Blood Pressure Control in Hispanics in the Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial

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Abstract—Historically, blood pressure control in Hispanics has been considerably less than that of non-Hispanic whites and blacks. We compared determinants of blood pressure control among Hispanic white, Hispanic black, non-Hispanic white, and non-Hispanic black participants (N = 32,642) during follow-up in a randomized, practice-based, active-controlled trial. Hispanic blacks and whites represented 3% and 16% of the cohort, respectively; 33% were non-Hispanic black and 48% were non-Hispanic white. Hispanics were less likely to be controlled (<140/90 mm Hg) at enrollment, but within 6 to 12 months of follow-up, Hispanics had a greater proportion <140/90 mm Hg compared with non-Hispanics. At 4 years of follow-up, blood pressure was controlled in 72% of Hispanic whites, 69% of Hispanic blacks, 67% of non-Hispanic whites, and 59% of non-Hispanic blacks. Compared with non-Hispanic whites, Hispanic whites had a 20% greater odds of achieving BP control by 2 years of follow-up (odds ratio: 1.20; 95% CI: 1.10 to 1.31) after controlling for demographic variables and comorbidities, Hispanic blacks had a similar odds of achieving BP control (odds ratio: 1.04; 95% CI: 0.86 to 1.25), and non-Hispanic blacks had a 27% lower odds (odds ratio: 0.73; 95% CI: 0.69 to 0.78). We conclude that in all patients high levels of blood pressure control can be achieved with commonly available medications and that Hispanic ethnicity is not associated with inferior control in the setting of a clinical trial in which hypertensive patients had equal access to medical care, and medication was provided at no cost. (Hypertension. 2007;50:854-861.)

Key Words: hypertension ■ Hispanic ■ ethnicity ■ race ■ clinical trials ■ blood pressure control

In the United States, there are racial and ethnic differences in the prevalence, awareness, treatment, and control of hypertension. Compared with non-Hispanic whites, Mexican Americans had a similar age-adjusted prevalence of hypertension (≈28%) in data collected in 2003–2004 for the National Health and Nutrition Examination Survey (NHANES), a national population-based study.1 In the same study, non-Hispanic blacks had the highest age-adjusted prevalence of hypertension (39%).

Between NHANES II (1976–1980) and NHANES III (1988–1991), there were substantial improvements in hypertension awareness, treatment, and control in both non-Hispanic whites and blacks.2 In contrast, between the Hispanic Health and Nutrition Examination Survey (1982–1984) and NHANES III, there was no improvement in awareness (60% versus 57%), treatment (38% versus 37%), or control (19% versus 21%) of hypertension in Mexican Americans.3 This resulted in large disparities in hypertension awareness, treatment, and control between non-Hispanics and Mexican Americans that persisted in the NHANES data from 1991 to 1994 and 1999 to 2002.4,5 The most recent data from 2003 to 2004 show improvements in hypertension awareness, treatment, and control in Mexican Americans. However, awareness (64%) and treatment (48%) were lower in Mexican Americans compared with non-Hispanics, and blood pressure (BP) control was still the lowest in Mexican Americans (27%), intermediate in non-Hispanic blacks (29%), and highest in non-Hispanic whites (35%).1 Even among treated

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individuals, BP control was lower in Mexican Americans (57%) than in non-Hispanic whites (68%). The reasons for these racial and ethnic differences in BP control may include such factors as lack of access to health care, inability to afford medication, other factors related to low socioeconomic status, beliefs about hypertension, language barriers, poor doctor-patient communication, family influences, diet, metabolic risk factors, or other biological factors contributing to insufficient treatment or resistance to antihypertensive medications.6–8

The Antihypertensive and Lipid-Lowering treatment to prevent Heart Attack Trial (ALLHAT) was a large, double-blind, randomized, active-controlled, practice-based trial in which 16% of the participants were Hispanic, and 35% of the participants were black.9,10 The overall purpose of ALLHAT was to determine whether an angiotensin-converting enzyme inhibitor, a calcium channel blocker, or an α1-blocker was superior to a thiazide-type diuretic in preventing cardiovascular complications of hypertension in high-risk men and women when each drug was used as the primary antihypertensive treatment (with step-up drugs as needed). ALLHAT participants had access to high-quality hypertension care with antihypertensive medications provided at no cost and were treated with a protocol that required dosage titration and additional medications when BP was ≥140 mm Hg systolic (SBP) or 90 mm Hg diastolic (DBP). Thus, many of the barriers to BP control may have been eliminated, as suggested by the high rate of BP control achieved over 5 years of follow-up in ALLHAT (66%).11 In this article, we evaluate differences in BP control among Hispanic white, Hispanic black, non-Hispanic white, and non-Hispanic black ALLHAT participants.

Methods

The ALLHAT cohort consisted of 42,418 patients with high-risk hypertension recruited between February 14, 1994, and January 31, 1998, at 623 clinical sites in the United States, Canada, Puerto Rico, and the US Virgin Islands. The rationale, design, and principal findings of ALLHAT have been described in detail previously.9,12,13

Programmed follow-up visits were scheduled at 6, 12, 24, and 48 months, and 30% and 70% of participants were expected to complete 72 and 120 months of follow-up, respectively. All of the BP was measured in a standardized manner using a mercury sphygmomanometer. The SBP was defined as the reading after the Korotkoff sound and the DBP as the reading at the disappearance of the Korotkoff sound. The measurements were taken after the participant had been seated quietly for ≥5 minutes, in a comfortable posture, with feet flat on the floor, with the back supported and the arm supported at or as close to the level of the heart as possible. The cuff was deflated at a rate of 2 mm/s until the Korotkoff sound was heard. Two measurements were taken within a 30-second interval, and the reading reported was the average of the 2 readings. The diastolic BP was less than the systolic BP. Treated BP was defined as “goal achieved” if the SBP and DBP were both ≤140/90 mm Hg. Treated participants were considered to have SBP ≤180/110 mm Hg at visit 1 and ≤180/110 mm Hg at visit 2. The highest reading at visit 2 allowed for gradual withdrawal of antihypertensive medication between the 2 visits when necessary. All of the participants signed an informed consent form, and all of the centers received institutional review board approval.

Participants were randomly assigned to 4 treatments: chlorthalidone, amlopidine, lisinopril, or doxazosin. The treatment goal was DBP <90 mm Hg and SBP <140 mm Hg. Dosages were 12.5, 12.5 (sham titration), and 25 mg per day for chlorthalidone; 2.5, 5, and 10 mg per day for amlopidine; 10, 20, and 40 mg per day for lisinopril; and 2, 4, and 8 mg per day for doxazosin. Participants were given standard advice on lifestyle factors (sodium, alcohol, physical activity, and caloric intake) with reinforcement as needed during the study.

If participants did not meet the BP goal while taking the maximum tolerated dosage of the initial blinded medication, an open-label step 2 agent (atenolol, 25 to 100 mg per day; reserpine, 0.05 to 0.2 mg per day; or clonidine, 0.1 to 0.3 mg twice per day) or an open-label step 3 agent (hydralazine, 25 to 100 mg twice per day) could be added until the goal was reached. After initial monthly titration visits, participants were seen routinely every 3 months during the first year of follow-up and every 4 months thereafter for ≥8 years of follow-up. Medication doses were increased or additional medications were added during follow-up if BP was not at goal. Nonstudy open-label drugs could be added to or substituted for step 2 or 3 open-label medications to improve tolerance or BP control, although investigators were discouraged from prescribing drugs from the step 1 drug classes unless maximum tolerated doses of ALLHAT drugs had been attempted or other compelling indications existed.

In each of the 631 clinical sites, study personnel were trained to measure BP in a standardized manner using a mercury sphygmomanometer. The DBP was defined as the reading at the Korotkoff sound and the SBP as the reading at the disappearance of the Korotkoff sound. The measurements were taken after the participant had been seated quietly for ≥5 minutes, in a comfortable posture, with feet flat on the floor, with the back supported and the arm supported at or as close to the level of the heart as possible. The cuff was deflated at a rate of 2 mm/s until the Korotkoff sound was heard. Two measurements were taken within a 30-second interval, and the reading reported was the average of the 2 readings. The diastolic BP was less than the systolic BP. Treated BP was defined as “goal achieved” if the SBP and DBP were both ≤140/90 mm Hg. Treated participants were considered to have SBP ≤180/110 mm Hg at visit 1 and ≤180/110 mm Hg at visit 2. The highest reading at visit 2 allowed for gradual withdrawal of antihypertensive medication between the 2 visits when necessary. All of the participants signed an informed consent form, and all of the centers received institutional review board approval.

Univariate logistic models for each variable were first examined. The univariate analysis included only the corresponding characteristic and a constant term in the logistic model. For race/ethnicity, terms for all 3 of the categories relative to white non-Hispanics were included in the univariate model with a constant term. For randomized treatment group, terms were included for both amlodipine versus chlorthalidone and lisinopril versus chlorthalidone. Multivariable logistic analyses were performed to assess the relative influence of the independent variables on 2-year BP control status: BP ≤140/90 mm Hg versus SBP ≥140 and/or DBP ≥90 mm Hg. The independent baseline variables included participant’s age, sex, race/ethnicity, history of diabetes, current smoking, history of atherosclerotic cardiovascular disease, body mass index ≥30 kg/m², use of BP drugs before enrollment, SBP, creatinine ≥1.5 mg/dL, electrocardiographic evidence of left ventricular hypertrophy, and treatment assignment.

Results

The baseline characteristics of the participants by race and ethnicity are shown in Table 1. Hispanic blacks and whites were next asked whether their ethnicity was Hispanic or not. Participants were asked to self-identify their race as white, black, Asian/Pacific Islander, or did not specify their ethnicity. Participants were randomly assigned to 1 of 4 treatments: chlorthalidone, amlopidine, lisinopril, or doxazosin. The treatment goal was DBP <90 mm Hg and SBP <140 mm Hg. Dosages were 12.5, 12.5 (sham titration), and 25 mg per day for chlorthalidone; 2.5, 5, and 10 mg per day for amlopidine; 10, 20, and 40 mg per day for lisinopril; and 2, 4, and 8 mg per day for doxazosin. Participants were given standard advice on lifestyle factors (sodium, alcohol, physical activity, and caloric intake) with reinforcement as needed during the study.

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Results

The baseline characteristics of the participants by race and ethnicity are shown in Table 1. Hispanic blacks and whites represented 3% and 16% of the cohort, respectively; 33%
were non-Hispanic black, and 48% were non-Hispanic white. Approximately 87% of the Hispanic blacks and 70% of the Hispanic whites were recruited from clinics in Puerto Rico and the US Virgin Islands, whereas 62% of non-Hispanic blacks were recruited from clinics in the Southern United States. Compared with non-Hispanic white participants, Hispanic participants were slightly younger, more likely to be female, had lower educational attainment, and were less likely to have been recruited from a clinic with previous research experience. Hispanics were more likely than non-Hispanic whites to have diabetes at baseline and less likely to have atherosclerotic cardiovascular disease, including coronary heart disease.

Although a similar proportion (~90%) of each group reported being treated with antihypertensive medication at baseline (Table 1), Hispanic blacks had the highest baseline SBP and DBP, followed by Hispanic whites (Table 2). Non-Hispanic blacks and whites had similar SBP, but non-Hispanic whites had lower DBP. Within 6 months of follow-up, Hispanic whites had the lowest SBP, followed by Hispanic blacks and non-Hispanic whites. Non-Hispanic blacks had the highest SBP. Hispanics had DBP intermediate between non-Hispanic whites and blacks. These patterns were generally consistent through 4 years of follow-up. At all of the time points, compared with non-Hispanics, Hispanics were treated with a lower mean number of antihypertensive medications (1.4 vs 1.8 at 4 years).

Approximately 30% of the Hispanic whites were enrolled from sites outside of the Caribbean. Compared with the non-Hispanic whites, these participants had nearly identical follow-up BP (eg, 137.7/78.2 mm Hg in Hispanic whites versus 137.7/78.1 mm Hg in non-Hispanic whites at 1 year for SBP/DBP; data not shown.) There were too few Hispanic blacks enrolled outside of the Caribbean for meaningful comparisons with other groups.

At baseline, Hispanic participants were less likely than non-Hispanic participants to have BP controlled to <140/90 mm Hg (Figure). By 6 months of follow-up and for the duration of the trial, BP control in Hispanics was similar to or superior to that in non-Hispanic whites. Non-Hispanic blacks had the lowest level of BP control throughout the trial. Analyses limited to participants from the United States and Canada, including 140 Hispanic black and 1558 Hispanic white participants, yielded similar results. After excluding participants from Puerto Rico and the Virgin Islands, BP was controlled in Hispanic whites in 51% at 6 months, 56% at 1 year, 60% at 2 years, and 62% at 3 years. Results were similar in Hispanic blacks.

The proportions of the 4 racial/ethnic groups with BP measurements at expected follow-up visits in each of the 4 years after randomization differed substantially, as follows: 45% for Hispanic blacks, 50% for Hispanic whites, 62% for non-Hispanic blacks, and 71% for non-Hispanic whites. Because this could have introduced bias, we conducted additional analyses of BP in the cohort of 19,569 participants who attended all of the clinic visits at baseline, 6 months of follow-up, and annually through 4 years of follow-up (data not shown). Baseline and follow-up BP were remarkably
similar in this cohort compared with the overall group, with <1 mm Hg difference at all of the time points, indicating that missed follow-up visits did not appear to be important sources of bias in estimating BP control. For this reason, all of the further analyses were conducted in the full study sample of 32,642 participants.

Table 3 shows that, after year 1, ≈25% to 35% of participants with uncontrolled BP on 1 drug were prescribed an increase in dose or a new drug at each time point. Although Hispanics with uncontrolled BP were somewhat less likely than non-Hispanics to have therapy intensified in the first 2 years of the study, there was little racial/ethnic variation after year 2. For uncontrolled participants on ≥2 drugs, the proportion prescribed a step up in therapy was slightly lower at ≈19% to 25%, also with little racial/ethnic variation after year 1.

The results from logistic regression analysis of BP control by race/ethnicity at year 2 are presented in Table 4. An odds ratio (OR) >1.0 implies that the group had better BP control than the reference group. There was little difference in the odds of achieving BP <140/90 mm Hg between the unadjusted and adjusted models. After adjustment for potential confounders of the relation between race/ethnicity and BP control, compared with non-Hispanic whites, Hispanic whites had a 20% greater odds of achieving BP control (OR: 1.20; 95% CI: 1.10 to 1.31), Hispanic blacks had a similar odds of achieving BP control (OR: 1.04; 95% CI: 0.86 to 1.25), and non-Hispanic blacks had a 27% lower odds (OR: 0.73; 95% CI: 0.69 to 0.78). In analyses excluding participants from Puerto Rico and the Virgin Islands, findings for both black Hispanics and non-Hispanics were nearly identical to those from analyses not excluding these participants, but the better BP control in white Hispanics was no longer found compared with white non-Hispanics (OR: 1.07; 95% CI: 0.94 to 1.22).

Discussion

The US Census Bureau estimates that, in 2004, people of Hispanic or Latino origin made up 14.1% of the population, the largest ethnic minority population in the United States. The findings from ALLHAT demonstrate that Hispanic participants had equivalent or superior BP control compared with non-Hispanics in the setting of a clinical trial in which patients with hypertension had equal access to medical care and medication provided at no cost. Compared with non-Hispanic whites, Hispanic whites had a 20% higher odds of achieving BP control than non-Hispanic whites, after adjusting for multiple factors that predict BP control. Hispanic participants were not treated with more medications, nor were their physicians more likely to follow the protocol-mandated increase in therapy when BP was uncontrolled.

In previous analyses of ALLHAT data, black race was associated with significantly lower likelihood of BP control, after accounting for other factors associated with worse BP control, including higher baseline BP, older age, female sex, obesity, diabetes, and left ventricular hypertrophy. In the present analysis, Hispanic blacks had slightly lower levels of
BP control compared with Hispanic whites, similar BP control as non-Hispanic whites, and better BP control than non-Hispanic blacks. No previous study has compared BP control in these 4 race/ethnicity categories, although the National Health Interview Survey reported on hypertension prevalence in these groups. Superior BP control among Hispanic compared with non-Hispanic participants was also reported in the International Verapamil SR/Trandolapril Trial, but the data were not separated by race among the Hispanics.

Hispanic ALLHAT participants were more likely than non-Hispanic participants to have uncontrolled BP at enrollment into the study. Although a similarly high proportion (90%) reported treatment with antihypertensive medications in all of the race/ethnic groups at entry, it is possible that the number of drugs, types of drugs, dosage, or adherence differed between Hispanics and non-Hispanics. Baseline data on these variables were not collected in ALLHAT. In population-based studies, such as NHANES, BP control rates in treated Mexican Americans have been consistently lower than in non-Hispanic white Americans for >2 decades. In a multiethnic national sample of perimenopausal women, Hispanic women had the lowest rates of BP control (11%). Other regional studies have reported similar results in Mexican Americans and Puerto Ricans living in Massachusetts. The only study that has directly compared different subgroups of Hispanic Americans was the 1982–1984 Hispanic Health and Nutrition Examination Survey. This study showed very low rates of BP control (8% to 9%) among Mexican American, Cuban American, and Puerto Rican men, although BP control was higher in women (34% in Mexican Americans, 28% in Puerto Ricans, and 14% in Cuban Americans).

Compared with non-Hispanic whites, Hispanics are less likely to have health insurance or a regular source of medical care and are less likely to receive preventive services, factors that have been linked to lower rates of BP screening and treatment in Hispanics. Most studies have shown lower use of antihypertensive treatment in Hispanics compared with non-Hispanics with

### Table 3. BP Control Status Among Participants Taking 1 or ≥2 Drugs During Follow-Up and the Percentage of Uncontrolled Participants Who Had Their Drug Regimen Stepped Up at the Visit by Racial/Ethnic Subgroup

<table>
<thead>
<tr>
<th>Follow-Up</th>
<th>Sample Size</th>
<th>Total</th>
<th>On 1 Drug</th>
<th>On ≥2 Drugs</th>
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</table>

BP uncontrolled was defined as SBP ≥140 mm Hg or DBP ≥90 mm Hg. Step up was defined as either an increased in the number of drugs prescribed or a change in prescription without a change in the number of agents.

*Percentage of total uncontrolled.
hypertension, although 2 studies found no difference after controlling for sociodemographic characteristics. In a study among patients with uncontrolled BP who were enrolled in primary care clinics in the Boston, MA, area, Hispanic patients were significantly less likely to have their medications intensified compared with non-Hispanic patients (71% versus 81%), although Hispanic patients whose treatment was intensified were equally likely to achieve BP control. Although there has been relatively little study of the efficacy of various classes of antihypertensive drugs in Hispanics, the published literature does not suggest much variation in response to antihypertensive drugs. Thus, Hispanic patients likely face barriers to hypertension screening, initiation of therapy, and appropriate intensification of therapy.

An alternative explanation for better BP control in ALLHAT Hispanic participants could be that they differed systematically from non-Hispanic participants in ways not measured in ALLHAT. For example, although ≈90% of Hispanics reported treatment at baseline, actual adherence to medication may have been lower, as reflected in the slightly higher baseline BP levels. Because treatment at baseline was inversely associated with the likelihood of achieving BP control in ALLHAT, if more Hispanic participants were actually untreated, this might explain why they achieved better BP control on fewer drugs.

Another possibility is that BP measurements were systematically biased in clinics that enrolled Hispanics. Zero-terminal digit preference has been associated with underestimates of BP and undertreatment of hypertension and has been reported among even well-trained hypertension nurse specialists. Despite the training of BP observers to a standard protocol for BP measurement that included taking the average of 2 readings at each visit, the frequency of 0-terminal digit was relatively high, as expected in a clinical setting. Overall, 24% of year-1 average SBP values had a 0-terminal digit; the percentage was greater in Hispanics than non-Hispanics (42% versus 21%), but the difference was less when participants from Puerto Rico and the Virgin Islands were excluded (30% versus 21%). The percentages for the most frequently reported SBP values, 130 and 140 mm Hg, were similar, both for Hispanics (13% and 12%) and non-Hispanics (5% and 6%), suggesting that there was no systematic effort to inflate BP control rates.

Clinical inertia may be defined as failure to advance therapy despite suboptimal BP control. Clinical inertia was observed in ALLHAT, although the protocol provided direction to increase therapy when BP was not controlled. Whether this inertia was attributable, at least in part, to efforts to minimize the open-label use of medications from the classes studied in ALLHAT cannot be determined; however, these efforts may have played some role. Nevertheless, this experience reinforces the need to develop effective methods to improve BP control through comprehensive programs targeting patient, provider, and health care systems factors.

Strengths of the ALLHAT study include its large sample size, which allows for comparison of treatment regimens, Hispanic black and white participants, and other subgroups of interest (eg, age, sex, baseline BP, and comorbidities). Several additional potential limitations of this analysis must be pointed out. Race and ethnicity were determined by self-report, which is the only practical method for a large clinical trial such as ALLHAT. The majority of the Hispanic participants in ALLHAT were recruited from clinics located in Puerto Rico and the US Virgin Islands, where they were cared for by physicians who spoke Spanish. Findings in this group of predominantly Caribbean Hispanics may not be generalizable to other subgroups of Hispanic patients, as evidenced in Table 4. It is also possible that regional variations in physician practice accounted for our results; however, the ALLHAT protocol and training should have minimized such variations. We have also pointed out that a lower proportion of Hispanic participants underwent follow-up BP measurements compared with non-Hispanic participants, but our analyses did not suggest that this accounted for the better BP control that was observed. Finally, the eligibility criteria (eg,
exclusion of people with untreated BP ≥180/110 mm Hg or treated BP ≥160/100 mm Hg may have affected the generalizability of the ALLHAT results to other hypertensive patients.

We conclude that the low rate of BP control in Hispanics in the United States is not a result of biological factors. BP was controlled in more than two thirds of Hispanic ALLHAT participants with commonly available medications, including thiazide-type diuretics, despite protocol restrictions on combinations. Efforts to improve BP control in Hispanic persons should focus on improving hypertension knowledge and awareness, doctor-patient communication, and access to medical care and affordable medications.

Perspectives
BP control in the Hispanic population has long fallen behind that of non-Hispanic white and black Americans. Various explanations have been proposed, including biological factors associated with race and ethnicity, physician practices, and consequences of low economic status (including inadequate or absent health insurance, poor access to medical care, and limited opportunity for hypertension screening). ALLHAT provided a large population in which to study hypertension treatment in Hispanics. The evidence is clear: BP control in Hispanic patients is an achievable goal and should therefore be declared a public health priority.

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References


Margolis et al Blood Pressure Control in Hispanics in ALLHAT 861


Blood Pressure Control in Hispanics in the Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial

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