

Predictive Validity of a Medication Adherence Measure in an Outpatient Setting

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This study examines the psychometric properties and tests the concurrent and predictive validity of a structured, self-reported medication adherence measure in patients with hypertension. The authors also assessed various psychosocial determinants of adherence, such as knowledge, social support, satisfaction with care, and complexity of the medical regimen. A total of 1367 patients participated in the study; mean age was 52.5 years, 40.8% were male, 76.5% were black, 50.8% graduated from high school, 26% were married, and 54.1% had income <\$5,000. The 8-item medication adherence scale was reliable ($\alpha=.83$) and significantly associated with blood pressure control ($P<.05$). Using a cutpoint of <6, the sensitivity of the measure to identify patients with poor blood pressure control was estimated to be 93%, and the specificity was 53%. The medication adherence measure proved to be reliable, with good concurrent and predictive validity in primarily low-income, minority patients with hypertension and might function as a screening tool in outpatient settings with other patient groups.

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Hypertension is one of the most important risk factors for coronary heart disease, stroke, heart failure, and end-stage renal disease and remains an important public health challenge.^{1–3} Although there are effective medical therapies for hypertension management, only 37% of hypertensive patients in a 2003–2004 survey were reported to have their blood pressure controlled.¹ One factor contributing to less than ideal blood pressure control is patient nonadherence to prescribed therapies. A meta-analysis revealed that the odds of blood pressure control among patients adherent to antihypertensive medications, compared with those who were nonadherent, was 3.44 (95% confidence interval, 1.6–7.37).⁴ Multiple factors that influence patient adherence to prescribed therapies have been described and include quality of life; complexity and side effects of medications; health care system issues; demographic, behavioral, treatment, and clinical variables; and lack of knowledge regarding hypertension, to name only a few.⁵ A recent Harris Poll survey suggested that there have been improvements in knowledge of hypertension risks, percentages of patients receiving specific medications, and numbers of patients controlled.⁶ Nevertheless, patient nonadherence to antihypertensive treatment recommendations remains a global problem, and promoting patient adherence is a major clinical hurdle that is necessary to decrease cardiovascular morbidity and mortality.^{7,8}

A first step in understanding adherence, or lack thereof, is assessing or measuring adherence. In outpatient clinical settings, there is a need for a valid, reliable, cost-effective tool that is accepted by both health care providers and patients for measuring medication adherence. Widespread use of such a tool, which could provide insight into modifiable factors regarding adherence in different patient populations, would lead to better understanding of



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nonadherence and lay the groundwork for interventions aimed at increasing adherence to therapies.

The primary objective of the current study is to examine the psychometric properties and test the concurrent and predictive validity of an 8-item structured, self-reported medication adherence measure in primarily low-income, minority patients with hypertension. Predictive validity is assessed through associations with blood pressure control, knowledge, social support, stress, and patient satisfaction with clinic visits, each of which was described previously to be associated with medication adherence.⁹

METHODS

As part of a randomized experimental pretest and posttest study design over a 12-month period to evaluate the effects of structural and educational interventions on blood pressure control,¹⁰ we examined the psychometric properties of an 8-item medication adherence measure. The study was undertaken at a large teaching hospital. Institutional review board approval was obtained from the medical center. A total of 1400 participants were randomly recruited from a list of approximately 2000 patients attending the hypertension clinic during regularly scheduled appointments at the medical center.^{10,11} Project staff explained the program to each patient. Individuals who consented to participate completed the baseline interview with a community health worker at the end of that clinic visit. More than 98% of the patients approached agreed to participate. The baseline interview assessed demographic information, medical history, pertinent health behaviors, appointment keeping, and medication adherence. Other psychosocial factors that were known to be related to treatment adherence were also evaluated, including satisfaction with medical care, social support, stress, knowledge and attitudes toward blood pressure control treatment, and coping skills.^{7,12-14}

Medication Adherence Measure

The self-reported measure of medication taking was developed from a previously validated 4-item scale and supplemented with additional items addressing the circumstances surrounding adherence behavior.¹⁵ The theory underlying this measure was that failure to adhere to a medication regimen could occur because of several factors such as “do you sometimes have problems remembering to take your medication?” “do you sometimes forget to take your medication?” and problems with the complexity of the medical regimen such as, “do you ever feel hassled about sticking to your treatment plan?” The questions are

phrased to avoid the “yes-saying” bias by reversing the wording of the questions about the way patients might experience failure in following their medication regimen, since there is a tendency for patients to give their physicians or other health care providers positive answers. Each item measures a specific medication-taking behavior and not a determinant of adherence behavior. Response categories are yes/no for each item with a dichotomous response and a 5-point Likert response for the last item.

Other Measures

Using a standardized protocol, a calibrated mercury sphygmomanometer and stethoscope were used by an American Heart Association certified nurse to measure blood pressure. At least 5 minutes after the patient arrived for his or her medical examination, 2 blood pressure measurements were taken 5 minutes apart on the right arm with the patient sitting. Measures were collected for all outpatient visits during a 6-month period following the baseline survey. The average of the measurements was calculated and used in the analyses. Blood pressure was considered to be uncontrolled if either the mean of the systolic pressure was ≥ 140 mm Hg or the mean of the diastolic pressure was ≥ 90 mm Hg.

Knowledge concerning high blood pressure was measured using a 6-item index from a previous study regarding patient knowledge of hypertension.¹⁶ The knowledge index ranged from 0 to 6, with higher scores indicating greater knowledge. Attitudes toward hypertension were measured with a 13-item instrument using a 4-point Likert-type scale (α reliability, .86).¹³ Patient satisfaction was measured by a 6-item scale (α reliability, .87) that measured the degree to which patients were satisfied with their clinic visit, including appointment waiting times, availability of doctor, amount of information received from doctor, and concerns the doctor had for the patients.^{17,18} A social support scale (α reliability, .76) measured the extent to which respondents were receiving social support from their family and friends to take their medications. A 7-item coping scale (α reliability, .84) was used to measure social coping behaviors.¹⁴ A 4-item scale (α reliability, .79) was used to measure psychological stress.¹⁹ A 2-item index that incorporates the number of antihypertensive drugs taken and the number of times the medication should be taken each day was used to measure medication complexity.

Statistical Analyses

Using standard statistical procedures described by Cronbach,²⁰ the reliability of the 8-item scale

was derived. Concurrent validity of the scale with a previously validated 4-item measure of adherence¹⁵ was assessed using Pearson's correlation coefficient. Predictive validity of the scale was assessed through associations with blood pressure levels, knowledge, attitude, social support, stress, coping, and patient satisfaction with clinic visits. Standard procedures, including confirmatory factor analysis, for assessing the dimensionality of the scale was used to confirm a single-factor scale.²¹

To determine how well the 8-item scale would serve as a screening tool for identifying patients with poor blood pressure control, sensitivity, specificity, and correct classification rates were estimated.²² Multivariate logistic regression analysis was conducted to evaluate the odds ratios of various risk factors associated with medication adherence.

RESULTS

The sociodemographic characteristics of the 1367 participants in the study are presented in Table I. The mean age of respondents was 52.5 years (SD=12.2 years), with 61.5% older than 50 years, 40.8% male, 76.5% black, 50.8% having graduated from high school, 26% married, and 54.1% having an income <\$5,000. The mean score for the medication adherence scale was 6.6 (SD=1.6). The item-total correlations were >0.30 for each of the 8 items composing the medication adherence scale. The internal consistency (Cronbach's alpha reliability) was 0.83 (Table II).

The current 8-item scale was significantly correlated with the previously validated 4-item self-reported medication-taking scale¹⁵ (Pearson correlation, 0.64; $P<.05$). Confirmatory factor analysis (Table III) indicated that the 8-item scale was unidimensional and the items loaded well on the single factor.

In assessing the sensitivity and specificity of the self-report measure to identify patients with poor blood pressure control, all possible cutpoints were examined. Final cutpoints were chosen based on the relationship with blood pressure control, so that the medication adherence scale could provide useful information in a clinical setting (Table IV). Highly adherent patients were identified with the score of 8 on the scale, medium adherers with a score of 6 to <8, and low adherers with a score of <6. Using these cutpoints, this study population had 32.1% low adherers, 52.0% medium adherers, and 15.9% high adherers. Patients who scored high on the adherence scale were more likely to have their blood pressure under control compared with patients who scored medium or low. A significant relationship between the adherence scale and blood pressure control (chi-

Table I. Sociodemographic Characteristics of the Participants at Baseline (N=1367)

SOCIODEMOGRAPHIC CHARACTERISTIC	%
Sex	
Male	40.8
Female	59.2
Age, y	
18–39	12.2
40–49	26.3
50–59	32.9
≥60	28.6
Ethnicity	
Black	76.5
Hispanic	20.6
Asian	1.1
White	0.9
Other	0.9
Income	
No income	31.4
<\$5,000	22.7
\$5,000–\$14,999	36.6
\$15,000–\$24,999	5.5
\$25,000–\$49,999	3.6
>\$50,000	0.2
Marital status	
Married	26.0
Living with someone	4.3
Divorced/separated, alone	28.9
Never married	27.0
Widowed, alone	13.8
Highest education level	
<High school	48.5
High school graduate	40.6
Some college	9.9
Graduate school	0.3
Other	0.7

square, 6.6; $P<.05$) was found (Table IV). Correct classification with blood pressure control was based on a dichotomous low versus high/medium level of adherence, which had a rate of 80.3%. Sensitivity and specificity of the 8-item scale were 93% and 53% respectively. In the multivariate model (adjusted for age, sex, ethnicity, marital status, income, and education level), attitude, knowledge, social support, patient satisfaction, coping, and stress were evaluated with respect to medication adherence (Table V). When all of these variables were included in the model, knowledge, patient satisfaction, coping, stress level, and medication complexity were each found to be significantly associated with adherence at the 0.05 level. Patients who displayed high knowledge of the medical regimen, higher satisfaction with medical care, positive family member social support, and stronger coping behavior were significantly more likely to have high levels of adherence. On the other

Table II. The 8-Item Medication Adherence Scale

ITEM	CORRECTED ITEM-TO-TOTAL CORRELATION
1. Do you sometimes forget to take your high blood pressure pills?	.4639
2. Over the past 2 weeks, were there any days when you did not take your high blood pressure medicine?	.5108
3. Have you ever cut back or stopped taking your medication without telling your doctor because you felt worse when you took it?	.4277
4. When you travel or leave home, do you sometimes forget to bring along your medications?	.4095
5. Did you take your high blood pressure medicine yesterday?	.3038
6. When you feel like your blood pressure is under control, do you sometimes stop taking your medicine?	.5044
7. Taking medication everyday is a real inconvenience for some people. Do you ever feel hassled about sticking to your blood pressure treatment plan?	.4009
8. How often do you have difficulty remembering to take all your blood pressure medication?	.5896
α Reliability, .83.	

Table III. Factor Loadings of the 8-Item Medication Adherence Scale

ITEM	FACTOR LOADINGS ^a
1. Do you sometimes forget to take your high blood pressure pills?	0.566
2. Over the past 2 weeks, were there any days when you did not take your high blood pressure medicine?	0.617
3. Have you ever cut back or stopped taking your medication without telling your doctor because you felt worse when you took it?	0.519
4. When you travel or leave home, do you sometimes forget to bring along your medications?	0.493
5. Did you take your high blood pressure medicine yesterday?	0.425
6. When you feel like your blood pressure is under control, do you sometimes stop taking your medicine?	0.543
7. Do you ever feel hassled about sticking to your blood pressure treatment plan?	0.479
8. How often do you have difficulty remembering to take all your blood pressure medication?	0.668
^a Root mean square error of approximation <0.01.	

hand, patients who reported high levels of stress, greater complexity of the medical regimen, and poor perceived health status were found to have significantly lower levels of medication adherence.

DISCUSSION

Hypertension is the most prevalent health problem among adult patients, affecting approximately 65 million persons in the United States and about 1 billion persons worldwide, but its recognition and treatment are still suboptimal.^{1,23,24} It is one of the leading risk factors for cardiovascular disease, the leading cause of death in the United States. Adherence to appropriate medical therapy for hypertension can result in controlled blood pressure and reduction in adverse outcomes. With increasing need for long-term adherence to treatment, a reliable and valid measure of patient adherence that can be easily administered is needed. This study reports the development and evaluation of a medication adherence scale that is easy to administer. The scale can be used as an initial tool to screen patients for low adherence, who are at risk for uncontrolled blood pressure, compared with patients with medium to high adherence. When appropriate, tailored interventions can be implemented, such as education of the patient regarding hypertension care, correcting misunderstandings and incorrect beliefs regarding hypertension treatment, reducing stress and improving coping skills among patients, or establishing a treatment regimen to foster medication adherence.

Adherence to treatment for high blood pressure is influenced by a number of factors, some of which are modifiable.¹⁴⁻¹⁹ Adherence rates have been shown to be associated with age, sex, and race. Several studies have noted demographic disparities regarding medication adherence with lower adherence reported among younger individuals,^{25,26} men,²⁶ and black persons.²⁷ Other factors reported to negatively impact adherence to prescribed therapies include depression,²⁸ lack of knowledge regarding hypertension and its treatment,²⁹ complexity of medication regimen,³⁰ health care system perceptions by the patient,³¹ sexual dysfunction,³² side effects of medication,³³ and poor quality of life.³⁴ In our study, we identified several modifiable variables in the logistic regression model that predict medication adherence. Some of the interesting findings in the model indicated that knowledge of hypertension, patient satisfaction, and coping skills were significantly associated with medication adherence. This implies the need for patient education to increase knowledge regarding hypertension treatment and for effective communication between the

physician and patients to improve understanding regarding hypertension and its treatment.

A national US survey found that 30% of the patients who reported a systolic blood pressure value of ≥ 140 mm Hg indicated that they did not have high blood pressure.²⁹ In addition, about 20% of patients acknowledging a diagnosis of high blood pressure were not taking medications as prescribed. Reasons for nonadherence were recorded as forgetfulness (46%), blood pressure under control (40%), did not like taking medications (33%), adverse effect (30%), blood pressure controlled other ways (28%), and cost (16%).²⁹ In another study, a similar finding was reported: hypertensive patients had poorer awareness of normal blood pressure values than normotensive participants.³⁵ In a general study of over 600 adults taking prescribed medications for hypertension, 80% reported having reservations about their therapy, with 66% indicating that they preferred to lower their blood pressure without taking blood pressure pills.³⁶ Another study found that hypertensive black patients with controlled blood pressure reported higher mean self-efficacy scores compared with patients with uncontrolled hypertension.³⁷ More recent surveys suggest that patient knowledge and control rates are improving.⁶ In addition to addressing patient nonadherence to therapy as a contributor to poor blood pressure control, there is an important issue of clinical or therapeutic inertia, in which physicians or other health care providers do not adhere to treatment guidelines to change or intensify antihypertensive therapy if blood pressure remains uncontrolled with pharmacotherapy.³⁸

In order for physicians or other health care providers to adequately address poor patient adherence to therapy as a key factor leading to inadequate blood pressure control, they must first be able to reliably assess it. In the outpatient setting, there are 4 approaches that are commonly reported for measuring medication adherence: self-report, electronic monitoring, pill count, and pharmacy fill rates.^{5,39,40} Each of these approaches can lead to a quantifiable measure of adherence and, with the exception of self-report, these approaches are objective. Recent attention has been given to electronic monitoring with systems such as medication event monitoring systems (MEMS). Provided they are used correctly, these systems capture data on daily intake and dosing over time, allowing analyses of long-term patterns and opportunities to identify "white-coat adherers."³⁹ However, these devices are relatively expensive and somewhat cumbersome to carry, are subject to interference by the patient or other devices, can fail, and are able to capture large quantities

Table IV. Relationship Between Adherence Scale and BP Control

	BP CONTROLLED ^a	
	NO	YES
Low adherence, <6	67.2%	32.8%
Medium adherence, 6 - <8	55.2%	44.8%
High adherence, 8	43.3%	56.7%

^aChi-square, 6.6; $P < .05$. Blood pressure (BP) controlled, systolic BP <140 mm Hg and diastolic BP <90 mm Hg.

Table V. Odds Ratios of Determinants of High Medication Adherence

	ODDS RATIO	95% CONFIDENCE INTERVAL
Knowledge	1.15	1.03–1.29 ^a
Attitude	0.99	0.96–1.03
Satisfaction	1.07	1.02–1.11 ^a
Social support	1.06	1.02–1.37 ^a
Coping	1.94	1.19–3.15 ^a
Stress	0.91	0.86–0.98 ^a
Medication complexity	0.55	0.38–0.81 ^a

^aSignificant at $P < .05$.

of data points over time, posing challenges for data analysis. Research involving MEMS caps as a measure of adherence identified several problems with this approach, including not using the electronic monitoring device consistently (36%), taking out more than 1 dose at a time (41%), and reporting opening the electronic monitoring device but not taking the medication (26%).⁴¹ In addition, each medication that is being monitored for adherence requires its own device, and reasons for nonadherence are not captured by the electronic system.

In contrast, self-report measures, such as the one proposed in this study, are simple and economical to use and can provide real-time feedback regarding adherence behavior and potential reasons for poor adherence including social, situational, and behavioral factors affecting adherence. Although self-report measures may be subject to recall bias, overestimation of adherence, and elicitation of socially acceptable responses, efforts aimed at increasing validity and reliability of self-report measures in different populations will facilitate the adoption and use of these tools in clinical practice. In a racially diverse sample of elderly patients with hypertension in a managed care setting, the 8-item medication adherence scale and antihypertensive medicine pharmacy fill rates were significantly correlated ($r=0.46$; $P < .001$).³⁴ Other work has been conducted

in research settings with self-reported medication adherence measures^{15,42,43}; however, further refinement of these tools and consistent demonstration of validity and reliability in different populations are needed before widespread adoption. Several studies have highlighted the importance of assessing medication-taking behavior and the positive benefits of enhanced provider-patient communication.⁴⁴

Given the validity and reliability reported with the 8-item instrument and its ease of use in the outpatient setting, this self-report measure could function as a screening tool in the clinic setting to identify patients who are poorly adherent and at risk for uncontrolled blood pressure. The 8-item scale had a higher sensitivity than the original 4-item scale. This sensitivity of 93% indicates that the scale is good at identifying patients who have low medication adherence and have uncontrolled blood pressure relative to all patients who have uncontrolled blood pressure. The specificity of the 8-item scale of 53% indicates moderate performance of the scale in identifying patients who do not have problems with medication adherence and have their blood pressure under control relative to all those with controlled blood pressure. This self-reported adherence classification, along with blood pressure control data, could be useful in the clinical decision-making process. For example, a patient with high medication adherence and good blood pressure control could be complemented on his or her medication-taking behavior and reminded of the benefits of controlled blood pressure and importance of continued adherence to medications. A patient with inadequate blood pressure control but high medication adherence could be considered a patient with difficult-to-control or refractory hypertension or with inappropriate or inadequate pharmacologic treatment. In this case, intensification of therapy or change in therapy to achieve the appropriate blood pressure response should be considered.⁴⁵ Alternatively, for patients classified as having low adherence to medications and with poor blood pressure control, the physician may consider discussing potential side effects of medications with the patient, engaging family member support, or using cueing behaviors or memory devices.⁴⁶

Limitations

The results of this study should be interpreted with the following limitations in mind. This study was conducted in very low-income minority patients treated for hypertension seeking routine care in a clinic setting and may not be representative of patients from other socioeconomic backgrounds. Also, as noted previously, a recent survey suggests

that patient knowledge and control rates are improving,⁶ yet opportunities still exist to improve these rates if we are to achieve the Healthy People 2010 goals for the nation. Although the scale was not validated with pharmacy refill rates in this study, it was correlated with another 4-item adherence scale¹⁵ that was previously found to have a moderate level of reliability and high levels of concurrent and predictive validity and was validated with a chemical marker for actual medication-taking behavior.⁴⁷ Further research is recommended with more objective measures in patients with hypertension.

CONCLUSIONS

The medication adherence scale presented in this research is relatively simple and practical to use in clinical settings. The instrument can be used initially to identify patients with adherence problems and can also be used to monitor adherence over the course of the treatment. One important feature of the scale is that treatment-related attitude and behavior problems that the patient may be facing can be immediately identified and health care providers may provide reinforcement and advice such that the patient can take positive steps early on to address these issues. Further research is needed to validate this measurement scale in other settings and with other health problems.

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