Compliance with Recommendations for Lipid Management among Patients with Type 2 Diabetes in an Academic Family Practice

Gavin Putzer, MD, Richard Roetzheim, MD, MSPH, Arnold M. Ramirez, MD, Kevin Sneed, PharmD, H. J. Brownlee, Jr, MD, and Robert J. Campbell, MD

Background: Lipid abnormalities are twice as common in patients with type 2 diabetes, and this contributes substantially to their increased risk of cardiac disease. The American Diabetic Association (ADA) has defined treatment goals for high-density lipoprotein (HDL) cholesterol (>45 mg/dL), triglyceride (<200 mg/dL), and low-density lipoprotein (LDL) cholesterol (<100 mg/dL). It is unknown, however, how frequently patients with diabetes managed in primary care settings are able to attain these treatment goals.

Methods: We randomly selected 239 patients with type 2 diabetes and conducted a chart review to determine whether patients had attained ADA lipid goals. We examined clinical predictors of goal attainment using logistic regression.

Results: The number and percentage of patients who had attained ADA lipid goals was as follows: HDL cholesterol, 87 of 207 (42.0%); LDL cholesterol, 93 of 208 (47.0%); and triglyceride, 142 of 206 (70.0%). Only 30 of 206 (14.6%) patients had achieved all 3 lipid goals. Three groups of patients with diabetes had greater odds of achieving the LDL treatment goal: men, patients taking a lipid-lowering drug, and patients with hypertension. Patients with diabetes had greater odds of achieving the HDL goal if they were female, were black, or if they had lower values for body mass index and triglyceride. The odds of achieving the triglyceride goal were greater for men, for patients having Medicare insurance supplemented by private insurance, and for those with increasing values of HDL.

Conclusion: We found that the majority of patients with diabetes failed to attain lipid goals set forth by the American Diabetes Association. Further study is needed in larger populations to confirm these findings, and if confirmed, to determine the reasons that patients fail to achieve lipid goals. (J Am Board Fam Pract 2004;17:101–7.)

Coronary artery disease (CAD) is the leading cause of death among patients with type 2 diabetes,¹ and patients with diabetes have been estimated to have a risk of myocardial infarction similar to those who have previously suffered myocardial infarction.² Lipid abnormalities contribute substantially to the increased CAD risk of patients with diabetes.^{3–7}

Lipid abnormalities are twice as common in patients with type 2 diabetes compared with the general population. Insulin resistance in type 2 diabetes leads to inhibited action of lipoprotein lipase, which tends to cause elevated triglyceride and low levels of high-density lipoprotein (HDL) cholesterol. Glycemic control may improve lipid levels but will usually not normalize them by itself.⁸

No study has specifically assessed the effect of lipid lowering on CAD risk among patients with diabetes. The only relevant findings have resulted from subgroup analyses of other lipid lowering trials. In these subgroup analyses, patients with diabetes have shown similar reductions in both lipid levels and CAD risk.^{9,10} Given the overall greater risk of CAD for patients with diabetes, the goal of lowering lipid levels may be particularly important.

In an attempt to improve diabetic control and prevent diabetic complications, the American Diabetic Association (ADA) has defined treatment goals for physicians managing patients with diabetes mellitus.¹¹ ADA guidelines include treatment goals for HDL cholesterol [>45 mg/dL (>1.15 mmol/L)], triglyceride [<200 mg/dL (<2.30 mmol/L)], and low-density lipoprotein (LDL) cho-

Submitted, revised, 27 August 2003.

From the Department of Family Medicine, University of South Florida, Tampa. Address correspondence to Arnold Ramirez, MD, Department of Family Medicine, University of South Florida, 12901 Bruce B. Downs Blvd., MDC 13, Tampa, FL 33612 (e-mail: aramirez@hsc.usf.edu).

lesterol [<100 mg/dL (\leq 2.60 mmol/L)]. It is unknown, however, how frequently patients with diabetes managed in primary care settings are able to attain these treatment goals. Because primary care physicians, rather than specialists, provide the majority of care to persons with diabetes, it is important to understand the effectiveness of diabetic care provided in primary care settings. This study was conducted, therefore, to determine the frequency with which patients with diabetes managed in an academic family practice clinic had achieved ADA treatment goals for lipids and to determine the clinical predictors of successfully reaching ADA goals. This information may be useful when developing quality improvement interventions.

Methods

This study was conducted at a university primary care clinic in Tampa, Florida. Ten board-certified family physicians, 4 advanced registered nurse practitioners, and a physician's assistant staff the clinic. The clinic provides more than 20,000 primary care patient visits each year. Attending physicians and staff provide all patient care. Residents do not provide patient care at the primary care clinic.

We used the computerized scheduling/billing database to identify all patients seen from March 1999 to March 2001 who had a diagnosis of diabetes mellitus (n = 581). We used the following International Classification of Diseases 9th Revision codes to identify patients diagnosed with diabetes: 250.00 to 250.01, 250.02, 250.03, 250.8, and 250.9. Using this as our sampling frame, we randomly selected 239 patients for study using a list of computer-generated random numbers. This method ensured that all patients with diabetes within the practice population had an equal probability of being included in the sample. Because treatment issues differ substantially for patients with type 1 diabetes, and because their number was limited in our sample, we excluded 21 patients whose medical record indicated a diagnosis of type 1 diabetes mellitus. The remaining 218 patients who had a diagnosis of type 2 diabetes mellitus constituted our final study sample.

The clinical course and laboratory analyses of 218 patients with type 2 diabetes mellitus during the years 1999 to 2001 were abstracted from a

structured review of the medical record. The following information was abstracted: sociodemographic characteristics (age, gender, race/ethnicity, marital status, education level, health insurance), chronic medical conditions other than diabetes, most recent body mass index, current medications used, smoking status (current, former, never), total number of visits to family physicians and nonphysician providers (advanced registered nurse practitioners, physician's assistants) in the previous year, systolic and diastolic blood pressures, and most recent laboratory results (including HDL, LDL, triglyceride, and hemoglobin A_{1c}).

We measured comorbidity of patients with diabetes using the Charlson Comorbidity Index.¹² The Charlson Comorbidity Index is not an exhaustive list of all possible comorbid conditions; rather, it is a weighted index of 19 selected categories of disease that have been found to be associated with mortality and other important health outcomes. Charlson comorbid conditions (and their corresponding weightings) include myocardial infarction,¹ congestive heart failure,¹ peripheral vascular disease,1 cerebral vascular disease,1 dementia,1 chronic pulmonary disease,¹ connective tissue disease,¹ peptic ulcer disease,¹ mild liver disease,¹ moderate/severe liver disease,³ diabetes without complications,¹ diabetes with complications,² hemiplegia,² renal disease,² and acquired immunodeficiency syndrome.⁶ Increasing scores on the Charlson Comorbidity Index reflect an increasing burden of comorbid conditions.12-14

We examined the most recent laboratory results available in the medical record to determine whether patients had met each of the 3 ADA treatment goals for lipids [HDL cholesterol >45 mg/dL (>1.15 mmol/L), triglyceride <200 mg/dL (<2.30 mmol/L), and LDL <100 mg/dL ($\leq 2.60 \text{ mml/L}$)]. We examined clinical predictors of having achieved lipid goals using the χ^2 test or t test as appropriate. We explored multivariate predictors of having achieved lipid goals using multiple logistic regressions. Separate models were developed for each lipid measure (HDL, LDL, triglyceride). All clinical predictor variables were eligible for inclusion in logistic models. Final models consisted of predictors that remained statistically significant at the 0.05 levels in a stepwise variable selection algorithm. The University's Institutional Review Board approved this study.

Clinical characteristics	Percentage of Patients Attaining Goal			
	N (%)	LDL	HDL	Triglycerides
Gender				
Male	101 (51)	58.4*	28.9***	74.0
Female	97 (49)	35.1	56.4	64.4
Marital Status				
Married	112 (76)	50.0***	37.6	66.4
Unmarried	36 (24)	41.9	47.8	72.2
Race/ethnicity				
Black	23(12)	34.8	75.0**	83.3
Hispanic	20(10)	35.0	35.0	55.0
Other White	22 (11) 133 (67)	50.0 50.4	37.5 38.1	82.6 66.2
	155 (07)	50.7	50.1	00.2
Insurance	97(41)	51.2	37.7	62.4
Private fee-for-service Private, HMO	82 (41) 39 (20)	51.2 41.0	57.7 41.9	62.4 61.9
Medicare + supplemental	23 (12)	34.8	56.6	91.3
Medicare alone	45 (23)	51.0	43.5	76.1
Other	9 (4)	44.4	40.0	70.0
Smoking status				
Nonsmoker	180 (95)	46.7	42.6	69.5
Smoker	9 (5)	0.0	36.8	63.2
Education				
Less than high school	52 (26)	36.5	40.7*	64.8
High school graduate	67 (34)	49.3	54.9	71.4
Post high school	79 (40)	51.9	31.7	69.5
Patient received patient education				
Yes	127 (64)	46.5	42.1	68.4
No	71 (36)	47.9	41.9	69.9
Patient taking ACE inhibitor or receptor blocker				
Yes	100 (51)	53.0	38.6	73.3
No	98 (49)	40.8	45.3	64.8
Patients taking lipid-lowering drug				
Yes	81 (41)	65.4***	34.9	63.5
No	117 (59)	35.0	47.1	72.7
Patients taking sulfonylurea				
Yes	73 (37)	46.6	43.6	65.4
No	125 (63)	47.2	41.1	71.1
Patients taking metformin				
Yes	109 (55)	48.6	38.1	63.7
No	89 (45)	44.9	46.8	75.3
Patients on insulin therapy				
Yes	25 (13)	32.0	46.2	61.5
No	173 (87)	49.1	41.4	70.0
Patients on a thiazolidinedione		1 0 -	10.5	
Yes	34 (17)	58.8	48.6	71.4
No	164 (83)	44.5	40.7	68.4

Table 1. Percentage of Patients Who Attained Lipid Treatment Goals

ACE, angiotensin-converting enzyme inhibitor. * P < .05

 1 < .01

Results

The number and percentage of patients who had attained ADA lipid goals was as follows; HDL cholesterol 87 of 207 (42.0%), LDL cholesterol 93 of 208 (47.0%), triglyceride 142 of 206 (70.0%). Only 30 of 206 (14.6%) patients had achieved all 3 lipid goals. Clinical predictors of attaining LDL cholesterol goals are shown in Table 1. Patients with diabetes who were married, who were male, and those who were taking statins, were more likely to have achieved the ADA recommended LDL goal. Patients who achieved the LDL goal were similar to those that did not with respect to age (mean 59.4 vs 59.4 years, P = .98), number of visits in the past year (4.5 vs 4.2 visits, P = .43), Charlson comorbidity scores (1.6 vs 1.7, P = .61), mean systolic

P < .05** P < .01

blood pressure (141.7 versus 139.3 mm Hg, P = .32), mean diastolic blood pressure (74.5 versus 74.8 mm Hg, P = .80), body mass index (32.9 vs 31.9, P = .31), mean number of prescription medications (1.2 vs 1.2, P = .78), and most recent hemoglobin A_{1c} (0.079 vs 0.074, P = .16).

Patients with diabetes who were female or black were more likely to have achieved the ADA goal for HDL cholesterol (Table 1). The likelihood of attaining HDL goal varied by educational attainment but not in a monotonic fashion. Patients with diabetes who achieved HDL goal were older (mean age, 61.5 vs 57.7 years, P = .04), had lower diastolic blood pressures (73.4 vs 76.4 mm Hg, P = .04), and had lower average BMI (31.1 vs 33.4, P = .02) than those who did not. Patients who achieved HDL goals were similar to those that did not in respect to the average number of physician visits in the previous year (4.1 vs 4.5 visits, P = .22), Charlson comorbidity scores (1.6 vs 1.6, P = .99), mean systolic blood pressure 142 vs 140 mm Hg, P =.52), most recent hemoglobin A_{1c} (0.077 vs 0.077, P = .90), and average number of prescription drugs taken (1.2 vs 1.2, P = .99).

Patients who achieved triglyceride goals were slightly younger than those who did not (56.1 vs 60.9 years, P = .01). Otherwise, the likelihood of attaining ADA treatment goals for triglyceride levels did not vary according to the clinical characteristics studied (Table 1). Patients who achieved goal were similar to those who did not in respect to number of provider visits (4.2 vs 4.5 visits, P = .32), comorbidity index scores (1.6 vs 1.6, P = .59), mean systolic blood pressure (141.3 vs 140.1 mm Hg, P = .65), mean diastolic blood pressure (74.1 vs 77.0 mm Hg, P = .07), mean BMI (32.0 vs 33.4, P = .17), mean hemoglobin A_{1c} value (0.077 vs 0.079, P = .50), and average number of prescriptions taken (1.2 vs 1.4, P = .11).

In multivariate analysis, 3 clinical predictors of having achieved LDL treatment goal emerged (Table 2). Men had 2.3 times greater odds of having achieved the LDL goal than women. Patients taking a statin and those with a history of hypertension had greater odds of achieving LDL goals than other patients with diabetes. Four predictors of achieving HDL goal emerged (Table 3). Patients with diabetes had greater odds of achieving the HDL goal if they were female or black. The odds of achieving the HDL goal also increased with decreasing BMI and triglyceride values. The odds

Table 2. Logistic Regression: Clinical Predictorsof Diabetic Patients Who Attained LDL Goal(LDL <100 mg/dL)</td>

Clinical Predictors	Odds Ratio	95% Confidence Interval	P Value
Gender Male Female	2.33	1.21–4.51 1.00	.01
Patient taking a statin Yes No	3.48	1.78-6.83	.0003 1.00
History of hypertension Yes No	2.57	1.26-5.23	.009 1.00

of achieving triglyceride goal were greater for men, for patients having Medicare insurance plus private insurance, and with increasing values of HDL (Table 4).

Discussion

We found that less than half of patients with diabetes had achieved ADA recommended treatment goals for LDL or HDL cholesterol. In the diabetic patient population studied, there was a clear gap between goals put forth in guidelines and outcomes achieved in clinical practice. The reasons that patients with diabetes in our sample failed to achieve lipid goals are not known. In previous studies, physicians have offered a number of explanations for why care has deviated from guidelines, including patient factors, system issues, simple oversights, and disagreement with the guidelines.^{23,24} Further research is needed to better understand the barriers

Table 3. Logistic Regression: Clinical Predictors of Diabetic Patients Who Attained HDL Goal (HDL >45 mg/dL)

Clinical Predictors	Odds Ratio	95% Confidence Interval	P Value
Gender Male Female	0.18	0.08–0.39	<.0001 1.00
Body mass index*	0.92	0.87-0.98	.006
Race-ethnicity Black All others	5.42	1.59–18.47	.007 1.00
Triglyceride level*	0.99	0.99–1.0	.006

* Odds ratios for BMI and triglyceride level reflect change in the odds of attaining HDL goal with each unit change in BMI and triglyceride level, respectively.

Table 4. Logistic Regression: Clinical Predictors ofDiabetic Patients Who Attained Triglyceride Goal(Triglycerides < 200 mg/dL)</td>

Clinical Predictors	Odds Ratio	95% Confidence Interval	P Value
Gender Male Female	3.22	1.46–7.11	.004 1.00
Health insurance Medicare + supplement All other types	5.70	1.16–27.97	.03 1.00
HDL*	1.08	1.04–1.12	<.0001

* Odds ratio for HDL indicates the change in the odds of attaining triglyceride goal with each unit change in HDL.

to attaining lipid goals and to guide the development of interventions to improve care. Interventions that include a pharmacist working in conjunction with the treating physician have been successful in attaining lipid goals in other settings and may be one promising approach for patients with diabetes managed in primary care.^{25–28}

Our results are similar to findings reported in the Lipid Treatment Assessment Project (LTAP), a study of 4888 patients with dyslipidemia.¹⁵ In the LTAP study, only 38% of adult patients with dyslipidemia achieved the LDL goal specified by the National Cholesterol Education Program (NCEP). Patients with diabetes mellitus in the LTAP study were only slightly more likely to have achieved NCEP goals for LDL cholesterol (41%) than were patients without diabetes. Most other studies assessing LDL goal attainment have been conducted among patients having myocardial infarction or existing coronary artery disease. Even in these highrisk groups, most studies have shown the majority of patients fail to achieve the LDL treatment goals specified by NCEP.16-18

Patients with diabetes taking a lipid-lowering drug were more than 3 times as likely to have achieved the LDL goal specified by the ADA. Previous studies, however, have found that even among patients using a lipid-lowering drug, many do not achieve the LDL cholesterol goal^{19,20}; in one study, the majority of patients who were currently using a lipid-lowering drug had not achieved goal.²¹ In almost all cases, patients were not taking the maximum drug dose, suggesting that inadequate dosing may be one explanation for failure to achieve goal.

Men and patients with a history of hypertension were more likely to have achieved the LDL goal, a finding that was also reported in the LTAP study. The reasons for this are not clear but may indicate that physicians are more aggressive with lipid management in the face of these additional risk factors. There may be other explanations, however, because in the LTAP study, patients with risk factors such as a family history of CAD or smoking were not more likely to have achieved the goal. In our study, there were too few diabetic smokers or patients with a family history of CAD to examine whether these groups were more likely to have reached lipid goals. Then again, male patients or those with hypertension may be more aware of the need for lipid management and may more aggressively pursue its treatment.

Even fewer (42.0%) patients with diabetes had reached the ADA treatment goal for HDL cholesterol. Being female, black, having lower BMI, and having lower triglyceride were all clinical predictors of successfully attaining the HDL goal. The HDL goal may be more difficult to achieve because many commonly used lipid-lowering drugs are more effective at lowering LDL cholesterol than they are at raising HDL cholesterol.²⁰ In addition, diabetes-related inhibition of lipoprotein lipase often leads to elevated levels of triglyceride and reduced levels of HDL cholesterol, which may persist even with good glycemic control.²²

There are several limitations to our study. This study was limited to an academic practice setting that may be different from community practice settings. We examined the attainment of lipid goals at a single point in time, and it is possible that some patients had attained goals in the past or would attain treatment goals in the future. We did not have information on the quantity or quality of lipid-related patient education that was provided to patients. We also did not have information on the extent to which patients pursued nonpharmacologic therapies or the extent to which patients complied with physician recommended therapies. Out study also did not take into account other medications that may affect lipids (diuretics, β -blockers). We examined care that occurred when guidelines published by NCEP II and the ADA were well known to physicians. For LDL, the treatment goals differ between the 2 guidelines, and it is possible that some physicians were striving for the less stringent goal of 130 mg/dL recommended by NCEP II. We also did not have information on other providers of diabetic care (endocrinologists for example), so we could not assess their effect on outcomes. Finally, treatment guidelines are not static but continue to be updated (ie, NCEP III). For example, NCEP III now specifies a triglyceride treatment goal of <150 mg/dL, which only 50% of our sample would have met.

In conclusion, we found that the majority of patients with diabetes studied failed to attain lipid goals set forth by the American Diabetes Association. Failing to increase the dose of lipid-lowering medications may be one reason that patients with diabetes are failing to reach treatment goals. More detailed studies are required to discern the reasons that treatment goals are not attained and to guide interventions to improve diabetic care.

References

- Garcia MJ, McNamara PM, Gordon T, Kannel WB. Morbidity and mortality in diabetics in the Framingham population. Sixteen year follow-up study. Diabetes 1974;23:105–11.
- 2. Grover S, Coupal L, Zowall H, Dorais M. Costeffectiveness of treating hyperlipidemia in the presence of diabetes: who should be treated? Circulation 2000;102:722–7.
- Rosengren A, Welin L, Tsipogianni A, Wilhelmsen L. Impact of cardiovascular risk factors on coronary heart disease and mortality among middle aged diabetic men: a general population study. BMJ 1989; 299:1127–31.
- Stamler J, Vaccaro O, Neaton J, Wentworth D. Diabetes, other risk factors, and 12-yr cardiovascular mortality for men screened in the Multiple Risk Factor Intervention Trial. Diabetes Care 1993;16: 434–44.
- 5. Haffner SM. Management of dyslipidemia in adults with diabetes. Diabetes Care 1998;21:160–78.
- Betteridge DJ. Diabetic dyslipidaemia: treatment implications. J Intern Med Suppl 1994;736:47–52.
- Betteridge DJ. Lipids and atherogenesis in diabetes mellitus. Atherosclerosis 1996;124:S43–7.
- Dunn FL. Management of hyperlipidemia in diabetes mellitus. Endocrinol Metab Clin North Am 1992;21:395–414.
- Pyorala K, Pedersen TR, Kjekshus J, Faergeman O, Olsson AG, Thorgeirsson G. Cholesterol lowering with simvastatin improves prognosis of diabetic patients with coronary heart disease. A subgroup analysis of the Scandinavian Simvastatin Survival Study (4S). Diabetes Care 1997;20:614–20.
- Steiner G. Lipid intervention trials in diabetes. Diabetes Care 2000;23:B49-53.
- 11. American Diabetes Association. Standards of medi-

cal care for patients with diabetes mellitus. Diabetes Care 2003;26 Suppl 1:S33-50.

- Charlson M, Pompei P, Ales K, Mackenzie C. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. J Chron Dis 1987;40:373–83.
- Charlson M, Szatrowski T, Peterson J, Gold J. Validation of a combined comorbidity index. J Clin Epidemiol 1994;47:1245–51.
- 14. West DW, Satariano WA, Ragland DR, Hiatt RA. Comorbidity and breast cancer survival: a comparison between black and white women. Ann Epidemiol 1996;6:413–9.
- Pearson TA, Laurora I, Chu H, Kafonek S. The lipid treatment assessment project (L-TAP): a multicenter survey to evaluate the percentages of dyslipidemic patients receiving lipid-lowering therapy and achieving low-density lipoprotein cholesterol goals. Arch Intern Med 2000;160:459–67.
- Andrade SE, Saperia GM, Berger ML, Platt R. Effectiveness of antihyperlipidemic drug management in clinical practice. Clin Ther 1999;21:1973–87.
- Allison TG, Squires RW, Johnson BD, Gau GT. Achieving National Cholesterol Education Program goals for low-density lipoprotein cholesterol in cardiac patients: importance of diet, exercise, weight control, and drug therapy. Mayo Clin Proc 1999;74: 466–73.
- Majumdar SR, Gurwitz JH, Soumerai SB. Undertreatment of hyperlipidemia in the secondary prevention of coronary artery disease. J Gen Intern Med 1999;14:711–7.
- 19. Latts LM. Assessing the results: phase 1 hyperlipidemia outcomes in 27 health plans. Am J Med 2001; 110:17S–23S.
- Vicari RM, Wan GJ, Aura AM, Alexander CM, Markson LE, Teutsch SM. Use of simvastatin treatment in patients with combined hyperlipidemia in clinical practice. For the Simvastatin Combined Hyperlipidemia Registry Group. Arch Fam Med 2000; 9:898–905.
- 21. Marcelino JJ, Feingold KR. Inadequate treatment with HMG-CoA reductase inhibitors by health care providers. Am J Med 1996;100:605–10.
- O'Brien T, Nguyen T, Zimmerman B. Hyperlipidemia and diabetes mellitus. Mayo Clin Proc 1998; 73:969–76.
- Mottur-Pilson C, Snow V, Bartlett K. Physician explanations for failing to comply with "best practices." Eff Clin Pract 2001;4:201–13.
- Cabana MD, Rand CS, Powe NR, et al. Why don't physicians follow clinical practice guidelines? A framework for improvement. JAMA 1999;282: 1458–65.
- 25. Ellis SL, Carter BL, Malone DC, et al. Clinical and economic impact of ambulatory care clinical pharmacists in management of dyslipidemia in older adults: the IMPROVE study. Impact of Managed

Pharmaceutical Care on Resource Utilization and Outcomes in Veterans Affairs Medical Centers. Pharmacotherapy 2000;20:1508–16.

- Bozovich M, Rubino CM, Edmunds J. Effect of a clinical pharmacist-managed lipid clinic on achieving National Cholesterol Education Program lowdensity lipoprotein goals. Pharmacotherapy 2000;20: 1375–83.
- Bluml BM, McKenney JM, Cziraky MJ. Pharmaceutical care services and results in project ImPACT: hyperlipidemia. J Am Pharm Assoc (Wash) 2000;40: 157–65.
- Bogden PE, Koontz LM, Williamson P, Abbott RD. The physician and pharmacist team. An effective approach to cholesterol reduction. J Gen Intern Med 1997;12:158–64.