Factors Associated with Glycemic Control in Patients with Type 2 Diabetes Mellitus in Rural Areas of the United States

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ABSTRACT

Background: According to the US Department of Health and Human Services, an estimated 18.2 million Americans, or 6.3% of the population, has diabetes mellitus (DM). Approximately 90% of these individuals have type 2 DM. The most widely used clinical test for defining glycemic control is measurement of blood glycosylated hemoglobin (A1C).

Objective: The goal of this study was to estimate the proportion of diabetic patients who achieved the A1C goal of ≤7.0% in a rural western Pennsylvania practice and to determine the factors that influence the achievement of the A1C goal.

Methods: This was an observational study conducted in a rural family medicine office in Clarksburg, Pennsylvania. To be included in the study, patients had to have been diagnosed with type 2 DM >2 years prior, had to be aged >18 years, and had to be adhering to a medical nutrition therapy diet. Both univariate analysis and logistic regressions were used to identify the factors that were associated with the outcome.

Results: A total of 136 diabetic patients were included in the study (70 men, 66 women; mean [SD] age, 59.7 [15.2] years). A1C of ≤7.0% was attained in 75.0% (n = 102) of the patients. Although the majority of patients were obese (69.1% [n = 94] with a body mass index ≥30 kg/m^2), weight was not a factor in reaching A1C goal. The data showed that those patients who were older (62.3 vs 51.9 years; $P = 0.004$), using oral antidiabetic medication (96.1% vs 87.9%; $P = 0.100$), and not using insulin (86.3% vs 69.7%; $P = 0.030$) were more likely to achieve A1C goal. The proportion of patients achieving A1C goal levels decreased as the number of oral medications used increased.

Conclusions: In this rural area of western Pennsylvania, the majority of our type 2 DM patients achieved glycemic control (ie, A1C ≤7.0%). The primary care physician, along with a DM care team, should address the issues of diet, exercise, weight management, and other comorbid illnesses to properly manage patients with type 2 DM. (*Insulin*. 2007;2:134–141)
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Key words: diabetes mellitus, glycosylated hemoglobin, rural population, body mass index.

INTRODUCTION

According to the US Department of Health and Human Services, an estimated 18.2 million Americans, or 6.3% of the population, has diabetes mellitus (DM). Approximately 90% of these individuals have type 2 DM.[1,2] The prevalence of type 2 DM has assumed epidemic dimensions.[1,2] Communities worldwide have benefited from advances in technology, such as the expanded use of computers and the Internet. Conversely, this advanced technology also promotes a sedentary lifestyle, with less time spent on physical activities. Increased body weight and sedentary lifestyle accelerate insulin resistance and β-cell dysfunction, which will increase the risk of type 2 DM.[3]

The most widely used clinical test for defining glycemic control is measurement of blood glycosylated hemoglobin (A1C). The mean A1C varies in such a way that it reflects the mean blood glucose concentration over the previous 6 to 8 weeks.[4,5] There is a strong linear correlation between that of A1C and mean blood glucose; for example, an A1C of 7.0% represents a mean blood glucose level of ~170 mg/dL, and an A1C of 8.0% represents a mean blood glucose level of ~205 mg/dL.[6,7] A1C remains the gold standard of testing: it provides an indication of glucose control over the previous few months and in turn directs the successful and effective management of DM. For every 1% reduction in A1C, the risk of developing microvascular complications (retinal, renal, and neurovascular) is reduced by 40%.[8] According to the American Diabetes Association (ADA), an A1C level ≤7.0% is the goal of effective DM treatment, but the American College of Endocrinology/American Association of Clinical

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Endocrinologists continue to recommend a goal A1C level ≤6.5%.[9,10]

There is concern regarding the quality of diabetic care and the level of compliance with clinical guidelines in rural and underserved areas with limited resources and limited educational programs that are isolated from large medical centers.[11] With this concern in mind, we conducted our study in a rural family medicine practice in western Pennsylvania. We evaluated A1C among patients diagnosed with type 2 DM and estimated the proportion of patients reaching the A1C goal of ≤7.0%. We also evaluated the factors that may influence whether a patient reaches his or her A1C goal.

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PATIENTS AND METHODS

The study was conducted in a rural family medicine office in Clarksburg, Pennsylvania. There were ~4500 patients in the practice in 2003–2004. In this practice, 15% of adult patients were diagnosed with type 2 DM, and they constituted 8% of the total number of visits. Oral informed consent was obtained from all patients.

Once a patient was diagnosed with DM, he or she was enrolled in the "diabetes outpatient education program" (**Figure 1**). This DM care team consists of a dietitian, DM nurse educator, and physician. A plan of care was developed specifically for the patient's clinical condition (**Figure 1**). The patient was prescribed a glucose meter to test the fasting and postprandial blood glucose levels and was advised to keep a diary of those readings to share with the physician at each office visit. The patient was referred for ophthalmologic and podiatric evaluations as soon as the diagnosis of DM was made. Laboratory tests were conducted at least twice a year, including but not limited to, A1C, fasting blood glucose, urine microalbumin, and lipid profile (ie, total cholesterol, low-density lipoprotein, high-density lipoprotein, triglycerides). Compliance with diet and medications was assessed at each visit by the physician and the licensed practical nurse; this included the use of any concomitant medications that had the potential to affect glucose control. Patients' medications were adjusted according to the treatment response, adverse effects, and affordability. A DM flow sheet (**Figure 2**) was created for each patient to keep track of the laboratory values, medications, and immunizations.

In the first 3 months of the study, the patient was seen once every 2 weeks, afterwards every month for 3 months, and then every 3 months for 12 months. Once a month, a "diabetes clinic" was held where DM patients were seen by the DM care team; each patient's progress was discussed, with recommendations made by each member of the team. The ADA guidelines were used for the diagnosis of DM and the A1C goal[9]; the Third Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) guidelines[12] were used for hyperlipidemia diagnoses; and the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure was used for hypertension diagnoses.[13]

Patients were eligible for analysis if they had been diagnosed with type 2 DM >2 years prior, were aged >18 years, and were following a medical nutrition therapy diet. They were identified by 2 licensed practical nurses through chart reviews. A1C was checked every 3 months, and A1C and medication use at the end of the 2 years were recorded and used in the analyses.

Statistical Analysis

Mean (SD) values for age and weight were calculated. Data were compared between those who achieved the glycemic control goal and those who did not. The following tests were used: *t* tests for comparison of the continuous variables and χ^2 tests or the Fisher exact test for the nominal data comparisons. Stepwise logistic regressions were used to identify those factors that were associated with the outcome. A *P* value of ≤0.05 was considered significant.

RESULTS

A total of 136 diabetic patients were included in the analyses. The mean (SD) age of the patients was 59.7 (15.2) years, and sex was equally distributed (70 men, 66 women). The majority of patients were obese (69.1%; body mass index [BMI] ≥ 30 kg/m^2) and had had DM <10 years (64.7%). One hundred eleven patients (81.6%) were treated only with oral antidiabetic medications, 16 (11.8%) were treated using both oral medications and insulin, and 8 (5.9%) took insulin only. Most of these diabetic patients were also hypertensive and dyslipidemic (69.9%) (**Table I**).

Characterization of Glycemic Control

A1C goal was reached in 75.0% of the patients (n = 102). **Table II** lists the patients' characteristics according to A1C goal. Weight and DM duration were similar between groups. One patient did not use insulin or oral medication, and this patient was excluded from the medication analyses. Those patients who were older (62.3 vs 51.9 years; *P* = 0.004), using oral antidiabetic medication (96.1% vs 87.9%; *P* = 0.100), and not using insulin (86.3% vs 69.7%; *P* = 0.030) were more likely to achieve A1C goal. Among those who used oral agents (n = 127), those who took multiple oral medications were less likely to reach A1C goal (35.7% vs 65.5%; *P* = 0.004), and the proportion of patients achieving A1C goal decreased as the number of oral medications used increased (**Figure 3**) (*P* values for trend: *P* = 0.004 for those who used oral medications only and *P* = 0.051 for those who used both

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PHYSICIAN ORDER FORM
DIABETES OUTPATIENT EDUCATIONAL SERVICES

I am referring: _____
for medically necessary outpatient self-management training.
Insurance/Health Plan _____
Insur. ID # _____ Authorization # _____
Date of Birth _____ S.S.# _____

Daytime Phone # _____ Eve. Phone # _____
Home Address _____
_____
Height _____ Weight _____ A1C _____ BP _____
Cholesterol _____ LDL _____ HDL _____ Trig _____

DIAGNOSIS
ICD-9 Code:

☐ 250.02 Diabetes type 2 uncontrolled
☐ 250.01 Diabetes type 1 controlled
☐ 250.03 Diabetes type 1 uncontrolled
☐ 648.83 Gestational diabetes
☐ Other _____
☐ 250.00 Diabetes type 2 controlled
☐ 648.00 Diabetes with pregnancy

MEDICAL STATUS AND/OR COMPLICATIONS:

☐ Newly Diagnosed	☐ Obesity	☐ Vascular Disease
☐ New to Insulin	☐ Nephropathy	☐ Gastroparesis
☐ New to Oral Anti-Diabetes Agents	☐ Retinopathy	☐ Foot Problem
☐ Unable to benefit from group changes due to impediment of speech, language, hearing or sight; cognitive, depression, physical or emotional limitations	☐ Other _____	☐ Severe Hypoglycemia or Hyperglycemia

PLAN OF CARE: PLEASE CHECK DESIRED COMPONENTS:
☐ PRE-MEAL: 90–130 MG/DL ☐ 1–2 HOUR POST-PRANDIAL: LESS THAN 120–150 MG/DL ☐ BEDTIME: 110–150 MG/DL

☐ Diabetes Self-Management (6 hours) – Includes: Assessment/Introduction to Behavior Change, Diabetes Overview and Treatment, Basics of Nutrition, Monitoring/Using Results, Acute and Chronic Complications, Physical Activity, Psychosocial Adjustment, A1C (Baseline, 3 Months, 12 Months), Follow-up within 3 Months, Follow-up at 12 Months

☐ Meal Planning/Exchange Lists (3 hours) – Strongly Recommended With Diabetes Self-Management

☐ Advanced Learning Modules (1–2 hours each) – Self-management classes are a prerequisite

- ☐ Hyperlipidemia
- ☐ Exercise and Weight Management
- ☐ Advanced Carbohydrate Counting
- ☐ Reducing Risk Factors
- ☐ Medication Management/Pattern Management
- ☐ Recipe Modification
- ☐ Second Year Follow-up

☐ Insulin Pump Overview (2 hours)

☐ Blood Glucose Monitoring (2 hours) no prerequisite

☐ Initiate Insulin (2 hours) Type: _____ Dosage: _____

☐ Understanding Diabetes (1 hour) one-on-one review

☐ Gestational Diabetes (individual 3 hours) includes Assessment/Introduction to Behavior Change, Overview, Monitoring, Nutritional Management, 1 week follow-up, 6 week post-partum follow-up

- ☐ Pre-Meal: _____ MG/DL
- ☐ 1–2 Hour Post-Prandial: Less Than _____ MG/DL
- ☐ Medical Nutrition Therapy
- ☐ _____Calorie Level
- ☐ _____ Dietitian to Determine
- ☐ Continuous Glucose Monitoring System/CGMS (Advanced Diagnostic Testing 2 hrs) This system provides a continuous graphic of blood sugar levels for a period up to three days. The data enable the health care provider to alter treatment plans.

Physician Signature _____ Date _____ Phone _____ Fax _____

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Figure 1. Diabetes mellitus outpatient education services.

CHERRY TREE FAMILY MEDICINE
71 South Main Street
Cherry Tree, PA 15724
Dr. Haney Wahba

DIABETES MELLITUS FLOW SHEET

PATIENT NAME _____ DOB _____

	DATE	DATE	DATE	DATE	DATE	DATE	DATE	DATE
MICRO ALB								
A1C								
CHOL								
LDL								
HDL								
TRIG								
ASA								
FOOT EXAM								
EYE EXAM								
FLU VACCINE								
PNEUMO								

Figure 2. Diabetes mellitus flow sheet. MICRO ALB = microalbumin; A1C = glycosylated hemoglobin; CHOL = cholesterol; LDL = low-density lipoprotein; HDL = high-density lipoprotein; TRIG = triglycerides; ASA = acetylsalicylic acid; exam = examination; PNEUMO = pneumococcal vaccine.

oral medications and insulin). The analyses of DM treatment and A1C outcome were then controlled by duration of DM (<10 vs ≥10 years), and the adjustment did not alter the results. A stepwise logistic regression analysis was conducted to assess the association of glycemic control and the effects of DM duration, age, obesity (BMI ≥30 kg/m^2), insulin use, and other diagnoses (hypertension and hyperlipidemia). After adjusting the model for duration of DM, the results showed that age was inversely associated with A1C goal, and the effects of other factors disappeared after age was inserted into the model.

DISCUSSION

One of the goals of this study was to estimate the proportion of diabetic patients in a rural US area who achieved the A1C goal of ≤7.0%. This goal level was attained in 75.0% of our patients who were treated by a family practitioner with input from a DM care team (nurse educator, dietitian) and ongoing self-monitoring of blood glucose values. This number is much higher than that found in other studies, which were also conducted in rural areas.[11,14]

In this study, we also tried to determine those factors that may influence DM management, with A1C goal in mind. As

Table I. Demographic characteristics of the study population with type 2 diabetes mellitus (DM) (N = 136).

Age, mean (SD), y	59.7 (15.2)
Sex, no. (%)	
Male	70 (51.5)
Female	66 (48.5)
Weight, mean (SD), lb	223.8 (52.4)
Obese (BMI ≥30 kg/m^2), no. (%)	
Yes	94 (69.1)
No	42 (30.9)
DM duration, no. (%)	
<10 Years	88 (64.7)
≥10 Years	48 (35.3)
DM treatment, no. (%)	
No treatment	1 (0.7)
Oral medications only	111 (81.6)
Oral medications and insulin	16 (11.8)
Insulin only	8 (5.9)
Oral medication use, no. (%)	
None	9 (6.6)
1 Oral medication	73 (53.7)
2 Oral medications	40 (29.4)
3 Oral medications	14 (10.3)
Diagnosis, no. (%)	
DM	6 (4.4)
DM, HPL	24 (17.6)
DM, HTN	11 (8.1)
DM, HPL, HTN	95 (69.9)

BMI = body mass index; HPL = hyperlipidemia; HTN = hypertension.

seen in **Table I**, 69.1% of the patients were obese; obesity is a factor known to accelerate insulin resistance and β-cell dysfunction (2 major pathophysiologic determinants of type 2 DM).[3] However, surprisingly, weight was not a factor in reaching A1C goal. One explanation may be that the overwhelming majority of patients in our study were obese, a finding which may have affected the statistical analysis. Another possibility is that while obesity plays a substantial role in the pathophysiology of type 2 DM, it does not do the same with A1C.

Our data showed that older patients were more likely to reach A1C goal, and this association has been found in other research as well.[15] Some published reports indicate that older diabetic patients (ie, ≥65 years) may have significant impairment of pancreatic insulin secretion, which may be more noteworthy than the presence of insulin peripheral resistance.[3,16] Therefore, an older diabetic patient with progressive and severe pancreatic insulin secretion deficiency will have less potential in terms of time to become more insulin exhausted. Another age-related difference is that reduced body fat and decreased food intake would result in improved metabolic control and A1C goal.

Our data showed that older patients were more likely to reach A1C goal, and this association has been found in other research as well.

Although diet and exercise can improve glycemic control earlier in the course of the disease, oral antidiabetic medications remain the first line of treatment for type 2 DM.[17] In our study, 81.6% of patients were treated with oral medications only, 11.8% with both oral medications and insulin, and 5.9% took insulin only. It is worth mentioning that the type of therapy in our study is somewhat similar to the data available from the Centers for Disease Control and Prevention for patients with DM in the United States from 2001–2003: 57% were on oral antidiabetic medications only, 12% were on oral medication plus insulin, and 16% were on insulin only.[18–20] Our study has more patients taking oral antidiabetic medi-

Table II. Patient characteristics and their relationship to achieving the glycosylated hemoglobin (A1C) goal.

Characteristic	Achieving A1C Goal		*P*
	No (n = 34)	Yes (n = 102)	
Age, mean (SD), y	51.9 (13.6)	62.3 (14.8)	0.004
Weight, mean (SD), lb	222.3 (52.5)	224.3 (52.6)	0.852
Obese (BMI ≥30 kg/m^2), no. (%)	25 (73.5)	69 (67.6)	0.520
Sex, no. (%)			
Female	21 (61.8)	45 (44.1)	
Male	13 (38.2)	57 (55.9)	0.075
DM duration, no. (%)			
<10 Years	21 (61.8)	67 (65.7)	
≥10 Years	13 (38.2)	35 (34.3)	0.679
DM treatment, no. (%)*			
Use insulin			
Yes	10 (30.3)	14 (13.7)	
No	23 (69.7)	88 (86.3)	0.030
Use oral medications			
Yes	29 (87.9)	98 (96.1)	
No	4 (12.1)	4 (3.9)	0.100
Insulin and oral medication use			
Oral only	23 (69.7)	88 (86.3)	
Insulin only	4 (12.1)	4 (3.9)	
Both oral and insulin	6 (18.2)	10 (9.8)	0.069
No. of oral medications used†			
1	10 (34.5)	63 (64.3)	
>1	19 (65.5)	35 (35.7)	0.004
Diagnosis, no. (%)			
DM	1 (2.9)	5 (4.9)	
DM, HPL	9 (26.5)	15 (14.7)	
DM, HTN	2 (5.9)	9 (8.8)	
DM, HPL, HTN	22 (64.7)	73 (71.6)	0.480

BMI = body mass index; DM = diabetes mellitus; HPL = hyperlipidemia; HTN = hypertension.
*One patient did not use insulin or an oral medication and was excluded from the analysis.
†Among those who took oral medications only or oral medication plus insulin.

cation because we only considered patients with type 2 DM. Our analyses found that those patients who reached A1C goal levels were more likely to take oral antidiabetic medication and less likely to use insulin. This finding follows the pathophysiologic paradigm of increased insulin peripheral resistance rather than decreased insulin production in type 2 DM. We noticed in our study that among those patients who used oral medications, those who achieved A1C goal were less likely to take multiple oral medications, and the proportion of patients achieving A1C goal actually decreased as the number of oral medications increased. This observation was similar to the INS-2061 study team finding.[21] This outcome highlights the difficulty in reaching the optimal glycemic control only with oral medications and allows the possibility of considering the idea of adding insulin to the treatment regimen.

We recognize that the sample size involved in the analyses were not adequately large, especially in the subgroup analyses for diabetic medication use. The small number of subjects may result in insufficient power to detect statistical significance. Furthermore, the analyses were based on data at the end of the 2-year period, and we do not have pretreatment data for comparison. Thus, it is difficult to make the conclusion that the improvement was purely due to the treatment program or whether it was due to other factors.

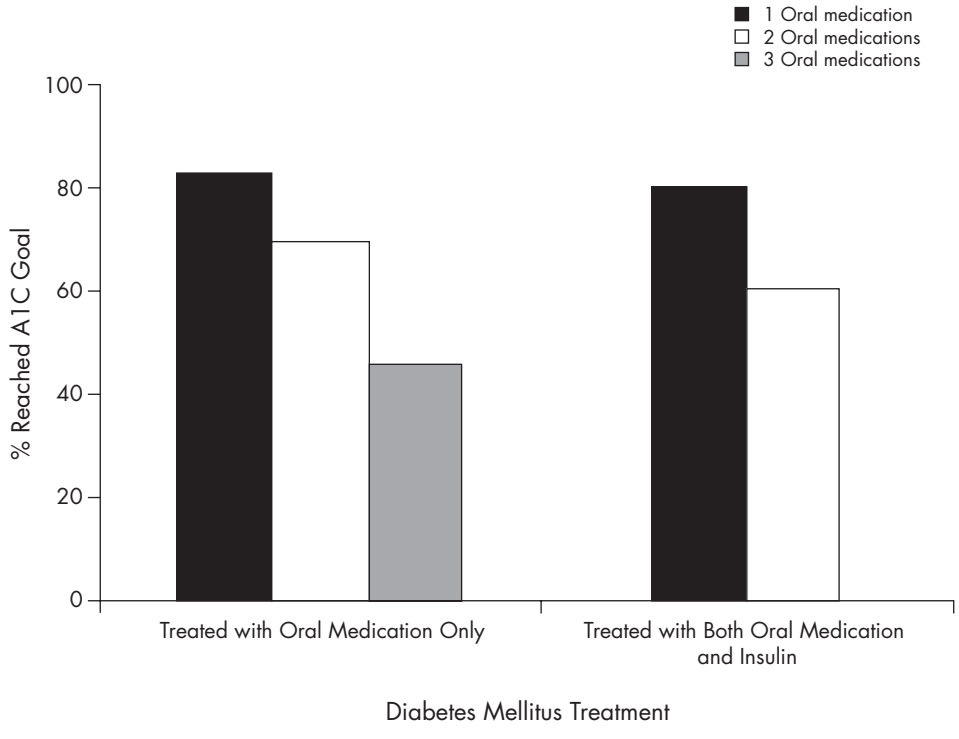

Figure 3. Percentage of patients with type 2 diabetes mellitus receiving either oral antidiabetic medications alone or oral medications in addition to insulin who reached the glycosylated hemoglobin (A1C) goal (ie, ≤7.0%).

CONCLUSIONS

DM is a chronic illness that can be managed and controlled with marked improvement in patients' daily activities. Decreasing the morbidity and mortality of DM are very rewarding goals for both patient and physician. In a rural area of western Pennsylvania, the majority of these patients with type 2 DM achieved glycemic control (ie, A1C ≤7.0%). Primary care physicians, along with a DM care team, should address the issues of diet, exercise, weight management, and other comorbid illnesses to properly manage their patients with type 2 DM.

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