

Effect of Home Blood Glucose Monitoring on the Management of Patients With Non-Insulin Dependent Diabetes Mellitus in the Primary Care Setting

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Abstract

The purpose of the study was to determine whether blood glucose monitoring strips influence the management of patients with non-insulin dependent diabetes (NIDDM) in the primary care setting. The medical records of 115 patients with NIDDM taking a sulfonylurea drug (oral hypoglycemic agent) during the review period were randomly selected for review. Patients were divided into two groups: those who did not receive a prescription for blood glucose monitoring strips during 1995 and 1996 and those who did for the same 2 years. The main outcome measures were hemoglobin A_{1c}, blood sugar, number of laboratory tests ordered, and number and type of treatment interventions. No statistically significant differences between groups were noted for any measured parameter. Glucose control was independent of number of strips dispensed. Home glucose monitoring strips did not affect the management of patients with NIDDM taking a sulfonylurea agent in the primary care setting.

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Home blood glucose monitoring has become a popular practice in the management of diabetes mellitus.¹ Reasons for routine monitoring of blood sugars at home include achievement and maintenance of proper glycemic control, detection and prevention of hypoglycemia, and avoidance of severe hyperglycemia.² Other benefits may include reinforcement of disease management by the patient and possibly decreased use of expensive laboratory testing.

It is not clear whether using home blood glucose monitoring in patients with non-insulin dependent diabetes (NIDDM) results in achievement of these goals in the primary care setting. In view of the high cost of blood glucose monitoring strips, we decided to determine whether prescribing of blood glucose monitoring strips by primary care providers impacts the management of patients with NIDDM who are receiving maintenance sulfonylurea therapy.

... METHODS ...

This study took place at the Prescott Veterans Affairs Medical Center, which serves the northern Arizona area. The medical center outpatient program is composed of six primary care teams staffed by a physician, nurse practitioner or physician assistant, nurse, nutritionist, and social worker. Patients see the same primary care provider at each clinic visit. An effort is made by the medical administration to assign most patients to a primary care team at this medical center. Patients who were prescribed blood glucose monitoring strips (Chemstrips, Boehringer Mannheim, Indianapolis, IN) underwent specialized training as to visual and metered techniques for the proper use of the strips. Prescription and application of home glucose monitoring were at the discretion of each primary care provider. Standardization on how these strips were applied (ie, clinical guidelines or algorithms) in the monitoring and treatment of diabetes was not employed at this facility.

The medical records of patients with the diagnosis of NIDDM who received a sulfonylurea drug for 2 years (1995 and 1996) were randomly selected from a computer-generated list of patients. Patients were divided into two groups: those who were not prescribed Chemstrips and those who were prescribed Chemstrips. Records were reviewed for laboratory measurements including all blood sugars, hemoglobin A_{1c} (HbA_{1c}), the number of these tests ordered, last dosage of oral hypoglycemic agent, and all dos-

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ing changes; primary care clinic visits; hospitalizations; and referral to ophthalmology. Hemoglobin A_{1c} measurements were performed by an external laboratory. Good glucose control was defined as an

HbA_{1c} result of 6.1% to 8%, and fair control was defined as 8.1% to 10%. All patients were routinely instructed to fast for 12 hours before laboratory phlebotomy for blood glucose testing. The pharmacy records were also reviewed for the number of prescriptions filled for the oral hypoglycemic agent. Each fill represented a 30-day supply. At the beginning of 1995, glipizide was the formulary hypoglycemic agent. During the midyear, 1995, glyburide was substituted for glipizide at half the daily dose of glipizide. This conversion was based on data demonstrating that a 2:1 ratio in daily dose (glipizide to glyburide) results in comparable glucose control.^{3,4} This conversion was not considered to be a dosing change.

Data were collected during 2 calendar years. Patients were excluded from review if they had received a sulfonylurea drug for less than 2 years or were receiving insulin and/or metformin therapy at the beginning of the review period. The means of fasting blood sugar and HbA_{1c} measurements were calculated over the 2 years for each patient. These means were then averaged for the entire 2 years and compared between groups. The means were compared between groups by using a *t* test or a Mann-Whitney rank-sum test, depending on normality testing. Proportional data were analyzed using a *z* test (SigmaStat, Jandel Scientific, San Rafael, CA). Approximately 120 patients would be required to determine a 0.6% difference in HbA_{1c} assuming a standard deviation of 1.3%, a *β* of 0.2, and an *α* of 0.05.⁵ Statistical significance was set at an *α* of <0.05.

... RESULTS ...

The medical records of 115 patients were reviewed. Fifty-eight patients received no Chemstrips and 57 received Chemstrips for the review period. The mean number of Chemstrip bottles dispensed was 9.2 ± 6 over the 2 years. The patients were well matched with respect to demographics and clinical parameters (Table 1). Eighty percent of patients using Chemstrips utilized a metering device.

No statistically significant difference existed between groups in glucose control and interventional parameters (Table 2).

Table 1. Patient Demographics and Clinical Parameters*

Characteristic	Patients not on Chemstrips (n = 58)	Patients on Chemstrips (n = 57)	P Value
Age (yr)	69 ± 7	66 ± 10	0.11
Weight (kg)	90 ± 20	91 ± 17	0.80
Last dosage of glyburide (mg/day)	10.4 ± 7	9.6 ± 7	0.55
Prescriptions filled	20.2 ± 4	20.7 ± 4	0.29
Baseline serum creatinine (mg/dL)	1.1 ± 0.3	1.1 ± 0.4	0.35
Patients with baseline proteinuria (%)	34	18	0.16

*Data are expressed as means ± standard deviation.

Table 2. Glucose Control and Treatment Interventions Over 2 Years*

Outcome Measure	Patients Not on Chemstrips	Patients on Chemstrips	P Value
HbA _{1c} (%)	8.1 ± 1.6	8.1 ± 1.3	0.65
No. of HbA _{1c} tests ordered	2.4 ± 1.6	2.3 ± 1.6	0.74
Blood sugar (mg/dL)	181 ± 46	182 ± 56	0.92
No. of blood sugar tests ordered	4.7 ± 2.6	5.1 ± 3.3	0.53
Dosing changes of hypoglycemic agent	0.93 ± 0.9	1.0 ± 1.1	0.73
No. of primary care clinic visits	7.9 ± 4.2	6.8 ± 2.9	0.09
No. (%) of patients referred to ophthalmology	12 (22)	10 (18)	0.76
No. (%) of patients admitted to the hospital	14 (24)	11 (19)	0.67

*Data are expressed as means ± standard deviation.

HbA_{1c} = hemoglobin A_{1c}

The mean for HbA_{1c} was less than 9% in both groups, indicating fair control in the majority of patients. Very low or high blood sugar measurements were not encountered in either group. One patient in each group had a blood sugar measurement of less than 75 mg/dL. Few dosing changes of the hypoglycemic agent were made in either group over the 2 years. There was no difference between groups in HbA_{1c} or blood sugar measurements when the data were analyzed separately for each year (Table 3). Subgroup analysis showed that patients who received nine or more bottles had blood sugar and HbA_{1c} values similar to those patients receiving less than nine bottles (Table 4). Metformin was prescribed for two patients in each group during the second year reviewed. One patient in the Chemstrip group was prescribed insulin during the same time frame.

... DISCUSSION ...

Our data indicate that the use of Chemstrips had little impact on the management of patients with NIDDM taking a sulfonylurea drug. Supportive evidence includes no differences in glucose control, laboratory testing, or treatment interventions. The mean HbA_{1c} value was 8.1% in both groups, indicating fair to good glucose control over the review period. These data are consistent with those of previous studies, which question the effectiveness of home glucose monitoring in a variety of settings. Two prospective studies in patients with NIDDM have shown that HbA_{1c} values were similar in patients who tested their blood sugar at home and patients who did not.^{6,7} In both studies, patients were taking oral hypoglycemic drugs and/or insulin. A retrospective study in patients with NIDDM in a nonresearch setting revealed similar results in patients using home glucose monitoring versus urine testing.⁸ In addition, this study showed that laboratory utilization was independent of the method of glucose testing. It is

not clear from this study whether the patients were followed in a primary care environment where continuity of care was emphasized. Another retrospective study in a teaching hospital showed similar glycemic control in patients on glyburide whether or not home glucose monitoring strips were used.⁹ Data were collected over 1 year in this study. To our knowledge, ours is the first study to assess the effect of home glucose monitoring in a nonacademic primary care setting.

A possible reason for our negative findings is that patients in the Chemstrip group may not have been monitoring their blood sugars frequently enough to make a difference in glycemic control. The mean number of bottles dispensed was nine over the 2-year period, suggesting that patients were monitoring their blood sugars two to four times a week. One prospective study demonstrated that measuring blood sugar six times daily along with dietary carbohydrate counting was associated with improved glycemic regulation compared with a control group.¹⁰ This monitoring is considerably more intensive than that done in the previous prospective trials, which showed no benefit with home glucose monitoring. Whether this degree of monitoring is feasible and necessary in most patients with NIDDM

Table 3. Glucose Control by Year^a

Year	HbA _{1c} (%)			Blood Sugar (mg/dL)		
	Chemstrips	No Chemstrips	P value	Chemstrips	No Chemstrips	P value
1995	8.2 ± 1.4	8.1 ± 1.5	0.70	182 ± 51	182 ± 55	0.98
1996	8.0 ± 1.3	8.2 ± 1.8	0.66	176 ± 37	177 ± 58	0.62

HbA_{1c} = hemoglobin A_{1c}.

^aData are expressed as means ± standard deviation

Table 4. Glucose Control According to Number of Chemstrip Bottles Dispensed

Outcome Measure	No. of Chemstrip Bottles		P Value
	<9 (n = 31)	≥9 (n = 26)	
HbA _{1c} (%)	8 ± 1.5	8.3 ± 1.1	0.44
Blood sugar (mg/dL)	180 ± 37	169 ± 30	0.21

HbA_{1c} = hemoglobin A_{1c}.

(receiving an oral agent only) is questionable because many patients in our study had good to fair glycemic control whether the strips were used or not.

This study was retrospective; therefore, bias may have entered into the data analysis. It is possible that the patients who were prescribed Chemstrips had worse disease and were prescribed these strips in an effort to better regulate their diabetes. Although this may have been possible, we think it was unlikely because patients in both groups were well matched as to age, weight, final dosage of glyburide, baseline renal function, and baseline proteinuria. The number of hospitalizations and referrals to the ophthalmology service were similar between groups, also suggesting homogeneity in the study cohort. In addition, it is possible that patients in the Chemstrip group had poorer control before the strips were prescribed and achieved diabetes control similar to that of patients with no Chemstrips. Our study goal was not to assess this condition, but to examine the effect of home glucose monitoring during maintenance treatment with sulfonylurea therapy. Although patients were taught the proper use of these strips, it is impossible from our study design to know whether the strips were used appropriately (if at all), the exact frequency of use, and the interaction patients had with their primary care provider. A prospective study in the primary care setting involving patients on oral agents only would further clarify these issues.

It is controversial whether patients with NIDDM need intensive monitoring of their blood sugars.¹¹ Data showing improved outcome and reduced sequelae of diabetes with intensive monitoring were in patients with insulin-dependent diabetes.¹² It is unclear whether these data can be extrapolated to patients with NIDDM, especially when their diabetes is controlled with diet or an oral agent only. Nevertheless, the American Diabetes Association recommends tight control of blood sugar in patients with NIDDM, which is presumably aided by the frequent use of home blood glucose monitoring strips.^{13,14} Whether continued use of home glucose testing is necessary for maintaining reasonable control of blood glucose in many patients receiving an oral agent is questionable, especially in view of our study results.

... CONCLUSION ...

In this setting, glucose control and treatment interventions in patients with NIDDM receiving maintenance sulfonylurea therapy were not related to the use of home glucose monitoring strips. A prospective randomized trial in this patient population and setting is needed to corroborate these findings.

... REFERENCES ...

1. Stolar MW. Clinical management of the NIDDM patient. Impact of the American Diabetes Association practice guidelines, 1985-1993. *Diabetes Care* 1995;18:701-707.
2. American Diabetes Association. Position statement: Self-monitoring of blood glucose. *Diabetes Care* 1996;19:62S-66S.
3. Kilo C, Meenan A, Bloomgarden Z. Glyburide versus glipizide in the treatment of patients with non-insulin-dependent diabetes mellitus. *Clin Ther* 1992;14:801-812.
4. Alexis G, Henault R, Sparr HB. Conversion from glipizide to glyburide: A prospective cost-impact survey. *Clin Ther* 1992;14:409-417.
5. Stolley PD, Strom BL. Sample size calculations for clinical pharmacology studies. *Clin Pharmacol Ther* 1986;39:489-490.
6. Wing RA, 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;81:830-836.
7. Allen BT, DeLong ER, Feussner JR. Impact of glucose self-monitoring on non-insulin treated patients with type II diabetes mellitus. Randomized controlled trial comparing blood and urine testing. *Diabetes Care* 1990;13:1044-1050.
8. 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 Gen Intern Med* 1993;8:597-601.
9. Wieland LD, Vigil JM, Hoffman RM, Janis LW. Relationship between home glucose testing and hemoglobin A_{1c} in type II diabetes patients. *Am J Health Syst Pharm* 1997;54:1062-1065.
10. Muchmore DB, Springer J, Miller M. Self-monitoring of blood glucose in overweight type 2 diabetic patients. *Acta Diabetol* 1994;31:215-219.
11. Nathan DM. Inferences and implications: Do results from the diabetes control and complications trial apply in NIDDM? *Diabetes Care* 1995;18:251-257.
12. The Diabetes Control and Complication Trial 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;329:977-986.
13. American Diabetes Association. Position statement: Standard of medical care for patients with diabetes mellitus. *Diabetes Care* 1996;19:8S-15S.
14. Schmitz-Fiorentino K, Burge MR, Shama L, Schade DS. Assessing the real-life relationship between average capillary blood glucose and hemoglobin A_{1c}: Is the average capillary blood glucose value clinically useful? *Am J Man Care* 1996;2:507-510.