

# Hypertension Treatment and Control Within an Independent Nurse Practitioner Setting

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**Objective:** To assess blood pressure (BP) control among patients with hypertension managed by nurse practitioners (NPs) vs physicians.

**Study Design:** Cross-sectional study.

**Methods:** Retrospective medical record reviews were conducted at 3 independent NP-based practices and at 21 physician-based practices. Investigators at each practice identified a sample of patients 18 years or older with a hypertension diagnosis. The primary outcome was controlled BP (<140/90 mm Hg for patients without diabetes mellitus and <130/80 mm Hg for patients with diabetes mellitus). Propensity score matching was used to minimize potential selection bias between NP-treated and physician-treated patients and to balance differences in patient characteristics. Logistic regression analysis was performed to estimate the odds of controlled BP for NP-treated vs physician-treated patients, adjusting for covariates.

**Results:** The NP-treated sample was composed of 684 patients; their mean age was 54.2 years, 62.6% were female, 59.7% were obese, and 19.2% had diabetes mellitus. Before propensity score matching, physician-treated patients were older, less likely to be female, and more likely to have diabetes. The propensity score–matched cohort ( $n = 623$  in each group) had similar baseline characteristics. Among the NP cohort, 70.5% had controlled BP compared with 63.2% among the physician cohort; the mean number of antihypertensive medications was lower among NP-treated patients (1.6 vs 1.8,  $P = .01$ ). The adjusted odds of controlled BP were slightly lower for physician-treated patients (odds ratio, 0.76; 95% confidence interval, 0.58-0.99).

**Conclusions:** Comparable controlled BP rates were observed among patients with hypertension receiving care from an NP vs a comparison group receiving care from a physician; the groups had similar baseline characteristics. Our findings support the increasingly important role of NPs in primary care.

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For author information and disclosures, see end of text.

Approximately 73.6 million adults in the United States have hypertension.<sup>1</sup> Among the US population with hypertension, 63% do not have blood pressure (BP) controlled to recommended goals (<140/90 mm Hg for individuals without diabetes mellitus and <130/80 mm Hg for individuals with diabetes mellitus).<sup>2,3</sup> Among those who are treated with an antihypertensive medication regimen, 43% of all hypertensive individuals and 62% of all hypertensive diabetic individuals are not controlled to target BP.<sup>2</sup> Most patients with hypertension will require treatment with 2 or more antihypertensive medications to achieve goal BP.<sup>3</sup>

The United States is experiencing a shortage of primary care providers, and this trend is expected to continue in coming years.<sup>4,6</sup> To address the potential implications of a continued physician shortage, the American College of Physicians<sup>7</sup> in a 2009 policy monograph outlined 7 positions related to the role of nurse practitioners (NPs) in primary care. In this monograph, the American College of Physicians acknowledged that NPs have an important role in meeting the current and future increasing demand for primary care, particularly in underserved populations.<sup>7</sup> As of 2010, the United States had approximately 135,000 practicing NPs across various specialty fields, and an estimated 600 million patient visits were made to NPs each year.<sup>8</sup> Several evaluations have suggested that NP-managed practices may be a cost-effective alternative to physician-based primary care practices.<sup>9,10</sup> Previous research has suggested similar treatment outcomes for NP-treated patients compared with physician-treated patients among those with chronic conditions such as diabetes, hypertension, or asthma.<sup>11</sup>

The objective of our study was to determine the proportion of patients with controlled BP among a sample of diabetic and nondiabetic hypertensive patients from 3 independent NP practices in the north-eastern United States. We aimed to compare the proportion of patients having controlled BP with that among a comparable hypertensive patient sample treated by primary care physicians.

## METHODS

### Study Design

This study was a retrospective medical record review conducted at 3 independent NP-based prac-

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tices located in the northeastern United States and at 21 physician-based practices. Participating physician practices represented internal medicine and family practice specialties and were located across the United States. Medical record review data for this study were collected by study investigators at each participating site between December 2007 and November 2009 using a secure Web-based data collection form. Participating site investigators identified their adult population ( $\geq 18$  years) with a hypertension diagnosis (*International Classification of Diseases, Ninth Revision, Clinical Modification* [ICD-9-CM] code of 401.x) in the patient's medical record during the previous year; the patient sample included both newly and previously diagnosed patients with hypertension. Patients were required to have had at least 1 visit during the previous 12 months and to have at least 12 months of visit history with the practice. Pregnant women were excluded from study eligibility. Investigators at physician-based sites identified a random sample of 150 to 300 eligible patients with hypertension from their practice's patient population for study inclusion. Because the NP-based sites had a smaller patient population than the physician-based sites, all eligible patients with hypertension were included in the study sample for these practices.

The primary outcome variable in this study was controlled BP, which was defined as BP less than 140/90 mm Hg for patients without diabetes and as less than 130/80 mm Hg for patients with diabetes based on each patient's most recent BP measurement. A prior BP measurement was also recorded. If multiple BP measurements were performed on the same date, study investigators were instructed to record the mean of these measurements; however, if different measurement techniques were recorded, such as standing, sitting, or supine, investigators were asked to record the sitting BP measurement for study purposes. Other patient information obtained included demographic data (age, sex, and race/ethnicity), specific risk factors such as body mass index (BMI, calculated as weight in kilograms divided by height in meters squared) and smoking status, current antihypertensive medication regimen, and total number of different medications used daily for all nonacute conditions. Specific cardiovascular-related comorbid conditions documented in the patient record were identified, including diabetes, dyslipidemia, coronary artery disease, prior myocardial infarction, renal disease, congestive heart failure, and cerebrovascular accident or transient ischemic attack; these conditions were identified based on the presence of corresponding ICD-9-CM codes or documentation of a clinical

### Take-Away Points

Blood pressure (BP) control was evaluated for patients with a diagnosis of hypertension who received primary care from a nurse practitioner (NP) vs a physician in this cross-sectional medical record review study.

- Patients who received care from an NP were younger, less likely to have diabetes mellitus, and more likely to be female than those who received care from a physician.
- After propensity score matching and logistic regression analysis to adjust for baseline differences in patient characteristics, the odds of controlled BP were slightly lower for physician-treated patients.
- Comparable controlled BP can be achieved in both settings, lending support to the role of NPs in the primary care setting.

diagnosis in the patient's medical record. Obesity was defined as a BMI of at least 30, while overweight was defined as a BMI between 25 and 29.9 and normal weight as less than 25.

A training session was conducted with investigators at each site before study initiation. Detailed abstraction instructions were provided for specific data elements, and investigators received a study guide that included the study protocol, detailed descriptions of each data element, instructions for abstracting the element from the patient's medical record, and comments for each element to assist sites in answering any questions they might have regarding that data element. The study was approved and monitored by an independent institutional review board.

### Statistical Analysis

Univariate descriptive statistics were calculated for all study variables, including means (SDs) for continuous variables and frequency distributions for categorical variables. Bivariate analyses were performed using *t* test and analysis of variance for continuous variables.  $\chi^2$  Test was used for categorical variables.

Because our study design was retrospective and patients were not randomized to receive care from an NP or a physician, selection bias was a distinct possibility in our study. For example, patients under the care of an NP, compared with patients under the care of a physician, may have been less likely to also have diabetes and other comorbid study conditions. This may have led to differences in baseline characteristics of the treatment groups. The propensity score method is commonly used in retrospective studies to minimize differences in baseline covariates between treatment groups.<sup>12-14</sup> To compare the probability of controlled BP between NP-treated patients and physician-treated patients, our primary study analysis used the propensity score matching method, whereby NP-treated patients were matched to physician-treated patients using a 1:1 ratio based on a minimum difference in propensity scores. Propensity scores were calculated using logistic regression analysis with provider type (NP vs physician) as the de-

**Table 1.** Baseline Demographic and Clinical Characteristics of Nurse Practitioner (NP)–Treated and Physician-Treated Patients in the Overall Eligible Cohort and the Propensity Score–Matched Cohort

Variable	Overall Eligible Cohort		Propensity Score–Matched Cohort	
	NP Treated (n = 684)	Physician Treated (n = 3232)	NP Treated (n = 623)	Physician Treated (n = 623)
Female sex, %	62.6 <sup>a</sup>	53.2	50.9	49.1
Age, mean (SD), y	54.2 (12.3) <sup>a</sup>	64.9 (14.0)	55.1 (11.6)	54.8 (12.3)
Female	55.3 (12.2)	66.9 (14.2)	56.7 (11.4)	56.4 (12.2)
Male	52.4(12.1)	62.8 (13.5)	52.5 (11.6)	52.4 (12.0)
BMI, mean (SD)	32.4 (6.9) <sup>a</sup>	31.0 (7.0)	32.2 (6.9)	32.5 (7.1)
Obese, BMI ≥30, %	59.7 <sup>a</sup>	49.7	58.6	60.5
Current smoker, %	18.6 <sup>b</sup>	12.3	17.7	15.7
No. of comorbid cardiovascular-related conditions, mean (SD)	1.1 (0.9)	1.1 (1.0)	1.1 (0.9)	1.0 (0.8)
<b>Cardiovascular-related comorbid conditions, %</b>				
Congestive heart failure	1.0 <sup>a</sup>	2.8	1.0	1.4
Cerebrovascular accident or transient ischemic attack	2.2 <sup>b</sup>	4.8	1.9	1.4
Renal disease or renal insufficiency	6.0 <sup>c</sup>	8.1	6.3	4.7
Prior myocardial infarction	2.5	1.5	2.6	1.0
Diabetes mellitus	19.2 <sup>a</sup>	23.5	19.3	20.5
Coronary artery disease	5.3 <sup>b</sup>	12.7	5.5	3.5
Dyslipidemia	71.8 <sup>a</sup>	59.9	71.6	71.9
No. of chronic medications, mean (SD)	4.6 (3.0) <sup>b</sup>	5.0 (3.4)	4.7 (3.0)	4.7 (3.2)

BMI is calculated as weight in kilograms divided by height in meters squared.  
<sup>a</sup>Statistically significant at  $P < .001$ .  
<sup>b</sup>Statistically significant at  $P < .01$ .  
<sup>c</sup>Statistically significant at  $P < .05$ .

pendent variable, and the following independent variables were used in the model: patient age, sex, BMI, total number of chronic medications, smoking status, and the presence of diabetes, renal disease, dyslipidemia, or cardiovascular disease.

Among the matched cohort, logistic regression analysis was used to assess the effect of provider type on controlled BP using the following factors as independent variables in the regression: age, sex, BMI, smoking status, total number of chronic medications, lifestyle modification counseling, antihypertensive medication regimen, and the presence of diabetes, renal disease, dyslipidemia, or cardiovascular disease. Adjusted odds ratios (95% confidence intervals [CIs]) of controlled BP were calculated. The variables included in the final model were selected based on clinical relevance and on the results of bivariate analyses. Finally, to assess the robustness of our study, logistic regression analysis was performed to estimate the odds of controlled BP for NP-treated patients vs physician-treated patients

among the entire study population, controlling for the covariates listed. Commercially available statistical software (SPSS version 17.0; SPSS Inc, Chicago, Illinois) was used for all study analyses.

## RESULTS

Our study included 684 patients who were receiving primary care from an NP. Clinical and demographic characteristics of patients treated by an NP are given in **Table 1**, as are characteristics of 3232 patients treated by a family practice or internal medicine physician. Patients in the NP-treated group were significantly more likely to be female (62.6% vs 53.2%,  $P < .001$ ) and were on average more than 10 years younger than patients in the physician-treated group (mean age, 54.2 vs 64.9 years;  $P < .001$ ). Patients in the NP-treated group were more likely to be obese or to be current smokers than patients in the physician-treated group. Although NP-treated patients had a similar total number of comorbid cardiovascular-related

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**Table 2.** Treatment Characteristics of Nurse Practitioner (NP)–Treated and Physician-Treated Patients in the Overall Eligible Cohort and the Propensity Score–Matched Cohort

Variable	Overall Eligible Cohort			Propensity Score–Matched Cohort		
	NP Treated (n = 684)	Physician Treated (n = 3232)	P	NP Treated (n = 623)	Physician Treated (n = 623)	P
No. of antihypertensive medications, mean (SD)	1.6 (1.0)	1.9 (1.1)	<.001	1.6 (1.0)	1.8 (1.1)	.01
Time between blood pressure measurements, mean (SD), mo	2.7 (3.2)	3.4 (3.9)	<.001	2.7 (3.2)	3.6 (4.3)	<.001
Lifestyle modification counseling, %	87.8	64.0	<.001	88.0	76.4	<.001
Controlled blood pressure, %	70.6	61.8	<.001	70.5	63.2	.008
Prescribed antihypertensive medication, %	88.2	93.6	<.001	88.8	92.6	.03
<b>Class of antihypertensive medication used, %</b>						
β-Blocker	31.6	35.1	.09	32.7	28.7	.14
Angiotensin-converting enzyme inhibitor or angiotensin receptor II receptor blocker	63.7	66.0	.25	64.4	66.9	.37
Calcium channel blocker	13.1	26.4	<.001	13.6	20.4	.002
Any diuretic	38.8	44.9	.004	38.5	46.4	.006

conditions as physician-treated patients, physician-treated patients were more likely to have advanced cardiovascular-related diseases, including congestive heart failure, diabetes, coronary artery disease, renal disease or renal insufficiency, and a history of cerebrovascular accident or transient ischemic attack, as well as a higher mean number of total chronic medications at baseline. Nurse practitioner–treated patients were significantly more likely to have dyslipidemia.

Among the entire eligible cohort, NP-treated patients had lower systolic BP but higher diastolic BP compared with physician-treated patients at the date of the most recent BP measurement in the patient's medical record (128.9/80.2 vs 130.2/77.1 mm Hg,  $P < .05$  for both). Treatment characteristics of the entire eligible patient cohort are given in **Table 2**. Nurse practitioner–treated patients were prescribed a mean of 1.6 antihypertensive medications compared with 1.9 for physician-treated patients ( $P < .001$ ). Nurse practitioner–treated patients were less likely to be prescribed an antihypertensive medication to control their hypertension. Among the entire study population, the use of other antihypertensive classes of medication was similar for NP-treated patients and physician-treated patients, except that NPs were less likely to prescribe calcium channel blockers and diuretics.

Baseline demographic and clinical characteristics of the propensity score–matched cohort, which consisted of 623 patients in each treatment group, were similar (Table 1). The mean age of the propensity score–matched cohort overall was 55 years, 50.0% were female, and 59.6% were obese. The prevalence of specific cardiovascular-related comorbid condi-

tions was similar for NP-treated patients and physician-treated patients. Among the propensity score–matched cohort, the physician-treated group was more likely to be prescribed angiotensin receptor II receptor blockers ( $P \leq .05$ ), calcium channel blockers ( $P < .01$ ), and loop or thiazide diuretics ( $P < .05$ ) and was more likely to receive antihypertensive medication ( $P < .05$ ) (**Figure 1**). Table 2 gives treatment characteristics of the propensity score–matched cohort, among whom physician-treated patients received a higher mean number of antihypertensive medications (1.8 vs 1.6,  $P = .01$ ). Nurse practitioner–treated patients were more likely to receive lifestyle modification counseling (88.0% vs 76.4%,  $P < .001$ ). Unadjusted for patient characteristics, 63.2% of physician-treated patients had controlled BP compared with 70.5% of NP-treated patients ( $P = .008$ ). The proportions of obese and diabetic patients with controlled BP are shown in **Figure 2**. Among physician-treated patients with diabetes, 38.3% had controlled BP compared with 54.2% among NP-treated patients with diabetes ( $P < .001$ ). Among obese patients, 57.6% of physician-treated patients had controlled BP compared with 66.8% of NP-treated patients ( $P < .001$ ).

The adjusted odds of controlled BP among patients in the propensity score–matched cohort who were prescribed antihypertensive medication are given in **Table 3**. The odds of controlled BP for obese patients were 0.53 (95% CI, 0.34-0.83) compared with normal-weight patients and 0.30 (95% CI, 0.22-0.42) for patients having diabetes or renal disease compared with those not having those diagnoses. The presence of dyslipidemia was associated with increased odds of controlled

BP, as was the use of a regimen containing an angiotensin-converting enzyme inhibitor or angiotensin receptor II receptor blocker. The number of antihypertensive medications in patients' drug regimens was not associated with controlled BP. Adjusted for covariates, the odds ratio of controlled BP for physician-treated patients was 0.76 (95% CI, 0.58-0.99) compared to NP-treated patients. Among the entire study population (without propensity score matching), the adjusted odds ratio for BP control for physician-treated versus NP-treated patients was 0.72 (95% CI, 0.59-0.89).

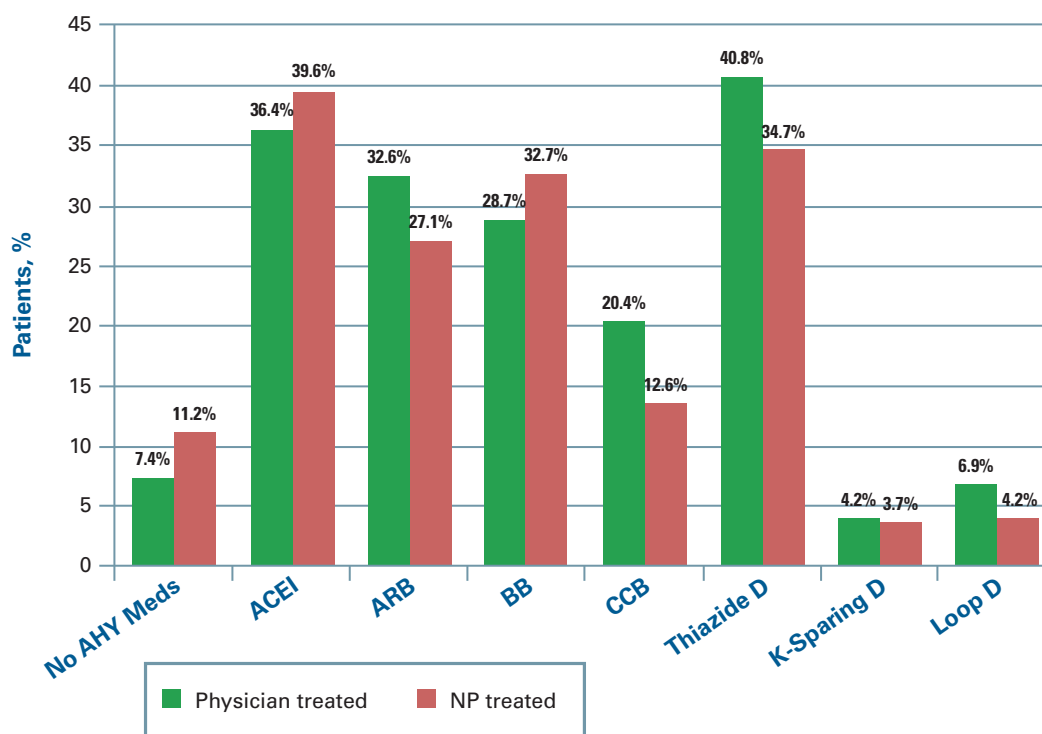
## DISCUSSION

Our cross-sectional study of hypertension management in a nonclinical trial setting found significant differences between patients diagnosed as having hypertension who were managed by an NP as opposed to an internal medicine or a family practice physician. Patients managed by an NP were on average 10 years younger than patients treated by a physician, were significantly more likely to be female and significantly less likely to have diabetes, and were prescribed a higher mean total number of chronic medications. Among NP-treated and physician-treated populations of hypertensive

patients matched to achieve similar baseline demographic and clinical characteristics, comparable proportions achieved controlled BP. Among the matched cohort, 70.5% of patients managed by an NP had controlled BP to their recommended goal, while 63.2% of patients managed by a physician were at goal BP. These figures compare somewhat favorably to national controlled BP estimates, as data from the National Health and Nutrition Examination Survey indicate that approximately 57% of antihypertensive medication-treated hypertensive individuals have controlled BP to recommended levels,<sup>2</sup> although it is noteworthy that our propensity score-matched patient cohort was somewhat younger than the overall US hypertensive population (54.8 vs 57.8 years) and had a higher prevalence of diabetes (20.5% vs 15.3%).<sup>15</sup> Finally, we found similar odds ratio estimates of controlled BP for physician-treated patients vs NP-treated patients using logistic regression analysis among the entire eligible cohort (without propensity score matching) and among the propensity score-matched cohort, supporting the robustness of the findings in our study.

Previous research has suggested that similar patient outcomes are achievable by NPs in a primary care setting compared with their physician counterparts. Munding

■ **Figure 1.** Use of Specific Antihypertensive Medication Classes Among 1246 Nurse Practitioner (NP)-Treated and Physician-Treated Propensity Score-Matched Patients



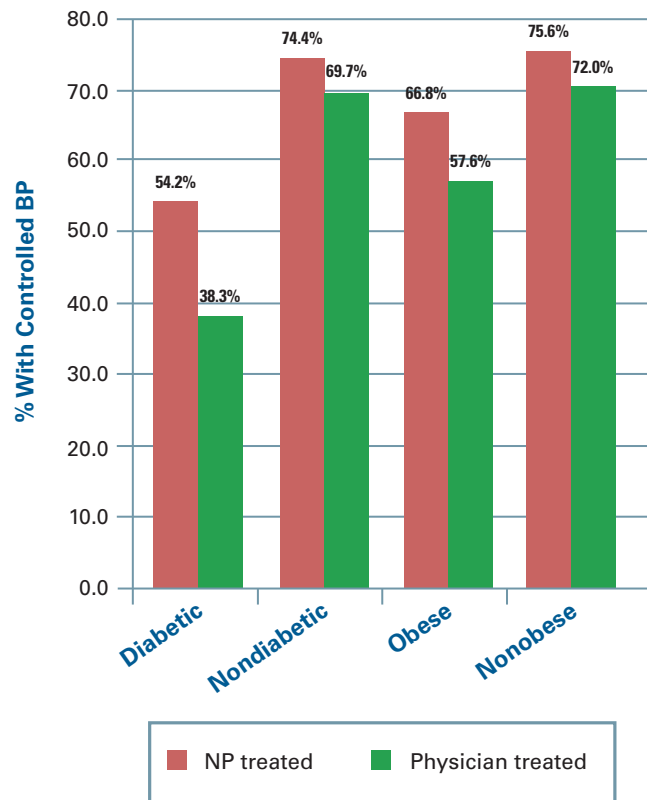
AHY meds indicates antihypertensive medications; ACEI, angiotensin-converting enzyme inhibitor; ARB, angiotensin II receptor blocker; BB,  $\beta$ -blocker; CCB, calcium channel blocker; D, diuretic; and K, potassium.

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and colleagues<sup>11</sup> studied 1316 patients randomly assigned to NPs or physicians for primary care after an emergency department or urgent care visit in a setting where NPs had the same authority, responsibilities, and administrative requirements as physicians. No differences were observed in the health status of the treatment groups at 6 months after enrollment. Furthermore, while outcome measures for patients with diabetes and asthma were similar, hypertensive patients randomized to the NP group had significantly lower diastolic BP at follow-up compared with those randomized to the physician group (82 vs 85 mm Hg). Another study<sup>16</sup> of patients with type 2 diabetes mellitus who were randomized to primary care with an NP or with a physician found that, although NPs were more likely to document lifestyle modification counseling and some patient clinical information than physicians, no differences were found in patient outcomes (glycosylated hemoglobin level) for NP-treated patients vs physician-treated patients at the 6-month follow-up visit. Andersen and colleagues<sup>17</sup> conducted a 4-year study of 130 hypertensive patients from Denmark who were initially examined by cardiologists but subsequently were managed exclusively by nurses in the hypertension clinic; 95% of these hypertensive patients achieved target BP. These studies lend further support to the conclusions of the present study and support the role of NPs in primary care.

Although our study provides important evidence to support the claim that similar outcomes are achievable in the management of chronic diseases by NPs, it is important to consider our findings in light of several key limitations. Most important, while the results of logistic regression analysis adjusting for patient covariates suggested that NP-treated patients had a higher probability of controlled BP, we would caution against interpretation of our study findings as one of better-controlled BP among NP-treated patients for several reasons. The statistical significance of the odds ratio for controlled BP was .045. Although statistically significant at  $P < .05$ , this finding may not be clinically significant for the following reasons: (1) we did not collect information for all possible comorbid conditions and baseline covariates, (2) we may not have been able to fully account for patient selection bias for one practitioner over another, and (3) with the small sample size of our study, a change in just a few patient characteristics may alter the  $P$  value (in either direction). Because our study was retrospective in nature, we were unable to obtain information on all potential

■ **Figure 2.** Proportion of 1246 Nurse Practitioner (NP)-Treated and Physician-Treated Propensity Score-Matched Patients With Controlled Blood Pressure (BP) Among Obese vs Nonobese Patients and Diabetic vs Nondiabetic Patients



patient clinical characteristics that may have led to baseline differences in our NP-treated and physician-treated patient populations, such as duration or severity of disease, length of antihypertensive medication use, and patient compliance with prescribed antihypertensive medication. Although we used the propensity score matching method to eliminate baseline differences between treatment groups for all measured patient characteristics, it is possible that treatment groups differed with respect to unmeasured ones. In addition, not all physician-treated patients may have had access to an NP as a primary care provider, and it is difficult to know how this may have affected the results of our study. Before propensity score matching, our NP-treated patient population was younger, was more likely to be female, was less likely to have diabetes, and had been prescribed fewer chronic medications. Relative to the comorbid conditions studied, this may suggest that the NP-treated patients were healthier overall than the physician-treated patients and that patients with more severe disease or more severe chronic conditions were more likely to be receiving primary care from a physician. While the proportion with controlled

**Table 3.** Odds of Controlled Blood Pressure Among 1130 Nurse Practitioner (NP)–Treated Patients and Physician-Treated Patients in the Propensity Score–Matched Cohort Who Were Prescribed Antihypertensive Medication

Variable	Odds Ratio (95% Confidence Interval)	P
<b>Age</b>	1.00 (0.99-1.01)	.74
<b>Smoking status</b>		
Current smoker	1 [Reference]	
Nonsmoker	1.23 (0.86-1.77)	.25
<b>Sex</b>		
Female	1 [Reference]	
Male	0.84 (0.63-1.12)	.24
<b>Body mass index category</b>		
Normal	1 [Reference]	
Overweight	0.84 (0.52-1.37)	
Obese	0.53 (0.34-0.83)	.005
<b>Diabetes mellitus or renal disease or renal insufficiency</b>	0.30 (0.22-0.42)	<.001
<b>Coronary artery disease</b>	1.21 (0.68-2.15)	.52
<b>Dyslipidemia</b>	1.76 (1.28-2.42)	.001
<b>No. of chronic medications at baseline</b>	1.02 (0.97-1.07)	.38
<b>Lifestyle modification counseling</b>		
No	1 [Reference]	
Yes	1.28 (0.91-1.80)	.16
<b>Prescribed antihypertensive medication</b>		
Monotherapy	1 [Reference]	
Combination, ≥2 classes	0.76 (0.49-1.20)	.24
<b>Class of antihypertensive medication used</b>		
Calcium channel blocker	0.91 (0.62-1.32)	.62
Angiotensin-converting enzyme inhibitor or angiotensin receptor II receptor blocker	1.73 (1.18-2.52)	.005
Diuretic	1.12 (0.76-1.70)	.58
β-Blocker	1.33 (0.93-1.91)	.12
<b>Provider type</b>		
NP	1 [Reference]	
Physician	0.76 (0.58-0.99)	.04

BP was higher for NP-treated diabetic and nondiabetic patients than for physician-treated patients, our study did not control for duration or severity of diabetes; therefore, these findings should be interpreted cautiously. Our NP-treated patient population was drawn from 3 independent practices in the northeastern United States; our physician-treated patient population included patients from the northeast and other geographical regions across the continental United States. The study was not designed to include a population

that was demographically representative of the entire US hypertensive population. Because 99.4% of NP-treated patients were of white race/ethnicity, our matched cohort was limited to white patients; therefore, our findings may not be generalizable to patients of other racial/ethnic backgrounds. Because we used a retrospective study design, BP measurements were not standardized or validated. Finally, although we did not find an association between the number of antihypertensive medications in patients' drug regimens and

controlled BP, our study by its cross-sectional nature did not control for patient baseline severity or duration of hypertension; therefore, caution should be used when interpreting this finding, as our cohort consisted of both newly and previously diagnosed patients with hypertension. Despite these limitations, our study is an important contribution to the limited existing body of research evaluating patient chronic disease care by NPs in a primary care setting.

In conclusion, our study findings suggest that, while patients treated by independent NP primary care practices may differ significantly from patients treated by primary care physicians, comparable patient outcomes are achievable in both settings. Patients receiving care from physician primary care practices in our study were older and had a greater comorbid disease burden. However, our study found that (at least among younger patients with a lower chronic disease burden) similar outcomes in hypertension management are attainable whether patients receive care from an NP or a physician. Therefore, our study lends support to the role of NPs in the primary care setting.

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**Authorship Information:** Concept and design (WLW, MAD, JW, DAB); acquisition of data (WLW, JER, MAD, JW); analysis and interpretation of data (JW, DAB); drafting of the manuscript (WLW, MAD, JW, DAB); critical revision of the manuscript for important intellectual content (WLW, JER, MAD, JW, DAB); statistical analysis (JW); provision of study materials or patients (WLW, JER); obtaining funding (DAB); administrative, technical, or logistic support (WLW, JER, JW); and supervision (WLW, JER, JW, DAB).

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