Compliance with National Guidelines in Patients with Diabetes in a Family Practice Clinic

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Study Objective. To assess whether clinicians are treating patients with both type 2 diabetes and hyperlipidemia according to national goals for blood pressure, low-density lipoprotein cholesterol (LDL), and glucose levels.

Design. Retrospective chart review.

Setting. University-based family medicine teaching practice.

Patients. One hundred twenty-four patients with both type 2 diabetes and hyperlipidemia.

Measurements and Main Results. Sixty-nine patients (58%) met the National Cholesterol Education Program Adult Treatment Panel II's goals for LDL (< 130 mg/dl for primary prevention and < 100 mg/dl for secondary prevention). Only 47 patients (38%) were in compliance with national standards for both systolic and diastolic blood pressures. The mean hemoglobin A_{1c} (A1C) level was 8.6%; 27 patients (21.8%) had A1C levels below 7%.

Conclusion. A high percentage of patients in our family practice clinic met their goals for reducing lipid levels, but more aggressive therapy is necessary to attain glucose and blood pressure goals. Data from this study emphasize the need for understanding which factors influence clinicians' treatment decisions.

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In the United States, cardiovascular disease (CVD) is responsible for 40% of all deaths, and heart disease is the leading cause of death for those aged 35 and older.[1] Type 2 diabetes is a risk factor for CVD and is estimated to affect 16 million people in the United States alone.[2] The leading cause of death in persons with diabetes is CVD.[3, 4] In fact, diabetes is associated with a 2–4-fold increased risk for coronary heart disease (CHD).[2, 5, 6] Patients with type 2 diabetes have been shown to have an equal, if not greater, risk for cardiac events than those without diabetes who have CVD.[7–10] Some of the modifiable risk factors for CVD complications are hypertension, dyslipidemia, and hyperglycemia. However, we found few studies that describe CVD goal attainment in primary care practices among patients with type 2 diabetes and known hyperlipidemia.[3, 11]

Diabetes and hypertension are both related to development of atherosclerosis and cardiovascular damage, and serious events are more than twice as likely to occur in patients with both diabetes and hypertension than in patients with either condition alone.[6, 12] Also, patients with diabetes and hypertension show an increase in stroke-related deaths.[6] Dyslipidemia is another established risk factor for CVD. Lipid management is targeted toward reducing low-density lipoprotein cholesterol (LDL), raising high-

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density lipoprotein cholesterol (HDL), and lowering triglycerides in order to reduce macrovascular disease and mortality in patients with diabetes.[4] The National Cholesterol Education Program (NCEP) Adult Treatment Panel (ATP) offers a fundamental approach to treating high cholesterol levels. According to the NCEP ATP III, individuals with diabetes have a risk equivalent to those without diabetes but with known CHD.[13] The American Diabetes Association (ADA) and the NCEP recommend an LDL goal of below 100 mg/dl, especially for patients with diabetes who have risk factors for CHD.[4, 13]

Few published studies have evaluated achievement goals for patients with diabetes as outlined by the ADA, NCEP, and the sixth Joint National Commission on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC VI).[13–17] Recently, data from the third National Health and Nutrition Examination Survey (NHANES III) and the Behavioral Risk Factors Surveillance System revealed that 65.7% of patients with diabetes had blood pressures below 140/90 mm Hg, 42% had LDL levels below 130 mg/dl, and 18% had hemoglobin A_{1c} (A1C) levels below 9.5%.[14]

The primary goal of this study was to determine whether patients with type 2 diabetes and hyperlipidemia are treated according to recommended national goals for blood pressure, LDL, and glucose control. We used the NCEP II and the 1999 ADA standards for medical care in patients with diabetes as our treatment guidelines.[15, 17]

Methods

This was a cross-sectional, retrospective analysis to evaluate the pharmacotherapy and CVD risk factors in a random sample of patients with both type 2 diabetes and hyperlipidemia. Data were obtained from a large university-based family medicine teaching practice. Medical charts were selected randomly using ICD-9-CM (*International Classification of Diseases, 9th revision, Clinical Modification*) codes for type 2 diabetes and hyperlipidemia. We set a target of reviewing 150 charts and requested a computer-generated list of randomly chosen patients. Our goal was to achieve reasonably good point estimates as indicated by a 95% confidence interval. A total of 124 charts, out of 448 charts identified, were reviewed. All data were entered into a computer and cross-referenced for accuracy. A physician and a research assistant reviewed the charts.

The family practice site where chart review was performed consisted of approximately 20 faculty physicians and physician assistants and 30 resident physicians who see patients on a regular basis. The breakdown of payer mix for this practice at the time of chart review was Medicare (15%), managed care (63%), commercial insurance (9%), Medicaid (8%), self-pay (4%), and workers' compensation (1%). This site has a total patient population of about 20,000. Over the past several years, approximately 55,000 patients have visited the clinic annually.

Data were collected on age, race, height, weight, and risk factors, including documented CHD (defined as history of angina, atherosclerosis, myocardial infarction, angioplasty, etc.). Family history was obtained for CHD (defined as heart attack before age 55 in father or brothers or before age 65 in mother or sisters), along with each patient's medical history with regard to hypertension, diabetes mellitus, current tobacco use, and HDL levels. Laboratory data, including lipid panels and A1C levels, and blood pressure were obtained. Aspirin therapy and pharmacotherapy for hypertension, cholesterol, and glucose were identified.

The national standards used in this study included blood pressure goals identified in the ADA Clinical Practice Recommendations for 1999.[15] Hypertension was defined as systolic blood pressure of 140 mm Hg or greater or diastolic blood pressure of 90 mm Hg or greater.[15] The ADA and the JNC VI recommend that patients with diabetes maintain their blood pressure below 130/85 mm Hg.[15, 16] The NCEP II guidelines, which we regarded as the national standards at the time of chart review, called for LDL levels below 130 mg/dl for patients without a history of CHD (but with two or more risk factors) and below 100 mg/dl for patients with CHD.[17] The guidelines treated HDL as a positive risk factor, provided a patient's level was below 35 mg/dl. The total cholesterol and triglyceride goals were each below 200 mg/dl. The 1999 ADA recommendations called for A1C levels below 7%.[15]

Descriptive statistics were calculated for all sociodemographic and clinical data. Logistic regression was used to identify predictive variables for each of the primary outcomes (blood pressure, lipid and A1C levels).

Results

This research study encompassed 124 charts

Table 1. Patient Demographics

Characteristic	No. (%)
Sex	
Men	54 (43.5)
Women	70 (56.5)
Race	
African-American	67 (54.0)
Caucasian	54 (43.6)
Hispanic	3 (2.4)
Postmenopausal women	51 (72.9)[a]
Taking hormone replacement therapy	23 (32.9)[a]
	Mean (range)
Age (yrs)	59.1 (44–87)
Height (in.)	
Men	69.7 (61–79)
Women	64.6 (55–78)
Weight (lbs)	
Men	218.3 (138–411)
Women	200.1 (116–331)
Body mass index	
Men	31.7 (26.1–46.4)
Women	33.8 (27.0–38.3)

[a]Percentage of the 70 women (excludes men).

Table 2. Drug Therapy of the 124 Patients

Drug or Drug Class	% of Patients Receiving Drug
Diuretic	28.3
α-Blocker	5.6
β-Blocker	9.7
ACE inhibitor	40.3
Angiotensin II receptor blocker	7.3
Calcium channel blocker	18.5
Sulfonylurea	71.0
Metformin	29.8
Troglitazone, rosiglitazone	10.5
Insulin	25.8
Aspirin	46.0
HMG CoA reductase inhibitor	36.3
HMG CoA reductase inhibitor + fibrate	1.6

ACE = angiotensin-converting enzyme; HMG CoA = 3-hydroxy-3-methylglutaryl coenzyme A.

Table 3. Clinical Data of the 124 Patients

Characteristic	No. (%) of Patients
Family history of CHD	30 (24.2)
Current CHD	27 (22.6)
Hypertension	86 (69.4)
	Mean ± SD
Blood pressure (mm Hg)	
Systolic	135.5 ± 20.8
Diastolic	75.0 ± 10.3
Lipid panel (mg/dl)	
Total cholesterol	201.3 ± 47.8
LDL	119.0 ± 42.3
HDL	40.7 ± 11.2
Triglycerides	219.2 ± 136.3
Hemoglobin A_{1c} (%)	8.63 ± 2.3
	% of Patients ± SD
HDL < 35 mg/dl	40 ± 32.8
Smoker	23 ± 18.5

CHD = coronary heart disease; LDL = low-density lipoprotein cholesterol; HDL = high-density lipoprotein cholesterol.

that met study criteria and were reviewed. All patients had the diagnoses of both diabetes and hyperlipidemia. In addition, 27 patients were diagnosed with both diabetes and CHD. Selected characteristics of all patients are outlined in Table 1. More than half were women, and the mean age was younger than 60 years. Blood pressure was documented in all patient charts; 58 charts indicated a diagnosis of hypertension that required pharmacotherapy. Cholesterol panels and A1C values were available for 119 medical records. Body mass index was calculated for 121 patients, based on weight and height as recorded in the charts. Most of the patients whose charts we reviewed were obese (82% had a body mass index $\geq$ 27 kg/m^2).

Of the 124 patients whose charts we reviewed, mean systolic blood pressure was 135.5 mm Hg (range 90–200 mm Hg) and mean diastolic blood pressure was 75.0 mm Hg (range 52–100 mm Hg). Seventy-six patients (61.3%) had systolic blood pressures above goal (> 130 mm Hg), and 19 patients (15.4%) had uncontrolled diastolic blood pressures (> 85 mm Hg). Only 47 of all patients (37.9%) met national goals for both systolic blood pressure and diastolic blood pressure (< 130/85 mm Hg). Table 2 shows the numbers of patients taking drugs to regulate their blood pressure by specific class. The average number of blood pressure drugs/patient for those who achieved their blood pressure goal was 1.4. Of those patients, nearly 50% were prescribed either an angiotensin-converting enzyme inhibitor or an angiotensin II receptor blocker.

The mean ± SD levels for total cholesterol, LDL, HDL, and triglycerides are shown in Table 3. Approximately 55% and 60% of patients had total cholesterol and triglyceride levels, respectively, below 200 mg/dl. Using an LDL level of below 130 mg/dl for primary prevention (no CHD history) and below 100 mg/dl for secondary prevention (positive CHD history) in patients with diabetes, 69 (58%) of 119 patients achieved their target end points. The goal for LDL was attained in 34 (64.2%) of 53 men and 35 (53%) of 66 women. Among the 27 patients

with both type 2 diabetes and CHD, LDL goal was achieved in 12 (44.4%). Thirty-six percent of all patients had LDL levels below 100 mg/dl, as advocated by the ADA and ATP III guidelines (these guidelines were recently published and were not available at the time of chart review).

Of patients meeting the LDL goal for primary prevention, 22 (31.9%) of 69 did not require additional lipid-lowering therapy. Fifty-three percent of women who received antihyperlipidemic drugs were within the LDL goal of 130 mg/dl, and 64% of men receiving these agents also met the LDL goal. Of patients who had started lipid-lowering therapy, 94% of women and 98% of men had lipid blood panels documented in their medical charts.

The mean A1C was 8.6% (range 4.5–17%); 21.8% had A1C levels below 7%. In terms of glucose pharmacotherapy, 71% of patients were taking a sulfonylurea drug, 30% metformin, and 11% an insulin sensitizer. Twenty-six percent of patients were prescribed insulin.

Logistic regression was used to examine associations among body mass index, family history of CHD, sex, age, and smoking with the outcome variables. The outcomes of interest were blood pressure, A1C, and LDL levels. Only blood pressure was significantly associated with any of the predictor variables. Younger age, lower body mass index, and not smoking were correlated ($p<0.05$) with blood pressure below 130/85 mm Hg. A high degree of intercorrelation between the predictor variables (high multicollinearity) and the small sample size did not permit additional multivariate analysis.

Discussion

People with diabetes are 2–4 times more likely to die from complications of CVD than people without diabetes.[6] To reduce the burden of CVD in patients with diabetes, interventions should be aimed at reducing risk factors, such as hypertension, dyslipidemia, and hyperglycemia. It has been estimated that hypertension affects 20–70% of adult patients with type 2 diabetes. Our chart review revealed that 46.8% of patients had a diagnosis of hypertension.[5, 6] Patients with type 2 diabetes often develop hypertension as part of a metabolic syndrome that includes obesity, hyperglycemia, and dyslipidemia.[4–6] In fact, a large majority (82%) of patients in this study were obese, according to the ADA's definition of obesity (body mass index $\geq$ 27 kg/m^2).[19] Hypertension substantially increases the risk for macrovascular and microvascular complications, including stroke and coronary artery disease.[15] Thus, aggressive treatment to lower both systolic and diastolic blood pressure is warranted, with a blood pressure goal of below 130/85 mm Hg. Approximately half of the charts reviewed indicated systolic blood pressures above 140 mm Hg.

Antihypertensive agents have been shown to be effective in reducing CVD events.[4] Research supports the use of these drugs to reduce risks for CVD complications and not simply for the purpose of decreasing blood pressure.[20] Data indicate that more than 65% of patients with concomitant diabetes and hypertension will require two or more antihypertensive drugs to achieve the newly suggested target blood pressure goal of 130/80 mm Hg.[4, 18] Our chart review revealed that a variety of antihypertensive drugs were prescribed for this purpose, although angiotensin-converting enzyme inhibitors were prescribed more frequently than other agents (Table 2).

Cholesterol patterns in patients with type 2 diabetes include elevated triglyceride levels, decreased HDL levels, and LDL levels comparable to those of patients without diabetes.[21] Over 40% of the charts we reviewed reflected elevated LDL or triglyceride levels. Many clinical trials have indicated that patients in primary care settings do not achieve lipid targets.[11, 22–25] The NHANES III found that only 18% of patients achieved the target LDL goal of 100 mg/dl.[25] Analysis of this chart review revealed that 58% of patients met goal, using the NCEP ATP II guidelines for LDL (< 100 mg/dl for secondary prevention and < 130 mg/dl for primary prevention). An LDL level below 130 mg/dl was attained in 38.9% of the population. Whereas LDL goals were not reached in all patients, the results of this study show better success than other published data.[11, 24]

In patients with both type 2 diabetes and hyperlipidemia, pharmacologic treatment should be administered if lifestyle modifications and improved glucose control inadequately change cholesterol levels.[4] Patients with preexisting CHD have been shown to be inadequately treated with pharmacotherapy.[11] In the patients whose charts we reviewed, the mean HDL level was 40.4 mg/dl, which is above the value recommended by the NCEP II guidelines (35 mg/dl). Thirty-six percent of patients had documented use of 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitors.

Reducing the A1C value to 7% or below is

associated with fewer long-term microvascular complications than higher A1C values; for every 1% absolute reduction in A1C the risk of such complications is reduced by 15–30%.[4] The United Kingdom Prospective Diabetes Study indicated a 35% reduction in the risk of complications for every percentage point decrease in A1C.[31] An A1C above 8% is associated with a higher risk for complications.[4, 14] The mean A1C value in our study was 8.6% (range 4.5–17.1%). Thus, more aggressive treatment is necessary. Seventy-one percent of the patients were receiving a sulfonylurea drug, and about one third were taking metformin. Only sulfonylureas and metformin have been shown to reduce microvascular complications; in obese patients, metformin provides additional benefits with regard to macrovascular risks.[26] Metformin and sulfonylurea agents can be expected to lower A1C by at least 1–2% individually and to a higher extent in combination, depending on where the patient is in the course of therapy.[26]

The ADA recommends that all patients with diabetes receive aspirin 75–325 mg/day.[27] We collected data on aspirin prophylaxis and found that aspirin use was documented in the medical records of 46% of patients. As aspirin is an over-the-counter drug, its use may not have been documented in many charts, which may represent a limitation of our chart review.

Analysis of associations among selected predictor variables and successful control of blood pressure, A1C, and LDL cholesterol revealed that blood pressure control was significantly associated with younger age, lower body mass index, and not smoking. These associations were as expected. The nature of our data and the small sample size did not permit further multivariate analysis. Thus, this study did not generate a model for predicting which patients are likely to succeed in meeting recommended goals for blood pressure, cholesterol, and glucose control. Identification of patients who are less likely than others to achieve these goals would help in the development of successful interventions. Further research involving larger numbers of patients with diabetes is indicated.

Limitations to the study, in addition to its small sample size, include selection bias in our chart review. We chose patients who already had a diagnosis of hyperlipidemia, as this population would be more likely to receive treatment than patients who had not been diagnosed with hyperlipidemia. However, the primary intent of the chart review was in fact to examine how primary care physicians were treating a population of patients with both type 2 diabetes and hyperlipidemia. There is also an inherent weakness in the study's cross-sectional, retrospective design. A significant time lag occurs in identifying which patients are in need of treatment or are achieving goals. This time lag can be up to a year or more because of time to treat, difficulties tolerating drugs, patient noncompliance, and follow-up. A longitudinal study may yield better results, and a follow-up chart review in several clinics would be useful.

Clinical trials have revealed that lipid reduction and blood pressure lowering in patients with type 2 diabetes are associated with reductions in cardiovascular events.[28] Some data support more aggressive treatment by physicians and more counseling for CVD risk factors in patients with diabetes compared with patients without diabetes.[3, 29] Our results in a primary care setting indicate that a high percentage of patients met their goals for lipid lowering, and more aggressive therapy is necessary to attain glucose and blood pressure goals. Data from this study emphasize the need for understanding factors that influence physicians' treatment decisions. Drug compliance, cost, use of nonpharmacologic therapies, monitoring of side effects, and patient involvement in self-management are all necessary components of treatment and goal attainment.[30]

Despite its limitations, this chart review is one of the first to provide information about benchmarking in a primary care setting and awareness of the need to control risk factors in patients with type 2 diabetes. The data collected provide information not only about lipid goals, but also about blood pressure achievement, aspirin use, and other drug therapies in patients with diabetes.

A quality improvement strategy was implemented in this practice to address the findings of the chart review. A diabetes flow sheet was developed with patient-specific parameters pertaining to diabetes (e.g., blood pressure and A1C measurements, foot and eye examinations, microalbuminuria evaluation) for physician monitoring. Further research into achievement of these benchmarks in other health care settings would shed light on the effectiveness of these and other strategies to control risk factors among patients with type 2 diabetes.

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