

The Need for Improved Medical Management of Patients With Concomitant Hypertension and Type 2 Diabetes Mellitus

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Objectives: To determine level of blood pressure (BP) control and to evaluate hypertension management strategies in patients with hypertension and type 2 diabetes mellitus.

Study Design: Retrospective review of 2 consecutive years of pharmacy and medical insurance claims data and medical charts from patients participating in 10 health plans in 9 states.

Patients and Methods: Patients 18 years and older with a medical or pharmacy claim related to hypertension were identified and assessed for inclusion in the database. A random sample of medical charts was reviewed to confirm the diagnoses of hypertension and diabetes mellitus and degree of BP control and to assess the prevalence of other cardiovascular disease risk factors and current antihypertensive treatment.

Results: Type 2 diabetes mellitus was documented in 977 patients. The mean age was 64.3 years, and 55.1% were women. A BP goal of less than 130/85 mm Hg was achieved in 192 patients (19.7%), and a BP goal of less than 130/80 mm Hg was achieved in 135 patients (13.8%). Fifty-two percent of patients had dyslipidemia, and 87.6% were overweight, obese, or morbidly obese; tobacco use was documented in 19.5%.

Conclusions: Hypertensive diabetic patients are frequently not treated to their goal BP, which requires the use of 2 or more agents in most patients. Quality improvement programs should emphasize the importance of treating hypertensive diabetic patients to their goal BP, as well as controlling other major cardiovascular disease risk factors, such as smoking, dyslipidemia, and overweight or obesity, that are prevalent among these high-risk patients.

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A recent survey released by the American Diabetes Association reports that cardiovascular disease is a major unrecognized problem in patients with type 2 diabetes mellitus in the United States.¹ While heart disease and stroke are the leading causes of death among people with diabetes mellitus, 68% of diabetic patients are not aware of the significant risk posed by cardiovascular disease. Fortunately, more than 90% of physicians surveyed are aware of the link between diabetes mellitus and cardiovascular disease, although there is recognition of the need to become more aggressive in treating not only blood glucose but also the multiple cardiovascular risk factors in these high-risk patients, including high blood pressure (BP), high blood cholesterol, smoking, and obesity (Table 1).

Hypertension and diabetes mellitus are common comorbidities that together result in a markedly increased risk for cardiovascular and renal complications.² Hypertension is diagnosed in more than 50% of patients with diabetes mellitus,^{3,4} and diabetes mellitus is almost 2.5 times as likely to develop in people with hypertension as in normotensive individuals.⁴ Not only is each of these diseases a major risk factor for target organ disease, but they also work synergistically to increase morbidity and mortality.² Recent epidemiologic data indicate that the risk of death due to cardiovascular disease in patients with type 2 diabetes mellitus is 2 to 4 times higher than in patients without diabetes mellitus.⁵ Up to 75% of cardiovascular and renal complications in patients with diabetes mellitus are attributable to hypertension.³

As reported by Saaddine et al,⁶ US population-based surveys, including the National Health and Nutrition Examination Survey conducted from 1988 to 1994, demonstrate that a gap exists between recommended diabetes care and the care that patients actually receive. Data from the 1999-2000 National Health and Nutrition Examination Survey demonstrate that only 25% of hypertensive diabetic patients had their BP controlled to less than 130/85 mm Hg and that only 31% of all hypertensive individuals had their BP controlled to less than 140/90 mm Hg.⁷

Aggressive control of BP in patients with diabetes mellitus will require the use of at least 2 agents in most patients.^{2,8-10} Effective control of hypertension in diabetic patients has a significant effect on mortality and morbidity; therefore, appropriate medication selection

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is an area of great interest to clinicians. A consensus has emerged that agents that block the renin-angiotensin system (angiotensin-converting enzyme [ACE] inhibitors and angiotensin II receptor blockers) are among the most effective and safe drugs for lowering BP and for providing renal protection in hypertensive diabetic patients. Many studies demonstrate the efficacy of renin-angiotensin system blockers in slowing the development and progression of diabetic nephropathy and in reducing macrovascular and microvascular complications in hypertensive diabetic patients. Selection of one of these agents as first-line treatment is now established practice for all patients with diabetes mellitus.^{2,8-10}

The primary goals of this study were to determine cardiovascular risk factors, level of BP control, and hypertension management strategies in patients with hypertension and type 2 diabetes mellitus enrolled in population-based healthcare settings. The then-current Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC VI)¹¹ recommendation of a BP goal of less than 130/85 mm Hg for hypertensive diabetic patients was used.

METHODS

Study Population

From January 1, 1999, to December 31, 2001, medical and pharmacy claims data were collected from 10 insurance plans that provide healthcare coverage for more than 4 million people from 9 states (Alabama, California, Florida, Massachusetts, New York, Ohio, Oklahoma, Pennsylvania, and Texas). All patients 18 years and older with diagnoses of hypertension or type 2 diabetes mellitus as defined by *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)* codes or a pharmacy claim for an antihypertensive or antidiabetic agent within the past 12 months were assessed for inclusion in the database. Exclusion criteria were the use of antihypertensive agents for ischemic heart disease, myocardial infarction, congestive heart failure, arrhythmia, migraine, lower extremity edema, benign prostatic hypertrophy, and anxiety or panic disorder. Patients were excluded if they had renal failure or their medical record was not available. The population represented a regionally and ethnically diverse hypertensive population.

Data Collection and Analysis

This retrospective analysis was conducted as part of

Table 1. Major Risk Factor Management Goals in Patients With Diabetes Mellitus*

Risk Factor	Treatment Goal
Cigarette smoking	Complete cessation
Blood pressure	< 130/80 mm Hg
Low-density lipoprotein cholesterol	< 100 mg/dL
Triglycerides 200-499 mg/dL	Non-high-density lipoprotein cholesterol < 130 mg/dL
High-density lipoprotein cholesterol <40 mg/dL	Raise high-density lipoprotein cholesterol
Prothrombic state	Low-dose aspirin in patients with coronary heart disease and other high-risk patients
Glucose	Hemoglobin A _{1c} < 7%
Overweight or obesity	Lose 10% of body weight in 1 year
Physical inactivity	3-4 h/wk (dependent on patient status)

SI conversion factors: To convert cholesterol to millimoles per liter, multiply by 0.0259; triglycerides to millimoles per liter, multiply by 0.0113. *Recommendations from the American Diabetes Association; the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure; and the National Cholesterol Education Program Adult Treatment Panel III.

an ongoing multiphasic hypertension quality improvement program for participating health plans.^{12,13} A random sample of the hypertensive population was selected for medical chart review to confirm the diagnoses of hypertension and diabetes mellitus and to assess the prevalence of other cardiovascular disease risk factors, presence of comorbidities, and degree of BP control. The BP goal of less than 130/85 mm Hg was defined according to the then-current JNC VI¹¹ guidelines for hypertensive patients with diabetes mellitus. Risk factors for cardiovascular disease, identified according to the same report, were smoking, dyslipidemia, age older than 60 years, sex (ie, male and postmenopausal female), and a family history of cardiovascular disease. Data on medication use were based on prescription claims, and medical chart reviews were used to confirm antihypertensive drug therapy; dyslipidemia and other comorbidities were identified using *ICD-9-CM* codes and medical chart documentation. Descriptive statistics were run for data on medication use and BP control collected during medical chart reviews. A minimum of 411 randomized medical charts was desired from each health plan, based on the 2-tailed test of significance between 2 proportions with $\alpha = .05$ and 80% power. A

Table 2. Demographic Characteristics and Cardiovascular Disease Risk Factors in 977 Diabetic Patients*

Characteristic or Risk Factor	Value
Age, mean ± SD, y (range)	64.3 ± 11.6 (25-96)
Sex	
Men	439 (44.9)
Women	538 (55.1)
Body mass index, mean ± SD (n = 276) [†]	32.3 ± 6.9
Age > 60 y	618 (63.3)
Tobacco use	191 (19.5)
Dyslipidemia	508 (52.0)
Family history of cardiovascular disease	243 (24.9)
History of coronary artery disease	128 (13.1)
History of angina	116 (11.9)
History of stroke	81 (8.3)
History of heart failure	78 (8.0)
History of peripheral arterial disease	63 (6.4)
Presence of left ventricular hypertrophy	32 (3.3)
Blood pressure control to	
< 130/85 mm Hg	192 (19.7)
< 130/80 mm Hg	135 (13.8)
Blood pressure control by No. of antihypertensive prescriptions, controlled/uncontrolled (% of controlled + uncontrolled) (n = 787) [‡]	
0	0/31 (0)
1	67/232 (22.4)
2	59/205 (22.3)
≥ 3	32/161 (16.6)

*Data are given as number (percentage) unless otherwise indicated.
[†]Body mass index calculated as weight in kilograms divided by the square of height in meters.
[‡]Blood pressure control to less than 130/85 mm Hg. Prescription information was not available from 1 of the health plans.

total of 707 263 patients with hypertension were identified using electronic claims data; 4414 of these patients were randomly selected for medical chart review.

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RESULTS

A diagnosis of type 2 diabetes mellitus was documented in 977 hypertensive patients. Their demographic characteristics, cardiovascular risk factors, and comorbidities are shown in **Table 2**. Most patients (87.5%) were overweight (25.3%), obese (50.3%), or

morbidly obese (11.9%). Documented tobacco use was nearly 20%. Most patients were older than 60 years. Of the 977 patients, 19.7% had BP controlled to less than 130/85 mm Hg, and 13.8% had BP controlled to less than 130/80 mm Hg.

Prescription claim information was available from 787 patients (80.6%). Using claims data from the most recent month of the study, 299 patients (38.0%) had claims for 1 antihypertensive agent (single therapy), 264 patients (33.5%) had claims for 2 agents (dual therapy), and 193 patients (24.5%) had claims for 3 or more agents (multiple therapy). Analysis of BP control by number of prescriptions shows that most patients had uncontrolled hypertension, regardless of single, dual, or multiple therapy. There remains a significant opportunity for improvement in the treatment of hypertensive patients with diabetes mellitus.

The most commonly prescribed antihypertensive classes were ACE inhibitors (45.9%), followed by diuretics (36.3%), calcium channel blockers (33.0%), β-blockers (24.3%), angiotensin II receptor blockers (9.8%), α-blockers (7.0%), and other antihypertensive drugs (3.3%). Angiotensin-converting enzyme inhibitor-based regimens were prescribed for 404 patients (51.3%) and diuretic-based regimens for 352 patients (44.7%). Fixed-dose combination therapy with an ACE inhibitor or a calcium channel blocker accounted for 1.4% of prescriptions.

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DISCUSSION

These data show that there is a large population of diabetic patients with hypertension receiving antihypertensive therapy in whom BP control remains inadequate. Furthermore, there is a need for more aggressive medical management of hypertensive diabetic patients, many of whom have other cardiovascular risk factors, including dyslipidemia, obesity, and family history of coronary artery disease.

Low rates of BP control are of concern given the evidence relating high BP to increased cardiovascular and renal disease in diabetic patients. Achieving target BP appears to present a unique challenge, and this study suggests that more aggressive treatment will be necessary to help patients in this high-risk population reach the appropriate BP goal. These data also suggest that numerous modifiable risk factors are not treated adequately according to 2001 American Diabetes Association treatment recommendations.¹⁴ These data can be used to identify and prioritize opportunities for improving the effectiveness of care in a high-risk population.

The low rates of effective treatment relative to risk factor goals are similar to those of other studies¹⁵⁻²⁰ among diabetic patients. For example, a recent study¹⁵ of 601 randomly selected patients with type 2 diabetes mellitus demonstrated that the proportions of patients screened for hypercholesterolemia and hypertension and treated aggressively for above-goal BP (78%) and low-density lipoprotein cholesterol levels (38%) were significantly lower than for hyperglycemia treatment (92%) ($P < .001$). These results are echoed in another study²⁰ that compared 274 hypertensive patients with diabetes mellitus and 526 hypertensive patients without diabetes mellitus and showed that patients with diabetes mellitus received less intensive treatment and had worse BP control than the patients without diabetes mellitus.

In our study, patients had a mean body mass index (calculated as weight in kilograms divided by the square of height in meters) of 32. Obesity, defined as a body mass index of 30 or higher, is associated with increased mortality from coronary artery disease and a 50% to 100% increased risk of death from all causes (but primarily from cardiovascular disease) compared with patients with a body mass index of 20 to 25.²¹ Current guidelines include an emphasis on the value of exercise in contributing to weight loss and reduction of cardiovascular risk factors.¹⁰ For example, a recent study²² in a cohort of 2896 adults with diabetes mellitus showed that regularly walking 30 minutes per day was associated with a 50% reduction in cardiovascular and total mortality.

In our study, tobacco use was documented in nearly 20% of patients. Cigarette smoking is the leading preventable cause of death and a major risk factor for cardiovascular disease, and the use of effective strategies to reduce the prevalence of tobacco use is therefore a high priority for primary and secondary prevention of cardiovascular disease. Every smoker should be urged to quit. Routine practice of diabetes care must incorporate the use of effective systems (screening for smoking status; advice, counseling, and support regarding cessation; and follow-up) for implementing smoking cessation guidelines.²³

Diabetic patients with coronary artery disease, dyslipidemia, or heart failure may need as many as 9 separate medications each day. Diabetes mellitus itself often requires 2 to 3 separate daily medications.¹⁷ Hypertensive diabetic patients may require at least 2 to perhaps 5 separate drugs to achieve a BP goal of 130/80 mm Hg.²⁴ Complex multiple drug regimens are needed to control these numerous comorbidities in hypertensive diabetic patients, including the need for rigorous control of BP. Because renin-angiotensin system blockade should be the initial therapeutic intervention, a logical

approach to lowering BP is to combine a low-dose diuretic with an ACE inhibitor or an angiotensin II receptor blocker.^{8,25,26} In addition, evidence from randomized controlled trials shows that calcium channel blockers reduce cardiovascular events in patients with diabetes mellitus; these drugs are a safe and effective addition to a renin-angiotensin system blocker to further improve BP control.^{8,25} It is increasingly recognized that lowering BP to target levels should be the overwhelming primary objective, regardless of the therapeutic agents chosen for antihypertensive combination therapy.^{8,25,26}

The percentage of patients achieving BP control in this study differs slightly from that in other reports. For example, the nationally representative sample of the civilian population from the National Health and Nutrition Examination Survey shows a rate of BP control of 25.4% in patients with hypertension and diabetes mellitus.⁷ In contrast, this study includes patients from 9 US states, and the findings can be generalized only to the patient population receiving therapy as reported in the pharmacy or medical claims database, which may account for the lower (19.7%) BP control rate.

As with all retrospective analyses of claims databases and medical charts, this study has several limitations. First, the study population included only patients covered by health insurance; therefore, the results may not be generalizable to the general population or to other healthcare settings. Coding errors or lack of documentation in medical charts may have resulted in missing data or the exclusion of some hypertensive patients with diabetes mellitus. It was outside the scope of the study to include lipid or hemoglobin A_{1c} values. Although these data were not available, clinical variables concerning risk factors and the prevalence of comorbid conditions were gathered to interpret the results of this study. Finally, as the JNC VI¹¹ guidelines were in effect during the study, it was not possible to measure the effect of subsequent guidelines on the treatment of hypertensive patients with diabetes mellitus and the ability of these patients to reach BP control given the new goal and treatment recommendations.

Based on the data generated from this analysis, the 10 health plans that contributed data to this study are developing organization-wide intervention programs that include the following: (1) education sessions for practitioners that focus on the importance of treating patients to goal and choosing optimal antihypertensive therapy, (2) medical management guidelines for practitioners, (3) physician profiling of prescribing patterns, (4) BP monitoring kits for patients, and (5) patient education. Each plan will continue follow-up for 1 year to evaluate the effect of the intervention initiative.

 CONCLUSIONS

The high mortality and morbidity rates for patients with coexisting diabetes mellitus and hypertension indicate the need for aggressive treatment to lower BP. The recommended BP goal of less than 130/80 mm Hg requires the use of 2 or more agents in most patients. It appears that diabetic patients frequently are not treated to their BP goal. Antihypertensive treatment must be aggressive and strategically used early and intensively, yet it must be simultaneously practical to meet the challenge of protecting hypertensive diabetic patients against the risk of cardiovascular complications. Furthermore, intensified efforts must be given to modification of other major cardiovascular risk factors in diabetic patients, such as smoking, dyslipidemia, and overweight or obesity, that are prevalent among these high-risk patients.

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