



NOTE

Treatment and control of blood pressure in patients with diabetes mellitus

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The prevalence of diabetes mellitus in U.S. adults ≥ 20 years old is estimated at 5.9%.¹ This represents approximately 11.8 million people, with the majority having type 2 diabetes mellitus.¹ Various reports suggest the prevalence of concurrent hypertension in these patients is high at 60% to 71%.²⁻⁵ A majority of the affected individuals are hypertensive at the time their diabetes is diagnosed, suggesting that both diseases may have a common cause or that a hormonal or metabolic disturbance may exist in essential hypertension before the onset of diabetes.⁶ Reported rates of treatment and control of elevated blood pressure (as defined by $< 140/90$ mm Hg) in patients with diabetes range from 45% to 66%, suggesting that considerable opportunity for improvement exists.^{2,7}

The risk of major cardiovascular morbidities such as coronary artery disease, stroke, peripheral vascular disease, lower-extremity amputations, nephropathy, end-stage renal disease, retinopathy, and blindness

Purpose. A study was conducted to characterize the prevalence of hypertension in patients with diabetes mellitus and the percentage of patients with diabetes and hypertension who achieved a targeted blood pressure goal ($< 135/80$ mm Hg).

Methods. A retrospective, cross-sectional study was conducted in an ambulatory care clinic. Eligible patients were those individuals being managed for type 2 diabetes mellitus at least once each year for two consecutive years. Blood pressure measurements that were recorded in the medical chart or written diagnoses of hypertension were used to determine the presence of comorbid hypertension. Data were collected from the chart and electronic record using a standardized form. Clinic visits over the previous 12 months were reviewed to evaluate hypertension criteria. A blood pressure of $\geq 135/80$ mm Hg was used to define hypertension.

Results. A final sample of 362 patients with type 2 diabetes mellitus was included in the study. Of these, 79% had concomitant

diabetes and hypertension. Blood pressure was controlled in 175 of 270 (65%) patients. Patients who met the blood pressure goal tended to be older and weigh less than those who did not. The adjusted odds of achieving the blood pressure goal were 1.9 times higher in those patients who also achieved their low-density-lipoprotein cholesterol goal. Most patients were on at least one antihypertensive agent; approximately 39% of the 89 patients treated with monotherapy were above the blood pressure goal. Combination therapy was used in 164 patients; approximately 32% of patients treated with combination therapy were above the blood pressure goal.

Conclusion. Among ambulatory care patients with diabetes, 79% also had hypertension. Hypertension was controlled in 65% of patients with that disorder.

Index terms: Age; Ambulatory care; Combined therapy; Diabetes mellitus; Hypertension; Hypotensive agents; Weight

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is increased in patients with diabetes who have uncontrolled hypertension relative to patients with either

disease alone.^{3,8} Patients with comorbid diabetes and hypertension also have an increased risk for mortality,

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with a majority of the deaths in patients with diabetes resulting from cardiovascular and renal disease.^{3,9} However, appropriate management of hypertension has been shown to significantly reduce or delay complications associated with diabetes in patients with this comorbidity.^{5,8,10,11}

There are substantial and compelling data indicating that optimizing blood pressure in patients with diabetes significantly reduces cardiovascular morbidity and mortality. In the Hypertension Optimal Treatment (HOT) randomized trial, Hansson and colleagues¹⁰ evaluated the effects of targeting diastolic blood pressures (DBPs) of ≤ 90 , ≤ 85 , and ≤ 80 mm Hg in patients with DBPs of 100–115 mm Hg. The lowest frequency of major cardiovascular events occurred at a mean DBP of 82.6 mm Hg. In patients with diabetes, there was a 51% reduction in the frequency of major cardiovascular events in patients whose DBP was lowered to ≤ 80 mm Hg compared with ≤ 90 mm Hg ($p = 0.005$).

The Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT) compared the effect of three different types of antihypertensive medications on cardiovascular morbidity in patients ≥ 55 years of age with hypertension and at least one other coronary heart disease (CHD) risk factor and provided important knowledge regarding blood pressure reduction in patients with diabetes.¹¹ Of the 33,357 patients enrolled in the trial,

approximately 36% had type 2 diabetes mellitus. The risk of nonfatal myocardial infarction and fatal CHD was similar in patients with diabetes and multiple cardiovascular risk factors regardless of whether they were randomized to amlodipine, chlorthalidone, or lisinopril. At the conclusion of ALLHAT, 63% of the patients were receiving two or more antihypertensive agents in an attempt to reach blood pressure targets. Therefore, it can be anticipated that combination therapy is needed in patients with and without diabetes to reach blood pressure goals.

In the U. K. Prospective Diabetes Study 38, researchers evaluated the effect of tight blood pressure control on microvascular and macrovascular complications in patients with type 2 diabetes mellitus.⁸ Mean blood pressure in the tight control group during follow-up was significantly lower (144/82 mm Hg) compared with the control group (154/87 mm Hg; $p < 0.0001$ for systolic and diastolic pressures). This reduction in blood pressure was associated with a 24% reduction in diabetes-related endpoints ($p = 0.0046$), a 32% reduction in deaths related to diabetes ($p = 0.019$), a 44% reduction in strokes ($p = 0.013$), and a 37% reduction in microvascular endpoints ($p = 0.0092$).

Therefore, obtaining blood pressure control is critical in patients with diabetes to reduce the progression of disease complications. In the general population, a guideline-based blood pressure goal is $< 140/90$ mm Hg.¹² However, for patients with diabetes, guidelines suggest that the goal is $< 130/80$ mm Hg.^{5,12,13} Randomized clinical trials suggest a significant benefit in targeting a DBP of < 80 mm Hg. However, the goal for systolic blood pressure is not as clear. Based on a review of the literature, it is suggested that a systolic pressure goal of < 135 mm Hg is reasonable.^{4,14}

The purpose of this study was to characterize the prevalence of hypertension in patients with diabetes.

Furthermore, we were interested in determining the percentage of patients with diabetes and hypertension achieving a targeted blood pressure goal ($< 135/80$ mm Hg). We also report key prescribing patterns of antihypertensive agents (i.e., the percentage of patients receiving diuretics or β -blockers, the percentage of patients receiving angiotensin-converting-enzyme [ACE] inhibitors or angiotensin-receptor blocker agents, and the percentage of patients receiving combination therapy). Finally, we identified potential factors associated with not achieving blood pressure goals.

Methods

Design and study population.

This was a retrospective, cross-sectional study conducted in an internal medicine ambulatory care clinic associated with an academic teaching institution. Eligible patients were identified from a patient care registry of individuals being managed for type 2 diabetes mellitus. Diabetes management was defined as receiving treatment in the clinic for a diabetes care-related issue at least once each year in two consecutive years (2002 and 2003 or 2003 and 2004). Blood pressure measurements that were recorded in the medical chart or written diagnoses of hypertension were used to determine the presence of comorbid hypertension. Patients were excluded from this study if they were under 18 years, no longer obtaining care from the clinic (i.e., did not meet management criteria outlined above), diagnosed with hypertension within six months before the most recent visit, or currently diagnosed with cancer. The health system's institutional review board approved the study protocol.

Data collection. Beginning with a patient's most recent clinic visit as the index, data were collected from the patient's chart and electronic medical record using a standardized form. Clinic visits over the previous 12

months were then reviewed to evaluate hypertension criteria and collect relevant data. Variables collected included medications prescribed, laboratory values, blood pressure, and weight. Blood pressure goal attainment was assessed using blood pressure measurement data from the patient's most recent visit, and patients not at goal were analyzed more in-depth. A blood pressure of $\geq 135/80$ mg Hg was used to define hypertension.⁴ If multiple blood pressure measurements were available at any given clinic visit, the lower value was used for goal-assessment purposes. This method was used to provide a more conservative estimate of inadequate blood pressure goal attainment. At this site, usual medical care was provided by attending and resident physicians, nurses, and pharmacists during the observation period. Furthermore, physicians had access to a clinical pharmacist at the site. Laboratory values were made available to the primary physician so that health care providers would have adequate access to the information before the patient's appointment.

Data analysis. Data for this project were compiled and analyzed using standard spreadsheet software (Excel 2000, Microsoft, Redmond, WA) and the statistical software, SAS, version 9.1 (SAS Institute Inc., Cary, NC). A sample size of 384 subjects with type 2 diabetes mellitus was required for this study in order to estimate the prevalence of hypertension in this population with a 5% margin of error. Our final sample of 362 patients resulted in a margin of error of $\pm 5.2\%$. Bivariate comparisons were made using chi-square tests (categorical data) and two-sample *t* tests (continuous data) for demographics, comorbid diseases, blood pressure measurement, use of antihypertensive agents, and lipid goal attainment. Logistic regression was used to identify variables associated with achieving blood pressure goals, and odds ratios (adjusted for age, sex, weight,

and hypertensive medication use) along with 95% confidence intervals (CIs) are reported. The a priori level of significance was 0.05.

Results

A total of 362 patients were included in this study. Of these, 286 (79%) had concomitant diabetes and hypertension. Sixteen patients were excluded because of a recent diagnosis of hypertension ($n = 5$), a diagnosis of cancer ($n = 5$), a change of clinics ($n = 3$), or missing blood pressure data ($n = 3$). Complete analysis was conducted on the remaining 270 patients.

Characteristics of patients with concomitant diabetes and hypertension are summarized in Table 1. Blood pressure was controlled in 175 of 270 patients (65%). Patients who met the blood pressure goal tended to be older (95% CI for difference, 0.73–6.8; $p = 0.02$) and weigh less (95% CI for difference, 0.05–32.2; $p = 0.054$) than those who did not. The groups of patients whose blood pressure was or was not controlled did not differ with regard to the percentage of men or the distribution

of comorbid diseases. Blood pressure measurements are summarized in Table 2 for patients who did and did not meet goal. Among the 175 patients whose blood pressure goal was met, 166 (95%) were receiving antihypertensive therapy, and among the 95 patients whose goal was not met, 87 (92%) were receiving such therapy ($p = 0.29$).

Most participants (253/270 [94%]) in this study were on at least one antihypertensive agent (Table 3). Of those treated with medication, 35% were receiving one agent, which was most commonly an ACE inhibitor. Approximately 39% of patients treated with monotherapy were above the blood pressure goal. Combination therapy was used in 164 patients (65%) in this study. Of those, 97 (59%) were receiving two-drug regimens while 67 (41%) were receiving regimens with three or more agents. Approximately 32% of patients treated with combination therapy were above the blood pressure goal. The difference in goal attainment between monotherapy and combination therapy was not significant ($p = 0.35$).

Table 1.

Characteristics of Patients with Diabetes and Hypertension^a

Item	Overall (<i>n</i> = 270)	BP Goal Met (<i>n</i> = 175)	BP Goal Not Met (<i>n</i> = 95)
No. (%) male	150 (56)	93 (53)	57 (60)
Mean \pm S.D. age (yr)	60.4 \pm 12.2	61.7 \pm 11.9	58.0 \pm 12.4
Mean \pm S.D. weight (lbs)	215.0 \pm 60.6	209.0 \pm 58.8	226.0 \pm 62.6
No. (%) with comorbid diseases			
Hyperlipidemia	172 (64)	113 (65)	59 (62)
Obesity	80 (30)	54 (31)	26 (27)
Depression	57 (21)	33 (19)	24 (25)
CAD	54 (20)	36 (21)	18 (19)
GERD	47 (17)	32 (18)	15 (16)
Microalbuminuria	29 (11)	12 (7)	17 (18)
CHF	19 (7)	14 (8)	5 (5)
Stroke	5 (2)	5 (3)	0
None	12 (4)	9 (5)	3 (3)
Other	161 (60)	101 (58)	60 (63)

^aBP = blood pressure, CAD = coronary artery disease, CHF = congestive heart failure, GERD = gastroesophageal reflux disease.

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Table 2.
Blood Pressure Values in Patients with Diabetes Mellitus^a

Variable	Mean ± S.D. Blood Pressure (mm Hg)			95% CI for Difference	p
	Overall (n = 270)	BP Goal Met (n = 175)	BP Goal Not Met (n = 95)		
Overall					
SBP	127 ± 16	119 ± 10	142 ± 15	20.3–26.4	<0.0001
DBP	74 ± 11	70 ± 9	82 ± 8	9.7–14.2	<0.0001
Receiving antihypertensive agents					
SBP	127 ± 16	119 ± 10	142 ± 15	20.3–26.5	<0.0001
DBP	74 ± 11	70 ± 9	82 ± 8	9.6–14.3	<0.0001
Not receiving antihypertensive agents					
SBP	131 ± 19	121 ± 7	142 ± 22	5.2–38.5	0.03
DBP	79 ± 7	75 ± 5	84 ± 5	4.2–15.0	0.002

^aBetween-group comparisons were made with the two-sample t test. BP = blood pressure, CI = confidence interval, DBP = diastolic blood pressure, SBP = systolic blood pressure.

Table 3.
Use of Antihypertensive Agents^a

Variable	No. (%) Patients		
	Overall (n = 253)	BP Goal Met (n = 166)	BP Goal Not Met (n = 87)
Regimen type			
Monotherapy	89 (35)	55 (33)	34 (39)
Combination therapy	164 (65)	111 (67)	53 (61)
Drug given as monotherapy			
ACE	55 (62)	33 (60)	22 (65)
D	13 (15)	10 (18)	3 (9)
BB	14 (16)	8 (15)	6 (18)
CCB	5 (6)	3 (5)	2 (6)
ARB	2 (2)	1 (2)	1 (3)
Combination therapy			
D + ACE	22 (13)	15 (14)	7 (13)
D + BB	19 (12)	12 (11)	7 (13)
D + BB + ACE	19 (12)	12 (11)	7 (13)
BB + ACE	18 (11)	13 (12)	5 (9)
ACE + CCB	14 (9)	8 (7)	6 (11)
D + ARB	11 (7)	8 (7)	3 (6)
D + ACE + CCB	8 (5)	7 (6)	1 (2)
D + BB + ACE + CCB	7 (4)	5 (5)	2 (4)
D + BB + ARB	6 (4)	5 (5)	1 (2)
Infrequent combinations (<5 patients/regimen)	38 (23)	24 (22)	14 (26)

^aNumber in parentheses are percentages by column. ACE = angiotensin-converting-enzyme inhibitor, ARB = angiotensin-receptor blocker, BB = β-blocker, BP = blood pressure, CCB = calcium-channel blocker, D = diuretic.

From our bivariate analysis, meeting the glycosylated hemoglobin (HbA_{1c}) or low-density-lipoprotein (LDL) goals were significantly associated with meeting the blood pressure goal (Table 4; *p* = 0.04). By logistic regression, if the LDL goal

is achieved, the odds of achieving the blood pressure goal are 1.9 times greater (95% CI, 1.1–3.4) compared with not achieving the LDL goal after adjusting for age, sex, weight, and use of any antihypertensive agents. Glycemic and cholesterol measure-

ments are summarized in Table 5 for patients who did and did not meet blood pressure goals. In general, patients above their blood pressure goal had significantly higher total and LDL cholesterol.

When the blood pressure goal was not obtained, physicians made and documented treatment changes for 20 of 95 (21%) patients. Changes were not made or documented in 66 (69%) patients. Of these 66 cases where no changes were made or documented, the most common reason cited was that the physician was satisfied with the blood pressure control (41% of cases). The judgment to categorize physician response in this manner was based on chart notes such as “well controlled,” “fairly controlled,” “appears to be stable,” and other similar comments. Other reasons cited were a conservative approach (15%) and the presence of a comorbid disease that was felt to preclude the initiation or modification of antihypertensive treatment at that particular time. A reason for not making a treatment change could not be identified for 26 cases (39%). Of the 20 treatment changes identified, 11 (55%) involved dose increases, 4 (20%) involved adding a medication, and 5 (25%) involved the reinforcement of diet and exercise.

Discussion

This study found a high prevalence of hypertension in patients with type 2 diabetes mellitus who were being

treated by general internists in an academic community setting. In this cohort of patients, the prevalence of having both hypertension and

diabetes was 79%, which was consistent but somewhat higher than published estimates of 60–71%.²⁻⁵ It was encouraging that the rate of blood pressure control (<135/80 mm Hg) in this cohort was better than expected at 65% and comparable to previous reports of approximately 66% of patients with hypertension and diabetes who had their blood pressure controlled to <140/90 mm Hg.^{2,7} Although the target DBP in the intensive group in the HOT trial was 80 mm Hg, the mean actual achieved DBP was 81 mm Hg, resulting in less than 50% of patients achieving the target of ≤80 mm Hg.¹⁰

In ALLHAT, almost two thirds of the patients were receiving two or more antihypertensive agents, and blood pressure goal attainment rates were approximately 66%.¹¹ Similarly, in our cohort, combination therapy and goal attainment rates were approximately 65%. Although there was a numerically higher rate of

Table 4.

Prevalence of Glycemic and Lipid Goal Attainment^a

Variable	No. (%) Patients Meeting BP Goal (n = 164–169)	No. (%) Patients Not Meeting BP Goal (n = 91 or 93)	p
HbA _{1c} concentration			0.04
At goal (<7%) (n = 95)	69 (41)	26 (28)	
Not at goal (n = 167)	100 (59)	67 (72)	
Total cholesterol			0.11
At goal (<200 mg/dL) (n = 182)	122 (74)	60 (65)	
Not at goal (n = 76)	43 (26)	33 (35)	
LDL cholesterol			0.03
At goal (<100 mg/dL) (n = 141)	99 (60)	42 (46)	
Not at goal (n = 114)	65 (40)	49 (54)	
HDL cholesterol			0.11
At goal (>40 mg/dL) (n = 160)	109 (65)	51 (55)	
Not at goal (n = 101)	59 (35)	42 (45)	
Triglycerides			0.87
At goal (<150 mg/dL) (n = 128)	83 (49)	45 (48)	
Not at goal (n = 133)	85 (51)	48 (52)	

^aBetween-group comparisons were made with the chi-square test. BP = blood pressure, HbA_{1c} = glycosylated hemoglobin, HDL = high-density-lipoprotein, LDL = low-density-lipoprotein.

Table 5.

Mean ± S.D. Concentrations for Glycemic and Lipid Variables^a

Variable	Overall	Met BP Goal	Above BP Goal	p
HbA _{1c} (%)				
Overall	7.7 ± 1.6	7.6 ± 1.7	7.7 ± 1.5	0.75
At goal (<7%)	6.3 ± 0.5	6.4 ± 0.4	6.1 ± 0.5	0.04
Not at goal	8.4 ± 1.5	8.5 ± 1.7	8.3 ± 1.2	0.39
Total cholesterol (mg/dL)				
Overall	183.0 ± 48.7	175.4 ± 37.0	196.8 ± 62.5	0.003
At goal (<200 mg/dL)	159.5 ± 23.1	158.2 ± 22.7	162.1 ± 23.8	0.30
Not at goal	239.7 ± 47.4	224.3 ± 23.4	259.9 ± 61.7	0.003
LDL cholesterol (mg/dL)				
Overall	98.9 ± 33.1	94.3 ± 26.6	107.2 ± 41.3	0.008
At goal (<100 mg/dL)	77.0 ± 16.4	77.7 ± 15.9	75.4 ± 17.6	0.47
Not at goal	126.1 ± 28.2	119.7 ± 18.5	134.5 ± 35.8	0.01
HDL cholesterol (mg/dL)				
Overall	45.7 ± 14.6	45.9 ± 15.3	45.3 ± 13.5	0.75
At goal (>40 mg/dL)	53.2 ± 13.8	52.8 ± 14.6	54.2 ± 12.0	0.52
Not at goal	33.8 ± 4.5	33.3 ± 4.7	34.6 ± 4.0	0.14
Triglycerides (mg/dL)				
Overall	206.9 ± 231.8	189.5 ± 136.6	238.2 ± 341.3	0.19
At goal (<150 mg/dL)	102.7 ± 27.9	101.7 ± 28.5	104.5 ± 27.1	0.59
Not at goal	307.2 ± 290.6	275.3 ± 145.7	363.6 ± 440.6	0.18

^aBetween-group comparisons were made with the two-sample t test. BP = blood pressure, HbA_{1c} = glycosylated hemoglobin, HDL = high-density-lipoprotein, LDL = low-density-lipoprotein.

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blood pressure goal attainment in patients who received combination treatment (67%) as compared to monotherapy (61%), this difference was not significant. Taken together, this information implies that combination therapy is a clinically appropriate strategy in many patients, but additional factors must be considered for each patient.

We estimate that physicians did not make changes in antihypertensive regimens in patients not achieving adequate blood pressure control in about 69% of patients. Our evaluation indicates that the most common reason for this was that they were satisfied with their patients' blood pressure. Perhaps satisfaction of inadequate blood pressure control may stem from the patients' blood pressure only being slightly higher than the recommended goal. However, each mm Hg may be important, and the goal is to be <135/80 mm Hg for patients with diabetes, which is even lower than the recommended goal of <140/90 mm Hg for patients who do not have diabetes. This 5–10-mm Hg difference may help patients with diabetes avoid complications of concurrent disease states, and it is important that health care providers monitor blood pressure accordingly. Because it is difficult to assess the overall blood pressure status of a patient in one office visit, it is understandable that some health care providers may take a conservative approach in making changes to antihypertensive regimens. However, in further analysis of our data, only 15% of physicians failed to make changes because of a conservative approach, while approximately 40% of physicians indicated that they were satisfied with their patients' blood pressure when the goal was not achieved.

Our findings also reinforce the variety of factors that are important with respect to the overall management of patients with type 2 diabetes mellitus. After adjusting for con-

founders such as age, sex, weight, and antihypertensive usage, the odds of achieving the blood pressure goal in patients who achieved the LDL cholesterol goal were almost double those of patients who failed to achieve the LDL cholesterol goal. Unadjusted analysis also indicated that meeting the blood pressure goal was more likely in patients who achieved their HbA_{1c} goal.

There are several limitations to this study because it was retrospective. Medical records are often not complete, and helpful information such as diet, exercise, and other factors associated with blood pressure control may be left out of the record. This type of study draws from information that has been previously documented, and it is impossible to incorporate data that have been left out of the chart or obtain clarifications on confusing chart notes. Also, a single blood pressure measurement cannot adequately determine the achievement of a patient's blood pressure goal. Self-monitoring of blood pressure by patients performed outside of our clinic was not evaluated or addressed in our work.

As described in the methods section, we took deliberate steps to minimize the chance of overstating findings. Assessments were made using conservative criteria, and evaluations without adequate supporting information were avoided. As described, another potential limitation to the interpretation of these findings is that a variety of health care providers were involved in delivering care to these patients. Resident physicians had a significant role in the delivery of care we observed. However, attending physicians oversee all activities of the residents and have final approval of treatment decisions. Clinical pharmacist support is available to all physicians, and therefore to all patients, at the clinic. For these reasons, the data were not stratified to test the effect of these issues as independent variables.

Medication adherence was not the focus of this study and was not explicitly addressed. However, as described in a recent systematic review, adherence represents one of many important challenges in the appropriate management of patients with hypertension.¹⁵ This issue should be addressed as a routine component of care as clinicians work with their patients.

Optimizing blood pressure control in patients with diabetes is a complex and multifactorial challenge. However, there are considerable clinical trial evidence and guideline support for aggressively pursuing this objective. Approximately one third of patients in this study had uncontrolled blood pressure. Nonmedication-related factors that appear to be associated with reaching blood pressure goals include achieving LDL cholesterol and HbA_{1c} goals. Patients, physicians, and other health care providers must increase the vigilance of their hypertension management with respect to overall patient monitoring and modification of antihypertensive regimens.

Conclusion

Among ambulatory care patients with diabetes, 79% also had hypertension. Hypertension was controlled in 65% of patients with that disorder.

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