

Medication Compliance in a Family Practice

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SUMMARY

For the physician in a primary care setting, a self-report questionnaire on medication compliance can help to determine whether a lack of hypertension control is due to a drug-taking behavior problem or inadequate medication. Such a questionnaire can easily be implemented as a part of routine care and can help clinicians increase the efficiency of medical care dispensed to hypertensive patients.

RÉSUMÉ

Différentes mesures permettent d'apprécier l'observance du traitement médicamenteux. En médecine familiale, le questionnaire du patient constitue un outil précieux qui peut aider à expliquer le contrôle inadéquat de l'hypertension artérielle en identifiant les patients qui ont des problèmes à gérer leur traitement. Cet outil peut être facilement intégré au processus de soins dispensés aux personnes hypertendues.

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NON-COMPLIANCE WITH LONG-term pharmacologic treatment is an important cause of inadequately controlled high blood pressure.¹ In order to manage non-compliance more efficiently, clinicians need a method of identifying non-compliant patients that is easy to apply. Such a method should accurately detect both true-positive (non-compliant) and true-negative (compliant) patients, enabling physicians to take appropriate action to control hypertension more effectively.

One such method, a self-report questionnaire on medication compliance (Table 1), has already been tested in two specialized outpatient clinics at a university hospital in Baltimore and validated against blood pressure control.^{2,3} This approach does not take into account variations in blood pressure control due to biologic factors or in the efficacy of various medica-

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tions and dosages; however, in the absence of a gold standard for compliance measurement,⁴ clinicians must rely on detection methods with inherent limitations.^{5,6}

Even with such limitations, this self-report questionnaire can benefit the clinician in specific ways. It provides a score of compliance, drawn from the patients' responses to four questions on their usual patterns of taking hypotensive medication. Patients report an experience of drug non-compliance when they answer "yes" to any of the four questions. This questionnaire is currently recommended to physicians as a detection test for non-compliance by the Working Group on Health Education and High Blood Pressure.⁷

The purpose of this study was to test and validate a French version of the questionnaire in a family practice setting. The sensitivity, specificity, and predictive values of the measure in validating blood pressure control are described.

METHODS

We recruited a sample of diagnosed hypertensive outpatients receiving care in a family medicine unit in the Quebec City area that keeps a log of hypertensive patients. The medical records of all potentially eligible subjects were reviewed at the beginning of the study.

All patients with uncomplicated essential hypertension who had been receiving

Table 1. ORIGINAL AND FRENCH VERSION OF SELF-REPORT QUESTIONNAIRE ON COMPLIANCE

French Version	Original Version in English	Affirmative Responses (N=109)
1. Vous arrive-t-il d'oublier de prendre votre ou vos médicament(s) pour l'hypertension?	1. Do you ever forget to take your medicine?	21
2. Vous arrive-t-il parfois de ne pas vous soucier de prendre votre (vos) médicament(s)?	2. Are you careless at times about taking your medicine?	5
3. Lorsque vous vous sentez mieux, vous arrive-t-il cesser de prendre votre (vos) médicament(s)?	3. When you feel better do you sometimes stop taking your medicine?	6
4. Si parfois vous vous sentez mal lorsque vous prenez votre (vos) médicament(s), cessez-vous de le(s) prendre?	4. Sometimes if you feel worse when you take the medicine, do you stop taking it?	5

care at the unit for more than 8 months and who had visited the unit at least once in the 6 months before selection were included. Subjects had to have been receiving antihypertensive medication for at least 6 months before the study and to have been prescribed the same medication for at least 3 months. Eligible subjects were approached and enrolled in the study after giving their informed consent.

The study took place between May and August 1988. Respondents were visited at home by a nurse; on this visit, the respondent's blood pressure was measured three times at 5-minute intervals and a self-reported questionnaire on compliance was administered, in that order. A mercury sphygmomanometer was used, and the World Health Organization guidelines for standardized measurement were followed.⁸ Blood pressure levels were determined by averaging the second and third readings.

Age-adjusted definitions of blood pressure control were used similar to those used by the investigators in the original study.³ Blood pressure was deemed to be controlled if both systolic and diastolic readings were 140/90 mm Hg or lower in patients younger than 40 years; 150/95 mm Hg or lower in patients between 40 and 59 years; and 160/100 mm Hg or lower in patients 60 and older. The decision to validate the questionnaire against blood pressure control was based on the fact that no adequate

standard for compliance measurements exists.

RESULTS

Characteristics of respondents

One hundred eighteen patients met the inclusion criteria and were asked to participate in the study. Seven declined, and home visits were not completed for two subjects. A total of 109 white French Canadian patients were interviewed (92% of all eligible patients). Women represented 66% of the sample; 42% had an annual income of more than \$25 000. The mean age was 64 years, and the average level of education was grade 11. The patients in the sample had been receiving pharmacologic treatment for hypertension for an average of 5.5 years.

Concurrent validity

Twenty-one subjects gave an affirmative answer to the first question, about forgetting medication, while a much smaller number of subjects gave an affirmative answer to the second, third, and fourth questions (Table 1). Eighty patients (73%) answered no to all four questions and thus obtained a high score of compliance (0/4). Less than 27% answered yes to one or more questions. Most (27/29) obtained a moderate score: 24 patients scored 1/4, and the remaining three scored 2/4.

Table 2. CONCURRENT VALIDITY OF THE SELF-REPORT QUESTIONNAIRE AGAINST BLOOD PRESSURE CONTROL: Blood pressure was controlled if both systolic and diastolic blood pressures were 140/90 mm Hg or lower for patients younger than 40 years of age; 150/95 mm Hg or lower for patients between 40 and 59 years; and 160/100 mm Hg or lower for patients 60 and older.^a

INDEX SCORE (N/%)	BLOOD PRESSURE		(N/%)TOTAL
	INADEQUATELY CONTROLLED	(N/%)CONTROLLED	
Low (3 or 4 affirmative answers) ^b	2/7	0/0	2/2
Moderate (1 or 2 affirmative answers) ^b	10/37	17/21	27/25
High (0 affirmative answers)	15/56	65/79	80/73
TOTAL	27/100	82/100	109/100

^aBlood pressure defined by Morisky et al.³

^bWith moderate and low scores pooled together: sensitivity = 12/27 = 0.44, positive predictive value = 12/29 = 0.41, specificity = 65/82 = 0.79, negative predictive value = 65/80 = 0.81.

The questionnaire's reliability was tested with Cronbach's alpha (0.54). Concurrent validity was tested against blood pressure control and is shown in Table 2. Patients with at least one affirmative answer were considered non-compliant; patients with no affirmative answers were considered compliant. Seventy-one percent (77/109) of the patients were thus accurately classified. Seventy-nine percent of the patients whose blood pressure was under control claimed compliance, while only 44% of the uncontrolled patients reported non-compliance.

To determine the questionnaire's clinical usefulness, we computed predictive values. Eighty-one percent of the patients identified as compliant by the questionnaire had controlled blood pressure. Forty-one percent of the patients reporting non-compliance had inadequately controlled blood pressure.

Interpretation of self-report performance depends, however, on pre-test probability, ie, the proportions of controlled and uncontrolled patients in the sample. Because the prevalence of uncontrolled hypertensives is 25% (27/109), a positive predictive value of non-compliance of 41% means that when non-compliance is identified, self-reporting increases the accuracy of the information by 16%. Because the prevalence of patients with adequately controlled blood pressure is 75%, a predictive value when negative

(compliant) of 81% increases the accuracy of the information by 6%.

Sensitivity analysis

Because sensitivity and specificity results depend both on the definition of blood pressure control and how compliers are categorized, we analyzed the concurrent validity of the self-report with the definition of blood pressure control proposed in the 1988 Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure¹: diastolic blood pressure under 90 mm Hg and systolic blood pressure under 140 mm Hg for people younger than 65 years, or under 160 mm Hg for people 65 and older. We also checked whether defining non-compliance differently would affect the accuracy of the self-report. We categorized as compliers those with one affirmative answer or no affirmative answers and as non-compliers those with two or more affirmative answers. The results are reported in Table 3.

Despite the change in the definition of blood pressure control, sensitivity and specificity remain almost unchanged; however, the new definition of non-compliance increased the specificity of the self-report questionnaire by about 20%.

Validity for first question

Fifty-seven percent of the affirmative answers were given in response to the first

Table 3. SENSITIVITY AND SPECIFICITY OF THE SELF-REPORT QUESTIONNAIRE ACCORDING TO DIFFERENT CATEGORIZATIONS OF NON-COMPLIANCE AND DEFINITIONS OF BLOOD PRESSURE CONTROL

NON-COMPLIANCE DEFINITION	MORISKY ET AL ^{3,a}		JOINT NATIONAL COMMITTEE ^{1,b}	
	SENSITIVITY	SPECIFICITY	SENSITIVITY	SPECIFICITY
One or more affirmative answers	0.44	0.79	0.34	0.82
Two or more affirmative answers	0.12	0.99	0.09	1.00

^aBlood pressure was controlled if both systolic and diastolic measures were 140/90 mm Hg or lower for patients younger than 40 years of age; 150/95 mm Hg or lower for patients between 40 and 59 years; and 160/100 mm Hg or lower for patients 60 and older.

^bBlood pressure was controlled if diastolic blood pressure was under 90 mm Hg and systolic blood pressure was under 140 mm Hg for people younger than 65 years of age, and under 160 mm Hg for patients 65 and older.

question, "Do you ever forget to take your medicine?" Because this question seemed to convey much of the information, we analyzed its concurrent validity against blood pressure control as defined by Morisky et al.³ Sensitivity remains low at 30%; this test is then specific at 84%. Both positive (38%) and negative (78%) predictive values remain similar to those obtained with the four-item self-report questionnaire (Table 2).

DISCUSSION

When faced with uncontrolled hypertension, physicians must determine whether the medication prescribed is adequate. Before increasing the dosage or adding or substituting another drug, physicians should consider non-compliance as a real possibility.¹ Despite the fact that it does not take into account variations due to biologic factors or the efficacy of medications and dosages, the self-report questionnaire has been proposed as a means of addressing the non-compliance issue.⁷

Despite differences in terms of culture, the care setting (primary versus specialized), and the length of time the patients received treatment, our results generally agreed with those of the investigators who tested the original questionnaire.³ Among patients with blood pressure under control, the percentage with high scores as well as the percentages with moderate or low scores were similar to those reported by Morisky et al.³ However, the percentage of high scores on the compliance scale is higher in our study population (73% versus 43%).

In our study, drop-out patients were

excluded because subjects had to have been patients of the family medicine unit for at least 8 months and receiving antihypertensive medication for at least 6 months. This could explain the high rates of blood pressure control observed. In our study, the subjects had been under the unit's care for an average of 5.5 years. Because patients remaining in the health care system are likely to be compliant, this could explain why only a few patients in this study had low compliance scores. This could also explain the similarity in the performance of the self-report in our study, conducted in a primary care setting, with the performance in Morisky's study, performed in a hypertension clinic.³

This self-report questionnaire is readily applicable in a clinical setting. The questions are worded so as to identify and assess barriers to compliance. This method enables clinicians to be more specific in terms of the support they provide to patients with compliance difficulties. In fact, some specific interventions are proposed to overcome any barriers to compliance that are identified.⁷ However, this questionnaire is subjective and susceptible to memory recall bias and social desirability bias. Because our patients were aware of the purpose of the study, it is possible that they were more inclined to tell the truth.

Self-report has consistently provided a specific method of measuring compliance to hypertension drug treatment with regard to the prediction of pill counts^{9,10} and blood pressure control assessments.^{3,11} The results of this study further support this finding. Thus, self-report seems valid when people

are reporting low compliance. Indeed, its usefulness to clinicians is based on its specificity, because patients reporting non-compliance are more likely to respond to strategies aimed at improving compliance.¹² This is reinforced by the need for clinicians to focus their interventions on patients with uncontrolled hypertension.

Even when the definition of high blood pressure control is changed, the self-report questionnaire remains specific. By categorizing non-compliers differently, we can achieve almost 100% specificity. This is important because physicians should not waste time trying to improve compliance in patients whose blood pressure is adequately controlled. The specificity of this questionnaire allows the physician to determine whether the lack of hypertension control is due to a drug-taking behavior problem, and to apply strategies enhancing compliance. However, because the sensitivity of this measurement is poor, it should not be used to rule out non-compliance.

Conclusion

Maintaining compliance to drug therapy is essential if adequate control of high blood pressure is to be achieved. However, clinical management of compliance must be based on accurate and simple methods of identifying non-compliant patients. The self-report questionnaire presented in this study has been shown to be useful in monitoring compliance to hypertension drug treatment. Its specificity has been reconfirmed by the results of this study, carried out in a different cultural setting and language. Although not ideal, this questionnaire can be easily implemented as a part of routine care.

This four-item compliance questionnaire is simple; however, in the clinical setting, some practitioners might find it time-consuming. Asking patients only the first question ("Do you ever forget to take your medicine?") instead of all four questions has produced similar, although somewhat reduced, specificity. Given the role of non-compliance in the failure to control hypertensive patients, and the prevalence and long-term consequences of hypertension, this finding could help clinicians treat their hypertensive patients more efficiently. ■

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