

# Compliance Characteristics of 291 Hypertensive Patients From a Rural Midwest Area

Reuben B. Widmer, MD, Remi J. Cadoret, MD, and Edward Troughton  
Iowa City, Iowa

Patient compliance with treatment regimens has been a concern of both researchers and clinicians. Research studies on compliance have generally originated in large city clinics and teaching institutions. The results paint a dismal picture. The question is, are the compliance percentages found in the literature applicable to the hypertensive population in the semirural Midwest who receive long-term care from their family physician?

This study was carried out in the practices of seven midwestern family physicians. The 291 patients in the study had a mean compliance percentage of 87 percent. By-product data indicate that outcome results were good.

Research on compliance traditionally has conceived of the problem in large part as one of defective behavior by both the patient and the health care system. The physician-patient relationship in a family practice should contribute to better medication compliance. In this study semirural patients with hypertension who receive continuing care from their family physician had better compliance than national figures suggest it should have been.

One fundamental component of medical practice is the patient's cooperation with the treatment regimen proposed by his or her physician. Physicians assume their patients are compliant, and few like to admit to having patient adherence problems in their own practices. Most physicians feel the

compliance figures in the literature apply to patients in some other clinic. No one likes to admit there is a lack of patient esteem for his management plan. But the truth is, there are patients who display little respect for that quintessence of health care activity, the prescription. According to studies in metropolitan centers, approximately one third of patients do not have their antihypertension prescriptions filled, and only one half of the rest take the medication as directed.<sup>1,2</sup> In the experience of one of the authors, however, patient compliance observed in an essentially rural midwestern practice did not seem to agree with the

---

From the Department of Family Practice and the Department of Psychiatry, University of Iowa, Iowa City, Iowa. Requests for reprints should be addressed to Dr. Reuben B. Widmer, Department of Family Practice, University of Iowa, Iowa City, IA 52242.

compliance figures quoted by most investigators.

The research question initiating this study was as follows: Are the compliance percentages in the literature applicable to patients with hypertension in the semirural Midwest who (1) receive long-term care from their family physician, and (2) purchase their own medication (with little help from third-party payers)?

## Literature Review

According to Dunbar and Stunkard,<sup>3</sup> compliance should be recognized as one of the most serious problems facing clinicians today. Medication cannot help if the patient does not take it. They list five common errors in adhering to drug regimens: (1) complete failure to follow the regimen, (2) improper dosage schedules, (3) missed doses, (4) increasing or reducing the doses or daily number of doses, and (5) miscellaneous errors, such as taking medication for the wrong purpose, taking outdated drugs, or taking more medication than the physician realizes. All methods for testing compliance suffer from an inability to measure one or more of these mistakes, yet each of the methods that have been utilized to measure adherence has some advantages and some specific disadvantages. Patient interviews are inexpensive and easy to do, but their validity depends on the skill of the interviewer and on patient honesty. Patient interviews are not so effective as pill count according to Haynes et al.<sup>4</sup> Pill counts, like patient interviews, are simple to do, but the evidence suggests that they overestimate adherence compared with the use of urine markers.<sup>5</sup> Biochemical markers, however, provide inaccurate information on the degree of adherence because of individual differences in rates of absorption. Blood and urine tests tell little more than what medication was taken during the period before the specimen was collected. Adherence over time is not measured.<sup>6</sup> Daily records in patient diaries to assess treatment are popular, a result in part of their effectiveness in helping patients take more responsibility for their own care. This method has been useful for some time in dietary regimens. Its usefulness in medication compliance studies is being investigated.<sup>7</sup>

It is tempting to use outcome to measure compliance, since successful outcome is the physi-

cian's ultimate goal. Individual variation in response to treatment, however, limits the usefulness of outcome as an assessment of compliance. The relationship between adherence and outcome is by no means understood.<sup>8,9</sup> Physician assessment of patient adherence is no better than chance.<sup>10</sup> If anything, clinicians tend to overestimate adherence.

Obviously, a reliable measurement of compliance has yet to be devised. The method used in this study has not previously been described. It assumes that patients who continue buying pills take them. As are pill count, patient interview, and daily record, this method is inexpensive and easy to use. Its advantage is that the patient is unaware of the study and thus his adherence is not apt to be biased by desire to impress the clinicians. The disadvantages are that the patient could conceivably continue buying the medication to please his long-time family physician but throw them away rather than take them, or more likely, take them but not follow directions correctly.

## Methods

This one-year prospective study examined the compliance behavior of patients on antihypertensive medication in several semirural midwestern communities.

Ten family physicians, located in towns varying in population from 700 to 8,500, were asked to participate. Seven physicians agreed, and of these, five dispensed medication from their office because there was no local pharmacy (Table 1).

All new and old patients with hypertension on medication were included in the study as they came to the office. The participating physicians diagnosed hypertension that needed treatment in those patients who had a consistent diastolic blood pressure over 90 mmHg. The number of abnormal readings required to make such a diagnosis varied among the practices. Patients who purchased only one supply of medication during the study were excluded from the sample ( $n = 16$ ) because there was no way to calculate their compliance. These well-controlled patients came in for follow-up and medication about once a year.

A designated person in each office recorded the demographic information and the date of each visit

for hypertension, the names and numbers of drugs dispensed or prescribed, directions for their use, and the blood pressure reading.

The three pharmacies in the large town also kept records of the prescriptions filled and refilled for each patient during the one-year study period. Eleven patients from the prescription-writing practice (two physicians) did not fill their prescriptions at one of the three local participating pharmacies and were not included in the sample because there were no data from which to calculate their compliance. Dates and numbers of pills dispensed were recorded by the three participating pharmacists. This was a state-of-the-art study, and physicians were not asked to follow any special treatment, blood pressure recording technique, or record-keeping protocol that would interfere with their usual practices. The patients were unaware of the study. There were no special blood levels or pill counts that would bias their compliance behavior in any way.

When applicable, chi-square tests with correction factor and *t* tests were used to analyze the data. Comparisons were considered statistically significantly different if a *P* level of .05 or less was computed.

The method of measuring compliance devised for this study was based on the following premises: (1) drugs bought and paid for by semirural and rural midwestern people are taken; and (2) refills purchased on schedule indicate adherence to the physician's directions. This method is considered to be comparable to measuring compliance by pill counts or blood levels. Since patients in this study were unaware of the study, their compliance behavior was not influenced by artificial constraints.

Each patient's compliance percentage was determined by dividing the number of pills that the patient purchased by the number of pills he or she required during the study period. The medication having the lowest patient compliance was used in calculating the compliance percentage for each patient on multiple medications. For example, if a patient refilled his hydrochlorothiazide prescription on time but not his methyldopa, only the methyldopa compliance percentage was used. The patient's first day in the study began with his first purchase of pills and closed on the date of his last refill, so that the last pills purchased were not included in the total pill count. The mean number of

days in the study was 272.3 days. The 291 individual compliance percentages were then used to calculate the mean compliance percentage for the entire group (86.6 percent).

The patients in this study purchased their pills with minimal help from third-party payers (Table 1). Insured patients were reimbursed for a prearranged percent of drug costs by filing completed insurance forms.

## Results

The mean age of the sample was 63.2 years; 37.5 percent were male with a median weight of 186 lb, and 62.5 percent were female with a median weight of 160 lb. Fifty-three percent were farm dwellers, and 47 percent lived in towns. Five physicians in the small nonpharmacy towns dispensed the medication to 82 percent of the sample, while 18 percent of the sample received prescriptions from the two physicians in the larger town. The mean diastolic blood pressure during the study was 83.7 mmHg. Patients had adequate pills 234.3 days out of the mean required 272.3 days (Table 2).

Table 3 compares several factors that were included in the study and gives the compliance percentage for each. Pills taken on a 1, 2, 3, or 4 times a day dosage schedule might be the same medication or multiple medications. As Table 3 indicates, taking pills three or more times a day was the only measured factor that significantly affected compliance. The mean compliance was 86.6 percent (*n* = 291). Falling below this mean were 101 patients (34.7 percent), whose mean compliance as a group was 68.6 percent. Those above the 86.6 percent mean (*n* = 190) had a compliance of 95.1 percent. The complications reported were strokes, congestive heart failure, or myocardial infarction, but no deaths were recorded.

Outcome blood pressures were recorded for 284 patients. Blood pressure readings were not available in seven patients.

The type of regimen affected compliance and caused a significant difference in treatment outcome. Of those patients who took medication once or twice daily, 78 percent had diastolic blood pressure of 90 mmHg or less, and of those patients who took medication three or four times daily, 63 percent had a diastolic blood pressure of 90 mmHg or



Table 1. Demographic Information of Participating Practices

Town Number	Number of Physicians in Practice	Prescription Writer or Dispenser	Town Size	Years in Practice	Patients in Study	Percentage of Patients with Third Party Payer
1	1	Dispenser	700	35	114	35
2	1	Dispenser	1,000	8	55	5
3	2	Dispenser	1,000	15	34	10
4	1	Dispenser	900	5	36	10
5	2	Writer	8,500	13	52	5
				3		

Table 2. Demographic Data of Sample

Mean age (yr)	63.2
Mean diastolic blood pressure (mmHg)	83.7
Mean number of times medication purchased	5.1
Mean number of days with adequate medication	234.3
Mean number of days medication was required	272.3
Male median weight (lb)	186.0
Female median weight (lb)	160.0

Table 3. Compliance Percentage by Study Factors

Factor	No.	Compliance Percentage
Male	109	85.7
Female	182	87.1
Dispense	239	86.3
Write prescription	52	87.9
Below median weight	123	87.4
Above median weight	121	85.4
No complications	251	86.9
At least 1 complication	40	84.6
Medication taken daily or twice daily	262	87.5*
Medication taken three or four times a day	29	78.0
Nonsmokers	260	87.0
Smokers	31	82.9

\*Indicates significant difference

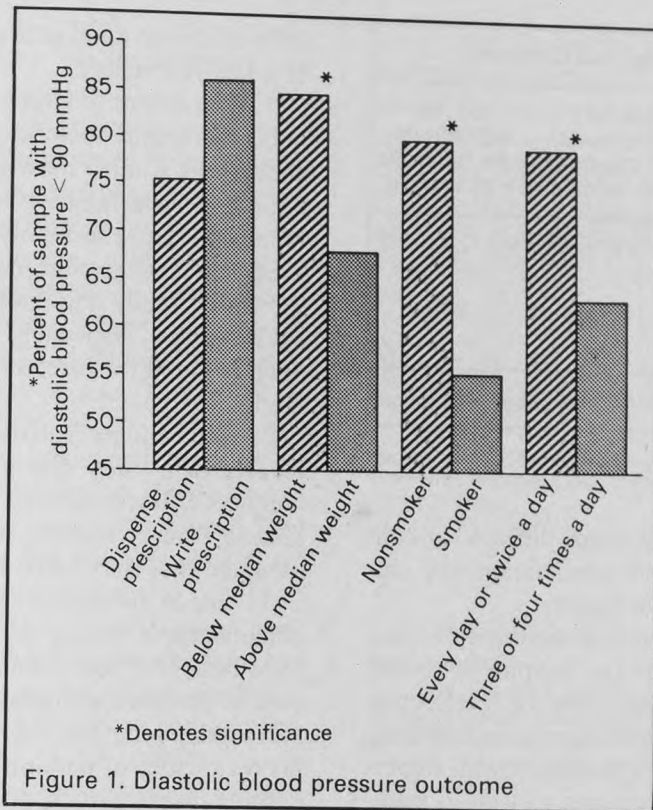
less. Weight and smoking significantly affected treatment outcome (Figure 1).

When compliance is related to outcome, the results tend to agree with Sackett et al,<sup>9</sup> who state that a compliance of at least 80 percent should achieve a positive outcome from an antihypertensive medication treatment regimen. In this study, 75 percent of the patients had a compliance of at least 80 percent (Table 4). Table 5 looks at outcome in relationship to compliance, where generally the compliant patients had a better outcome. Statistical analysis using the chi-square gives a P value of .0506. Seventy-eight percent of the 219 patients who achieved goal blood pressure were at least 80 percent compliant. Two hundred twelve patients had an 80 percent compliance rate, and 80 percent of these achieved goal blood pressure, whereas 68 percent of the 72 patients with a lower compliance achieved goal blood pressure. Even though there was no significant difference in compliance between the sexes, significantly more

women than men had diastolic blood pressure under 90 mmHg.

## Discussion

Determining the compliance of patients to anti-hypertension regimens in a family practice was the primary purpose of this study. Outcome results were recorded as the state of the art in practices of seven different physicians. The results are



Compliance Percentage Interval	Number of Individuals	Percentage Sample	Cumulative Percentage
95-100	126	43	43
90-94.9	43	15	58
85-89.9	25	9	67
80-84.9	23	8	75
75-79.9	13	4	79
70-74.9	16	6	85
≤ 69.9	45	15	100

presented with the realization that the design for future prospective studies of blood pressure outcome would need the following changes: (1) include only newly diagnosed hypertension patients, (2) give criteria used for diagnosis of hypertension, (3) standardize the method of blood pressure measurement, (4) control for age of patient, (5) follow up on patients who drop out of treatment, and (6) determine goals of treatment for physicians collecting the data.

The mean diastolic blood pressure of 83.7

mmHg for this sample (n = 284) indicates good control compared with pretreatment blood pressures of greater than 90 mmHg. A compliance percentage better than 80 percent produced a better outcome than the results of the study noted above by Sackett et al.<sup>9</sup> As shown in previous studies, a complicated regimen resulted in significantly poorer compliance and outcome. This effect on compliance supports the practice of prescribing medication that can be taken once or twice a day. A more complicated dosage schedule would imply

**Table 5. Compliance and Outcome**

	No. of Individuals with Diastolic ≤ 90 mmHg	No. of Individuals with Diastolic > 90 mmHg
Individuals with compliance ≥ 80%	170	42
Individuals with compliance < 80%	49	23
$\chi^2 = 3.822, df = 1, P = .0506$		

that the hypertension was more difficult to control, which could be another explanation why outcomes were significantly different.

There is no good explanation for the difference in outcome between the sexes in spite of similar compliance. The discrepancy may be a reflection of the severity of the hypertension when first diagnosed, or it could indicate that men with hypertension generally do not respond as well to medication. That there are many elderly widows in small midwestern communities could well explain both the mean age of the sample (63.2) and the five-to-three ratio of women over men.

The mean weight of the sample, 186 lb for men and 160 lb for women, supports the impression that obesity is endemic in Iowa. The less favorable blood pressure outcome in the portion of the sample above the mean weight could be the result of using the wrong-sized cuff. Further investigation might find other reasons for this significant difference in outcome in the face of similar compliance percentages.

The marked preponderance of nonsmokers over smokers (89 percent and 11 percent, respectively) is encouraging, a result of successful patient education by the physician and office staff. Even though there were no compliance differences between smokers and nonsmokers, there was a significant difference in outcome (Figure 1).

During a 24-year practice in a small midwestern town, it has been the authors' impression that adherence studies in metropolitan clinics did not reflect the way all patients cooperated with treatment plans. The results of this study confirm that impression.

Five characteristics described in the literature

as favorable to good adherence are usually present in a family practice:

1. The extent to which the patient obtains support from family members determines his compliance. Most studies show greater adherence among patients whose families are supportive.<sup>11</sup> This relationship between family members can easily be used as a management tool in a specialty in which the entire family may be in the practice. The family physician, especially in a rural setting, frequently cares for three or four generations in one family.

2. The patients' satisfaction with the care they receive from their physician influences their adherence.<sup>12</sup> Since the patients in this sample could choose from a number of physicians, it may be assumed that they were satisfied with their care.

3. One of the most consistent findings for better compliance is seeing the same clinician at each appointment.<sup>13</sup> Such continuity was obviously the case in the three solo practices studied. In the two partnership practices each physician regularly saw his own cadre of patients, particularly those with chronic diseases such as hypertension.

4. Clinicians in private practice usually obtain better compliance than those in a clinic setting, explained in part by long-term relationships and the continuity of care.<sup>14</sup> Clinician lateness and block scheduling systems increase waiting time, which can have an adverse effect in large clinic settings. The five practices studied are managed with a minimum of waiting time.

5. Positive identification with the clinic is encouraged by a warm positive environment in the office.<sup>15</sup> As a rule most patients from a small community continue to obtain care from the same family physician for many years, and there tends to be little turnover in office staff. The staff know how to cope with patients because over the years they have become acquainted with their special needs and idiosyncrasies.

Given these characteristics, then, it is not surprising that the compliance percentage in this sample (86.6 percent) is better than those percentages usually reported from large medical centers (35 to 50 percent). Furthermore, good outcomes should be expected (77 percent in this study).

There are, of course, other factors that contribute to the patient's ability or inability to follow directions in any kind of practice situation. Dunbar and Stunkard<sup>3</sup> included among these the pa-



tient's comprehension and recall of physician's directions, the complexity of the regimen, and alarming or unexpected side effects.

Compliance studies and practice experience alike suggest that health care would be improved if physicians would make themselves aware of their patients' compliance. Where problems are detected or suspected, a number of remedial steps could be considered. The physician should reconsider his management regimen when good compliance does not result in a good outcome or if poor compliance still has good results. The physician could seek out the specific factors involved in a patient's poor compliance habits and discuss them with the patient. This investigation should lead to a better understanding of the reasons the patient has come for treatment and his attitude toward taking medicine. The clinician can also convey to the patient the rationale for the treatment plan. Regimen adjustments based on discussion and mutual agreements will give the patient a sense of the clinician's interest in his welfare and a feeling that the treatment plan is a joint venture. People are prone to be more interested in plans they understand and help develop.

There is probably no single ideal method to study patient adherence to drug regimens. The appropriateness of any method to any patient population is affected by geographical area, cultural differences, type of practice or clinic, and prevalent means of payment for medication. The method used in this study is applicable to patients in private practice who purchase their own medication. This method of measuring adherence could be used by clinicians who have a good working relationship with the pharmacies their patients frequent. Information could be shared by chart or computer whereby the number of pills purchased could be compared with pills ordered. (The dispensing physicians already have this record in their offices.)

The results of medical studies in general and adherence studies in particular are often not applicable to private practices. In Iowa, for example, 1 out of 1,000 (0.1 percent) people seeking medical care are eventually referred to a tertiary care medical center, yet more than 90 percent of the medical literature emanates from such centers. Such a sample could produce biased data. The continuing development of a body of knowledge appropriate to primary care practice is a challenge to all pri-

mary care specialties and to family practice departments in particular. The accumulation of data that will describe the process of family practice must come from practicing family physicians as they care for patients in their office. Research in such a setting is essential to improving the quality of health care for the greatest number of people.

### Acknowledgment

Robert Carlton, DO, David Hull, DO, Keith Mills, MD, Bill Nordyke, MD, Steve Redinger, MD, Warren Scott, MD, and J. Glenn Widmer, MD, collected data for this compliance study.

### References

1. Sackett DL: The magnitude of compliance and non-compliance. In Sackett DL, Haynes RB (eds): *Compliance With Therapeutic Regimens*. Baltimore, The Johns Hopkins University Press, 1976, pp 9-25
2. Ball WL: Improving patient compliance with therapeutic regimens: Hamilton symposium examines the problems and solutions. *Can Med Assoc J* 111:268, 1974
3. Dunbar JM, Stunkard AJ: Adherence to diet and drug regimen. In Levy R, Rifkind B, Ernst D, Ernst N: *Nutrition, Lipids, and Coronary Heart Disease*. New York, Raven Press, 1979, pp 391-423
4. Haynes RB, Sackett DL, Gibson ES, et al: Improvement of medication compliance in uncontrolled hypertension. *Lancet* 1:1265, 1976
5. Maddock RK Jr: Patient cooperation in taking medicines. *JAMA* 199:137, 1967
6. Soutter BR, Kennedy MB: Patient compliance assessment in drug trials: Usage and methods. *Aust NZ J Med* 4:360, 1974
7. Zifferblatt SM: Increasing patient compliance through the applied analysis of behavior. *Prev Med* 4:173, 1975
8. Feinstein AR, Ransohoff DR: Problems of compliance as a source of bias in data analysis. In Lasagna L (ed): *Patient Compliance*. Mount Kisco, NY, Futura Publishing Company, 1976, pp 65-76
9. Sackett DL, Haynes RB, Gibson ES, et al: Randomized clinical trial of strategies for improving medication compliance in primary hypertension. *Lancet* 1:1205, 1975
10. Blackwell B: Drug therapy: Patient compliance. *N Engl J Med* 289:249, 1973
11. Haynes RB: A critical review of the "determinants" of patient compliance with therapeutic regimens. In Sackett DL, Haynes RB (eds): *Compliance With Therapeutic Regimens*. Baltimore, The Johns Hopkins University Press, 1976, pp 26-50
12. Francis V, Korsch BM, Morris MJ: Gaps in doctor-patient communication: Patients' responses to medical advice. *N Engl J Med* 280:535, 1969
13. Charney E: Patient-doctor communication: Implications for the clinician. *Pediatr Clin North Am* 19:263, 1972
14. Alpert JJ: Broken appointments. *Pediatrics* 53:127, 1964
15. Caldwell JR, Cobb S, Dowling MD, de Jonga D: The dropout problem in antihypertensive treatment. *J Chronic Dis* 22:579, 1970