Systolic Blood Pressure Control After Participation in a Hypertension Intervention Study

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Objective: To evaluate whether systolic blood pressure (SBP) control is maintained following participation in a multimodal hypertension intervention.

Study Design: This was a retrospective cohort of patients completing the Improving Blood Pressure in Colorado study, a randomized trial comparing a multimodal intervention with usual care for patients who had uncontrolled hypertension.

Methods: Chart review assessed the first SBP measurement recorded as part of routine care after the study ended. Among patients who had controlled SBP at the final study visit, the proportions who had uncontrolled SBP during follow-up were compared for the intervention and usual care (UC) groups. Kaplan-Meier estimates assessed time to uncontrolled SBP by treatment arm.

Results: Of 283 patients completing the Improving Blood Pressure in Colorado study, 51.5% in the intervention and 46.9% in the UC group had controlled SBP at the final study visit. Of patients with controlled SBP, 37.0% and 46.4% of patients in the intervention and UC groups, respectively, had uncontrolled SBP at their initial measurement during follow-up ($P = .32$). There was no difference in median time to uncontrolled SBP (126 vs 114 days for the intervention and UC groups, respectively; $P = .47$).

Conclusions: SBP control was not maintained in a significant proportion of patients in both groups following hypertension study participation. These findings suggest the need for interventions to focus on longer-term BP control in contrast to the short duration of most hypertension intervention trials.

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Approximately 65 million US adults have hypertension and this number is expected to grow as the population ages.[1] Hypertension is a significant cardiovascular risk factor and the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7) recommends achieving systolic blood pressure (SBP) goal as the primary focus of hypertension therapy.[2] Although the degree to which SBP is lowered is directly related to the degree to which adverse outcomes are reduced, national surveys demonstrate that only about half of patients with hypertension have their blood pressure (BP) treated to levels recommended by guidelines.[3] Further, BP control over time is directly associated with cardiovascular events, suggesting that both achieving and maintaining BP goals are important.[4,5]

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Interventions using pharmacists, nurses, home BP monitoring, and/or technology such as interactive voice response (IVR) alone or in combination have resulted in improved BP control compared with usual care in the short term (6-12 months).[6] However, given that hypertension is a chronic condition, long-term management is necessary. Unfortunately, little is known about maintenance of BP control following patients' participation in hypertension intervention studies or about the durability of BP reduction after the conclusion of a study.

The Improving Blood Pressure in Colorado study was a randomized study that evaluated a multimodal intervention for patients with uncontrolled hypertension, utilizing IVR technology and clinical pharmacist–physician management for 6 months.[7] The objective of the current study was to evaluate maintenance of SBP control in the short term after participation ended in the clinical trial, when patients returned to their primary care providers for care.

METHODS

The Improving Blood Pressure in Colorado study (clinicaltrials.gov; Identifier: NCT00520988) was conducted from 2006 to 2009 at 3 healthcare systems across the Denver metropolitan area, including the Denver Veterans Affairs Medical Center, Kaiser Permanente Colorado, and the Denver Health Medical Center. The randomized study was approved by the institutional review board at each site. The current study was ap-

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Take-Away Points

A randomized trial compared a multimodal intervention with usual care for patients who had uncontrolled hypertension.

- Systolic blood pressure control was not maintained in a significant proportion of patients in both groups following participation in this study.
- These results suggest the need to focus on long-term hypertension control.

proved as an addendum to the initial study and included patient waiver of consent.

Methods for the Improving Blood Pressure in Colorado Study

Criteria for enrollment into the main prospective, randomized study were the following: 18 to 85 years of age, diagnosed with hypertension, uncontrolled BP (>140/90 mm Hg, or >130/80 mm Hg for patients with diabetes or chronic kidney disease), and receiving ≤4 antihypertensive medications. All patients attended a baseline, in-person clinic visit to have their BP assessed. Three BP measurements were obtained and if the average of the latter 2 measurements was above patient-specific targets, those patients were eligible for enrollment. Patients randomized to the intervention were provided a hypertension educational booklet from the National Institutes of Health (*Your Guide to Lowering Blood Pressure*), instruction on the use of the IVR system, and an electronic BP monitoring machine. Patients were taught how to measure home BP, instructed to take their BP 3 to 4 times per week, and told to report their BP readings via IVR weekly. A clinical pharmacist reviewed the BP entries from the IVR system and managed BP via telephone visits, utilizing treatment protocols approved by primary care physicians. Patients randomized to usual care were given the same educational booklet on hypertension and instructed to follow up with their primary care providers for BP management. All patients returned at 6

Table 1. Baseline Characteristics of Patients With and Without Follow-up Blood Pressure Measurement After End of Participation in the Clinical Trial

Characteristic	Missing Follow-up Blood Pressure Measurements (n = 55)	Follow-up Blood Pressure Measurements (n = 228)	*P*
Age, y, mean (median)	61.5 (61.0)	65.4 (64.5)	.02
Male, % (n)	63.6 (35)	64.9 (148)	.86
Diabetes or chronic kidney disease, % (n)	47.3 (26)	57.5 (131)	.17
Married or living with partner, % (n)	58.5 (31)	53.9 (119)	.67
Education, % (n)			.46
Less than high school education	11.3 (6)	6.8 (15)	
Completed high school	32.1 (17)	24.1 (53)	
Some college	34.0 (18)	40.5 (89)	
College graduate	9.4 (5)	15.0 (33)	
More than college	13.2 (7)	13.6 (30)	
Drinking, % (n)			.86
Never	39.6 (21)	39.7 (87)	
Monthly or less	24.5 (13)	22.8 (50)	
2-4 times/month	22.6 (12)	21.9 (48)	
4-5 times/week	1.9 (1)	5.5 (12)	
6 or more times/week	11.3 (6)	10.1 (22)	
Smoking, % (n)			.22
Current	25.9 (14)	16.4 (36)	
Former	35.2 (19)	44.1 (97)	
Never	38.9 (21)	39.6 (87)	
Exercise, % (n)			.15
Never	35.9 (19)	21.0 (46)	
1-2 times/week	15.1 (8)	20.6 (45)	
3-4 times/week	18.9 (10)	20.6 (45)	
5-6 times/week	30.2 (16)	37.9 (83)	
SBP at goal at end of study, % (n)	52.7 (29)	48.3 (110)	.55

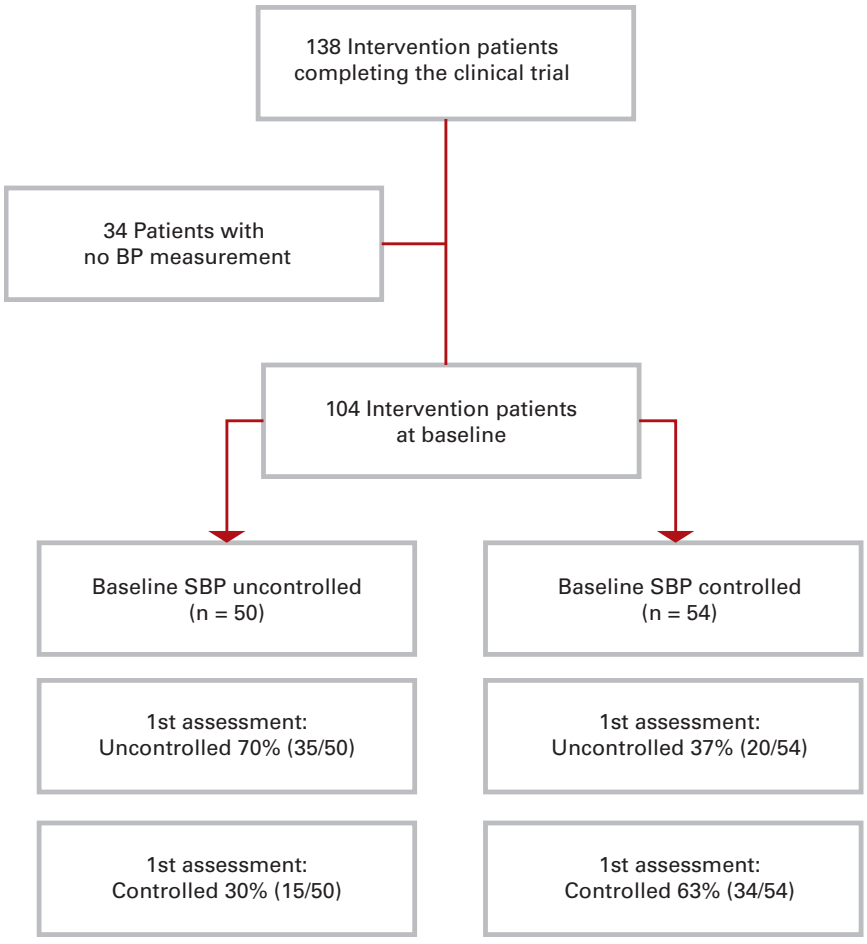
SBP indicates systolic blood pressure.

months and had 3 BP readings taken, with the latter 2 averaged to determine the final BP reading for the study. The person obtaining the final readings was blinded to patient group assignment. Blood pressure control was defined as <130/80 mm Hg for patients with diabetes or chronic kidney disease and <140/90 mm Hg for all others.[7]

Methods for the Current Study

To evaluate maintenance of SBP control following patient participation in the current study, we performed chart reviews for all participants who completed the end-of-study visit (n = 283). We abstracted BP measurements taken as part of routine clinical care at all outpatient nonemergent care visits within 6 months following the end of participation in the clinical trial. Data were collected for both intervention and usual care group patients. Patients with no follow-up BP values in the 6-month period (n = 55) were not included in the analysis. The primary outcome for the follow-up study was the proportion of patients with uncontrolled SBP using JNC 7–defined goals (ie, SBP >140 mm Hg, or >130 mm Hg for those with diabetes or chronic kidney disease) based on their first BP measurement following the end of participation in the Improving Blood Pressure in Colorado study.[2]

Figure 1. Systolic Blood Pressure Control at First Assessment of Intervention Patients



BP indicates blood pressure; SBP, systolic blood pressure.

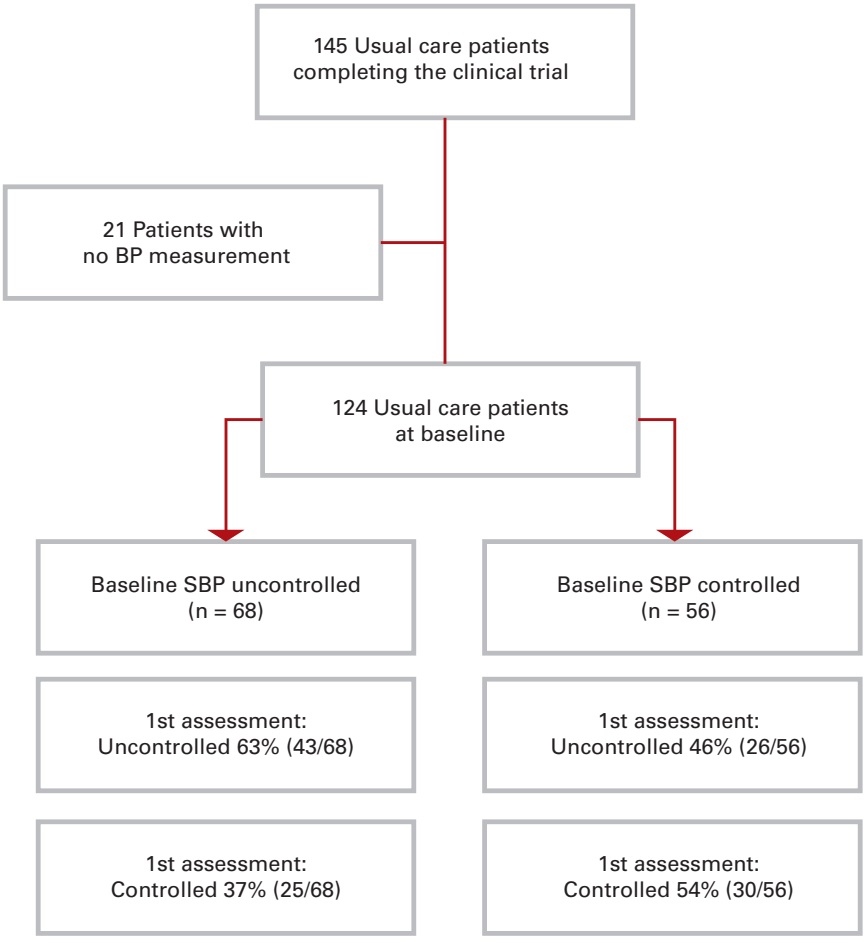
Statistical Analysis

Descriptive statistics (means, standard deviations, and percentages) were used for patient demographics at baseline for each group. χ^2 tests for categorical variables and *t* tests for continuous variables were used for group comparisons between intervention and usual care patients. Kaplan-Meier estimates were used to model the probability of uncontrolled SBP by follow-up time for each treatment arm. To identify predictors of uncontrolled SBP, a multivariable logistic regression model was created, using baseline characteristics at the time of participation in the clinical trial and included all Table 1 variables. As a secondary analysis, we also assessed the proportions of patients with uncontrolled SBP in the intervention and usual care groups by averaging all available SBP measurements during the initial 6 months following the end of study participation. Statistical analyses were performed using SAS version 9.2 (SAS Institute, Inc, Cary, NC).

RESULTS

Of the 283 patients who completed the Improving Blood Pressure in Colorado study, 51.5% (71/138) in the intervention group and 46.9% (68/145) in the control group had controlled SBP at the final study visit. The magnitude of SBP reduction was greater in the intervention group than in the usual care group despite similar rates of patients with controlled SBP (–13 mm Hg vs –7 mm Hg for the intervention group vs the usual care group, respectively; *P* = .004). More than 24% (n = 34) and 14% (n = 21) of the intervention and usual care group members, respectively (*P* = .03), did not

Figure 2. Systolic Blood Pressure Control at First Assessment of Usual Care Patients



BP indicates blood pressure; SBP, systolic blood pressure.

have follow-up BP measurements within 6 months of study completion. Patients with a BP measurement following study completion were older than patients without a BP measurement (65.4 vs 61.5 years; $P = .02$), but other baseline characteristics were comparable (Table 1).

Baseline characteristics of patients with BP measurements within the 6 months following study end were comparable, including the number of patients with diabetes or chronic kidney disease ($P = .31$; see Table 2). The mean and median numbers of BP measurements in the 6 months after end of study participation were 2.8 and 2.0, respectively. The median time to first BP assessment was 48 days with no difference between treatment groups (45.5 vs 51.0 days [$P = .61$] for intervention vs usual care patients). Of the 54 intervention patients whose SBP was controlled at the end of the study, 37.0% (n = 20) had out-of-control SBP at their first follow-up (Figure 1), with SBP increasing from 128 mm Hg to 139 mm Hg. Of the 56 usual care patients whose SBP was controlled at the end of the study, 46.4% (n = 26) had out-of-control SBP at their first follow-up, with SBP increasing from 129 mm Hg to 143 mm Hg (Figure 2) ($P = .32$ for comparison between treatment arms for the percentage of patients with uncontrolled SBP and $P = .60$ for comparison between groups for average SBP at first follow-up). There was no significant difference in the median time to uncontrolled SBP for intervention (126 days) and usual care (114 days) patients ($P = .47$). In the assessment of factors associated with follow-up SBP control, only SBP control at end of study was associated with subsequent control (odds ratio, 0.31; 95% confidence interval, 0.16-0.57).

In secondary analysis (when we used all available SBP measurements taken during the 6 months after the study ended), a similar proportion of intervention (29.6%) and usual care (29.1%) patients had uncontrolled SBP. For patients with uncontrolled SBP at the study's end, 70% (n = 35) of intervention patients and 63.2% (n = 43) of usual care patients continued to have uncontrolled SBP at their first assessment following the study ($P = .43$).

DISCUSSION

The objective of this study was to describe SBP control following participation in a hypertension intervention study, when patients returned to their usual care settings. Among patients whose SBP was controlled at the end of the study, 42% had out-of-control SBP at the first BP measurement obtained within 6 months of study completion. Among patients whose SBP was not controlled at the end of the study, the majority continued to have uncontrolled SBP during follow-up (~66%). These findings highlight the difficulty of maintaining SBP control and suggest the importance of trying to obtain consistent BP control over time rather than control at discrete time points.

Little is known about SBP control following participation in hypertension intervention studies. To date, only 1 prior published study assessed BP control following participation in a hypertension intervention study, which compared a physician–pharmacist collaborative intervention with usual care. Carter

Table 2. Baseline Characteristics of Patients With Follow-up Blood Pressure Measurements Based on Initial Randomization

Characteristic	Usual Care (n = 124)	Intervention (n = 104)	*P*
Age, y, mean (median)	66.3 (65.7)	64.4 (63.1)	.21
Male, % (n)	62.9 (78)	67.3 (70)	.49
Diabetes or chronic kidney disease, % (n)	60.5 (75)	53.9 (56)	.31
Married or living with partner, % (n)	55.0 (66)	52.5 (53)	.06
Education, % (n)			.27
Less than high school education	7.5 (9)	6.0 (6)	
Completed high school	23.3 (28)	25.0 (25)	
Some college	44.2 (53)	36.0 (36)	
College graduate	15.8 (19)	14.0 (14)	
More than college	9.2 (11)	19.0 (19)	
Drinking, % (n)			.50
Never	43.2 (51)	35.6 (36)	
Monthly or less	24.6 (29)	20.8 (21)	
2-4 times/month	19.5 (23)	24.8 (25)	
4-5 times/week	5.1 (6)	5.9 (6)	
6 or more times/week	7.6 (9)	12.9 (13)	
Smoking, % (n)			.11
Current	11.8 (14)	21.8 (22)	
Former	44.5 (53)	43.6 (44)	
Never	43.7 (52)	34.7 (35)	
Exercise, % (n)			.72
Never	22.0 (26)	19.8 (20)	
1-2 times/week	20.3 (24)	20.8 (21)	
3-4 times/week	17.8 (21)	23.8 (24)	
5-6 times/week	39.8 (47)	35.6 (36)	

et al showed that at 9 months following the completion of the study, SBP had worsened for both intervention and control patients, although to a greater degree in the usual care group.[8] In their study, approximately one-third of patients whose SBP was controlled at the end of the study lost that control at 9 months. In contrast, we found that a greater proportion of patients developed uncontrolled SBP and that the uncontrolled SBP developed much sooner, at around 4 months in our patient population. These findings demonstrate that gains in SBP control made during the study were not sustained. Future studies should identify potential reasons for loss of SBP control, including nonadherence to medications or lifestyle changes.

The findings of our study highlight the importance of approaching hypertension control longitudinally rather than at discrete time points. This conclusion is supported by studies that have demonstrated that ambulatory BP measurements (which generally include more measurements over time) predict cardiovascular outcomes better than clinic BP measurements.[9-11] In addition, the INVEST Study showed that a higher proportion of visits where BP was controlled (which indicated consistency of control) were associated with a reduction in death, nonfatal myocardial infarction, or stroke.[4] Despite the importance of longitudinal BP control, national epidemiologic studies such as the National Health and Nutrition Examination Survey and quality-of-care performance measures from the Healthcare Effectiveness Data and Information Set still assess BP control based on measurements at 1 point in time or a single measurement, which may overlook the chronic nature of hypertension.[12,13] Future studies are needed on how to better define hypertension control for epidemiologic studies and for quality-of-care assessment, incorporating the variability of BP.

Limitations

Potential limitations of the study should be acknowledged. First, approximately 19% of patients did not have a BP measurement within 6 months following the end-of-study visit. We do not know whether these patients had a follow-up visit scheduled with their primary care provider. However, our findings that SBP became uncontrolled shortly after the end of study participation suggest that interventions are needed for routine follow-up of patients with hypertension to ensure that BP is assessed regularly and adequately controlled. These findings differ from those in hyperlipidemia studies (in which low-density lipoprotein cholesterol control was maintained following discharge from a lipid intervention program) and might be related to the greater variability of hypertension.[14,15] Prior studies have

not assessed glucose control in patients with diabetes following their participation in intervention studies. Second, this was a small study. It was underpowered to assess whether there was a difference in rates of uncontrolled SBP between intervention and usual care patients, despite an absolute difference of 9% in favor of the intervention patients. Future larger hypertension studies should assess the sustainability of intervention effects following the end of the clinical trial to better determine whether patients need additional interventions. Third, we cannot exclude the possibility that our findings reflected regression to the mean. However, in a secondary analysis when we used all available SBP measurements during the 6 months following study participation, the findings regarding the proportions of patients with out-of-control SBP were consistent with the primary analysis. Fourth, it is possible that BP was incorrectly measured during follow-up; however, those BP measurements reflect the BP measurement that was in the medical record and was used during routine clinical care for decision making. Finally, this study was conducted within 3 integrated healthcare systems and may not be generalizable to other healthcare settings. Additional studies are needed to assess the consistency of BP control following attainment of SBP goals in different healthcare settings.

CONCLUSION

We found that patients whose SBP was controlled at the end of a hypertension intervention study lost SBP control quickly after they stopped participating in the trial. These findings suggest the need for interventions to focus on longer-term BP control, in contrast to the short duration of most hypertension intervention trials.

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