

Effectiveness of a Two-Part Educational Intervention to Improve Hypertension Control: A Cluster-Randomized Trial

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Study Objective. To measure the effectiveness of a multifaceted educational intervention to improve ambulatory hypertension control.

Design. Cluster-randomized trial.

Setting. Academic health system using an ambulatory electronic medical record.

Subjects. A total of 10,696 patients with a diagnosis of hypertension cared for by 93 primary care providers.

Intervention. Academic detailing, provision of provider-specific data about hypertension control, provision of educational materials to the provider, and provision of educational and motivational materials to patients.

Measurements and Main Results. The primary outcome was blood pressure control, defined as a blood pressure measurement below 140/90 mm Hg, and was ascertained from electronic medical records over 6 months of follow-up. We determined the adjusted odds ratio for the association between the intervention and the achievement of controlled blood pressure. When we accounted for clustering by provider, this adjusted odds ratio was 1.13 (95% confidence interval 0.87–1.47). Adjusted odds ratios were 1.03 (95% confidence interval 0.78–1.36) in patients whose blood pressure was controlled at baseline and 1.25 (95% confidence interval 0.94–1.65) in those whose blood pressure was not. These odds ratios were not significantly different ($p=0.11$).

Conclusions. These results were consistent with no effect or, at best, a relatively modest effect of the intervention among patients with hypertension. Had we not included a concurrent control group, the data would have provided an unduly optimistic view of the effectiveness of the program. The effectiveness of future interventions may be improved by focusing on patients whose blood pressure is uncontrolled at baseline.

Key Words: hypertension, quality assurance, health care, randomized controlled trials, patient education, academic detailing.

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Of the nearly 50 million Americans with hypertension, only 34% achieve a blood pressure below 140/90 mm Hg.¹ Reports of several studies of programmatic efforts to improve blood pressure control in ambulatory practice have been published. Most of these studies were

conducted to examine single-component interventions, and most produced discouraging results. One group found no effect of audit and feedback.² Another found an increase in systolic blood pressure in association with the implementation of clinical practice guidelines

and education, although the increase was less than that seen in the control group.³ Mailing educational and motivational materials to patients did not improve blood pressure control.⁴ Likewise, group or individual academic detailing⁵ and computerized treatment suggestions⁶ had no effect on blood pressure control.

Given that physicians' knowledge and beliefs and patient nonadherence are frequently cited as potential contributors to poor blood pressure control^{7, 8} and given that multifaceted intervention programs offer the best opportunity for improvements in practice,⁹ we evaluated the effectiveness of an intervention consisting of provider-specific data about blood pressure control (audit and feedback reports), academic detailing, and provision of educational and motivational materials to physicians and patients.

Methods

Study Design

We performed a cluster-randomized trial in which we randomly assigned eligible providers and their patients with hypertension to receive or not receive an educational intervention. The study took place in the outpatient practices of the University of Pennsylvania Health System and was restricted to practices using an electronic medical record. Eligible providers consisted of physicians and nurse practitioners in family medicine, internal medicine, and obstetrics-gynecology who, over a 1-year baseline period,

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cared for at least 10 eligible patients each, defined as those with a diagnosis of hypertension (*International Classification of Diseases, Ninth Revision, Clinical Modification*, codes 401.x or 402.x). Interns, residents, and fellows were excluded. Using a commercially available spreadsheet program, we assigned a random number to each eligible provider and sorted the provider list in order of this random number. Using the number of eligible patients cared for by each provider, we then selected the intervention providers from the top of the randomly ordered list until the sum of eligible patients in the intervention group was approximately 5000.

The Committee on Studies Involving Human Beings of the University of Pennsylvania approved this study and granted a waiver of informed consent.

Intervention

The intervention consisted of an academic detailing visit that generally lasted 20–30 minutes, the provision of provider-specific data about hypertension control, the provision of educational materials to the provider, and the mailing of educational and motivational materials to patients.

A clinical pharmacist conducted the academic detailing visits by presenting blood pressure targets from the seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure and by summarizing a clinical advisory statement from the National Heart, Lung, and Blood Institute (NHLBI).¹⁰ In addition, the pharmacist presented a provider-specific audit report showing the proportion of that provider's patients with hypertension whose blood pressures were below 140/90 mm Hg, and the provider's percentile rank in the health system. On approval from the providers, educational and motivational materials were mailed to all of their eligible patients with hypertension.

The materials were sent in two mailings approximately 1 month apart. The first mailing consisted of a cover letter signed by the provider, an NHLBI-produced booklet entitled *Your Guide to Lowering Blood Pressure*, and an NHLBI-produced booklet entitled *Facts About the DASH [Dietary Approaches to Stop Hypertension] Eating Plan*. The second mailing consisted of a cover letter signed by the provider, a trifold brochure we produced, entitled *What You Can Do About Controlling Your High Blood Pressure*, a laminated

Table 1. Baseline Characteristics of the Study Patients

Characteristic	Intervention Group (n=5401)	Control Group (n=5295)	p Value ^a
	Mean ± SD		
Age (yrs)	62.1 ± 14.3	62.5 ± 14.5	0.75
Blood pressure			
Systolic	134 ± 18	136 ± 18	0.40
Diastolic	79 ± 11	80 ± 11	0.36
	No. (%) of Patients		
Female sex	2928 (54)	3163 (60)	0.20
Race			0.52
African-American	2035 (38)	2370 (45)	
Caucasian	2884 (53)	2296 (43)	
Other	211 (4)	275 (5)	
Unknown	271 (5)	354 (7)	
Comorbidity			
Diabetes mellitus	1596 (30)	1129 (21)	0.051
Kidney disease	588 (11)	444 (8)	0.25
No. of antihypertensives			0.48
0	1718 (32)	1836 (35)	
1	1842 (34)	1750 (33)	
2	1186 (22)	1145 (22)	
3	503 (9)	436 (8)	
≥ 4	152 (3)	128 (2)	
Blood pressure < 140/90 mm Hg	2917 (54)	2783 (53)	0.72

^aAccounts for clustering by provider.

bifold card we produced and based on a NHLBI-designed publication, entitled *What to Ask Your Doctor If You Have High Blood Pressure*, and a heart-shaped, picture-frame refrigerator magnet with a message about hypertension control.

The control group received no intervention.

Outcome Measures

The primary outcome measure was the proportion of patients achieving blood pressure control, defined as a blood pressure of below 140/90 mm Hg, on the last visit during 6 months of follow-up. We also performed secondary analyses in which patients with diabetes mellitus or kidney disease were considered to have controlled hypertension only if their blood pressure was below 130/80 mm Hg. In addition, we examined systolic and diastolic blood pressure as continuous variables, and we extended follow-up to 12 months. We ascertained blood pressure and other patient data from automated queries of the electronic medical records.

Statistical Analysis

We used the intent-to-treat principle for primary analysis, including each patient in the

group to which they were randomly assigned regardless of whether they received the intervention. We accounted for a potential lack of independence (i.e., clustering) by patients for a given provider using generalized estimating equations, and we adjusted for potentially important baseline factors using generalized estimating equations logistic regression models.¹¹ We performed secondary, as-treated analyses, controlling for unmeasured factors using randomization as an instrumental variable.¹² We specified a priori that our primary analysis would include only patients with at least one recorded blood pressure during follow-up. Finally, we looked for differences in the apparent effectiveness of the intervention based on whether baseline blood pressure was controlled or uncontrolled. A p value less than 0.05 was considered to indicate a statistically significant difference.

Results

Of 93 providers who met the eligibility criteria, 39 were randomly assigned to the intervention group, and 54 to the control group. At baseline, these providers cared for 5401 and 5295 eligible

Table 2. Relationship Between Intervention Status and Dichotomous Blood Pressure Control in Patients with at Least One Blood Pressure Measurement Recorded During Follow-up

Blood Pressure (mm Hg)	No. (%) of Patients		Odds Ratio (95% CI) ^a	
	Intervention Group	Control Group	Unadjusted	Adjusted ^b
	(n=3617)	(n=3542)		
<140/90 at last follow-up	2379 (66)	2179 (62)	1.20 (0.84–1.73)	1.13 (0.87–1.47)
<140/90 without or <130/80 with diabetes or kidney disease	1935 (54)	1895 (54)	1.00 (0.72–1.39)	1.08 (0.84–1.38)

CI = confidence interval.

^aAccounts for clustering by provider.

^bAdjusted for sex, race, diabetes, kidney disease, baseline systolic blood pressure, and baseline diastolic blood pressure.

Table 3. Relationship Between Intervention Status and Continuous Blood Pressure in Patients with at Least One Blood Pressure Measurement Recorded During Follow-up

Blood Pressure	Blood Pressure (mm Hg)		Unadjusted Effect ^a (95% CI)	Adjusted Effect ^{a,b} (95% CI)
	Mean ± SD			
	Intervention Group	Control Group		
Systolic	131 ± 16.8	133 ± 17.1	-2.42 (-5.48–0.64)	-1.80 (-3.97–0.37)
Diastolic	77 ± 10.2	77 ± 10.4	-0.27 (-1.50–0.96)	0.04 (-1.05–1.12)

CI = confidence interval.

^aAccounts for clustering by provider.

^bAdjusted for sex, race, diabetes, kidney disease, baseline systolic blood pressure, and baseline diastolic blood pressure.

patients, respectively. Sixty-nine percent of the providers in the intervention group and 57% of providers in the control group were practitioners in family practice or general internal medicine. The remainder were internal medicine subspecialists or obstetrician-gynecologists.

Table 1 lists baseline characteristics of the study patients. Potentially important differences between treatment groups were observed. For example, diabetes was more prevalent in the intervention group than in the control group (30% vs 21%), as was kidney disease (11% vs 8%). Mean baseline blood pressures were similar in the intervention (134/79 mm Hg) and control (136/80 mm Hg) groups, as were percentages of patients who had a blood pressure below 140/90 mm Hg (intervention vs control, 54% vs 53%).

The clinical pharmacist met with 36 (92%) of 39 providers in the intervention group. Thirty-five (97%) of these providers agreed to have educational materials mailed to their patients.

Table 2 presents the relationships between intervention status and dichotomous variables measured during follow-up. At least one blood pressure measurement was recorded during the 6-month follow-up for 67% of patients in both groups. Among these patients, 66% achieved

blood pressure control (< 140/90 mm Hg) in the intervention group, and 62% achieved control in the control group, for an adjusted odds ratio for the association between intervention status and blood pressure control of 1.13 (95% confidence interval [CI] 0.87–1.47). The adjusted odds ratios were 1.03 (95% CI 0.78–1.36) in patients whose blood pressure was controlled at baseline and 1.25 (95% CI 0.94–1.65) in those whose blood pressure was not. These odds ratios did not differ significantly ($p=0.11$). The effect of the intervention did not differ whether the ratio of patients/provider was above or below the median ($p=0.87$). By using the stringent definition of blood pressure control, the adjusted odds ratio was 1.08 (95% CI 0.84–1.38).

Table 3 presents the relationships between continuous blood pressure control and intervention status. When we adjusted for baseline variables, mean systolic blood pressure was 1.80 mm Hg lower (95% CI -0.37–3.97) in the intervention group than the control group, but diastolic blood pressure was 0.04 mm Hg higher (95% CI -1.05–1.12) in the intervention group than in the control group.

In the as-treated analysis with randomization used as an instrumental variable, we considered

as untreated three providers who did not meet with the clinical pharmacist and one provider who met with the clinical pharmacist but refused permission to send materials to his patients. The adjusted odds ratio for the association between intervention status and the primary definition of blood pressure control was 1.27 (95% CI 0.79–2.07) compared with 1.13 (95% CI 0.87–1.47) in the intent-to-treat analysis.

In the analysis for 12-month follow-up, all of the effect estimates were attenuated toward the null value (data not shown).

The intraclass correlation coefficient for the primary outcome was 0.077. In cluster-randomized trials, an important determinant of the minimum detectable difference is the design effect, which is defined as $1 + ICC(k - 1)$, where ICC is the intraclass correlation coefficient, and k is the mean cluster size. The mean cluster size (i.e., number of patients with hypertension/provider) among those completing the study was 77, which gave a design effect of 6.85. The effective sample size (based on independent observations) for the primary analysis was the number of patients completing the study divided by the design effect, or $7159 \div 6.85 = 1045$. Therefore, this study had statistical precision equivalent to a study in which 1045 patients completed the study and in which no within-provider correlation of blood pressure outcomes is performed.

Discussion

Our results are consistent with no effect or, at best, a relatively modest effect of the intervention among patients with hypertension. Because the confidence intervals for all of the effect measures include the null value, this study did not demonstrate that the intervention was effective overall or in any subgroup. The point estimates for the as-treated analyses, which were not significant, were somewhat stronger than those for the intent-to-treat analyses, as would be expected if a true intervention effect occurred. However, unmeasured factors could not be ruled out in the as-treated analyses. The point estimate from the primary intent-to-treat analysis suggested a 13% relative increase in the odds of controlled blood pressure among all patients with hypertension. This is less than the 25% increase (i.e., odds ratio of 1.25) that we considered a priori to be the minimum important difference. Part of the difficulty in achieving a strong effect may have been the result of improved blood

pressure control in the control group, which could be due to an unrelated secular trend or to contamination of the control group by components of the intervention.

Of importance, had we not included a concurrent control group, we would have concluded that the program had a stronger effect than what was truly warranted. Findings from the subgroup analysis based on baseline blood pressure control tentatively suggested that any effect of the intervention may have been limited to patients whose blood pressure was not controlled at baseline. This conclusion seems plausible but deserves confirmation.

The design effect of 6.85 was larger than our a priori estimate of 2 to 3, indicating strong clustering of blood pressure control by provider. Clustering by provider reduces statistical precision, increasing the difficulty of excluding chance as an explanation for observed associations. Contamination of the control group by the intervention could also have occurred and would have tended to reduce the apparent effectiveness of the program.

The attenuation in effect estimates in the analysis of 12-month versus 6-month follow-up suggested that any effects of our discrete intervention were transient. This observation was consistent with previous findings.⁹

Conclusion

Our findings were consistent with, at best, a modest effect of the intervention among all patients with treated hypertension. Therefore, we do not recommend that programs based on this model be implemented on an ongoing basis without rigorous evaluation. Data from the subgroup analysis suggested that future programs may be more effective than this one if they focus on patients whose baseline blood pressure is poorly controlled rather than all patients with hypertension. This suggestion deserves empiric confirmation. One may speculate that, had we performed intensive intervention with several academic detailing sessions, the results may have been more favorable than what we observed. Finally, evaluations of quality improvement interventions should include a concurrent, preferably randomized, control group whenever possible.

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