

Blood Pressure Control and Pharmacotherapy Patterns in the United States Before and After the Release of the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7) Guidelines

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Objectives: Despite recommendations from the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7), only 36.8% of patients were at target blood pressure (BP) in 2003 and 2004. The objective of this study was to assess improvements in BP control and treatment patterns before and after the publication of JNC 7.

Methods: This was a retrospective, time series analysis of 27 provider groups and managed care organizations from 1998 through 2006. Patients with hypertension were identified from more than 4000 physicians. Medical charts were collected and clinical data were evaluated using prevailing JNC criteria during the time period before and after JNC 7.

Results: A total of 19,258 patients were identified with hypertension: 15,258 included in the before-JNC 7 cohort and 4,000 in the after-JNC 7 cohort. BP control in the before-JNC 7 cohort was 40.8% compared with 49.3% in the after-JNC 7 cohort ($P < .0001$). After controlling for demographic and clinical covariates, patients in the before-JNC 7 cohort were 45% less likely to achieve BP control compared with the after-JNC 7 cohort (odds ratio, 0.551; $P < .0001$).

Conclusion: Although findings indicate BP control is improving, a significant need for further improvement remains. (J Am Board Fam Med 2008;21:512–21.)

Hypertension is a prevalent medical condition that affected nearly 1 in 3 adults (72 million) in the

United States in 2004.¹ Termed “the silent killer” because of its asymptomatic nature, hypertension contributed to approximately 54,186 deaths in 2004 and is expected to result in \$69.4 billion in direct and indirect costs in 2008.¹

Because hypertension is a precursor to multiple disease conditions, maintaining blood pressure (BP) control and adherence to goals are imperative to reducing morbidity and mortality, especially in patients with high risk.^{2,3} Since its first report in 1977, the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC) has guided the medical community in the awareness, prevention, and treatment of hypertension.⁴ Seven published reports (JNC 1 to JNC 7) define acceptable BP level and recommend treatment strategies based on a patient’s comorbid disease states and level of BP control. Each successive report has been updated based on new clinical evidence about hypertension and its treatment.

The acceptable BP level has become more rigorous through the years, with normal diastolic

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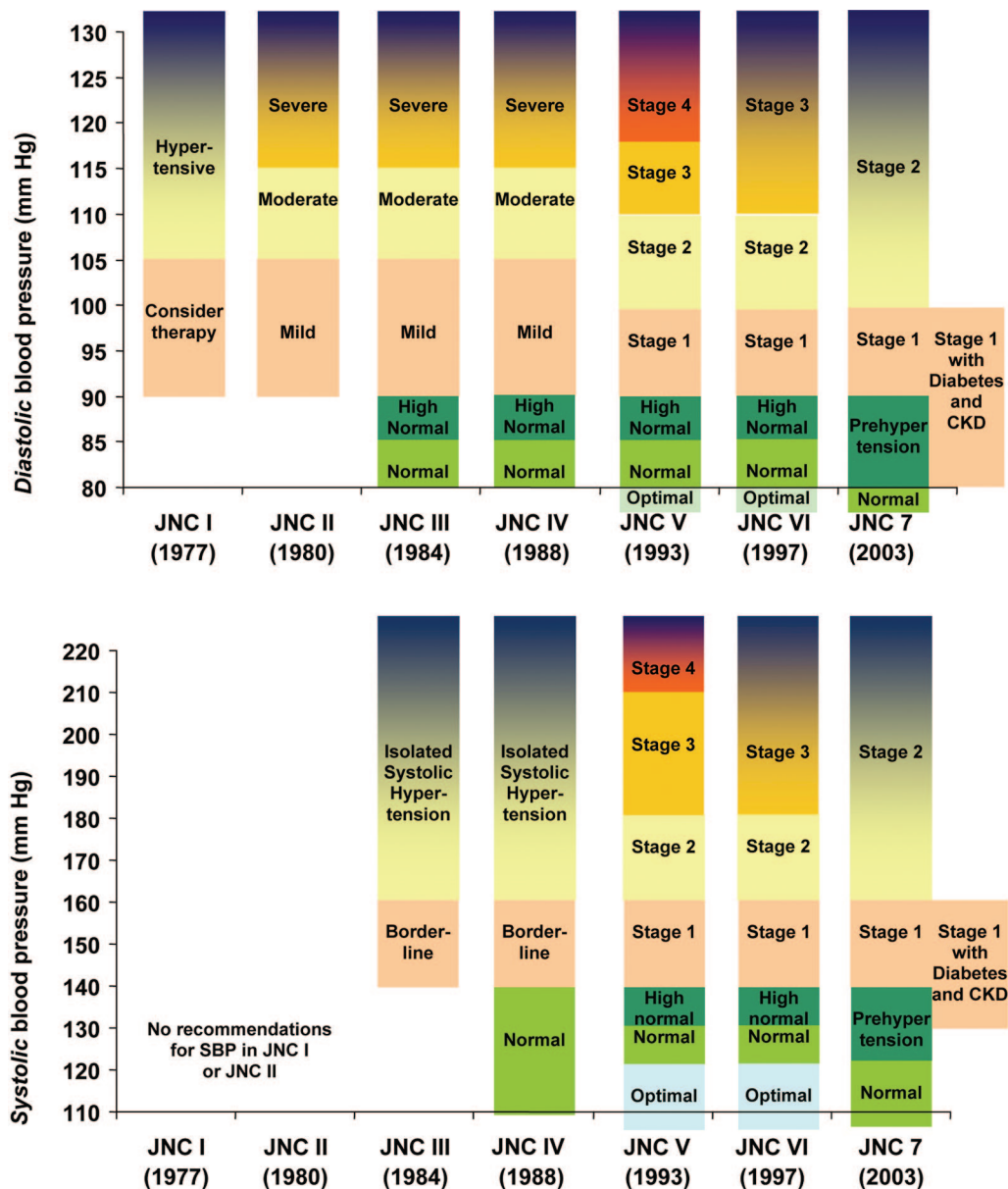


Figure 1. Classification of diastolic and systolic blood pressure according to JNC Guidelines 1 to 7.

blood pressure (DBP) defined as <90 mm Hg in JNC 1 versus <80 mm Hg in JNC 7; normal systolic blood pressure (SBP) was defined as <140 mm Hg in JNC 3 versus <120 mm Hg in JNC 7 (Figure 1). Until the 1980s, SBP was listed separately from DBP. However, beginning with JNC 5 (1993), hypertension was defined as a systolic/diastolic reading of at least 140/90. To better guide evaluation and treatment, in JNC 5 the categorization of BP ranges changed from a severity classification to a staging classification. JNC 7 reduced the staging categories from 3 to 2 but added “prehypertension,” defined as those patients at risk of

developing hypertension. Most notably, JNC 7 recognizes the increased risk of cardiovascular events in individuals with diabetes and chronic kidney disease and recommends more aggressive BP control (<130/80 mm Hg).

Each JNC report has also provided drug therapy recommendations. Although diuretics have consistently been recommended as first-line therapies, notable modifications have been made over the years. For example, angiotensin converting enzyme inhibitors (ACEIs) and calcium channel blockers were added to diuretics and beta-blockers as recommended first-line drug therapy options in JNC

5, but were removed as first-line in JNC 6 because of evidence suggesting that diuretics and beta-blockers reduced cardiovascular morbidity and mortality.

Released in May 2003, the JNC 7 report focuses on greater awareness for at-risk patients, lower BP goals for people with diabetes, the use of multiple agents, and specialized treatment recommendations for compelling indications. For example, ACEIs and angiotensin II receptor blockers (ARBs) are recommended for patients with diabetes because they have been shown to also provide cardiovascular protection and slow the progression of nephropathy.⁵ Beta-blockers were moved to second-line treatment after results from a meta-analysis that demonstrated superiority of diuretics on all outcomes of cardiovascular heart disease, stroke, congestive heart failure, major cardiovascular events, and cardiovascular and total mortality. In addition, 2-drug combination therapy is recommended as initial therapy for patients with stage 2 hypertension.^{5,6}

Despite significant JNC efforts, a majority of patients are not reaching their BP goals. A 2003 study conducted in 8 managed care organizations in the United States concluded that less than 50% of plan members diagnosed with hypertension met their BP goal (JNC 6). This conclusion held even after various educational and awareness campaigns were initiated.⁷ In addition, data from the National Health and Nutrition Examination Survey (NHANES) revealed that only 36.8% of patients (including those undiagnosed) were at their target BP.⁸

Given the significant changes in JNC 7 and the fact that the most recent data on BP control in the United States was obtained before its release, an updated investigation of hypertension treatment patterns and control after JNC 7 is warranted. This study was conducted to 1) assess improvements in BP control since publication of the JNC 7 guidelines, and 2) examine patterns of drug therapy regarding recommended best practices within the JNC guidelines.

Methods

Study Design

This was a retrospective, time series analysis assessing BP control and treatment patterns in patients with hypertension. Data were obtained from a nationwide hypertension quality and awareness initia-

tive conducted between 1998 and 2006 involving 27 medical provider groups and managed care organizations including more than 4000 physicians. Minimum criteria for each medical provider group and managed care organization included a desire to measure hypertension, willingness to participate in a research study, and ability to provide access to a sufficient number of patient charts. With the priority of trying to ensure broad representation across the county, the medical provider groups and managed care organizations were geographically dispersed throughout the United States, including Alabama, California, Florida, Illinois, Indiana, Kentucky, Massachusetts, Michigan, Ohio, Oklahoma, New Jersey, New York, Pennsylvania, Texas, and Wisconsin. A total of 411 patients were needed from each of the 27 medical provider groups and managed care organizations to detect a difference in blood pressure control based on the following statistical assumptions: 2-tailed test of significance between 2 proportions with $\alpha = 0.05$ and power = 80%. A total of 500 patients were randomly selected for medical chart abstraction, which accounted for missing charts, misdiagnosis, etc. Data were collected at each site once during the 9-year time frame. Patients were categorized into a before-JNC 7 cohort or after-JNC 7 cohort based on the time frame of their collected data. The time frame for the before-JNC 7 cohort was January 1, 1998, to May 31, 2003, whereas the time frame for the after-JNC 7 cohort was June 1, 2003, to December 31, 2006. An independent Institutional Review and Privacy Board approved the overall study as well as each site's participation. Based on the approval status of the Institutional Review and Privacy Board, consent was not required for each patient.

Inclusion and Exclusion Criteria

Inclusion and exclusion criteria were the same for all patients regardless of the time frame sampled. Patients were identified using medical and pharmacy claims data obtained from participating health plans or from clinical data systems within the physician group practices. Patients were considered for inclusion if they had a medical claim with a diagnosis of hypertension (defined as an International Classification of Disease, 9th Revision, Clinical Modification, code of 401–404) or a pharmacy claim for an antihypertensive medication. If pharmacy claims data were available, antihypertensive agents were identified us-

ing the Generic Product Identifier, Universal System Classification, or American Hospital Formulary Service codes. Patients were required to be continuously enrolled in the health plan and/or seen by the medical provider group throughout the time frame of analysis.

Patients were excluded if they were younger than 18 years of age. To capture only those patients with a principal diagnosis of hypertension, patients identified by an antihypertensive pharmacy claim without a coexisting hypertension medical claim were excluded if any claim contained a diagnosis of congestive heart failure, benign prostatic hyperplasia, ischemic heart disease, arrhythmia, migraine, or lower extremity edema. Patients without documentation of hypertension in the medical chart were excluded.

Data Collection

Five hundred patients from each of the 27 participating sites were randomly selected for chart review. Data were collected by a nurse or pharmacist trained in standardized data abstraction methods. Data collected included age, gender, hypertension diagnosis, cardiovascular risk factors, relevant comorbidities, SBP and DBP measurements, and prescribing patterns. A hypertension diagnosis was confirmed when at least one of the following terms was found in the medical chart: hypertension, HTN, high blood pressure, high BP, HBP, or \uparrow BP. Consistent with the Health Care Effectiveness Data and Information Set, technical specifications for determining BP control, the representative BP reading documented for this study was the reading taken during the most recent visit within the time frame of interest, provided that the visit occurred after a diagnosis of hypertension was documented.⁹ If more than one BP reading was documented during a single visit, the lowest reading was recorded. If multiple positional readings were documented during a single visit, only the sitting measurement was recorded. If there were supine and standing BP readings, but not a sitting BP reading, the supine measurement was recorded. A standing BP measurement was recorded if it was the only one documented.⁵ BP control was evaluated in all patients with a hypertension diagnosis, regardless of status of treatment.

BP control was defined under the prevailing JNC criterion applicable for each time period. In the before-JNC 7 cohort, BP control was defined consistent with JNC 6 guidelines: $<140/90$ mm Hg

in patients with hypertension and without diabetes and $<130/85$ mm Hg in patients with hypertension and diabetes or renal disease.⁶ In the after-JNC 7 cohort, BP control was defined as $<140/90$ mm Hg in patients with hypertension and without diabetes and $<130/80$ mm Hg in patients with hypertension and diabetes or chronic kidney disease.⁵

Best practice recommendations evaluated in this study included the use of an ACEI or ARB in patients with comorbid diabetes; the use of an ACEI, ARB, or beta-blocker in patients with comorbid congestive heart failure; and the use of beta-blockers in patients with a history of myocardial infarction.

Statistical Analysis

A secure relational database was used to validate and house all data collected from each site. Statistical analyses were performed using SAS software (version 8.2, SAS Institute, Inc, Cary, NC). Descriptive statistics, such as mean \pm SD, frequency, and percentages, were generated for all demographic variables, clinical indicators, BP values, and prescribing metrics. χ^2 and t tests were performed to assess any between-group differences in these variables individually. Because of the difference in sample size between the cohorts, tests for equal variances were conducted and accounted for statistically. A binomial logistic regression model was developed to assess differences in BP control between the 2 independent cohorts. To account for differences in cohort characteristics, the covariates of age, gender, ethnicity, geographic location, risk factors, comorbidities, and treatment were included in the model.

Results

Baseline Characteristics

A total of 19,258 unique patients were identified as having hypertension during the specified time frame. Of these patients, 15,258 were included in the before-JNC 7 cohort and 4,000 in the after-JNC 7 cohort, based on the time frame of their data. The mean age of patients in the before-JNC 7 and after-JNC 7 cohorts was 61.6 years and 63.9 years, respectively ($P < .0001$). The majority of patients in both cohorts were women and either white or African-American. Additional baseline characteristics are provided in Table 1.

Older age, obesity, and hyperlipidemia were the most common cardiovascular risk factors in both

Table 1. Demographic Characteristics

	Before-JNC 7 Cohort (n = 15,258)	After-JNC 7 Cohort (n = 4000)	<i>P</i>
Gender (n [%])			
Female	8442 (55.3)	2390 (59.8)	<.0001
Male	6777 (44.4)	1610 (40.2)	
Not indicated	39 (0.3)	0 (0.0)	
Race (n [%])			
White	4444 (29.1)	1484 (37.1)	<.0001
African-American	924 (6.0)	876 (21.9)	
Hispanic	269 (1.8)	119 (3.0)	
Asian	135 (0.9)	25 (0.6)	
Other	72 (0.5)	11 (0.3)	
Not indicated	9414 (61.7)	1485 (37.1)	
Age, years (n [%])			
18–44	1223 (8.0)	383 (9.6)	<.0001
45–54	3528 (23.1)	746 (18.6)	
55–64	4313 (28.3)	940 (23.5)	
65–74	3414 (22.4)	834 (20.9)	
75+	2763 (18.1)	1097 (27.4)	
Mean (SD)	61.6 (12.8)	63.9 (14.6)	<.0001 (unpaired <i>t</i> test)
Not indicated	17 (0.1)	0 (0.0)	
Body Mass Index			
Mean (SD)	31.0 (6.9)	30.7 (6.97)	.1038 (unpaired <i>t</i> test)
Not indicated	10,174 (66.7)	1021 (25.5)	
Geographic Distribution (n [%])			
Region 1 (Northeast)	4364 (28.6)	984 (24.6)	
Region 2 (Midwest)	2755 (18.1)	1015 (25.4)	
Region 3 (South)	5847 (38.3)	1000 (25.0)	
Region 4 (West)	2292 (15.0)	1001 (25.0)	

cohorts. A significantly higher rate of all comorbid conditions and cardiovascular risk factors reported in the after-JNC 7 cohort were observed, with the exception of cigarette smoking (5.9% less in the after-JNC 7 cohort) and obesity. Additional details are provided in Table 2.

Prescribing Patterns

The majority of patients in each cohort were prescribed antihypertensive drug therapy (93.3% and 93.8%, respectively). A trend toward more aggressive prescribing behavior was observed in the after-JNC 7 cohort, with 35.6% prescribed dual therapy and 24% prescribed 3 or more antihypertensive agents concomitantly. These rates compared with 31.4% and 16.5% in the before-JNC 7 cohort, respectively (Table 3). Of the patients who were prescribed medication, ACEIs were the most commonly prescribed agents in the before-JNC 7 cohort (33.4%), whereas di-

uretics were most commonly prescribed in the after-JNC 7 cohort (40.6%). ACEIs, diuretics, and beta-blockers were the 3 most commonly prescribed classes in both cohorts. Alpha-blockers were the least commonly prescribed antihypertensive agents in each cohort (5.6% and 6.9%, respectively). Of the drug classes studied, those with the greatest relative increase in use between the before-JNC 7 and after-JNC 7 cohorts were thiazide diuretics (7.0% versus 19.9%; $P < .0001$); fixed-dose combination products (11.9% versus 20.8%; $P < .0001$); and ARBs (8.1% versus 13.5%; $P < .0001$).

Best Practices

A significantly greater number of patients in the after-JNC 7 diabetes cohort (75.6%) were treated with either an ACEI or an ARB compared with patients in the before-JNC 7 diabetes cohort (60.6%) ($P < .0001$). Similarly, significantly more

Table 2. Comorbid Conditions and Cardiovascular Risk Factors

Presence of Comorbid Conditions and Cardiovascular Risk Factors	Before-JNC 7 Cohort n = 15,258 (n [%])	After-JNC 7 Cohort n = 4000 (n [%])	P
Age (years)*	7726 (50.8) [†]	2246 (56.2)	<.0001
Angina	1739 (11.4)	796 (19.9)	<.0001
CABG	1582 (10.4)	296 (7.4)	<.0001
Cigarette smoking	3006 (19.7)	551 (13.8)	<.0001
Diabetes	3369 (22.1)	1481 (37.0)	<.0001
Family history of CVD	3545 (25.1) [‡]	1805 (45.1)	<.0001
Heart failure	692 (4.5)	310 (7.8)	<.0001
Hyperlipidemia	7882 (53.0) [§]	2646 (66.2)	<.0001
Left ventricular hypertrophy	524 (3.7)	377 (9.4)	<.0001
Nephropathy	390 (2.8)	207 (10.3) [#]	<.0001
Obese	2542 (50.0) ^{**}	1433 (48.1) ^{††}	.1092
PAD	614 (4.0)	234 (5.9)	<.0001
Previous MI	876 (5.7)	387 (9.7)	<.0001
Retinopathy	270 (2.0) ^{‡‡}	149 (3.7)	<.0001
Stroke	880 (5.8)	266 (6.7)	.0392

Because of the retrospective, naturalistic design of this study, some data elements were either not available or unable to be determined from the chart reviews. In those cases, the missing values were not included in the denominator of the above percentages. The frequency of this missing information (thus, the number subtracted from the denominator) is as follows: [†]51, [‡]1116, [§]389, ^{||}1116, ^{||}1505, [#]1988, ^{**}10174, ^{††}1021, ^{‡‡}1505.

*>55 for men and >65 for women.

CABG, coronary artery bypass graft; CVD, cardiovascular disease; PAD, peripheral artery disease; MI, myocardial infarction.

Table 3. Prescribing Patterns

	Before-JNC 7 Cohort (n = 15,258)	After-JNC 7 Cohort n = 4,000	P
Number of agents (n [%])			
No drug therapy	908 (6.7)	249 (6.2)	<.0001
Monotherapy	6196 (45.4)	1365 (34.1)	
Dual therapy	4283 (31.4)	1425 (35.6)	
Triple+ therapy	2251 (16.5)	961 (24.0)	
Class of agents used in patients receiving therapy (n [%])	n = 14,350 [†]	n = 3751	
Beta-blockers	3739 (29.4)	1340 (35.7)	<.0001
ACE inhibitors	4248 (33.4)	1229 (32.7)	
Calcium channel blockers	3644 (28.6)	967 (25.8)	
ARBs	1033 (8.1)	508 (13.5)	<.0001
Diuretics—total	3950 (31.0)	1522 (40.6)	<.0001
Thiazide	889 (7.0)	748 (19.9)	<.0001
Nonthiazide	3061 (24.0)	774 (20.6)	
Alpha-blockers	708 (5.6)	259 (6.9)	.0020
Fixed-dose combination agents*	1516 (11.9)	783 (20.8)	<.0001

*Fixed-dose combination agents included ACE inhibitor/calcium channel blocker, ACE inhibitor/diuretic, ARB/diuretic, beta-blocker/diuretic, or vasodilator/diuretic.

[†]Includes patients' prescribed antihypertensive therapy.

ACE, angiotensin converting enzyme; ARB, angiotensin II receptor blocker.

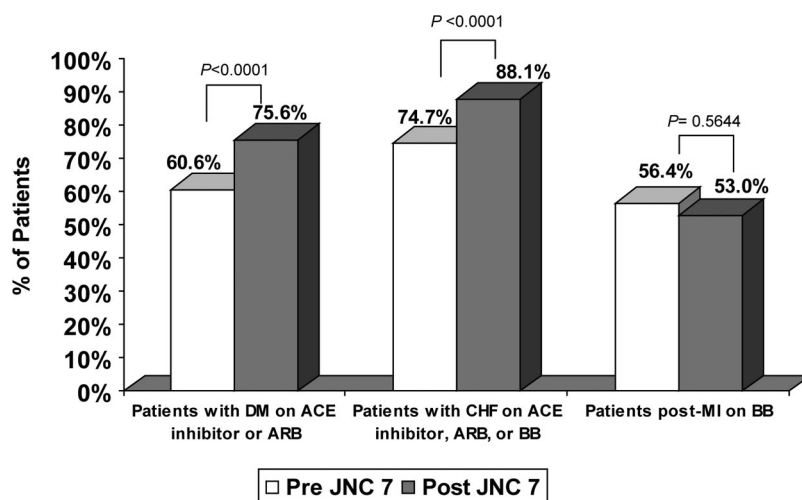


Figure 2. Recommended angiotensin converting enzyme inhibitor, angiotensin II receptor blocker, and beta-blocker use in patients with compelling indications.

hypertensive patients with congestive heart failure in the after-JNC 7 cohort were prescribed either an ACEI, ARB, or beta-blocker compared with the before-JNC 7 cohort (74.7% and 88.1%, respectively; $P < .0001$). This trend was not observed in those patients with a history of myocardial infarction prescribed a beta-blocker (56.4% and 53.0%, respectively; $P = .5644$) (Figure 2).

Blood Pressure Control

A significantly higher percentage of nondiabetic patients achieved BP control in the after-JNC 7 cohort compared with those in the before-JNC 7 cohort (60.9% versus 45.7%; $P < .0001$). For those with comorbid diabetes, 23.5% in the before-JNC 7 cohort had their BP controlled compared with 29.4% in the after-JNC 7 cohort ($P < .0001$). In the total study population, BP control in the be-

fore-JNC 7 cohort was 40.8% compared with 49.3% in the after-JNC 7 cohort ($P < .0001$). In each analysis, control was defined according to the prevailing JNC criteria for that time period (Figure 3). BP control rates by patient characteristics are summarized in Figure 4.

Evaluating data by year revealed a relatively consistent trend toward improved BP control year over year. In both the nondiabetes and diabetes populations, BP control rates increased after 2003, the year JNC 7 was released (Figure 5). However, these unadjusted, annualized results should be viewed with caution because such segmentation of the data may increase sampling bias.

BP Control Adjusted for Cohort Differences

A logistic regression evaluating the likelihood of BP control was performed to account for differences ob-

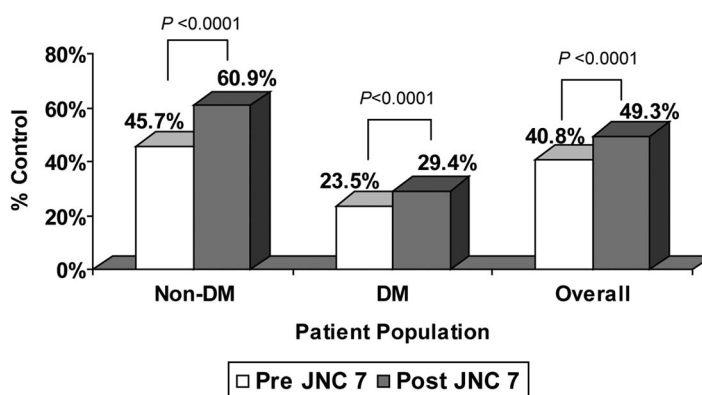


Figure 3. Blood pressure control as defined by prevailing criteria.

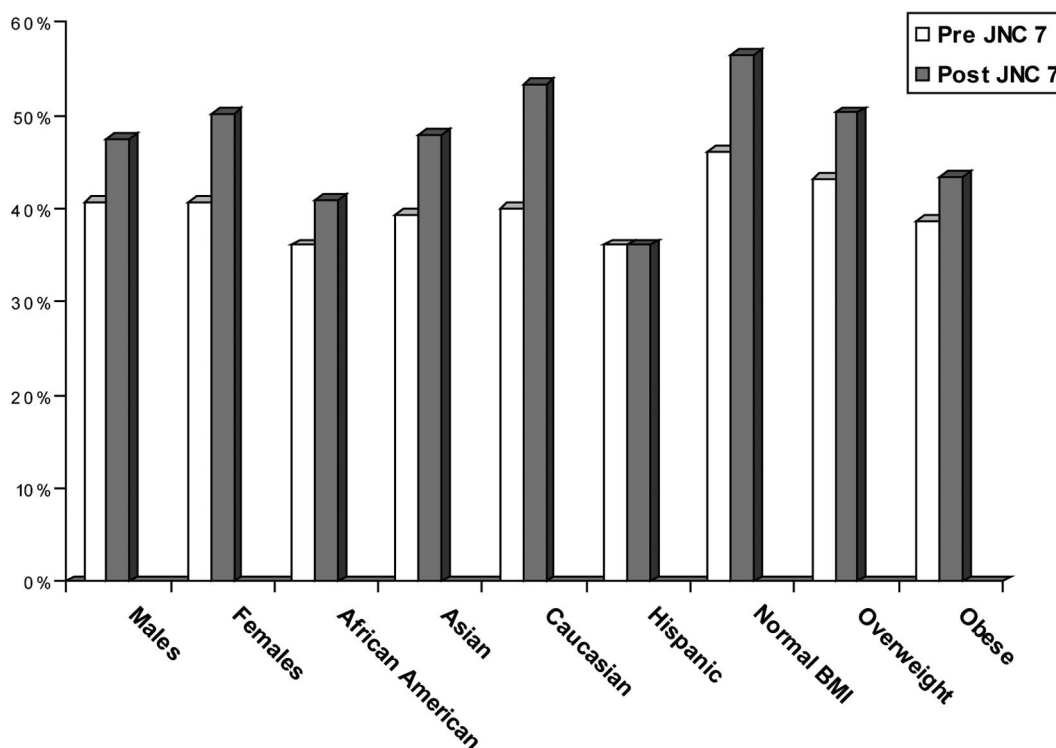


Figure 4. Blood pressure control by patient characteristics.

served in the characteristics between the 2 study cohorts. After controlling for age, gender, ethnicity, body mass index, physical inactivity, family history of cardiovascular disease, diabetes, hyperlipidemia, med-

ication use, and geographic region, patients in the before-JNC 7 cohort were 45% less likely to achieve BP control compared with those in the after-JNC 7 cohort (odds ratio, 0.551; $P < .0001$).

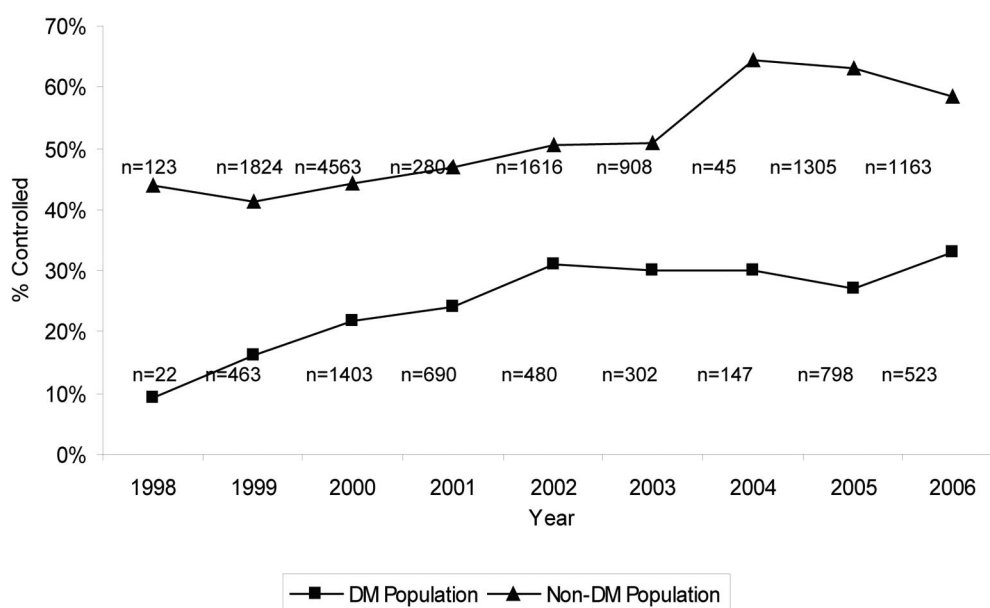


Figure 5. Blood pressure control over time (prevailing JNC guidelines). N = total sample size during time point of interval.

Discussion

BP control for hypertensive patients with and without diabetes improved over the 9-year time frame studied. Increased awareness of hypertension and the importance of lower BP may have prompted providers and patients to more aggressively treat high BP, especially in the year after the publication of the JNC 7 report in 2003. As shown in Figure 5, the greatest increase in BP control occurred between 2003 and 2005 in the nondiabetic population. These data provide an encouraging observation that BP control in diabetic patients (even with the more rigorous definition in JNC 7) continued to improve through 2006. In addition, the BP control rate in patients without diabetes was higher in 2006 than in 2003. These trends are similar to those recently reported by Wang¹⁰ even though the study population and methods were somewhat different from those reported here.

Other research indicates that reported levels of BP control can vary greatly depending on the study population, methods, and time frame. For instance, data reported from NHANES suggest that 36.8% of patients in the United States with hypertension had controlled BP during 2003 and 2004.⁸ The difference in this estimate and the 49.3% reported here (after JNC 7) may be explained by the fact that NHANES includes respondents who are undiagnosed, uninsured, and less likely to be treated. Similarly, Andros et al¹¹ conducted a retrospective observational study of BP control in an insured diabetic population. In that population, the BP control rate (defined by JNC 7) was 28%, similar to the 29.4% reported here.

Rates of BP control reported in clinical trials have ranged from 45% to 66%.^{12,13} Because clinical trials typically represent a motivated, closely controlled, and monitored patient population, control rates would be expected to be higher than those observed in the general population.

Results from this study suggest that prescribers may increasingly be following the JNC 7 drug therapy recommendations, especially those related to compelling indications. Increase in the use of diuretics in the after-JNC 7 cohort follows the recommendation of thiazide-type diuretics as the preferred initial agent in patients without compelling indications. Similarly, fixed-dose combination therapy had the largest absolute percent increase in prescribed therapy after the release of the JNC 7

guidelines. Fixed-dose combination products provide patients with a more convenient once-daily medication regimen, which has been shown to improve medication adherence.¹⁴ The significant increase in the use of ACEIs and ARBs coincides with the JNC 7 recommendation for their use in patients with diabetes and/or congestive heart failure. Data reported here do not, however, suggest that improvements have been made with respect to treating patients with beta-blockers after a myocardial infarction.

Limitations

Several factors must be considered when interpreting the results of this study. First, the 2 study cohorts were different in several important characteristics. Patients in the after-JNC 7 cohort were typically older, more likely to be women, and more likely to have diabetes, hyperlipidemia, angina, nephropathy, or a family history of cardiovascular disease. Likewise, there was a greater percent of Africa-Americans in the after-JNC 7 cohort. In contrast, there was a higher percent of smokers in the before-JNC 7 cohort. Even accounting for these differences, patients in the after-JNC 7 cohort had a greater likelihood of achieving their target BP goal. Because this study included independent samples from multiple sites and geographic locations, sampling bias may have influenced the results.

Because of the retrospective design of the study, some data were not available or not able to be determined during the data collection process (Tables 1 and 2). Although missing data were accounted for during calculations, the possibility exists that certain patient characteristics, conditions, and risk factors were over- or under-represented.

The naturalistic design of this study limits inferences of causality. For instance, there was no ability to control for universal changes that may have occurred independent of any influences from JNC 7, including the introduction of new branded products (and any associated promotion), the generic availability of established market leaders, or any quality improvement initiatives that may have been implemented in participating sites. In addition, because of the study design, we were unable to follow within-patient trends over time. Likewise, the data used for this study was limited by provider documentation. As a result, the presence of concomitant medications or disease states may have been over-

or under-reported. In addition, a provider may have prescribed a medication that was never filled or taken by the patient.

Conclusions

The findings of this study indicate that BP control is improving, both overall and in patients with diabetes, but that there is still a significant need for improvement. Although the results from this study do not definitively establish a causal relationship between the publication and adoption of the JNC 7 guidelines and increased BP control and adherence to recommendations, this study does provide evidence to suggest that there has been a consistent and significant trend toward greater attainment of BP control and more aggressive treatment regimens since the release of JNC 7.

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