correlation with education level (r=0.67), years in the US (r=0.32), and HBP knowledge (r=0.33). Also, both the print and functional health literacy subscales were significantly and positively associated with participants' educational level (print health literacy, r=0.68; functional health literacy, r=0.60), years of staying in the US (print health literacy, r=0.32; functional health literacy, r=0.27), and HBP knowledge (print health literacy, r=0.30; functional health literacy, r=0.34).

3. 4. Preliminary evaluation as an intervention evaluation tool

As shown in Table 3, participants in the intervention group reported a statistically significant increase in overall health literacy (p=0.008) upon completion of 12 months of intervention **as compared to the comparison group**. Both print literacy (p=0.012) and functional health literacy (p=0.007) were also significantly increased **in the intervention group** after 12 months of intervention. In addition, there was a significant increase in both the modified TOFHLA (p=0.008) and modified NVS (p=0.031) in the intervention group compared to the comparison group after 12 months of intervention. The between-group differences were notable. In terms of within-groups difference between baseline and 12-months of follow-up, the scores in the overall HBP-health literacy scale and both subscale domains were statistically increased in the intervention group at the follow-up, while the health literacy scores in the control group tended to decreased over the same period.

4. Discussion and conclusion

4.1. Discussion

The issue of health literacy has become a major focus of research and practice in the context of chronic disease management, since limited health literacy has long been recognized as a major barrier to successful management of chronic diseases in general population (12, 30). Several health literacy instruments have been used in various patient populations. The majority of health literacy instruments, however, are not specially designed for use in the context of managing particular chronic diseases, are too long for routine use in health care setting, and/or do not include all the essential domains needed to address the multifaceted nature of patients' chronic disease management (7, 27).

To the best of our knowledge, this is the first study to develop a HBP-specific health literacy tool and test its efficacy in non-English speaking immigrants. The results we obtained indicate that this newly constructed HBP-HLS is highly reliable (KR-20=0.98) and demonstrates strong validity. We also found strong evidence of content validity (CVI >0.80) and reasonable convergent validity, as indicated by high positive correlations with the modified TOFHLA (r=0.80) and modified NVS (r=0.76). Moreover, the HBP-HLS was statistically significantly associated with theoretically relevant variables such as education and HBP knowledge.

We are confident that the HBP-HLS can have high clinical utility. In particular, the items on the scale are focused on the patient's level of health literacy in the context of BP care and management. In addition, the scale is relatively easy to use and administer, requiring only about 10 to 15 minutes to complete. The HBP_HLS can quickly assess patients' individual health literacy levels as well as provide pertinent information for clinicians planning patient-centered care. Both the print literacy and functional health literacy subscales include highly relevant HBP-focused medical terminology that may be encountered in various real-life settings including, medical visits, communication with health professionals, or even in the course of self-care activities such as reading medical instructions and nutritional labels.

We believe that efforts to assess and improve the level of patients' functional health literacy and print literacy are essential for improving the health of ethnic minority populations with chronic disease. Given that successful management of chronic diseases such as HBP requires "the ability to read, understand, and process health information" (31, 32), adequate functional literacy with regard to HBP-relevant content is vital for adequate management of this condition. Moreover, we recognize that measuring functional health literacy is a more accurate approach for measuring an individual's health literacy in populations that have limited English skills or whose primary language system is based on a phonetic language system (since one can potentially pronounce words without understanding its meaning).

Our findings also suggest that this newly constructed scale can be used as an effective evaluation tool for interventions designed to improve HBP-focused print and functional health literacy. As one of the major limitations of the current health literacy scales is a lack of specificity in terms of their ability to capture potential intervention effects (because most of them consist of broad and general medical terms), our study demonstrated the clinical utility of this new scale as an intervention evaluation tool. More importantly, our study now offers an important tool for clinicians and researchers who deal with populations in need of improving health literacy. Traditionally, health education programs have rarely included topic contents or activities that are directly focused on improving health literacy directly, in part, because of the lack of a sensitive instrument to measure health literacy, and particularly disease-specific health literacy.

4.2. Conclusion

Our study has demonstrated that disease-specific health literacy can easily be merged into an intervention approach, allowing researchers and patients to focus more closely on the disease-specific context during both the assessment and implementation of the intervention. Currently, health literacy studies among ethnic minority groups with limited English skills are scarce. It is difficult to find valid health literacy tools for certain ethnic minority immigrant populations. Furthermore, cultural differences and language barriers make it more difficult for non-English speaking population to achieve cultural and linguistic competency (28, 33).

Future researchers and clinicians who are committed to improving self-care activities of people with chronic diseases should consider interventions to improve disease-specific health literacy. As this study has suggested, foreign-born individuals and people with limited English skills would be an appropriate first target group to benefit from a blended approach involving focused and repeated exposure to disease-specific terminology and content.

It is important to note that the participants in this study were exclusively foreign-born, ethnic minority immigrants and the development of this tool was explicitly designed and tested in Korean American population; thus, cross-validation of the study in other populations is necessary before making any claims regarding the generalizability of the instrument. In addition, further research is needed to determine the mechanism(s) underlying the role of health literacy in both psychosocial and clinical outcomes.

4.3. Practice implications

Given the multifaceted nature of health literacy and chronic disease management in vulnerable populations, utilizing a disease-specific health literacy instrument should be considered by future clinical researchers and practitioners as a potential tool for improving health literacy and evaluating the outcomes of disease-specific interventions.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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Table 1

Demographic characteristics of the participants (n=440)

Characteristics	n (%) or Mean ± SD
Age (Range: 60-89 years)	70.9 ± 5.5
≤ 69	186 (42.3%)
70~79	223 (50.7%)
≥ 80	31 (7.0%)
Gender	
Male	134 (30.5%)
Female	306 (69.5%)
Education (Years of education range 0-25 years)	11.08 ± 4.3
≤ Middle school graduate	165 (37.5%)
Some high school	126 (28.6%)
≥ Some college	149 (33.9%)
Years in U.S. (range: 3 months-77 years)	24.2 ± 11.3
Medical history	
On antihypertensive medication	371 (84.3%)
Family history of hypertension	229 (52.0%)
Co-morbidity	199 (45.2%)
Controlled BP[†]	171 (38.9%)
Years of hypertension (range : 0-50 years)	9.6 ± 8.8

[†]Defined as BP <140/90 mm Hg (130/80 mm Hg for patients with diabetes)

Table 2

Psychometric properties of health literacy scales including print and functional health literacy and modified newest vital sign.

	Mean ± SD	Range	KR-20	Range of inter-item correlation	Range of corrected item-total correlation
Health literacy sum (PHL*+FHL**)	16.91 ± 15.79	0 - 43	0.98	0.32 - 0.91	0.54 - 0.87
PHL	12.10 ± 11.85	0 - 30	0.98	0.38 - 0.87	0.70 - 0.90
Level 1	4.98 ± 4.30	0 - 10	0.96	0.58 - 0.87	0.70 - 0.87
Level 2	4.23 ± 4.31	0 - 10	0.97	0.61 - 0.86	0.71 - 0.90
Level 3	2.89 ± 3.81	0 - 10	0.96	0.56 - 0.82	0.74 - 0.88
FHL	4.81 ± 4.54	0 - 13	0.93	0.32 - 0.91	0.58 - 0.80
Modified TOFHLA	2.79 ± 2.58	0 - 7	0.89	0.42 - 0.91	0.66 - 0.76
Modified NVS	2.02 ± 2.19	0 - 6	0.88	0.40 - 0.82	0.57 - 0.80

*PHL (Print health literacy subscale)

**FHL (Functional health literacy subscale)

Table 3

Changes in health literacy scores between baseline and 12-month follow-up

Health Literacy Tests	Baseline (N=440) mean (SD)				After 12 months (N=386)** mean (SD)			
	Intervention mean (SD)	Control mean (SD)	p[a]	95% CI	Intervention mean (SD)	Control mean (SD)	p[b]	95% CI
HL(PHL+FHL)	17.76 (15.12)	16.02 (16.45)	0.249	−1.22~4.70	19.96 (15.86)*	15.72 (15.67)	0.008	1.09~7.40
PHL	12.82 (11.48)	11.35 (12.20)	0.194	−.75~3.69	14.19 (11.56)*	11.22 (11.56)	0.012	.66~5.28
FHL	4.94 (4.27)	4.67(4.81)	0.531	−.58~1.13	5.78 (4.74)*	4.50 (4.48)	0.007	.35~2.20
Modified TOFHLA	2.84 (2.43)	2.74 (2.73)	0.684	−.38~.59	3.45 (2.71)*	2.71 (2.62)	0.008	.19~1.28
Modified NVS	2.10 (2.09)	1.93 (2.29)	0.411	−.24~.58	2.48 (2.19)*	2.01 (2.03)	0.031	.05~.91

[a]Between-group difference at baseline

[b]Between-group difference (calculated by within-group difference of intervention group minus within-group difference of comparison group)

*Statistically significant at p<0.01

**Drop-out analyses were executed using independent samples t-tests and chi-square test.