

CROSS-CULTURAL VALIDATION OF THE HILL-BONE COMPLIANCE TO HIGH BLOOD PRESSURE THERAPY SCALE IN A SOUTH AFRICAN, PRIMARY HEALTHCARE SETTING

Objectives: Hypertension is prevalent, underdiagnosed, and inadequately treated in Black South Africans. However, few studies have addressed barriers to hypertension care and control in this community. The aim of this study was to validate the Hill-Bone Compliance to High Blood Pressure Therapy Scale (HB Comp Scale) for use in a South African primary healthcare setting. This instrument consists of three subscales, medications-compliance, appointment making, and salt intake.

Methods: A demographic questionnaire and the HB scale were translated into the first language of the subjects and then back-translated into English. Hypertensive patients (N=98) were recruited from primary healthcare clinics in Cape Town. Blood pressure was measured with an Omron electronic blood pressure manometer, after 5 min of seated rest. Item-analysis was conducted to determine internal consistency of the HB Comp Scale; Spearman rank order correlations were used to assess the relationship between compliance scores and blood pressure.

Results: A modified scale consisting of only 10 items demonstrated reasonable internal consistency (item-total correlations all >.31, and a standardized Cronbach α of 0.79), with an average interitem correlation of .26. In addition, the modified scale had significant predictive validity in that noncompliance predicted higher diastolic blood pressures ($\rho=.21$, $P<.05$) and medication noncompliance tended to predict higher systolic blood pressures ($\rho=.20$, $P<.06$). Appointment-making and dietary salt-intake subscales were not internally consistent.

Conclusions: We demonstrated criterion validity and internal consistency for a modified Hill-Bone Compliance Scale, in Black, urban, hypertensive, South African patients. Results compare favorably with those from an urban African-American setting (standardized Cronbach α was .74–.84). (*Ethn Dis.* 2006;16:286–291)

Key Words: High Blood Pressure, Compliance, BP Treatment, Compliance

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INTRODUCTION

Effective treatment of hypertension reduces mortality and morbidity related to the end-organ damage.^{1,2} Despite this fact, control of hypertension has rarely been achieved in most people with hypertension, even by the most sophisticated healthcare services. The cause of this failure to achieve adequate blood pressure control in patients attending health services is often attributed to patients' lack of compliance or adherence to prescribed hypertension treatment. The degree of compliance with medication regimes averages 50%, while compliance with recommended lifestyle modifications has been found to be as low as 10%.^{3,4} Complex factors related to the patient, the healthcare provider, the healthcare system and the nature and availability of services all contribute to the levels of compliance observed in a given setting.^{5,6}

For a true understanding of the determinants of compliance to prescribed hypertension management, studies of all these factors are necessary. To date most studies have focused on compliance issues related to patient behavior. Haynes et al³ emphasized that

one of the major impediments to improving compliance is the difficulty experienced in measuring compliance. A systematic review of studies on compliance suggests that asking nonresponders about the degree of compliance to treatment and pill counts will only identify $\approx 50\%$ with low levels of compliance.⁷ Other means of measuring compliance can be costly and include measuring plasma drug levels or using electronic equipment to ascertain the number of times that drug containers have been opened in a given period of time. Most of these measures are impractical for usual clinical practice or for large, community-based studies. Thus, estimation of compliance to hypertension treatment in these settings necessarily reverts to questioning the patient or, at best, using validated instruments that elicit patients' reported compliance-related activities.

One such questionnaire is the Hill-Bone Compliance to High Blood Pressure Therapy Scale. (HB Comp Scale).^{4,8} This scale was developed, in part, as a response to earlier instruments that measured patient's self reported compliance.^{7,8} Morisky et al⁹ introduced a four-item medication compliance scale for hypertension that consisted of questions focused on forgetting or being careless in taking blood pressure pills or failing to take medication because patients were feeling either well or sick. Although this instrument demonstrated reasonable internal consistency and construct validity, it was later extended by Shea et al,¹⁰ and a fifth question, "Do you ever miss taking your blood pressure medication for any reason?" was incorporated. The internal consistency of this revised scale was

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The objective of the HB Comp Scale was to create a valid and reliable instrument that was also culturally appropriate for people of limited literacy . . .

α rho=0.71 for 202 subjects drawn from 2 inner-city hospitals in New York. Moreover, this revised instrument correlated strongly with other negative health behaviors such as cigarette smoking and alcohol-related problems, and was associated with a pattern of care in which subjects were more likely to have blood pressure measured in an emergency room and less likely to have a primary care physician.

The objective of the HB Comp Scale was to create a valid and reliable instrument that was also culturally appropriate for people of limited literacy and could be self- or interviewer-administered in a brief period of time. The goal was to obtain clinically verified data that could be used to both diagnose and monitor compliance behaviors. In contrast to the previous two instruments, the HB Comp Scale measures patient behaviors for three domains of high blood pressure management, ie: 1) reduced sodium intake; 2) appointment keeping; and 3) medication taking. The original scale consists of 14 items, each graded according to a four-point Likert scale. In two separate validation samples of inner-city men and women that comprised 480 subjects, the item-analysis for the instrument yielded Cronbach α of α .74-.84.⁸ Further, a significant relationship was seen between compliance score and blood pressure control, at one year of follow-up ($P<.03$).⁸

Compliance to hypertension treatment and barriers to hypertension treatment and control are a major

public health concern for countries such as South Africa.^{7,11} In the first National Demographic and Health Survey, conducted in 1998, hypertension and very poor levels of blood pressure (BP) control were shown to be prevalent, particularly in Black South Africans. More than 20% of Black South Africans (20.5% in men, and 23.5% in women) had blood pressures >140/90 mm Hg. Furthermore, <50% of women and 32% of men with blood pressures \geq 60/95 mm Hg were undergoing treatment.⁹

To address this major health problem, we must first identify the determinants of the poor level of hypertension control. Ideally, this step requires some valid and reliable measure of hypertension compliance. Therefore, the aim of the present study was to measure the validity and reliability of the HB Comp Scale. This paper reports on the findings of the validation of the HB Comp Scale in Black South Africans in Cape Town.

METHODS

The instrument's original validity was tested by determining that responses to all 14 questions were adequately dispersed.³ Second, the reliability of the instrument was assessed by using item and factor analyses, taking into consideration the interitem correlation, item-to-total scale correlation, and part-whole correlation (scale to total), as well as the standardized Cronbach α coefficients. Finally, the predictive validity of the scale and the various subscales for degree of compliance was determined by using correlational analysis against blood pressure level and blood pressure control, at baseline, and at one year of follow-up.

The South Africa version of the HB Comp Scale was developed by translating the original scale into Xhosa, the African language spoken by the target population, and then back-translating it into English. Translation was followed

by repeated pilot interviews with members of the target population and discussions with local Xhosa-speaking healthcare providers and researchers. This process ensured that the language used in the South African version of the scale was likely to be understood by the target population living in the periurban areas of Cape Town. Further, the 14-items used in the original HB Comp Scale were adapted to reflect the situation in the local healthcare services and the high-sodium condiments frequently used by the target population.

A convenience sample of subjects living in the periurban areas of Cape Town ($N=98$, 48 men and 50 women) was recruited from the hypertension clinics at periurban community health centers or a government work site within the city. All subjects had a diagnosis of hypertension, were between 35 and 65 years of age and had lived in urban areas for at least nine months. Informed consent was obtained after explaining the project's objectives and the interviewee's role. Trained Xhosa-speaking fieldworkers administered the questionnaire, which was composed of sociodemographic variables, as well as the HB Comp Scale.

Blood pressure (BP) measurements were taken after the participants were seated for five minutes with an Omron M1 electronic BP manometer (Omron Corp; Schaumburg, Ill) using appropriate, adult-sized cuffs. The BP and pulse were taken three times on the left arm, with the palm upward, resting on a table or support at the level of the heart. The mean value of the last two measurements was used in the data analyses.

Statistical analyses involved item analyses of the scales and subscales. In addition, we tested predictive validity with Spearman rank-order correlation between the 14-item original scale, a modified 10-item scale and the salt-intake and medication-compliance subscales.

The protocol was approved by the institutional review boards of Johns

Table 1. Demographic characteristics and blood pressure pattern of the study population (N=98)

Demographic Characteristic	Values
Age (y)	52.0±7.6
Gender (M/F)	48/50
Blood pressure	
Systolic blood pressure (mm Hg)	148.6±30.2
Diastolic blood pressure (mm Hg)	91.9±15.6
Proportion of sample who are hypertensive (%)	
<140/90 mm Hg	31.6%
140/90–160/95 mm Hg	41.8%
≥160/95 mm Hg	26.5%
Marital status	
Married	51%
Never married	16.3%
Separated/divorced	19.4%
Widowed	13.3%
Employment status	
Employed	38%
Unemployed	29%
Homemaker	11%
Pensioner	12%
Disability/other	10%

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had mean blood pressures ≥140/90 mm Hg. Only 39% of the sample was employed outside the home. Just more than half were married.

RESULTS

The demographic characteristics of the study sample are presented in Table 1. The mean age was 52 ± 8 years, and >68.3% of the participants

Item Analysis Results and Subscale Analyses

All of the response distributions of the 14 original HB Comp Scale items were significantly positively skewed. For

question 13, “How often do you take someone else’s high blood pressure pills?” only two out of four possible responses were selected, however, the less frequent response constituted >10% of the total and was, therefore, not excluded. In addition, we were not able to apply the criteria for an adequately dispersed sample that was used in the original validation study.¹ In general, the standard deviations of the scores for individual questions were 70%–110% of half of the mean for each item.

We evaluated the reliability of the entire original 14-item instrument by using item analysis. The results are presented in Table 2. The 14-item scale did not perform as well, in terms of interitem and item-to-scale correlations as a 10-item scale, in which only one each of the items in the appointment-keeping, and salt-intake subscales were retained. The standardized Cronbach α for the 10-item scale was .79, and mean item-total correlation was .45 (± .11). The mean interitem correlation was .26, compared to that for the 14-item scale which was .20.

The salt-intake and medication-compliance subscale scores correlated significantly to the total 14 item scale (p=.68 and p=.88, P<.001, respectively) and to the 10-item scale (p=.50, and p=.94, P<.001, respectively). However, not surprisingly, the internal consistency of the appointment-keeping and salt-intake subscales were poor. The salt-intake subscale had a Cronbach α of .41, a mean interitem correlation of .19 and an item-total correlation of .27. The appointment-keeping subscale did not provide an interpretable result, probably as a result of the South African public health system, in which reappointments are standard procedure. The eight-item medication-compliance subscale had good internal consistency, with a Cronbach α of .76, a mean interitem correlation of .29, and an item-total correlation of .46.

Table 2. Instrument reliability and item analysis:

	Xhosa Hill-Bone Compliance Scale (14-items)	Xhosa Adapted Hill-Bone Compliance Scale (10 items, after exclusion of items 4, 5, 6, 8)
Valid cases	n=79	n=82
Responses (scale total)		
Range	14–33	10–25
Mean (SD)	19.37 (4.02)	13.41 (3.35)
Interitem correlation		
Range	-.16–.51	-.03–.53
Mean	.20	.26
Item-to-total scale correlation		
Range	.10–.64	.31–.64
Mean (SD)	.38 (.18)	.45 (.11)
Standardized Cronbach α	.77	.79

Table 3. Predictive validity of the 14-item and 10-item modified Hill-Bone scales and medication compliance subscale (Spearman ρ)

	Valid n	ρ	P level
14-item scale vs mean SBP (mm Hg)	77	.17	.14
14-item scale vs mean DBP (mm Hg)	77	.18	.13
10-item scale vs mean SBP (mm Hg)	85	.19	.08
10-item scale vs mean DBP (mm Hg)	85	.21	.05
Medication subscale vs mean SBP (mm Hg)	88	.20	.06
Medication subscale vs mean DBP (mm Hg)	88	.19	.08

SBP = systolic blood pressure; DBP = diastolic blood pressure.

Predictive Validity of the Compliance Scales

The predictive validity of the original 14-item scale, the modified 10-item South Africa scale, and the South Africa medication compliance subscale are presented in Table 3. A positive and significant association was seen between noncompliance as measured on the modified, 10-item scale and diastolic blood pressure ($\rho=0.21$, $P=.05$). In addition, a trend for an association was seen between medication noncompliance and diastolic blood pressure ($\rho=.19$, $P=.06$).

DISCUSSION

This study demonstrates that many of the behavioral aspects of the fundamental elements of high blood pressure care and control, such as medication taking, appointment keeping, and salt-intake reduction, are measurable across cultures. Second, we have shown that vigorous psychometric methods can be used effectively in different cultural groups. Third, the study demonstrates that both concurrent and predictive validity can be assessed quickly in a clinical setting. Information gathered with such a scale, whether self-administered or interviewer-administered, can be used to create patient education, behavioral reinforcement, and treatment decisions. Although no single theory has guided the development and testing of the original scale or the modified 10-item South Africa version, the clinical utility is based on a rich background of

psychological and behavioral research and an eclectic integrated approach to planning and implementing health education and behavior-change programs.¹²

The results of this study are of particular relevance in light of the recent National Demographic and Health Survey, in which >20% of Black South Africans were shown to have blood pressures >140/90 mm Hg and <50% of women and 32% of men with blood pressures $\geq 160/95$ mm Hg were undergoing treatment.¹¹ In a recent study, Steyn et al⁷ described blood pressure treatment status and experiences in a large, primary healthcare clinic representative of the district health system in the Cape Peninsula. Many logistic barriers were identified, for example, for filling prescriptions. These included long waiting times, insufficient medication, and a perception of negative attitudes of professional staff. Despite these constraints, the medications non-compliance sub-scale demonstrated good internal consistency with the overall scale and suggested predictive validity of poor blood pressure control.

One aspect of adherence to blood pressure treatment that was not addressed directly by the current instrument is that of self-efficacy, which has been implicated in a wide range of health behaviours.¹¹ Ogedegbe et al¹² identified low self-efficacy as a potential barrier to adequate blood pressure control and medication compliance in a clinical population of African-American hypertensives. This instrument may be useful in combination with a compli-

The results of this study are of particular relevance in light of the recent National Demographic and Health Survey, in which >20% of Black South Africans were shown to have blood pressures >140/90 mm Hg . . .

ance scale, such as the one validated in the present study, as it highlights potential high-risk situations and potential reasons for medication noncompliance, such as side effects, costs, busy at work or home, traveling, and concern over taking them long-term or becoming dependent.

Other factors not taken into consideration in the present study included education, socioeconomic status, demographic and household factors, age, length of treatment, nature of the primary healthcare experience, and the severity of hypertension or associated medical sequelae.^{10,12} These factors influence medication-compliance behavior as well as the use of alternative treatments, especially in certain cultural groups.¹³ Therefore, a scale of non-compliance should be used in conjunction with other information gathering to formulate appropriate information for education and awareness and an appropriate plan of action that addresses the underlying etiology of noncompliance.

Future use of these scales, alone or in combination, for purposes of clinical research fulfills the original mandate from the preliminary psychometric evidence published in 1995. The stated aim at that time was to "gain increased understanding of the problems hypertensive patients have with recommended

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treatment and to develop effective interventions to minimize these problems and enhance adherence, thereby achieving treatment goals.”⁵ This study represents the first cross-cultural assessment of the Hill-Bone Compliance to High Blood Pressure Therapy Scale, not previously analyzed in any sample. It has been conducted in an “at-risk” population, with demonstrated low compliance to hypertension treatment and poor blood pressure control. We hope that this scale will be further applied in clinical research as a means of identifying noncompliance and to develop more effective interventions to address the underlying barriers to treatment and control of hypertension in this population.

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Original 14-Item HB Blood Pressure Compliance Scale

HILL-BONE HIGH BLOOD PRESSURE COMPLIANCE SCALE						
(NA=not applicable / DK=don't know)	None of the time	Some of the time	Most of the time	All the time	NA	DK
1. How often do you forget to take your HBP medicine?	1	2	3	4	8	9
2. How often do you decide not to take your HBP medicine?	1	2	3	4	8	9
3. How often do you eat salty food?	1	2	3	4	8	9
4. How often do you shake salt, fondor, or aromat on your food before you eat it?	1	2	3	4	8	9
5. How often do you eat fast food? (KFC, McDonalds, fat cook, fish and chips)	1	2	3	4	8	9
6. How often do you get the next appointment before you leave the clinic?	1	2	3	4	8	9
7. How often do you miss scheduled appointments?	1	2	3	4	8	9
8. How often do you leave the dispensary without obtaining your prescribed pills? (due to long line, closure of clinic, forgot)	1	2	3	4	8	9
9. How often do you run out of HBP pills?	1	2	3	4	8	9
10. How often do you skip your HBP medicine 1–3 days before you go to the clinic?	1	2	3	4	8	9
11. How often do you miss taking your HBP pills when you feel better?	1	2	3	4	8	9
12. How often do you miss taking your HBP pills when you feel sick?	1	2	3	4	8	9
13. How often do you take someone else's HBP pills?	1	2	3	4	8	9
14. How often do you miss taking your HBP pills when you care less?	1	2	3	4	8	9

Revised 10-Item HB Blood Pressure Compliance Scale for South Africa

HILL-BONE HIGH BLOOD PRESSURE COMPLIANCE SCALE

(NA=not applicable / DK=don't know)	None of the time	Some of the time	Most of the time	All the time	NA	DK
1. How often do you forget to take your HBP medicine?	1	2	3	4	8	9
2. How often do you decide not to take your HBP medicine?	1	2	3	4	8	9
3. How often do you eat salty food?	1	2	3	4	8	9
7. How often do you miss scheduled appointments?	1	2	3	4	8	9
9. How often do you run out of HBP pills?	1	2	3	4	8	9
10. How often do you skip your HBP medicine 1-3 days before you go to the clinic?	1	2	3	4	8	9
11. How often do you miss taking your HBP pills when you feel better?	1	2	3	4	8	9
12. How often do you miss taking your HBP pills when you feel sick?	1	2	3	4	8	9
13. How often do you take someone else's HBP pills?	1	2	3	4	8	9
14. How often do you miss taking your HBP pills when you care less?	1	2	3	4	8	9

AUTHOR CONTRIBUTIONS

Design and concept of study: Lambert; Steyn; Stender; Everage; Fourie; Hill
Acquisition of data: Steyn; Stender; Everage

Data analysis and interpretation: Lambert; Hill
Manuscript draft: Lambert; Steyn; Fourie; Hill
Statistical expertise: Lambert

Acquisition of funding: Steyn; Hill
Administrative, technical, or material assistance: Lambert; Steyn; Stender; Fourie; Hill
Supervision: Lambert; Steyn; Hill