Impact of a Diabetes Disease Management Clinic on the Total Glycosylated Hemoglobin of Patients With Type 2 Diabetes Mellitus

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OBJECTIVE: To assess the impact of a diabetes disease management clinic (DDMC) on the total glycosylated hemoglobin of patients with type 2 diabetes mellitus.

DESIGN: Retrospective chart review

SETTING: A Veterans Affairs Health Care System where patient care was provided either by traditional medical management or by a pharmacist or nurse practitioner in a diabetes disease management clinic.

PATIENTS: 81 veterans with type 2 diabetes mellitus managed with oral antidiabetic agents alone. These patients were divided into two groups: 1) those who were initiated on self-monitoring of blood glucose (SMBG) by their primary care provider (control group); and 2) those who began receiving care in the DDMC when they initiated SMBG (treatment group).

MAIN OUTCOME MEASURES: Change in total glycosylated hemoglobin value from baseline values.

RESULTS: The median baseline total glycosylated hemoglobin values were similar between the two groups (11.5% vs.11.4%, p=0.550). Patients enrolled in the DDMC achieved a significantly greater reduction in glycosylated hemoglobin compared to those patients not enrolled in the clinic (-1.6% vs. -0.4%, p=0.047). Patients who were not enrolled in DDMC also failed to achieve a significant reduction in glycosylated hemoglobin from baseline (p=0.231), whereas the follow-up glycosylated hemoglobin values in patients enrolled in the DDMC were significantly lower than baseline (p<0.001).

CONCLUSION: Participation in the DDMC appeared to be associated with improved glycemic control. Furthermore, patients who received SMBG alone did not benefit; only patients who were enrolled in clinic in addition to the initiation of SMBG achieved a reduction in total glycosylated hemoglobin.

KEYWORDS: Diabetes mellitus, Blood glucose, Self monitoring

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The American Diabetes Association (ADA) recommends near normal glycemic control in all diabetic patients.[1] This recommendation is based on findings from the Diabetes Care and Complication Trial (DCCT) in which 1,441 type 1 diabetes mellitus patients were followed for a mean of 6.5 years to assess the impact of intensive therapy on diabetic complications. In this study, a reduction in glycosylated hemoglobin (HbA1c) delayed the onset and slowed the progression of diabetic microvascular complications.[2] Recently, similar findings have been demonstrated in patients with type 2 diabetes mellitus in prospective clinical and epidemiologic studies.[3-5, 26]

One tool used to help patients achieve improved glycemic control is the diabetes disease management clinic (DDMC). Current literature has shown that patients who attend diabetes clinics have improved glycemic control,[6-8] as well as improved blood pressure control, fewer diabetic complications, and better weight control.[6] However, because these studies predominately involved patients with type 1 diabetes, the impact of a diabetes clinic on patients with type 2 diabetes mellitus is less well established.

Pharmacists have been increasingly involved in the management of patients with diabetes since the early 1970s.[9] In a large survey of American acute-care hospitals, diabetes clinics were the most common clinics to involve pharmacists in providing care.[10] Despite these survey results, few published studies exist that evaluate the effectiveness of pharmacist-managed diabetes clinics.[11-14] The few reports available were published in the 1970s and 1980s, and describe programs in

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Table 1: Patient Demographics

	Group I (N=37)	Group II (N=47)
General Characteristics		
Age (years)	66*	68*
Ethnicity		
White	33%	39%
Nonwhite	67%	61%
Weight (lb.)	204	202
Duration of diabetes (years)	7	4
Social Characteristics		
Alcohol use (% yes)	38	40
Tobacco use (% yes)	42*	16*
Diet (% yes)	43	55
Exercise (% yes)	57	72
Lipid Panel		
triglycerides (mg/dl)	210	182
LDL-C (mg/dl)	122	117
HDL-C (mg/dl)	35	36
LDL/Cholesterol	6.4	5.6
Medication dosage		
Glyburide (mean, mg)	9.5	11
Glipizide (mean, mg)	18.9	15.7
Glipizide XL (mean, mg)	10	10
Metformin (mean, mg)	1511.0	1705.0
Evidence of diabetic complications		
Neuropathy (% yes)	30	38
Nephropathy (% yes)	50*	26*
Retinopathy (% yes)	23	13
PVD (% yes)	26	33

**Denotes statistically significant difference ($p<0.05$)*

detail with regard to structure and the type of services provided. Some examine the effectiveness of the programs by measuring outcomes such as patient compliance, subjective and objective complaints of diabetes, and fasting blood sugar. The knowledge of diabetes and the role of pharmacists in the clinics have been evolving over the last 20 years, and results of these studies may no longer be applicable. For example, none of these studies assess the impact of diabetes clinics on total glycosylated hemoglobin or diabetic complications, two measures more recently recognized as standard methods of assessing diabetes care. This retrospective study assesses the impact of a diabetes disease management clinic (DDMC) on the total glycosylated hemoglobin (GHb) of patients with type 2 diabetes mellitus.

METHODS

Study Site/Setting

This study examined patients with type 2 diabetes mellitus followed between March 1995 and March 1997 in the outpatient clinics at the Veterans Affairs Health Care System in Palo Alto, California, a university-affiliated teaching hospital. Pharmacists, pharmacy practice residents, doctor of pharmacy students, and a nurse practitioner provide patient care in the Diabetes Disease Management Clinic. All of the pharmacist practitioners have completed general residencies and three of four have a Doctor of Pharmacy degree. Their clinical experience ranges from three to 15 years, and one is a certified diabetes educator.

The DDMC provides care on three half-days per week and averages approximately 120 patient visits per month. Primary care providers refer patients diagnosed with diabetes mellitus to the clinic for comprehensive disease state management, which includes both education and diabetes medication management. Education is provided on disease state, medication usage, and the importance of diet and exercise. In addition, patients receive extensive training in the use of a blood glucose testing device. Under protocol, the clinic practitioners modify the patient's antidiabetic regimen following consultation with the patient's primary care provider. The DDMC practitioners also play a vital role in ensuring each patient receives the proper specialized follow-up care from other providers such as dietitians, podiatrists, and ophthalmologists.

Traditional medical management was delivered at the discretion of the patient's primary care provider. Patient education could involve nurses, nurse practitioners, or medical residents. No formal educational process or algorithm was used.

Inclusion Criteria

Patients included in this study were those diagnosed with type 2 diabetes mellitus and receiving treatment with oral antidiabetic agent(s). These patients were divided into two groups: 1) those who were initiated on self-monitoring of blood glucose (SMBG) by their primary care provider (Group I); and 2) those who began receiving care in the DDMC when they initiated SMBG (Group II).

Inclusion also required either two total glycosylated hemoglobin (GHb) values—a baseline value taken no more than 12 months before beginning SMBG +/- clinic enrollment, and a follow-up value taken between three and 18 months following this intervention—and a documented initiation date of SMBG. In addition, patients receiving insulin were excluded, as were those with questionable medication refill histories, defined as pharmacy profile antidiabetic medication(s) refill requests which were less than 90% of the projected usage rate over time.

Patient Accession

From the Decentralized Hospital Computer Program (DHCP), four patient databases were obtained: 1) patients receiving oral antidiabetic agent(s); 2) patients receiving blood glucose strips; 3) patients receiving insulin; and 4) patients enrolled in the DDMC. The four databases were cross-referenced using a relational database program (Paradox 7.0, ©Borland Intl. Inc.) to obtain the two groups of study patients. Patients were randomly selected from the list of patients generated by this program.

Patient Demographics

General characteristics, social characteristics, evidence of diabetic complications, lipid panel, and total glycosylated hemoglobin values were determined through retrospective chart review, DHCP computer outpatient pharmacy profiles, and the DHCP computer lab database (see Table 1).

General characteristics examined included age, sex, ethnicity, weight, medication(s) dosage, and duration of disease. Due to the retrospective nature of this study and the limitations of available databases, more accurate assessment of obesity, such as body mass index or percent of ideal body weight, could not be determined.

Social characteristics, including alcohol use, tobacco use, diet, and exercise, were noted because evidence has demonstrated that patients who modify their life styles can dramatically improve glycemic control.[15] All social demographic data was self-reported by patients and documented in medical records.

Evidence of diabetic complications was extracted from chart review or the computer problem list, or through lab data. Definitions were adapted from previous studies.[2,16] Nephropathy was defined as the presence of proteinuria or serum creatinine persistently greater or equal to 1.5 mg/dL. Peripheral neuropathy, retinopathy, and peripheral vascular disease (PVD) were documented in the medical record.

Lipid panel values were obtained because evidence exists to show that lipid control is associated with the level of glycemic control.[17]

Total glycosylated hemoglobin value range at this institution is 4%–8%. At the time of this study, the laboratory used total glycosylated hemoglobin as the measurement. The percent HgbA1c equals (%total GHB)(0.6%) + 2.10.

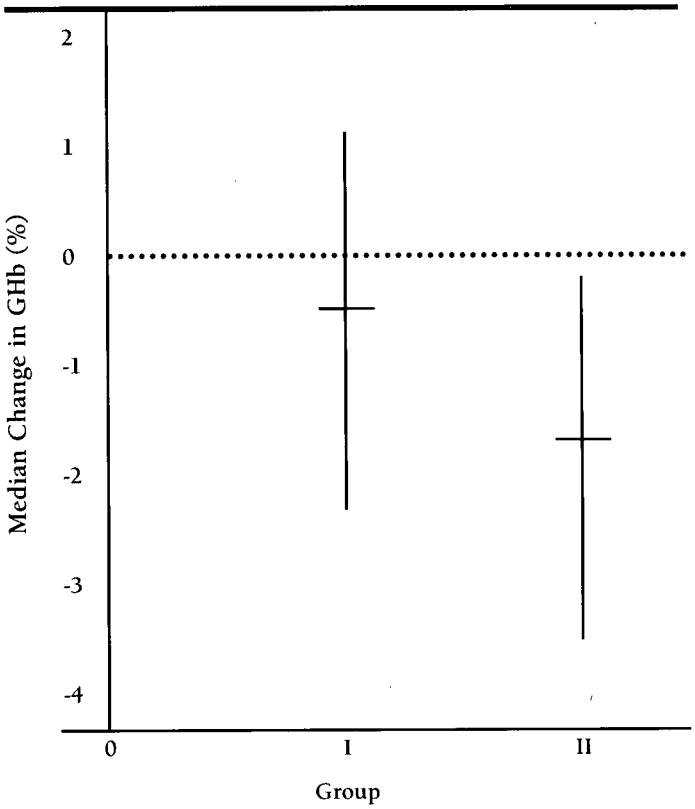
Statistical Analysis

Because the data was not normally distributed, results are presented as medians and nonparametric statistic tests were employed where applicable. Patient demographic data were analyzed using the Mann-Whitney Rank-Sum test for interval data and Chi Square test with Yates correction for nominal data comparisons. The Wilcoxin Signed-Rank test was used to compare baseline versus follow-up total glycosylated hemoglobin values for each group. To compare the change in total glycosylated hemoglobin values between the two groups, the Mann-Whitney Rank-Sum test was used. Statistical tests were performed using Sigma Stat (Version 2, ©Jandel, Sausalito, CA).

RESULTS

One hundred and five patients followed in the outpatient clinics at the Veterans Affairs Health Care System in Palo Alto, California between March 1995 and March 1997 were randomly selected from the database. Twenty-four of these patients were excluded; 13 patients were excluded due to inadequate HgA1c levels and 11 patients were excluded due to lack of a documented initiation date of SMBG. The remaining 81 patients met the criteria for analysis in this study (34 patients in group I and 47 patients in group II).

Figure 1. Change in Total Glycosylated Hemoglobin



Data are presented as the median and 25th–75th percentile range.

Patient Demographics

Nearly all patients enrolled were male, consistent with the Veterans Affairs Health Care System patient population. Baseline patient demographics were similar in both groups, except that the control patients were slightly younger (median age 66 vs. 68, $p<0.005$), more likely to use tobacco (42% vs. 16%, $p<0.005$), and more likely to have evidence of nephropathy (50% vs. 26%, $p<0.005$).

Total glycosylated hemoglobin

The median baseline total glycosylated hemoglobin values were similar between the two groups, 11.5% and 11.4% for group I and group II, respectively ($p=0.550$). On follow-up, a significant difference existed in the median glycosylated hemoglobin reduction between the two groups (-0.4% in group I vs. -1.6% in group II, $p=0.047$) (see Figure 1). In group I, the median follow-up glycosylated hemoglobin did not significantly differ from baseline ($p=0.231$). In contrast, the median follow-up glycosylated hemoglobin in group II significantly decreased from baseline ($p<0.001$). Thus, only patients who were

enrolled in the DDMC clinic in addition to the initiation of SMBG achieved a reduction in total glycosylated hemoglobin.

DISCUSSION

The primary finding of this retrospective chart review study was that patients with type 2 diabetes who initiated SMBG and enrolled in DDMC at the same time had a significantly better improvement in their glycemic control, measured by total glycosylated hemoglobin, than those who only initiated SMBG. A secondary finding was that the addition of SMBG to antidiabetic agent(s) therapy without DDMC clinic care (e.g. traditional medical care) provided an insignificant reduction in total glycosylated hemoglobin value from each patient's baseline value.

The reduction of glycosylated hemoglobin in DDMC patients was not only found to be statistically significant, it is also of clinical relevance. In the DDMC patients, the median baseline glycosylated hemoglobin was 11.4%, which on follow up declined 1.6% to a value of 9.8%. The Wisconsin epidemiologic study results suggest that a glycosylated hemoglobin change of this magnitude would predict for a decrease in the incidence of proliferative diabetic retinopathy from approximately 40% to 10%.[4] Unfortunately, the retrospective nature of this study did not allow for the assessment of progression of retinopathy in patients.

The retrospective nature of this study also did not allow us to determine precisely why DDMC patients had improved control in total glycosylated hemoglobin. Neither patient selection nor referral bias appear to be responsible for this result, because the baseline GHb was strikingly similar in both groups. Several possible explanations exist and should be examined in prospective evaluation.

The education that DDMC patients received may be partially responsible for those patients achieving greater reduction in total glycosylated hemoglobin. Because our clinic is a specialized disease state management clinic, patients underwent comprehensive education on the various aspect of diabetes, such as disease states, medication usage, behavior modification (e.g. diet, exercise), self-care skills, and blood glucose device training. Previous studies suggest that systematic intensive education itself can have a positive effect on indicators of glycemic control, including fasting blood glucose and glycosylated hemoglobin, in patients with diabetes mellitus.[18-19] Unfortunately, due to the retrospective nature of this study, we were unable to accurately document actual changes in patient behavior (e.g. increased compliance with diet, exercise, or blood glucose device use).

Another possible explanation for the greater reduction in the total glycosylated hemoglobin in DDMC patients was the close follow-up these patients received. Depending on the level of glycemic control, some patients were seen as frequently as once every one to two weeks, with telephone follow-up for those patients who required closer monitoring. In addition, clinic staff also consulted with dietary, podiatry, and ophthalmology services to ensure patients received specialized care when necessary. This type of close follow-up could allow clinic staff to detect poor glycemic control early and take appropriate action.

Successful management of diabetes involves numerous psychological factors that determine whether patients will comply with treatment. Patient perception of symptoms, fear, unawareness of symptoms, attitudes, and control issues are all important factors.[20] A recent study on the psychological needs of patients with diabetes reports that 23% of newly diagnosed diabetic patients desire more emotional support.[21] The psychological impact of the DDMC on patients may also have contributed to improved glycemic control in clinic patients. In this DDMC, patients and staff members work as a team to manage the illness. Patients are encouraged to ask questions or express concerns regarding their disease. Many patients have developed trust in the DDMC staff, which may have helped to convince these patients that the education they receive at the DDMC is highly relevant to their well-being.

The secondary finding in this study demonstrated that the addition of SMBG to an oral antidiabetic regimen did not improve glycemic control in patients receiving traditional medical care. Although the American Diabetes Association recommends the use of SMBG and as many as 60% of the general practitioners routinely recommend SMBG in patients with type 2 diabetes mellitus, the benefits of SMBG in these patients remain unclear.[16, 22-25] This study's findings correlated well with results of previous studies that showed that the addition of SMBG does not affect glycemic control in patients with type 2 diabetes.[16,24] However, this study was not designed to measure the usefulness of SMBG, and prospective controlled studies will be helpful in defining the role of SMBG in these patients.

SUMMARY

This retrospective study gives supportive evidence that participation in a diabetes disease management clinic predominately managed by pharmacists may be effective in improving the glycemic control of patients with type 2 diabetes mellitus. This study's findings that SMBG without specialized clinic care does not improve glycemic control confirms the results of several small, previously published trials. However, future prospective studies designed to address this question are necessary to further elucidate the role of SMBG in these patients.

▲ References

1. American Diabetes Association. Clinical Practice Recommendations 1998. Diabetes Care 1998; 21(Suppl 1): S2-S97.
2. The DCCT Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med 1993; 329(14): 977-86.
3. Ohkubo Y, Kishikawa H, Araki E, Miyata T, et al. Intensive insulin therapy prevents the progression of diabetic microvascular complications in Japanese patients with non-insulin-dependent diabetes mellitus: a randomized prospec-

tive 6-year study. Diabetes Research and Clinical Practice 1995; 28: 103-17.
4. Klein R, Klein BE, Moss SE. Relation of glycemic control to diabetic microvascular complications in diabetes mellitus. Ann Intern Med 1996; 124(1 pt 2): 90-96.
5. Klein R, Klein BE, Moss SE, Davis MD, DeMets DL. The Wisconsin epidemiologic study of diabetic retinopathy: III. Prevalence and risk of diabetic retinopathy when age at diagnosis is 30 or more years. Arch Ophthalmol 1984; 102: 527-32.
6. Hammersley MS, Holland MR, Walford S, Thorn PA. What happens to defaulters from a diabetic clinic? Br Med J 1985; 291: 1330-32.
7. Jacobson AM, Adler AG, Derby L, et al. Clinic attendance and glycemic control: study of contrasting groups of patients with IDDM. Diabetes Care 1991; 14(7): 599-601.
8. Beggan MP, Cregan D, Drury MI. Assessment of the outcome of an educational programme of diabetes self-care. Diabetologia 1982; 23: 246-51.
9. DeYoung M. Research on the effects of pharmacist-patient communication in institutions and ambulatory care sites. Am J Health-Syst Pharm 1996; 53: 1277-91.
10. Raehl CL, Bond CA, Pitterle ME. Ambulatory pharmacy services affiliated with acute care hospital. Pharmacotherapy 1993; 13(6): 618-25.
11. Huff PS, Ives TJ, Almond SN, Griffin NW. Pharmacist-managed diabetes education service. Am J Hosp Pharm 1983; 40: 991-94.
12. Schilling KW. Pharmacy program for monitoring diabetic patients. Am J Hosp Pharm 1977; 34: 1242-45.
13. Hawkins DW, Fiedler FP, Douglas HL, Eschbach RC. Evaluation of a clinical pharmacist in caring for hypertensive and diabetic patients. Am J Hosp Pharm 1979; 36: 1321-25.
14. Sczupak CA, Conrad WF. Relationship between patient-oriented pharmaceutical services and therapeutic outcomes of ambulatory patients with diabetes mellitus. Am J Hosp Pharm 1977; 34: 1238-42.
15. Kaplan RM, Hartwell SL, Wilson DK, Wallace JP. Effects of diet and exercise interventions on control and quality of life in non-insulin-dependent diabetes mellitus. J of Gen Intern Med 1987; 2: 220-28.
16. Klein CE, Oboler SK, Prochazka A, et al. Home blood glucose monitoring: effectiveness in a general population of patients who have non-insulin-dependent diabetes mellitus. J of Gen Intern Med 1993; 8: 597-601.
17. Uusitupa M, Siitonen O, Voutilainen E, et al. Serum lipids and lipoproteins in newly diagnosed non-insulin-dependent (type II) diabetic patients, with special reference to factors influencing HDL-cholesterol and triglyceride levels. Diabetes Care 1986; 9(1): 17-22.
18. Mazzuca SA, Moorman NH, Wheeler ML, et al. The diabetes education study: a control trial of the effects of diabetes patient education. Diabetes Care 1986; 9(1): 1-10.
19. Rubin RR, Peyrot M, Saudek CD. Effect of diabetes education on self-care, metabolic control, and emotional well-being. Diabetes Care; 12(10): 673-79.
20. Strauss GJ. Psychological factors in intensive management of insulin-dependent diabetes mellitus. Nursing Clinics of North America 1996; 31(4): 737-45.
21. Beeney LJ, Bakry AA, Dunn SM. Patient psychological and information needs when the diagnosis is diabetes. Patient Education and Counseling 1996; 29: 109-16.
22. Henry RR, Genuth S. Forum one: current recommendations about intensification of metabolic control in non-insulin-dependent diabetes mellitus. Ann Intern Med 1996; 124(1 pt 2): 175-77.
23. Chwalow AJ, Costagliola D, Mesbah M, et al. SMBG in NIDDM patients treated by general practitioners in France. Diabetes Care 1990; 13(4): 454.
24. Wing RR, Epstein LH, Nowalk MP, et al. Does self-monitoring of blood glucose levels improve dietary compliance for obese patients with type II diabetes? Am J Med 1986; 81: 830-36.
25. Cohen M, Zimmet P. Self-monitoring of blood glucose levels in non-insulin-dependent diabetes mellitus. Med J Aust 1983; 2: 377-80.
26. UKPDS Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). Lancet 1998; 352: 837-53.