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Concurrent and Predictive Validity of a Self-reported Measure of Medication Adherence

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Adherence to the medical regimen continues to rank as a major clinical problem in the management of patients with essential hypertension, as in other conditions treated with drugs and life-style modification. This article reviews the psychometric properties and tests the concurrent and predictive validity of a structured four-item self-reported adherence measure (alpha reliability = 0.61), which can be easily integrated into the medical visit. Items in the scale address barriers to medication-taking and permit the health care provider to reinforce positive adherence behaviors. Data on patient adherence to the medical regimen were collected at the end of a formalized 18-month educational program. Blood pressure measurements were recorded throughout a 3-year follow-up period. Results showed the scale to demonstrate both concurrent and predictive validity with regard to blood pressure control at 2 years and 5 years, respectively. Seventy-five percent of the patients who scored high on the four-item scale at year 2 had their blood pressure under adequate control at year 5, compared with 47% under control at year 5 for those patients scoring low ($P < 0.01$). Key words: concurrent validity; predictive validity; compliance; blood pressure control; provider-patient interaction; chronic disease. (Med Care 1986, 24:67–74)

The problem of nonadherence to medication regimens has received much attention during the past two decades. Through 1984, approximately 700 studies had been conducted, using more than 200 variables to assess the determinants of adherence behavior. The major categories investigated include disease factors,[1,2] patient characteristics,[3,4] referral and appointment process,[5,6] therapeutic regimen,[7] and patient–provider interaction.[8–10] The first two categories have received the most attention, mainly because they are easy to measure, but unfortunately well over half of these determinants have not been shown to have significant associations with adherence behavior. Those areas that displayed higher levels of association include patient–provider interaction, psychosocial and sociologic aspects of the patient, and various types of environmental support given to the patient.[11,12]

Adherence to the medical regimen is the

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single most significant clinical problem in the management of patients with essential hypertension. Drawing on data collected in the early 1970s, less than 50% of the population was aware of their hypertension status; today almost 75% of the population is aware.[13] Although awareness has increased significantly throughout the 1980s, the percent of controlled hypertensives had remained proportionately constant.[14] Results from the most recent national survey indicate that approximately 34% of hypertensive patients are controlling their blood pressure.[15] Data from recently funded NHLBI Statewide Coordination Programs also substantiate the need for greater emphasis on the management and long-term control of high blood pressure. Two cross-sectional surveys in Maryland and California indicate significant improvements in levels of awareness and treatment, but only moderate improvements in proportions of patients with their blood pressure under control.[16,17] The majority of the problem still remains in long-term adherence and control, once an individual has been brought under control. The goal of achieving adherence with medical recommendations for hypertensive patients is to improve blood pressure control and ultimately to reduce the risk of premature cardiovascular morbidity and mortality. It is assumed that one who adheres to the medical recommendations will benefit significantly, through the lowering of risk status. The clinical importance of nonadherence relates to the degree to which it interferes with the therapeutic goal. According to Sackett, blood pressure begins to fall significantly only when patients take more than 80% of their medication.[18] Thus, even if adherence rates improve to 50–60%, it is still possible that blood pressure levels will remain uncontrolled. Consequently, health care providers are becoming increasingly aware of the significance and detection of nonadherence in the long-term management of patients with high blood pressure.

The term "compliance" usually refers to the extent to which patients follow the instructions—proscriptions and prescriptions—of their physician or other health care provider. The concern is generally with nonadherence, but the use of the term "noncompliance" implies a pejorative or negative affect toward patients, who are often presumed to be uncooperative. Several investigators, however, have suggested that the provider and his or her style or communicating with the patient may alter the patient's ability and inclination to comply.[8,18–20] Although the provider–patient relationship has received wide attention and is assumed to be important in the delivery of medical services, remarkably little is known about what it is; what its components are; and how the components are defined and measured. As Hulka stated in 1979 regarding the provider–patient relationship, "there is hardly a phrase in all the health services literature about which so much is said yet so little is known."[21] Much research since then has been directed at investigating this important interaction.[22–24]

Although health care practitioners may be increasingly aware that nonadherence is a significant public health problem, individual patients do not readily divulge their nonadherence without specific efforts to detect levels of adherence. Several studies continue to confirm the work by Haynes[2] and the earlier conclusions of Mitchell[25] and Caron and Roth[26]: no readily observable characteristics of patients correlate consistently with poor rates of adherence that may permit their easy identification. Drug levels or pharmacologic markers are sometimes used by providers, but this is not feasible in most practice settings and is not available for many drugs, and interpretation as a measure of adherence is complicated by potential pharmacokinetic differences between drugs and patients.[27] Other methods involve checking on the filling of the prescriptions or conducting pill counts, which are also not feasible in most practice settings and are char-

acterized by many methodologic difficulties.[28,29] One of the major improvements in assessing adherence rates among hypertensive patients has been the use of interview data. The advantages of this method over other measures include its feasibility in all care settings, simplicity, speed, and potential enhancement of validity. The purpose of this research report is to describe a technique to assess patient medication-taking behavior. The technique employed is simple and straightforward and easily incorporated into patient care processes. Data are presented to evaluate the internal consistency of the measure as well as its sensitivity and specificity in validating blood pressure control. Further, in assessing compliance levels, the technique provides a mechanism of improving and strengthening provider–patient communications.

Methods

Setting

The study was undertaken in two outpatient clinics of a large teaching hospital.[30] The clinics were treated as two separate strata within which random sampling procedures were applied. To be included in the study, patients had to have been receiving care at the clinic at least 6 months prior to selection. A total of 400 patients were randomly selected for interviews. They were 91% black and 70% female and had a median age of 54 years and a median of 8 years of formal education. Patients had been receiving care for their high blood pressure at these two clinics for an average of 6 years.

Based on a prior needs assessment of patients attending these same clinics, an educational program designed to improve compliance with treatment, appointment keeping, and weight loss was developed. Three complimentary educational interventions, tailored to the identified needs of the patients, were implemented over an 18-month period. The interventions were directed at explaining and reinforcing the instructions of the practitioner concerning the medical regimen, increasing family member understanding and support, and strengthening patient self-confidence through small-group discussions centering on hypertension management and compliance.[31–34]

TABLE 1. Self-reported Medication-taking Scale and Item-to-total Correlation Coefficients

	Corrected Item-to-total Correlation
1. Do you ever forget to take your medicine?	0.515
2. Are you careless at times about taking your medicine?	0.479
3. When you feel better do you sometimes stop taking your medicine?	0.527
4. Sometimes if you feel worse when you take the medicine, do you stop taking it?	0.561

Scoring: high–low; yes = 0; no = 1.
Range: 0–4.
Mean (weighted): n = 290; $\bar{x}$ = 2.31.
Cronbach alpha: 0.61.

Measurement

Previous methods used to assess patient adherence to medical regimens were reviewed. Pill counts, the most commonly used method, did not prove to be a reliable indicator because of multiple pharmacies in which each patient obtained prescription refills and because some patients combined all antihypertension medication into one container. Chemical tests were neither feasible nor affordable nor available on all drugs used. Green et al.[30] first described an alternative approach with the presentation of a five-item self-reported scale measuring medication-taking behavior in outpatients being treated for high blood pressure. The self-reported measure of medication-taking behavior used in this study (Table 1) was developed from the original five items. The theory underlying this measure was that drug errors of omission could occur in any or all of several ways: forgetting, careless-

TABLE 2. Patient Responses to Medication-taking Behavior Scale

Patient Answered "Yes" to:		%	n
0 items	(High)	43	125
1 item	(Med)	24	70
2 items		17	49
3 items	(Low)	7	20
4 items		9	26

ness, stopping the drug when feeling better, or starting the drug when feeling worse. The tendency in responding to questions about their regimen adherence is for patients to give their physicians or other health care provider positive answers, because providers usually phrase their questions in such a way that the answer they want to hear is "yes."[35] By reversing the wording of four questions about the way patients might experience drug omissions, the sum of "yes" answers would provide a composite measure of nonadherence. Rather than attempting to overcome the "yes-saying" bias, this approach attempts to use it to obtain disclosures of nonadherence.

Patients in the study were interviewed at the end of the 18-month formalized educational program. The same instrument used in the baseline needs assessment was used to assess medication-taking behavior on the study population. The rationale and baseline experiences with the instrument are reported elsewhere.[36] This report is based on the 2- and 5-year follow-up measure.

The reliability of the scale is reflected in its relatively high (0.61) measure of internal consistency. Each item in the scale contributed significantly to the overall reliability coefficient, with a decrease in the alpha level if any single item was deleted. This result was achieved after eliminating items whose item-to-total correlations were lower or contributed negatively to the reliability estimate. The corrected item-to-total correlations present the correlation between that item's score and the scale score computed from the other items in the set.

Principal components analysis was used to determine the extent to which the set of items measure the same construct or measure two or more clusters of variables that represent different dimensions of adherence. A single factor was identified through this method, with convergence being reached in six iterations. Factor loadings for each item in the scale significantly contributed to the accounted variance in the factor score. The frequency of responses to the composite items in the scale are displayed in Table 2. A total of 43% responded "no" to all four items, indicating high levels of medication-taking behavior. Patients answering "yes" to one or more items comprised 57% of the responses.

Blood pressure levels were determined by averaging systolic and diastolic measures found in the medical record over the final 6 months of the follow-up period. An age-specific measure that had been agreed on by physicians in these clinics was used to determine blood pressure control status.[37] The definitions for elevated blood pressure were as follows: for patients aged 39 years and younger, greater than 140/90 mm Hg; 40–59 years, greater than 150/95 mm Hg; and 60 years or older, greater than 160/100 mm Hg. If either the systolic or diastolic readings exceeded the limit set for controlled blood pressure, the level was considered elevated.

In addition to the unidimentionality and reliability of this measure, the scale also demonstrated concurrent validity with blood pressure control at baseline. Individuals scoring low on the scale had a control rate of 42%, compared with 54% for those who scored high.[36]

Results

A total of 290 of the original 400 patients who participated in this study have follow-up data on both medication-adherence behavior and blood pressure control at year 2 and year 5 and comprise this analysis. Previous analyses compared the baseline char-

acteristics of these 290 patients with those of the original 400 patients and found no significant differences with respect to age, race, sex, years of diagnosed high blood pressure, or other comorbidities. Patients who dropped out or who discontinued medical care tended to have lower medication-adherence measures and were more likely to have elevated blood pressures.[38]

This study extends this prior work by investigating the longer-term prediction of the self-reported measure using blood pressure control as a criterion. This analysis expands the concurrent validity of this measure and assesses the predictive validity using subsequent blood pressure control measures. To test the hypothesis that the medication-taking behavior scale has both concurrent and predictive validity with blood pressure control as the standard, the relationship between these two measures was assessed at year 2 and year 5.

Figure 1 presents the proportion of individuals with their blood pressure under control at 6 month and 42 month time periods according to their score on the four-item medication-taking scale. At the 6 month interval, a significant relationship was found between these two variables. Individuals who scored high on the scale were more likely to have their blood pressure under control than those individuals who scored low. The point biserial correlation was equal to 0.43 ($P < 0.01$). This finding reconfirms the previously assessed concurrent validity as noted in the baseline needs assessment.[36] Analysis of the scale's predictive validity (medication-taking behavior at baseline regressed with blood pressure control levels at 42 months) indicates a more pronounced linear relationship. Individuals scoring high on the adherence scale were significantly more likely to have their blood pressure under control compared with individuals who scored low ($r = 0.58$; $P < 0.01$). Seventy-five percent of the individuals who scored high on the adherence scale at baseline had their blood pressure under control at 42 months,

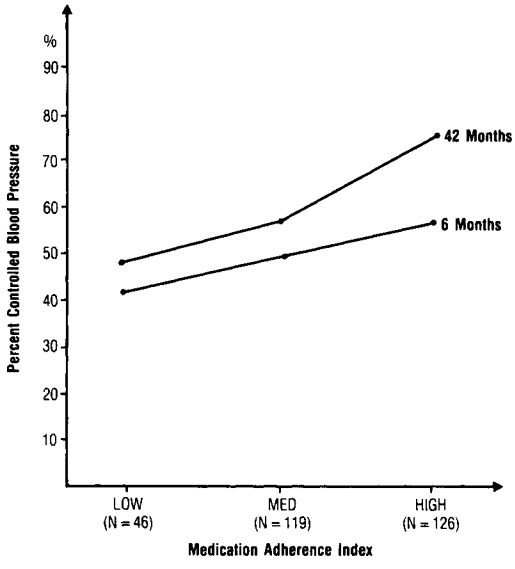

FIG. 1. Blood pressure control by verbal medication-adherence index (n = 290); $r_{6\ ms.} = 0.43$, $P < 0.01$; $r_{42\ ms.} = 0.58$, $P < 0.01$.

compared with only 47% of those scoring medium or low, respectively (Fig. 1). In other words, a 5-percentage-point improvement in blood pressure control was noted for persons scoring low on the self-reported medication adherence scale between 6 and 42 months, while for individuals scoring high, a 21-percentage-point increase was observed. A paired t-test between groups using diastolic blood pressure as the criterion revealed statistically significant differences as well ($t = 6.43$; $P < 0.01$). To assess the strength of the relationship between the self-reported medication-taking scale and blood pressure-control measure, the coefficient of determination (R^2) was used. This coefficient was also found to be significant ($R^2 = 0.33$; $P < 0.01$), indicating reasonable predictive ability with respect to blood pressure control.

Sensitivity and Specificity

The actual use of the scale in predicting an individual patient's adherence or blood pressure control level cannot be based entirely on statistical validity. Mushlin[39] found that without such a formal procedure or tool

TABLE 3. Sensitivity and Specificity of the Medication-taking Behavior Scale

	Adequately Controlled at 42 months	Inadequately Controlled at 42 months	Total
Predicted to be adequately controlled by (high) index score	94	31	125
Predicted to be inadequately controlled by (low) index score	22	24	46
Total	116	55	171

Sensitivity = $\frac{94}{116} = 0.81$.

Specificity = $\frac{24}{55} = 0.44$.

$PV_+ = 0.75$.

$PV_- = 0.47$.

$PV = 0.69$.

for measuring patient adherence, physicians correctly identified patients as compliant or noncompliant less than one half of the time and that at least three fourths of their predictions of noncompliance were incorrect. To what extent does the compliance scale in this study improve upon the less than 50:50 odds of estimating adherence? Using only "high" adherence scores on the scale to select the adherent patient, the predicative value when positive would be 0.75, as indicated by the proportion with their blood pressure control at year 5. The predicative value if negative, that is using only the "low" score to predict nonadherence, would be 0.47. The sensitivity and specificity of the measure can be calculated from the data presented in Table 3. Using information from the 171 patients in the high (n = 125) and low range (n = 46) of index scores (Table 3), the sensitivity is 0.81 and the specificity is 0.44. This index is an "inefficient" predictor of blood pressure control, since 119 patients have midrange scores. Including the midrange scores into these estimates, overall predictive value is reduced from 0.69 ((94 + 24)/171) to 0.60 ((94 + 82)/290).

Discussion

With the increased prevalence of chronic disease requiring long-term adherence to treatment, a feasible, reliable, and valid measure of patient adherence, usable in the usual medical practice circumstance, is needed. This article presents analyses of such an adherence scale. The properties of the scale are designed to facilitate the identification and addressing of problems and barriers to adequate compliance. The scale can be utilized initially as a diagnostic tool in which patient levels of understanding as well as adherence behaviors are assessed. When specific problems are identified, appropriate education of the patient can then be implemented. Such approaches may include correcting misbeliefs (e.g., should one discontinue treatment if feeling better); adapting the regimen to the patient's daily schedule to address forgetting (e.g., linking medication taking to brushing teeth or eating meals); or involving other family members for long-term support and reinforcement.

Inui et al.[40] provided evidence that providers of care can carefully monitor blood pressure control levels based on verbal inquiry and patient self-reports and adjust dosage and frequency appropriately. Haynes et al.[41] also provided evidence of the increased sensitivity and specificity of self-reports over other techniques.

In connection with the adjustment of dosage and frequency of medication, future studies should monitor both the adherence measure and blood pressure levels over time to assess the long-term effectiveness of the index. For patients found to be under adequate control but with a midrange score on the index, it is recommended that health care

providers consider altering the dosage or frequency of medication. This is particularly true for individual patients who are on weight-reduction and/or salt-restriction diets in addition to a medical regimen. This "step-down" approach has been recommended by the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure.[42]

Individuals who are included in this analysis represent the "survivors" of a 60-month follow-up period; consequently, the performance of this index is characterized by a population of relatively compliant patients. Given the fact that drop-out patients tended to score low on the adherence scale and have higher rates of uncontrolled blood pressure, it is suspected that the performance of the index in its "low range" would be enhanced by data from the drop-out patients. These individuals, however, were excluded from the analysis because of missing blood pressure information.

We believe that this relatively simple scale is an added contribution to the literature in assessing adherence levels of hypertensive patients and perhaps compliance with drug treatment in general. The scale has continued to be implemented and found to be reliable, valid, and useful in other patient populations as well as in the general population in community-based educational outreach programs.[43,44] The scale has been incorporated into the care process for patients in the Adult Hypertension Clinic in the General Medical Clinic Practice at both Johns Hopkins Hospital and the Baltimore City Hospital. The senior author is currently assessing the concurrent validity of this scale in several worksite-based high blood pressure control programs in California. We continue to utilize this instrument to diagnose adherence problems initially and to monitor adherence over time, particularly when there is recidivism. An important feature of the scale is that attitudinal and behavioral problems the patient may be facing are identified and that positive steps can be taken early to address them. Further work is needed to test and validate this measure in other settings and with other health problems; it is hoped that this will lead eventually to the identification of a "gold standard" for compliance measurement.[45]

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