

Pharmacist-Physician Comanagement of Hypertension and Reduction in 24-Hour Ambulatory Blood Pressures

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Background: Pharmacist-physician comanagement of hypertension has been shown to improve office blood pressures (BPs). We sought to describe the effect of such a model on 24-hour ambulatory BPs.

Methods: We performed a prospective, cluster-randomized, controlled clinical trial, enrolling 179 patients with uncontrolled hypertension from 5 primary care clinics in Iowa City, Iowa. Patients were randomized by clinic to receive pharmacist-physician collaborative management of hypertension (intervention) or usual care (control) for a 9-month period. In the intervention group, pharmacists helped patients to identify barriers to BP control, counseled on lifestyle and dietary modifications, and adjusted antihypertensive therapy in collaboration with the patients' primary care providers. Patients were seen by pharmacists a minimum of every 2 months. Ambulatory BP was measured at baseline and at study end.

Results: Baseline and end-of-study ambulatory BP profiles were evaluated for 175 patients. Mean (SD) ambu-

latory systolic BPs (SBPs), reported in millimeters of mercury, were reduced more in the intervention group than in the control group: daytime change in (Δ) SBP, 15.2 (11.5) vs 5.5 (13.5) ($P < .001$); nighttime Δ SBP, 12.2 (14.8) vs 3.4 (13.3) ($P < .001$); and 24-hour Δ SBP, 14.1 (11.3) vs 5.5 (12.5) ($P < .001$). More patients in the intervention group than in the control group had their BP controlled at the end of the study (75.0% vs 50.7%) ($P < .001$), as defined by overall 24-hour ambulatory BP monitoring.

Conclusion: Pharmacist-physician collaborative management of hypertension achieved consistent and significantly greater reduction in 24-hour BP and a high rate of BP control.

Trial Registration: clinicaltrials.gov Identifier: NCT00201045.

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HYPERTENSION AFFECTS 65 million persons in the United States and is associated with increased risks for stroke, myocardial infarction, and heart failure.^{1,2} Blood pressure (BP) control among patients with hypertension remains below national targets. A large number of effective antihypertensive medications are available, which

See also pages 1640
and 1646

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suggests that lack of effective BP control is caused not by a dearth of effective drugs but rather by such barriers as access to care and clinical inertia. Many strategies have been evaluated to improve BP control, including algorithmic approaches to drug selection and case management and collaborative team-based approaches.³⁻⁶

Previously, in a large, prospective, cluster-randomized, controlled trial, our research group⁷ demonstrated that pharmacist-physician comanagement improved office BP control and significantly decreased mean systolic BP in patients with uncontrolled BP at baseline. In our earlier study, 89.1% of the patients in the intervention group achieved their goal BP within 9 months compared with only 52.9% of patients in the control group ($P < .001$). Although the results of this and other studies have documented the efficacy of collaborative management to improve BP control,⁵⁻¹⁰ to our knowledge, the impact of these strategies on ambulatory BP measurements has not been reported. Ambulatory BP measurements more accurately reflect the patient's true BP, and even after adjustment for traditional cardiovascular (CV) risk factors such as office BP, they remain strongly predictive of the risk of end-organ damage.¹¹⁻¹³ There-

fore, the true effect size of any intervention to control BP is best established using 24-hour ambulatory BP monitoring. Our objective herein is to report the results of 24-hour ambulatory BP monitoring obtained during a pharmacist-physician collaborative model of hypertension management.⁷

METHODS

STUDY DESIGN

The Collaborative Management of Hypertension Study design, methods, and results have been reported previously in greater detail.^{7,14,15} Briefly, patients with uncontrolled hypertension from 5 Iowa City area primary care clinics were recruited. Patients were eligible for the study if they were men or women aged 21 to 85 years and were receiving treatment with 0 to 3 antihypertensive agents with no changes to their regimen within the past 4 weeks. To qualify, patients without diabetes were required to have a clinic systolic BP value (average of the last 2 readings) between 145 and 179 mm Hg or a diastolic BP of 95 to 109 mm Hg. Patients with diabetes were required to have clinic systolic BP readings of 135 to 179 mm Hg or diastolic BP readings of 85 to 109 mm Hg. Patients with serious renal or hepatic disease were excluded, as were those with recent myocardial infarction or stroke, unstable angina, or New York Heart Association class III or IV congestive heart failure.

The study was a cluster-randomized design in which clinics were randomized to control or intervention groups. Subjects received either pharmacist-physician comanagement (intervention) or usual care (control) according to their clinic randomization. This procedure avoided contamination of the intervention at the physician level.

Patients in both groups had scheduled, structured study visits with a research nurse at baseline and at 2, 4, 6, 8, and 9 months. At each data collection visit, the nurse measured the subjects' BP 3 times with a mercury sphygmomanometer using standardized American Heart Association criteria.¹⁶ The second and third values were averaged and reported as the clinic BP, as is often the standard procedure in other large clinical trials.¹⁷ The clinic BP values were provided to the primary care provider for patients in the usual care group, and follow-up interventions were left to the discretion of the primary care providers.

For patients in the intervention group, clinical pharmacists reviewed patient data obtained by the research nurse and then interviewed the patient. During the interview, the pharmacists evaluated (1) patient factors that might impede achieving the goal BP and (2) the patients' current treatment strategies compared with clinical guidelines. The pharmacists then discussed treatment recommendations with the patients' physicians. The physicians could choose to accept or reject the pharmacists' recommendations, at their discretion. Medication regimens in both the control and intervention groups could be adjusted at any time by the patients' primary care providers outside of any study visits.

At the baseline and 9-month visits, patients in both the intervention and control groups underwent an ambulatory BP monitoring session. All sessions were performed using the same type of BP monitor to ensure uniformity (SpaceLabs 90217A; SpaceLabs Medical, Redmond, Washington). During the ambulatory BP monitoring session, BPs were measured every 20 minutes during the day (6:00 AM to 10:00 PM) and every 30 minutes at night (10:00 PM to 6:00 AM), according to accepted criteria.¹¹ The physicians and pharmacists in the intervention clinics were blinded to the 24-hour BP results until the patient

completed the trial. The results of the baseline ambulatory BP session and the office BPs at the structured study visits were shared with physicians in the control clinics.

DATA ANALYSIS

We based the sample size calculation for this study on office BP because, to our knowledge, there have been no studies examining the effects of collaborative management of hypertension using the outcome of 24-hour ambulatory BP measurements. In addition, we know of no clinical trials of this model prior to this study that randomized by clinic. Thus, several fixed and random effects that affect power were unknown a priori, such as within- and between-patient variability, between-physician variability, and between-clinic variability. Therefore, we used several techniques to estimate power and sample size; these techniques are described in further detail in a previous report.⁷ The estimated sample size to detect a 3.4-mm Hg population standard deviation (SD) of the change in mean BP averaged across physicians in each clinic at the 80% level was 47 patients per group. However, since this was a longitudinal study with several fixed and random effects, we inflated the sample size to 90 patients per group in consideration of this unknown variability.

There were 8 subjects in the intervention group (8%) and 11 subjects in the control group (15%) with missing values for ambulatory BP measurements at the end of the study. To reduce bias in favor of the intervention group that might occur with the last-observation-carried-forward method, we used the multiple-imputation procedure described by Rubin¹⁸ for the missing values, with the assumptions that the data are multivariate normally distributed and that the missing data are missing at random.

The primary outcome of this analysis was the comparison of the change in 24-hour mean ambulatory systolic BP (SBP) and diastolic BP (DBP) from baseline to 9 months between the intervention group and the control group. For analysis of the ambulatory BP monitoring data, daytime and nighttime hours were defined in a clock time-dependent manner, with daytime hours from 6:00 AM to 10:00 PM, and nighttime hours from 10:00 PM to 6:00 AM. These were selected as modified from recommended guidelines.^{19,20}

Values for the upper limit of normal ambulatory SBPs/DBPs were lower than 130/80 mm Hg for the overall 24-hour period, lower than 135/85 mm Hg for the daytime period, and lower than 120/70 mm Hg for the nighttime period, according to American Heart Association recommendations.²¹ The same goal ambulatory BP averages were used for all patients, including patients with diabetes, because current ambulatory BP monitoring recommendations do not differentiate separate levels of BP control.²¹

The mean BP reductions were compared between the control group and the intervention group using the 2-sample *t* test, and the BP controlled proportion was compared between the control group and the intervention group using the χ^2 test. All analyses were performed using statistical package SPSS for Windows, version 17.0 (SPSS Inc, Chicago, Illinois) and SAS, version 9.2 (SAS Institute Inc, Cary, North Carolina).

RESULTS

A total of 179 patients were enrolled in the study. Nineteen patients withdrew from the study, 10 from the control group and 9 from the intervention group. Of the total 179 patients, 24-hour ambulatory BP profiles were obtained for 175 patients at baseline (100 in the interven-

Table 1. Demographic Characteristics of Study Participants

Characteristic	Group ^a	
	Intervention (n=101)	Control (n=78)
Sex		
Male	42 (41.6)	36 (46.2)
Female	59 (58.4)	42 (53.8)
Race		
White	89 (88.1)	74 (94.9)
Nonwhite	12 (11.9)	4 (5.1)
Insurance status		
Individual or group plan	89 (88.1)	65 (83.3)
Medicare/Medicaid	12 (15.4)	7 (6.9)
Self-pay or other	1 (1.3)	5 (5.0)
Education beyond high school	64 (63.4)	42 (53.9)
Age, mean (SD), y	59.6 (13.7)	61.9 (11.3)
BMI, mean (SD)	32.3 (7.7)	31.8 (14.7)
Comorbid conditions		
Diabetes	25 (24.8)	19 (24.4)
Stroke or TIA	9 (8.9)	2 (2.6) ^b
Myocardial infarction	4 (4.0)	5 (6.4)
Peripheral arterial disease	3 (3.0)	2 (2.6)
Angina	2 (2.0)	0
Heart failure	2 (2.0)	0
Coronary artery bypass graft	1 (1.0)	6 (7.7) ^c
Nephropathy	1 (1.0)	0
Office systolic BP, mean (SD), mm Hg	153.1 (10.0)	150.3 (9.0)
Office diastolic BP, mean (SD), mm Hg	84.9 (12.0)	85.4 (11.0)

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); BP, blood pressure; TIA, transient ischemic attack.

^aUnless otherwise indicated, data are reported as number (percentage) of patients, and differences between groups were not significantly different.

^b $P = .12$, Fisher exact test.

^c $P = .04$, Fisher exact test.

tion group and 75 in the control group). At the end of the study, ambulatory BP monitoring data were collected for 156 patients (92 in the intervention and 64 in the control group). Patient demographic data for the 175 patients included in these analyses are summarized in **Table 1**. The mean (SD) age for the intervention and control groups was 59.6 (13.7) and 61.9 (11.3) years, respectively. No significant differences were noted between the groups, except that the control group had a higher percentage of patients with a history of coronary artery bypass grafting than the intervention group (7.7% vs 1.0%) ($P = .04$).

By the end of the 9-month study, the mean (SD) number of antihypertensive medications increased from 1.5 (1.0) to 2.4 (0.9) in the intervention group and 1.4 (1.0) to 1.9 (1.0) in the control group ($P < .01$ for comparison between the groups).⁷ Mean office SBP decreased by 28.9 mm Hg in the intervention group compared with 17.3 mm Hg in the control group ($P < .001$ for between-group difference).⁷ **Table 2** summarizes the mean BP reduction at the end of the study for daytime, nighttime, and overall 24-hour ambulatory BP measurements for the intervention and control groups. While both groups began the study with similar BP readings, there was a significantly greater mean SBP reduction in the intervention group than in the control group for daytime, nighttime, and overall 24-hour period. The overall 24-

hour mean (SD) SBP for the intervention group was reduced from 135.5 (11.3) mm Hg to 121.4 (9.7) mm Hg compared with a reduction from 136.0 (13.3) mm Hg to 130.5 (11.4) mm Hg in the control group ($P < .001$ for intervention vs control).

In addition to the multiple imputation method, we performed a sensitivity analysis on complete data only (summarized in **Table 3**). Under both methods of analysis, the between-group differences were similar and remained statistically significant: mean (SD) SBP reduction in millimeters of mercury changed from 5.5 (12.5) to 3.4 (11.6) for the control group and 14.1 (11.3) to 14.4 (11.0) for the intervention group ($P < .001$ for between-group comparison).

The **Figure** illustrates the percentage of patients in both groups with BP control at baseline and at the end of the study as defined by ambulatory BP monitoring criteria.²¹ Again, while both the control and intervention groups had a similar percentage of patients at goal at baseline, the intervention group achieved higher control rates by the end of the study across all periods (daytime, nighttime, and overall 24 hour) of the 24-hour session.

Data regarding pharmacist recommendations have been previously reported.¹⁴ Briefly, changes in drug therapy were recommended 267 times for the 101 intervention patients, where most recommendations for a change in treatment involved adding a new antihypertensive medication (46.4%) or up-titrating the dose of an existing medication (33.3%). Of the pharmacist recommendations to add a new antihypertensive medication, 36.3% were for the addition of a thiazide-type diuretic. Physicians accepted and implemented 95.9% of the 267 pharmacist recommendations to modify drug therapy.

COMMENT

Pharmacist-physician comanagement is an effective method for improving BP control in patients with hypertension, as traditionally defined by office BP readings.^{5,9,10} To our knowledge, our study is the first team-based care approach to evaluate the impact of the intervention on ambulatory BP measurements and demonstrates that pharmacist intervention results in greater decreases in the mean BP and an increase in the number of patients meeting their BP goal (75% [n=75] vs 51% [n=38]) compared with usual care. The lower BPs achieved in the pharmacist intervention group were primarily attributable to the increased mean (SD) number of medications per patient in the intervention group (from 1.5 [1.0] to 2.4 [0.9]) compared with the control group (from 1.4 [1.0] to 1.9 [1.0]), which suggests that such a strategy can reduce clinical inertia. Since typical physician visits are short and may not provide adequate time to address multiple issues, the collaborative management with pharmacists allowed specific time to focus on improving medication regimens to meet BP goals. The rate of acceptance of the pharmacist recommendations (95.9%) indicates a relatively high level of satisfaction with the pharmacist-physician comanagement model on the part of physicians in the clinics randomized to the intervention.

Table 2. Results of Blood Pressure (BP) Measurement and Mean BP Reduction From Baseline to End of Study^a

Characteristic	Daytime		Nighttime		Overall 24-Hour		Office BP	
	SBP	DBP	SBP	DBP	SBP	DBP	SBP	DBP
Control (n=75)								
Baseline	140.0 (13.1)	79.2 (10.7)	128.4 (17.8)	71.5 (11.0)	136.0 (13.3)	76.6 (9.9)	150.3 (9.0)	85.4 (11.0)
End of study	134.6 (11.6)	76.6 (9.8)	122.7 (15.2)	68.1 (10.0)	130.5 (11.4)	73.7 (9.0)	133.0 (14.2)	78.5 (10.9)
Mean BP reduction	5.5 (13.5)	2.7 (6.7)	5.7 (14.3)	3.5 (8.8)	5.5 (12.5)	2.8 (6.5)	NR	NR
Intervention (n=100)								
Baseline	140.7 (11.1)	79.7 (10.7)	125.5 (15.7)	68.8 (10.3)	135.5 (11.3)	76.0 (9.8)	153.1 (10.0)	84.9 (12.0)
End of study	125.5 (10.1)	72.3 (9.8)	113.4 (13.9)	63.2 (9.3)	121.4 (9.7)	69.2 (8.7)	124.2 (9.7)	74.7 (9.6)
Mean BP reduction	15.2 (11.5)	7.4 (5.9)	12.2 (14.8)	5.6 (9.1)	14.1 (11.3)	6.8 (5.9)	NR	NR
P value ^b	<.001	<.001	.004	.12	<.001	<.001	<.001	<.001

Abbreviations: DBP, diastolic blood pressure; NR, not reported; SBP, systolic blood pressure.

^aUnless otherwise indicated, data are given as mean (SD) millimeters of mercury.

^bP value for comparing mean BP reduction between the control group and the intervention group.

Table 3. Ambulatory Blood Pressure (BP) Measurement and Mean BP Reduction in Study Completers From Baseline to End of Study^a

Characteristic	Daytime		Nighttime		Overall 24-Hour	
	SBP	DBP	SBP	DBP	SBP	DBP
Control (n=64)						
Baseline	138.8 (12.7)	78.5 (9.3)	126.3 (17.6)	70.3 (9.9)	134.7 (13.0)	75.7 (8.6)
End of study	135.6 (11.7)	76.7 (8.8)	122.5 (15.7)	67.5 (9.3)	131.3 (11.8)	73.7 (8.0)
Mean BP reduction	3.1 (12.5)	1.7 (6.6)	3.8 (13.9)	2.8 (8.6)	3.4 (11.6)	2.0 (6.4)
Intervention (n=92)						
Baseline	141.0 (11.2)	79.8 (10.9)	125.0 (15.9)	68.6 (10.6)	135.5 (11.3)	76.0 (10.0)
End of study	125.4 (10.2)	72.3 (9.8)	112.9 (14.3)	63.1 (9.1)	121.2 (9.9)	69.1 (8.6)
Mean BP reduction	15.5 (11.3)	7.4 (5.7)	12.1 (14.6)	5.5 (9.0)	14.4 (11.0)	6.9 (5.7)
P value ^b	<.001	<.001	.001	.06	<.001	<.001

^aUnless otherwise indicated, data are given as mean (SD) millimeters of mercury.

^bP value for comparing mean BP reduction between the control group and the intervention group.

The present study showed that daytime, nighttime, and overall 24-hour BPs were consistently lower in the pharmacist intervention group. These findings indicate that pharmacist-physician comanagement can effectively sustain BP control throughout the entire 24-hour period. This is an important finding because traditional office BP measurements would likely be taken during a time of peak antihypertensive activity during daytime hours, thus allowing a potential overestimate of the effect of the intervention.

Our findings are also noteworthy in that the control group was subjected to structured research nurse visits, and the BP data were regularly shared with the patients' primary care providers. Patients in the control group were informed of their BP results and their goal BP in a structured, consistent manner and were provided written information on BP management. In this respect, the control group represented an enhanced "usual care" group, compared with what is traditionally found in team-based BP intervention studies. In this group, the BP decreased from baseline to the end of the study, and BP control rates increased, but the intervention group saw greater BP reduction in both areas of measurement that remained statistically significantly lower.

It is well established that traditional office BP measurements do not provide the most accurate assessment of the true BP. Banegas et al²² found that office BP un-

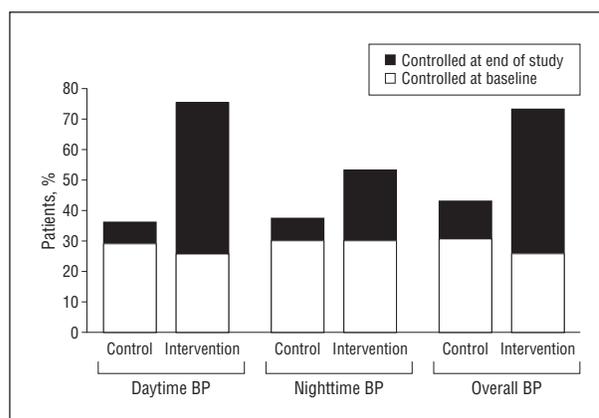


Figure. Patients at ambulatory blood pressure (BP) monitoring goal, baseline vs end of study. Control of BP is defined as follows according to American Heart Association recommendations²¹: daytime, lower than 135/85 mm Hg; nighttime, lower than 120/70 mm Hg; overall, lower than 130/80 mm Hg.

derestimated BP control 33.4% of the time and overestimated BP control 5.4% of the time. This has been shown specifically in patients undergoing hydrochlorothiazide treatment²³ and may be due in part to the fact that BP measurement often occurs during the peak effect of many antihypertensive medications during the day. In the intervention group of our study, 36.3% of the pharmacist

recommendations to add therapy were to add a thiazide-type diuretic, and the intervention group maintained significantly lower BP throughout the full 24-hour period. Gorostidi et al²⁴ found significant discrepancies between office and ambulatory BP measurements in high-risk patients and also found that 60% of patients demonstrated a nondipper pattern. Ambulatory BP monitoring is able to provide a more accurate picture of overall CV risk because it includes nocturnal BPs, which are known to correlate strongly with CV risk.^{12,13,25} Patients receiving pharmacist-physician comanagement in our study experienced significantly reduced BPs, including during the important nighttime period (mean SBP reduction, 12.2 vs 5.7 mm Hg).

Our study should be interpreted within the context of several limitations. First, our analysis defined daytime and nighttime periods in a fixed-clock manner rather than patient-specific awake/sleep periods. Patient-specific measurement of awake/sleep cycles can be performed using actigraphy, but this method is not standard among all BP studies, and there is little evidence to suggest that definitions of daytime and nighttime based on fixed-clock intervals or actual time spent in bed significantly impacts the determination of CV risk.²⁶

Second, the differential attrition rate with 8 subjects in the intervention group (8%) and 11 subjects of the control group (15%) with missing values at the end of the study would potentially bias the results in favor of the intervention. To control for this potential bias, we performed the multiple imputation procedure to replace missing values and also performed an additional analysis only on completed data. In both analyses, the results remained significant. While we do not know the reason for the withdrawal of these patients, we suspect that the lower rate of attrition in the intervention group may be partially owing to the relationship formed between patients and clinical pharmacists and the incentive of receiving enhanced care.

A final limitation is the unknown generalizability of our intervention. The patient population examined was largely white patients with hypertension and relatively few comorbidities. We do not know the scalability of the model because we have not yet conducted a cost-effectiveness analysis or examined the efficiency of the model. A larger study of this model conducted in 27 clinics serving large minority populations across the United States is under way and will answer many of these questions.²⁷

In conclusion, despite smaller changes in ambulatory BP readings than in office BPs, pharmacist-physician comanagement achieved significantly greater reduction in BP and a high rate of BP control compared with patients receiving usual care. Given the strong correlation between ambulatory BP and CV risks, our study findings suggest that pharmacist-physician comanagement of hypertension can reduce these risks in patients with uncontrolled hypertension through sustained 24-hour BP lowering.

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Correction

Age Error and Typographical Errors. In the Original Investigation titled “Prognostic Implications of the Urinary Albumin to Creatinine Ratio in Veterans of Different Ages With Diabetes” by O’Hare et al, published in the June 14th issue of the *Archives* (2010;170[11]:930-936) the age was misstated on page 933, left-hand column, first paragraph, in lines 6 and 17. The age should have been “younger than 65 years” in both places. The sentences should have read as follows: “Across age groups, the proportion of all patients who met the criteria for CKD (defined as an eGFR <60 mL/min/1.73 m² or an ACR ≥30 mg/g) increased from 26.5% in those younger than 65 years to 56.4% in those aged 75 years and older (Figure 2).” “On the other hand, 44.6% of patients 75 years or older who met the criteria for CKD did so because of an isolated low eGFR (ie, ACR <30 mg/g) compared with 23.6% of patients younger than 65 years.”

On page 930, right-hand column, “Results” section of the Abstract, the last sentence should have read as follows: “In younger age groups, this association was present at higher levels of eGFR but seemed to be attenuated at lower levels.” On page 935, left-hand column, the last sentence of the complete paragraph should have read as follows: “Collectively, these findings suggest that the ACR may be a valuable tool for mortality risk stratification in the elderly, particularly in the large group with a moderate reduction in eGFR.”