Development and Testing of the Hill-Bone Compliance to High Blood Pressure Therapy Scale

Miyong T. Kim, RN, PhD;[1] Martha N. Hill, RN, PhD;[1] Lee R. Bone, RN, MPH;[2] David M. Levine, MD[3]

The Hill-Bone Compliance to High Blood Pressure Therapy Scale assesses patient behaviors for three important behavioral domains of high blood pressure treatment: 1) reduced sodium intake; 2) appointment keeping; and 3) medication taking. This scale is comprised of 14 items in three subscales. Each item is a four point Likert type scale. The content validity of the scale was assessed by a relevant literature review and an expert panel, which focused on cultural sensitivity and appropriateness of the instrument for low literacy. Internal consistency reliability and predictive validity of the scale were evaluated using two community based samples of hypertensive adults enrolled in clinical trials of high blood pressure care and control. The standardized α for the total scale were 0.74 and 0.84, and the average interitem correlations of the 14 items were 0.18 and 0.28, respectively. The construct and predictive validity of the scale was assessed by factor analysis and by testing of theoretically derived hypotheses regarding whether the scale demonstrated consistent and expected relationships with related variables. In this study, high compliance scale scores predicted significantly lower levels of blood pressure and blood pressure control. Moreover, high compliance scale scores at the baseline were significantly associated with blood pressure control at both baseline and at follow up in the two independent samples. This brief instrument provides a simple method for clinicians in various settings to use to assess patients' self reported compliance levels and to plan appropriate interventions. (Prog Cardiovasc Nurs;15:90–96)

From the John Hopkins University, School of Nursing,[1] School of Public Health,[2] and School of Medicine,[3] Baltimore, MD
Address for correspondence/reprint requests: Miyong T. Kim, RN, PhD, The Johns Hopkins University, School of Nursing, 525 North Wolfe Street, Room 426, Baltimore, MD 21205–2110
Manuscript received June 21, 1999; accepted August 16, 1999

High blood pressure (HBP) is among the most prevalent and important risk factors for cardiovascular, cerebrovascular, and renal disease. Effective care and control of HBP cannot be achieved without compliance to treatment regimen recommendations by patients, providers, and organizations.[1] Estimates of controlled blood pressure (BP) among identified HBP patients typically ranges from 20%–30%[2,3] in the U.S., in large part, because only one half of the individuals diagnosed with hypertension are in treatment and one half of these are not receiving treatment adequate to control BP. In a critical review, Rogers and Bullman[4] found that noncompliance rates with prescribed therapeutic regimens range from 30%–60%, and at least 50% of patients for whom drugs are prescribed failed to receive full benefit through inadequate compliance. The high noncompliance rates in HBP treatment have multiple implications at the individual and societal levels. These rates jeopardize patients' health and well being, result in suboptimal health outcomes, lead to inefficient use of health resources, and incur costly treatment for the complications of untreated or inadequately treated HBP.[1,5,6] In spite of the critical role played by compliance in the treatment of HBP, clinicians are not routinely assessing patient's compliance level and patients rarely volunteer this information to their clinician.[5,7]

Several types of measures have been used to assess compliance in HBP research studies, including biological measures, such as drug assays, pill

counts (both manual and electronic monitoring), treatment outcomes, physician estimates, and patient reports. Each method of measuring compliance has advantages and disadvantages.[6] Drug assays and pill counts are considered to be more objective measures of compliance than provider estimates and patient self report. However, assays and pill counts, to a lesser extent, are expensive, relatively invasive, and time consuming to administer. Thus, they are not practical strategies for use in routine clinical practice. Although compliance levels reported by patients tend to over-estimate the level of compliance, self report has the advantages of being the most economical and simplest way to gather information and provides a ready opportunity for teaching and feedback.[6]

Prior development of instruments to measure patient self reported compliance was found to be limited. The most commonly used instrument, developed by Morisky et al,[8] was a four item tool assessing medication compliance with yes/no response categories and an internal consistency α of 0.64.[9] Shea et al[10] in later work added a fifth item ("Do you have a doctor for HBP care?"). In recognition of the need to more comprehensively assess HBP treatment adherence we undertook the challenge of developing a new instrument.

The American Heart Association recently issued a medical/scientific statement on the multilevel compliance challenge.[1] In the statement, the authors called for future research to improve compliance, including identifying persons at highest risk for noncompliance, methods for monitoring and improving compliance, and strategies to sustain recommended health behaviors over time. Researchers and clinicians interested in improving health outcomes for patients with HBP need reliable, valid, efficient, and cost effective assessment tools to assess the critical domains of HBP care during the screening, diagnosis, monitoring, and feedback processes.

METHODS

Instrument Development

A review of the literature identified the three behavioral domains of compliance that are critical for HBP care and control: 1) reducing sodium intake; 2) appointment keeping; and 3) medication taking. Experience from 30 years of clinical practice and research in hypertension clinics and the community was used to further delineate specific target behaviors in each behavioral domain. For example, patients with HBP may skip medication before they go to the doctor or when they feel good or sick. The Hill-Bone Compliance to HBP Therapy Scale was then constructed using a Likert scaling model so that subjects would respond to each item indicating the frequency with which the item is relevant for them. The scale has 14 items with a four point response format: (4) all the time, (3) most of time, (2) some of time, and (1) never (Table I). Items are assumed to be additive, and, when summed, the total score ranges from 14 (minimum) to 56 (maximum). The sodium subscale contains 3 items

TABLE I. HILL-BONE HBP COMPLIANCE SCALE

No.	Item	Response 1. None of the Time 2. Some of the Time 3. Most of the Time 4. All of the Time
1	How often do you forget to take your HBP medicine?	
2	How often do you decide not to take your HBP medicine?	
3	How often do you eat salty food?	
4	How often do you shake salt on your food before you eat it?	
5	How often do you eat fast food?	
6	How often do you make the next appointment before you leave the doctor's office?*	
7	How often do you miss scheduled appointments?	
8	How often do you forget to get prescriptions filled?	
9	How often do you run out of HBP pills?	
10	How often do you skip your HBP medicine before you go to the doctor?	
11	How often do you miss taking your HBP pills when you feel better?	
12	How often do you miss taking your HBP pills when you feel sick?	
13	How often do you take someone else's HBP pills?	
14	How often do you miss taking your HBP pills when you are careless?	

HBP=high blood pressure; *Reverse coding.

assessing dietary intake of salty foods; the appointment keeping subscale contains 3 items assessing appointments for doctor visits and prescription refills; and the medication taking subscale contains 8 items assessing medication taking behavior. The scale has been used both as a self and interviewer administered questionnaire, and takes about 5 minutes to complete.

Content Validity

From a pool of questions derived from a review of relevant literature, previous research, and clinical experience, 25 items were initially selected for the first draft of the scale. A panel of eight experts (five nurses and three physicians) who specialized in BP clinical research and practice, assessed the content validity of the initial 25 item scale. They were asked to evaluate: 1) the relevance of each item in the scale to the behavioral domain being measured; 2) the representativeness of the items in relation to the behavioral domains; 3) the appropriateness of the items for the target populations; and 4) the clarity of the questions and instructions.

All experts judged the scale to be representative of the behaviors being measured, and 14 items achieved the criterion level of relevance. The instrument was revised following the suggestions of the experts. The revised scale was then administered in interview format to a convenience sample of seven hypertensive patients chosen to represent different ages, races, and care settings, and assess previously undetected item flaws with respect to clarity, vocabulary, and response choices. The final version of the scale was reviewed by three of the original content experts (two nurses and one physician). They reached 100% agreement on all of the content related criteria of the scale (Table I). In addition, two reading experts analyzed the reading difficulty of the scale items and concluded that it approximated a high fifth grade reading level.

INSTRUMENT TESTING

The internal consistency reliability and the construct and predictive validity of the scale were tested in two separate samples of hypertensive adults enrolled in clinical trials to improve HBP care and control. Appropriate institutional review and community advisory committees approved these studies and all subjects provided written informed consent prior to participation. Study 1, entitled "Comprehensive HBP Care for Young Black Males," was conducted with a sample of 309 men. The subjects for this study were recruited if they met the following criteria: African American male, between ages of 18–55, residing in inner city Baltimore, and systolic blood pressure ≥140 mm Hg and/or diastolic blood pressure ≥90 mm Hg on two separate occasions. Study 2, entitled "Urban African American Community HBP Control Program," was a community based clinical trial with a sample of 718 hypertensive adults. The HBP eligibility criteria of Study 2 were similar to those of Study 1, however, Study 2 included both males and females without age restriction. The scale was administered at both baseline and one year follow up by trained interviewers blinded to study group assignment.

The medication taking subscale was relevant only for those who were taking HBP medication at the time of interview. Therefore, for the purpose of validity testing, only those who had both a prescription for medication and responded to all 14 items were included in this analysis. The demographic characteristics for the 139 men from Study 1 and the 341 men and women from Study 2 are summarized in Table II. Although all participants in both studies were hypertensive African Americans residing in the inner city, the demographics of the two samples were quite different. Subjects from Study 1 were younger, more educated, and had higher educational attainment than subjects from Study 2. This variation was due to the differences in the inclusion criteria of two studies. The use of the Hill-Bone Compliance Scale in these heterogeneous samples will attest the validity of the scale.

Psychometric Analysis Procedures

Psychometric analysis was conducted in three stages. First, the frequency distribution of each item was assessed. Criteria for an acceptable item were: 1) subject selected the full range of possible responses; 2) the standard deviation for the item was equal to or greater than half of the mean for the item; and 3) missing responses were minimal. Although the responses were moderately positively skewed in all three domains, responses to all items met the criteria for adequate dispersion (Table III). Second, the reliability of the instrument was assessed based on estimates of internal consistency and factor analysis. These estimates were based on the average interrelation of the items: interitem correlation, interscale correlation, part whole correlation (item and subscale), and standardized Chronbach α coefficients.

Certain criteria were imposed for acceptance as an instrument for this project. First, a fairly high reliability co-efficient (Chronbach $\alpha > 0.70$) was required to assess the construct validity of the instrument. This was an important objective of this study. Second, the items within each subscale were examined for consistency, with desired criteria of item total cor-

TABLE II. DEMOGRAPHIC CHARACTERISTICS OF THE TWO SAMPLES

	Study 1	Study 2
Number of subjects	139	341
Age (mean/SD)	41.3 (5.3)	59.2 (13.1)
Gender		
Male	139 (100.0%)	105 (30.8%)
Female	0 (0.0%)	236 (69.2%)
BP (mean/SD) at baseline		
Systolic	145.8 (19.3)	148.5 (20.2)
Diastolic	98.2 (15.5)	88.3 (14.0)
BP (mean/SD) at follow up*		
Systolic	137.9 (19.2)*	144.1 (20.8)
Diastolic	91.2 (13.6)*	85.7 (14.9)
Education (N/%)		
Less than high school	53 (38.1%)	200 (58.7%)
High school graduate	54 (38.8%)	114 (33.4%)
College or higher	33 (23.1%)	27 (7.9%)
Employment status (N/%)		
Full time	27 (19.4%)	53 (15.5%)
Part time	13 (9.4%)	17 (5.0%)
Unemployed	37 (26.6%)	60 (17.6%)
Other (retired, disabled, homekeeping)	62 (44.6)	211 (61.9%)

BP=blood pressure; SD=standard deviation; *N=120.

relation set at ≥0.30 and interitem correlation 0.30–0.70. Although the adequate internal consistency of an instrument does not translate into adequate construct validity, a valid measurement requires fairly strong evidence of the internal consistency of the scale.[11] Item analysis revealed that the interitem correlation for one item from each sample was <0.30, failing to achieve the empirically desirable interitem correlations. The items were: "How often do you eat fast food?" (Study 1) and "How often do you make the next appointment before you leave the doctor's office?" (Study 2). Standardized Chronbach α values are reported to adjust the sample-based α statistics to a population-based value, thereby correcting for any sampling error.[10]

For the second part of psychometric testing, a factor analysis of each subscale was conducted to gain more evidence for construct validity. Although the validity of an instrument can never be supported based solely on empirical testing, factor analysis is useful for finding structures through clustering items by common variance. For example, factor analysis provides information about the dimensionality of a scale through identification of the number of factors (dimensions) in a scale or within subscales. The principal component method with orthogonal (varimax) rotation was used for this analysis. A minimum eigenvalue of one (1.0) was specified as the extraction criterion.[12] Factors were determined when item loading co-efficients were ≥0.45. A factor loading

TABLE III. INSTRUMENT RELIABILITY AND ITEM ANALYSIS

	Study 1	Study 2
Valid cases	139	341
Responses (Sum)		
Range	14–43	11–53
Mean (SD)	21.4 (5.1)	18.1 (4.0)
Interitem correlation		
Range	-0.16–0.60	-0.05–0.57
Mean	0.18	0.28
Item to total scale correlation		
Range	-0.02–0.60	0.01–0.64
Mean (SD)	0.34 (0.17)	0.46 (0.16)
Standardized α	0.74	0.84

SD=standard deviation.

TABLE IV. COMPARISON OF FACTOR LOADINGS OF HILL-BONE HBP COMPLIANCE SCALE BETWEEN STUDY 1 AND STUDY 2

No.	Item	Study 1	Study 2
1	How often do you forget to take your HBP medicine?	0.61	0.60
2	How often do you decide not to take your HBP medicine?	0.55	0.72
3	How often do you eat salty food?	0.30	0.43
4	How often do you shake salt on your food before you eat it?	0.18	0.47
5	How often do you eat fast food?	-0.08	0.31
6	How often do you make the next appointment before you leave the doctor's office?*	0.25	0.03
7	How often do you miss scheduled appointments?	0.38	0.55
8	How often do you forget to get prescriptions filled?	0.40	0.64
9	How often do you run out of HBP pills?	0.45	0.68
10	How often do you skip your HBP medicine before you go to the doctor?	0.64	0.59
11	How often do you miss taking your HBP pills when you feel better?	0.82	0.80
12	How often do you miss taking your HBP pills when you feel sick?	0.69	0.76
13	How often do you take someone else's HBP pills?	0.57	0.54
14	How often do you miss taking your HBP pills when you are careless?	0.70	0.71
	Eigenvalue	3.74	4.95
	Percent total variance	0.27	0.35

HBP=high blood pressure; *Reverse coded before analysis; Note: reducing sodium intake subscale: items 3,4,5; appointment keeping subscale: items 6,7; medication taking subscale: items 1,2,8,9,10,11,12,13,14.

difference of 0.20 was also required to retain the item within a factor with a higher co-efficient.[11]

A three-factor solution was predicted because the theoretical concept being indexed by the scale had three dimensions. An eigenvalue of 1.0 was considered adequate to establish the existence of the factor. Principal component analysis extracted five factors from Study 1 with eigenvalue (% variance explained) 3.74 (27%), 1.66 (12%), 1.30 (9%), 1.11 (8%), and 1.02 (7%), respectively. From Study 2, four factors were extracted with eigenvalue (% variance explained) 4.97 (35%), 1.65 (12%), 1.08 (8%), and 1.01 (8%), respectively. The number of factors extracted was different from the originally predicted number of compliance domains. However, factor loading of each item to the first factor seemed to be consistent in both studies, which indicated that only the first factor was meaningful for interpretation across items used in the two studies. In general, the larger drop from one eigenvalue to the next eigenvalue with slightly decreasing subsequent values indicate the end of a meaningful factor.[13] The large drop from the first to second factor, 3.74 to 1.66 in Study 1 and 4.97 to 1.65 in Study 2, confirmed that all 14 items could be represented by a single factor (Table IV).

Third, correlational analysis was utilized to test the predictive validity of the scale to assess whether the degree of compliance predicted the level of BP cross-sectionally at baseline and BP control at one year follow up in Study 1 and 3 year follow up in Study 2. Since the scale items were assumed to be additive, scores from the theoretically derived subscales were summed. For instance, sodium intake score was calculated by summing three items: medication compliance, eight items, and appointment keeping, three items, respectively. These scores were correlated to BP level and BP control status (BP <140/90 mm Hg = yes, BP >140/90 mm Hg = no) at baseline and at follow up (Study 1 and Study 2).

The scale total score and its subscale scores were correlated to BP control and some of the relationships were statistically significant at $p < 0.05$ (Table V). The sodium intake subscale in Study 1 showed a significant correlation to BP control at baseline and at one year follow up. The appointment keeping subscale was significantly related to BP control at 3 year follow up in Study 2. The medication taking subscale was significantly associated with BP control at follow up only in Study 2. Importantly, the total scale score was significantly correlated with BP control at follow up in both studies. The directions of the correlations were as expected, that is, a higher compliance score was associated with BP control.

Lastly, construct validity was assessed using a hypothesis testing approach.[14] The assessment of BP control (yes/no) status at both baseline and follow up yielded four groups: 1) BP uncontrolled at

TABLE V. COMPARISON OF CORRELATION OF STUDY 1 (YBMII) AND STUDY 2 (SAND-TOWN) SAMPLES BETWEEN HILL-BONE COMPLIANCE SCALE AND HBP CONTROL AT BASELINE AND ONE YEAR LATER

Compliance	N*		Medication		Sodium Intake		Appointment		Total Score	
Study	1	2	1	2	1	2	1	2	1	2
Controlled BP at baseline	139	328	0.01 p=0.91	0.05 p=0.41	-0.20 p=0.02	0.01 p=0.86	0.13 p=0.14	0.07 p=0.21	-0.05 p=0.59	0.05 p=0.37
Controlled BP one year later	120	341	0.15 p=0.11	0.14 p=0.01	0.18 p=0.05	0.08 p=0.16	0.08 p=0.40	0.14 p=0.01	0.21 p=0.03	0.16 p=0.00

HBP=high blood pressure; *Casewise deletion.

both baseline and follow up; 2) BP controlled at baseline but not at follow up; 3) BP uncontrolled at baseline but controlled at follow up; and 4) BP controlled at both baseline and follow up.

It was expected that those with BP controlled at baseline and follow up (Group 4) would have the highest total compliance score, followed by Group 3, Group 2, and then Group 1 (in order) and that the total score differences would be statistically significant. The total scale score for each BP control group was as we had expected, with one exception (i.e., the reversal between Groups 3 and 4 in Study 2) (Table VI). Although the differences between baseline and one year follow up in Study 1 were not statistically significant, the trend is in the expected direction. The lack of statistical significance is probably due to the narrow range of mean scores. The group differences between baseline and 3 year follow up in Study 2 were statistically significant (Table VI). This significant difference in total scores supported the validity of the Hill-Bone Compliance Scale to predict BP control status, which is the primary goal of HBP care and treatment.

DISCUSSION

The results of these analyses support the reliability and validity of the scale. The scale was useful in measuring three aspects of HBP treatment in two samples of hypertensive urban African American adults. In its current form, it can be administered by interview in <10 minutes, thus making it a clinically useful tool for diagnosing problems with compliance. For clinicians wishing to use a briefer form, one of the subscales, such as the 8 item medication taking behavior subscale, may be useful.

Use of this instrument at each visit was beneficial in planning and implementing effective individualized HBP care. Nurses, physicians, and community health personnel working in both clinic and community settings may also find the instrument useful as a teaching tool to guide behavior modification that will lead to HBP control.

This instrument assesses HBP behaviors more comprehensively in comparison to existing tools. It is not surprising that the psychometric property of internal consistency is higher because of the additional items. Although, item analysis revealed that in each sample there was one different item that failed to achieve the empirically desirable interitem correlations (<0.30); we feel that it is premature to delete the items at this time, because these two items assess critically important patient behavior. Further testing is needed in different populations to cross validate the findings from this study. Our findings may be an indication of the socio-economic conditions in the community from which the Study 1 sample was drawn and the structural/administrative arrangements in the clinics in which the Study 2 sample received care, rather than an indication of poor items.

TABLE VI. COMPARISON OF HILL-BONE COMPLIANCE SCALE BASELINE SCORES AND HBP CONTROL IN STUDY 1 SAMPLE (1 YEAR FOLLOW UP) AND STUDY 2 SAMPLE (3 YEAR FOLLOW UP)

Compliance	Total Compliance Scale Score					
Study	Study 1			Study 2		
BP Control Group	N	Mean	SD	N	Mean	SD
1. Uncontrolled at both baseline and follow up	56	47.8	5.8	173	51.3	4.7
2. Controlled at baseline, but not at follow up	17	47.9	4.3	45	51.6	3.7
3. Uncontrolled at baseline, but controlled at follow up	37	50.1	4.2	68	52.7	3.3
4. Controlled both at baseline and follow up	10	49.2	4.1	41	52.8	2.9

HBP=high blood pressure; SD=standard deviation.

The higher standardized α coefficient in Study 2 (0.85) compared to Study 1 (0.74) may be related to the larger sample size. The sensitivity and the specificity of the scale as a diagnostic tool have not yet been established because the scale does not yet have a definite cut off point (compliant vs. non-compliant). Clinically meaningful cut off points of the scale will be established as more studies using the scale are completed.

A major limitation of this analysis originates in the characteristics of the study samples. Since only urban African American subjects were used for the two clinical trials, cultural bias could have existed. While this analysis demonstrates the reliability and validity of this instrument in adult African American urban populations, the ultimate usefulness in other population groups will need to be determined through further testing in different populations. More rigorous cross validations are needed to establish the generalizability of the instrument to hypertensive adults in general.

Note: This research was supported by National Institute of Nursing Research grant #R01 NR04119, a NIH-NCRR, NHLBI #R01HL51111-02, OPD-GCRC grant #5M01RR00052, and an educational grant from Merck & Co.

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