Home Blood Pressure Monitoring for Mild Hypertensives

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Synopsis

A clinical trial of 204 untreated patients with mild hypertension was conducted to assess the effect of home blood pressure monitoring on blood pressure level, pharmacologic treatment, reduction of risk factors, and use of health services.

After 1 year, no statistically significant differences were found between the treatment and control groups. The findings indicate that, while home blood pressure monitoring may be useful, it has no measurable short-term impact on these aspects of blood pressure management for patients with mild hypertension.

THE ISSUE OF WHETHER to treat mildly hypertensive patients with drugs is debated in the medical literature. Strong arguments have been made in support of routine drug treatment for most people with mild hypertension (*1, 2*). More recent evidence from the Multiple Risk Factor Intervention (MRFIT) study (*3*) and from a later analysis of the Australian trial (*4*) have led some researchers to conclude that there is need for a more "cautious, conservative approach toward drug therapy" for most patients with diastolic blood pressures (BP) below 100 millimeters of mercury (mm Hg) (*5*). Rather than begin pharmacologic treatment at the first sign of mildly elevated diastolic readings (90–99 mm Hg), a period of observation during which BP levels can be more thoroughly evaluated has been suggested (*6*). During this observation period, nonpharmacologic methods can be introduced to lower risk factors for hypertension. It is hoped that these methods will ultimately reduce BP levels, thus obviating the need to begin drug treatment.

To help patients reduce risk factors, BP monitoring at home has been suggested both as a way to provide ongoing information to patients about their blood pressure and to remind them to take other health actions. Glanz and colleagues (*7*) found that approximately one-quarter of the diagnosed hypertensives in their study who monitored their pressure at home for 2 weeks reported that they took action because of the intervention. This finding suggests that the activity of taking blood pressure readings at home triggered other preventive behaviors and that this "spillover" effect might be useful for reducing blood pressure by lowering risk factors and perhaps reducing routine visits to practitioners.

A further advantage of home BP monitoring is that it offers health care providers an opportunity to obtain more baseline information about a patient before a treatment decision is made. This method was suggested almost 50 years ago by Ayman and Goldshine, who recognized the value of home BP readings, "... to teach the patient the nature of his disease, to help the physician observe better the natural course of the disease, to aid in the prognosis of the individual case, and to permit the clear-cut evaluation of therapy" (*8*). More recently, Burch has advocated a "sphygmomanometer in every home" (*9*).

Studies of home BP monitoring have shown that patients can easily learn to take and report their pressure (*10, 11*) and that the readings patients take at home are accurate enough to detect small fluctuations (*12*).

While previous studies of home BP monitoring have focused on medicated hypertensive patients, our study assessed the effects of home monitoring on patients with untreated, mild hypertension. We compared patients with mild hypertension who monitor their BP at home for 1 year with patients receiving usual care. We sought to determine if the home-monitoring patients were

1. more likely to have lower BPs,
2. less likely to be started on pharmacologic treatment,

Table 1. Mean systolic and diastolic blood pressures at intake and followup and mean difference by study group

Status	Home BP (N=74) Mean BP	SD	Usual Care (N=72) Mean BP	SD	Probability
Intake:					
Systolic	144.4	15.7	144.0	16.8	.98
Diastolic	91.3	9.1	92.7	7.7	.32
Followup:					
Systolic	142.6	15.6	144.8	18.0	.42
Diastolic	92.3	9.5	93.6	9.3	.39
Mean difference:					
Systolic	−1.6	14.5	.8	14.2	.33
Diastolic	1.0	10.0	.9	8.0	.96

NOTE: BP = blood pressure, SD = standard deviation.

3. more likely to reduce risk factors associated with hypertension, and
4. more likely to use fewer health services.

Methods

Study sample. Our study sample consisted of 204 members of the Kaiser Foundation Health Plan in Oakland, CA, who had untreated, mild hypertension (defined as an average of two consecutive clinic BP readings below 180 mm Hg systolic and between 90–99 mm Hg diastolic). The sample was directly referred by physicians and nurse practitioners in our Department of Medicine. Of the 291 patients referred to the study, 11 refused to participate, 40 failed to keep their intake appointments, 10 were unable to be scheduled for intake appointments, and 26 were inappropriate referrals.

Study procedures. The 204 patients who met the eligibility criteria and agreed to participate signed a consent form, and 102 were assigned randomly to the Home BP Group and 102 to the Usual Care (UC) Group. All patients were told that the study would last 1 year, during which time they would remain under their provider's care and would be required to return for a followup visit. Providers were sent a letter for each enrolled patient, informing them of the group assignment. These letters were put in the patients' medical charts. All patients were given a book on risks associated with hypertension and were referred to a hypertension education class.

Characteristics of study groups. There were no significant differences between the two study groups for demographic variables, self-reported health status, risk factors for hypertension, and lifestyle factors. About half of each study group were female (58 percent for Home BP and 47 percent for UC). Forty-four percent of the Home BP Group and 53 percent of the UC Group were black, with a large proportion of both groups currently employed (81 percent of the Home Group, 86 percent of the UC) and married or living with a partner (63 percent and 62 percent). The mean age of the two study groups was similar (47.5 years and 47.0 years), as were mean household income ($26,495 and $27,675) and mean educational level (13.7 years of school and 13.4 years). A large proportion of both groups rated their health excellent or good (81 percent and 82 percent).

In terms of risk factors, the groups were also similar. Sixty-four percent of the Home Group and 65 percent of the UC Group reported a family history of hypertension. Few reported salting their food often or almost always before tasting it (7 percent and 13 percent). Mean body mass index, defined as kilograms of weight divided by centimeters of height squared multiplied by 100, was 4.1 for both groups. Mean level of stress, based on a 10-point semantic differential scale, and mean drinks of alcohol per day were similar for both groups (mean stress, 6.3 and 5.7; mean drinks, 0.7 and 0.8).

Finally, there were no differences in terms of the proportion of those who exercise regularly (40 percent and 39 percent), currently smoke (37 percent and 47 percent), and mean cups of coffee per day (1.6 and 1.5).

Home blood pressure protocol. Patients in the Home BP Group were trained to measure their BP at home using a Tycos Self-Check digital device, which was evaluated favorably against standard auscultatory methods in unpublished data by J. Terdiman and L. Hurley, of the Division of Research, Kaiser Permanente Medical Care Program, Oakland, CA. They were given a kit and instructed in its use. They were asked to take two consecutive readings twice a week following at least 5 minutes of rest and not less than 1 hour after any significant exercise and to send in their readings every 4 weeks for 1 year. A breakout protocol was given to Home BP patients that instructed them to call their providers if any readings were unusually high or low (systolic more than 220 mm Hg; diastolic lower than 50 or higher than 120 mm Hg). Patients in the Home BP Group were assessed on their ability to use the home monitoring device properly. This was done 2 weeks and 3 months after training by use of a biaural stethoscope. Patients were also told that their providers would receive copies of the Home BP reports and would contact them if necessary. Providers received copies of all reports as they were received throughout the study period.

Patients in both groups continued to see their providers as usual during the study year for blood pressure checks. The UC group, however, was not instructed to monitor their BP at home and was asked

Table 2. Mean systolic and diastolic blood pressures at intake and followup and mean difference for Home BP compliers and Usual Care Group

Category	Usual Care (N=72) (A)		Home BP high compliers[1] (N=40) (B)		Probability (A, B)	Home BP total compliers[2] (N=25) (C)		Probability (A, C)
	BP	SD	BP	SD		BP	SD	
Intake:								
Systolic	144.0	16.8	145.2	15.9	.72	143.8	16.2	.95
Diastolic	92.7	7.7	90.4	10.4	.22	88.9	10.7	.11
Followup:								
Systolic	144.8	18.0	143.7	14.4	.72	140.8	14.4	.26
Diastolic	93.6	9.3	91.0	9.7	.17	88.7	10.2	.04
Mean difference:								
Systolic	.8	14.2	−1.6	16.5	.46	−3.0	17.1	.33
Diastolic	.9	8.0	.6	9.9	.87	−.3	10.2	.61

[1]Patients who sent in 9 or more of the 13 4-week interval reports.
[2]Patients who sent in all 13 of the 4-week interval reports.
NOTE: BP = blood pressure; SD = standard deviation.

not to do so during the study year. The scheduling of provider visits and the decision of whether to treat a patient was determined by each provider independent of the study.

Data collection. On entry and at the followup visit, all patients had their weight and BP recorded. Patients completed a questionnaire which included items on demographic characteristics and accepted risk factors for hypertension (family history of hypertension, salt intake, stress, and usual alcohol consumption). We also asked questions about frequency of exercise, usual caffeine consumption, and cigarette smoking to determine possibly related lifestyle effects. Medical chart reviews were conducted to collect data for all patients on their use of services during the year before entry in the study, the study year, and the year following the study.

Use of health services was defined three ways: (*a*) total contacts (visits and phone calls); (*b*) hypertension-related contacts; and (*c*) nonhypertension-related contacts made during the study year. Hypertension-related visits were defined as any visit associated with labile hypertension, hypertension or elevated BP, hypertensive heart disease, or hypertensive renal disease. Hypertension-related phone calls were defined as any phone call with BP care content, a request to refill an antihypertensive medication, or both.

Analysis. Data were analyzed by comparing the Home BP Group with the UC Group. The 58 patients who either were started on antihypertensive medication or did not complete the followup questionnaire or both were excluded from the analyses on BP level and risk factors. Chi-square analysis was used for categorical level variables and Student's *t*-tests were used for continuous level data. Analysis of covariance was used to compare utilization rates between groups while controlling for potentially confounding variables.

Table 3. Comparison of body mass index, alcohol consumption, coffee consumption, and stress at intake, followup, and mean change by study group

Status	Home BP			Usual care			
	Number	Mean	SD	Number	Mean	SD	Probability
Intake:							
BMI	74	4.1	.8	71	4.0	.9	.82
Alcohol consumption	69	.8	1.3	65	.8	1.2	.95
Coffee consumption	70	1.9	1.8	67	1.5	1.6	.25
Stress	72	6.4	2.6	60	5.9	2.6	.29
Followup:							
BMI	74	4.0	.7	70	3.9	.9	.98
Alcohol consumption	68	.6	1.0	68	.6	.9	.91
Coffee consumption	70	1.8	1.6	68	1.0	1.4	.004
Stress	73	6.0	2.6	72	5.8	2.3	.56
Mean difference:							
BMI	74	−.1	.2	70	−.1	.2	.52
Alcohol consumption	64	−.2	.9	61	−.2	.8	.87
Coffee consumption	66	−.1	1.4	64	−.5	1.4	.05
Stress	71	−.4	2.8	60	.1	2.6	.33

NOTE: BMI = Body mass index (weight divided by height squared multiplied by 100); alcohol and coffee in drinks per day; stress on a scale of 1-10 (from "no stress" to "a lot of stress").

Results

BP level. The means of two blood pressure readings at intake and at followup for the study groups are shown in table 1. At intake, there were no statistically significant differences between the mean diastolic and systolic readings for the two groups, although the UC Group had a mean reading of 92.7 mm Hg diastolic compared with 91.3 mm Hg for the Home BP Group. Mean differences from intake to followup were not significantly different. When the data were stratified by sex, age, ethnicity, and family history of hypertension, no differences were found between the two groups.

A maximum of 13 reports could have been completed by patients in the Home BP Group. About half of the Home BP Group returned either 12 or 13 reports. When we compared higher compliers in the Home BP Group

Table 4. Mean total, hypertension-related and nonhypertension-related visits and phone calls during study year by study group, adjusted for visits and phone calls in the year before the study, sex, and age

Category	Home BP (N=102)	Usual care (N=102)	Difference (HBP–UC)	Probability
Total:				
Visits	7.3	6.3	1.0	.09
Phone calls	1.5	1.6	–.1	.85
Hypertension-related:				
Visits	2.5	2.3	.2	.45
Phone calls	.2	.3	–.1	.38
Nonhypertension-related:				
Visits	4.4	3.6	.8	.12
Phone calls	1.3	1.3	.0	.85

(defined in two ways as 9–13 reports and 13 reports returned) with the UC Group, no statistically significant differences were found between systolic and diastolic BPs of either group of higher compliers compared with the UC patients at followup (table 2).

Pharmacologic treatment. Since there were no statistically significant differences in BP levels at followup between the two groups, we expected and found no difference in the proportion of patients put on antihypertensive medication within each group. Approximately 18 percent (18 of 102) of the Home BP Group and 17 percent (17 of 102) of the UC Group were taking medication by the end of 1 year. Of those who were put on medication and completed their followup interview (14 Home BP, 16 UC), followup diastolic BPs were similar (90.2 mm Hg and 89.5 mm Hg). Among the 14 Home BP patients who were put on medication, we found that the mean followup diastolic pressure of the 7 patients sending in less than half of the reports was higher than that of the 7 sending in more than half (87.1 mm Hg and 93.4 mm Hg).

Because home monitoring provides more information to health care providers, thus allowing treatment decisions to be made earlier, we compared the period of time between intake and start of treatment for the Home BP and UC patients who were put on medication during the study period. No significant differences were found (6.1 months for Home BP and 5.7 months for UC).

Risk factors. The two study groups showed no statistical difference at intake or at followup with respect to mean body mass index (BMI), alcohol consumption, or perceived stress (table 3). The UC Group reported a lower coffee consumption at followup than the Home BP Group; the mean difference approached statistical significance ($P = .052$). The two groups also did not differ significantly with respect to exercise, salt intake, or cigarette smoking at either intake or followup.

Use of health services. Analysis of covariance was used to assess the differences in use rates by study group, controlling for use 1 year before the study. There were no statistically significant differences between the groups with respect to total use of services, hypertension-related use, or non hypertension-related use during the study year (table 4).

Discussion

After 1 year of observation, we found no relation between home BP monitoring and BP level, initiation of pharmacologic treatment, reduction of risk factors, or use of health services as compared with usual care. Several factors may explain this finding.

First, perhaps home BP monitoring has an impact on these outcomes, but our measures are not sensitive enough to show such an effect. For example, our measures of alcohol consumption and salt intake were aimed at "usual" intake and perhaps were not able to measure smaller changes which may have occurred.

Second, we may have observed changes in BP, risk factors, and use if we extended the period of observation over several years. Specifically, changes in use might have occurred if providers had been encouraged to use home readings instead of relying on routine BP checks. In a 1989 unpublished paper, Soghikian and colleagues of the Division of Research, Kaiser Permanente Medical Care Program, Oakland, CA, did find some differences in health services use, but providers in that study were asked not to schedule routine appointments with their home monitoring patients unless medically necessary; that is, routine appointments for BP checks alone were discouraged as long as the reports showed satisfactory BP control.

Third, beyond a certain minimal number, additional readings may not be important for physicians who are trying to decide whether or not to treat a patient. This decision may depend more on BP level and length of time it is elevated, which could explain why the two groups did not differ in the length of time after which patients were started on medications.

Fourth, there may have been contamination between groups. Patients in the UC Group may have also been taking their BPs at home regularly. To test this hypothesis, we excluded 11 patients from the UC Group who reported on the followup questionnaire that they took their BPs at home on a regular basis during the study year, and we analyzed the changes in BP level. There were still no significant differences between the groups.

Finally, as conceptualized by the Health Belief Model (*13*), perhaps patients with mild hypertension who are not yet labeled as hypertensives do not perceive themselves to be "sick." It may be that mild hypertensives do not see themselves as having a serious problem and thus do not readily initiate any preventive health behaviors. However, 45 people in each group reported that they had read a book on hypertension risk, and 30 in the Home BP Group and 32 in the UC Group had attended the hypertension class. It is also notable that intake diastolic BP was inversely related to compliance with the Home BP regimen. The more reports returned, the lower the diastolic BP at the onset of the study (91.1 mm Hg for 6 or more reports; 90.4 mm Hg for 9 or more reports; 88.9 mm Hg for 13 reports).

It has been continually demonstrated in the literature that casual BP readings in physicians' offices may not be representative of usual BP level and, moreover, that office readings may be unusually higher due to "white coat hypertension" (*8, 14, 15*). To assess the extent of these elevated office BPs, several studies have used home BP monitoring in mild or borderline hypertensive patient populations as a method to compare with office readings and ambulatory monitoring (*16, 17*). Kleinert and colleagues argue strongly that for diastolic BP, home readings were not only lower than office and 24-hour BPs, but they were also more accurate (*16*). This leads them to suggest that home BP readings may be used as a cost-effective method of assessing mild hypertensive patients.

Studies that have assessed home BP readings as a way to evaluate mild hypertensive patients have used study periods of less than 1 month. While Laughlin and colleagues have suggested that BPs taken at home will decline during a period as short as 7 days, no other studies have reported this finding (*18*). Moreover, no other studies have assessed the effects of home monitoring on lowering BPs for a longer period, which seems surprising given the trend to withhold treatment for mild hypertensive patients and encourage nonpharmacologic strategies to lower BPs (*19*).

A recent report has stated that, as people become more concerned about the dangers of hypertension, home BP kits have become "one of the hottest consumer markets" (*20*). Our findings after the 1-year study period indicate that, while home monitoring may be useful in BP management, in a group of mild hypertensives it did not lead to reduction of BP, risk factors, or health services use, nor did it lead to fewer people being started on pharmacologic treatment compared with usual care. We do not recommend the discontinuance of home BP monitoring by hypertensive patients, since this approach can be a useful adjunct to the management of high BP. Based on our findings, however, we do question whether home BP monitoring has an impact on either preventive behavior or BP management for mild hypertensives. We hope future research will provide additional answers to these questions.

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Equipment

A. Tycos Self-Check Model 7052–08™, Ritter-Tycos Division of Sybron Corp., Arden, NC.