REPORT

Association between self-monitoring of blood glucose and glycemic control in patients with type 2 diabetes mellitus

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Purpose. The relationship between the self-monitoring of blood glucose (SMBG) and glycemic control in patients with type 2 diabetes mellitus in a Veterans Affairs (VA) medical center was studied.

Methods. Laboratory, inpatient, outpatient, and demographic data for patients with type 2 diabetes mellitus who were seen for three years continuously or receiving their care regularly from a single Texas VA facility between October 1, 1999, and September 30, 2002, were obtained. Local pharmacy data were used to identify patients who received blood-glucose-monitoring strips. Patients were assigned to one of four mutually exclusive groups: those who did not receive monitoring strips at all, those who received strips in fiscal year (FY) 2002 only, those who received strips in FYs 2001 and 2002, and those who received strips during all three years (FYs 2000, 2001, and 2002). Frequency of monitoring and case-mix scores were measured. Nonparametric statistics were used to compare the demographic and clinical characteristics of the four groups. Robust regression was used to analyze the relationships between SMBG and glycemic control in FY 2002.

Results. Of the 1185 patients who received oral hypoglycemic medications during all three fiscal years, 976 patients met the criteria for inclusion in one of the four groups. There were no significant differences among the four groups in baseline hemoglobin A_{1c} (HbA_{1c}) values, body mass index, or case-mix scores. The Kruskal-Wallis test found no significant difference among the four groups in the number of laboratory blood glucose tests conducted, but there were significant differences in the number of HbA_{1c} tests conducted among the groups.

Conclusion. SMBG was not associated with glycemic control in VA patients with type 2 diabetes mellitus managed on oral hypoglycemic medications.

Index terms: Diabetes mellitus; Home tests

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Numerous studies have examined the relationship between the self-monitoring of blood glucose (SMBG) and glycemic control among patients with type 2 diabetes mellitus. Although a majority of the studies found that SMBG does not affect glycemic control in patients with type 2 diabetes mellitus,[1-9] data obtained from several studies support the use of SMBG in these patients.[10,11] Karter et al.[10] evaluated the ability of SMBG to improve glycemic control in a managed care population and found that patients with type 1 diabetes mellitus (with SMBG occurring more than three times per day) and patients with type 2 diabetes who received drug therapy (with at least daily SMBG) had lower hemoglobin A_{1c} (HbA_{1c}) levels than patients who self-monitored blood glucose less frequently. Cohen and Zimmet[11] found that SMBG was associated with improved blood glucose levels in patients managed on diet alone or receiving oral hypoglycemic therapy.

Some of the previous studies mentioned were conducted among patients in a Veterans Affairs (VA) medical center. Klein et al.[1] used retrospective chart review to determine whether SMBG, when used by

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229 veterans with non-insulin-dependent diabetes mellitus, was associated with improved glycemic control or reduced number of laboratory tests of blood (glucose and HbA_{1c} levels). They concluded that the frequency and duration of SMBG had no apparent effect on glycemic control. In addition, there was no decrease in the number of laboratory test performed among these patients. In another study, researchers concluded that among patients who received glyburide, no demographic or clinical differences were found between those who performed SMBG and those who did not.[2] Rindone and colleagues,[4] in a retrospective chart review that included a control group, found that the use of blood-glucose-monitoring strips did not affect the diabetes management of 115 veterans who received oral diabetes medication.

Thus, the role of SMBG in patients with type 2 diabetes mellitus remains uncertain. A systematic review of randomized studies among patients with type 2 diabetes mellitus found that SMBG did not improve patients' glycemic control.[9] Benefit from SMBG was measured by improvements in HbA_{1c} levels and weight loss. Important limitations of the reviewed reports included lack of statistical power; the largest sample was 200 patients. Observational studies have limitations as well, such as lack of a control group[1] and small sample sizes.[1,4] Studies conducted with VA patients to determine whether SMBG improves glycemic control in those with type 2 diabetes mellitus have small sample sizes (115–229). While Karter and associates[10] used a large sample (n = 24,312), they studied a managed care population, and their results cannot be generalized to other settings. To overcome these limitations, we studied SMBG in VA patients and used a large administrative database that allowed for the use of a control group.

The objectives of this study were threefold: (1) compare the demographic and clinical characteristics of VA patients with type 2 diabetes mellitus receiving oral hypoglycemic medications who perform and do not perform SMBG, (2) determine the relationship between SMBG, the duration of monitoring, and glycemic control, and (3) determine the relationship between SMBG and the number of laboratory tests performed to measure blood glucose and HbA_{1c} levels.

Methods

Data sources. Pharmacy and administrative data were obtained from an electronic information system within a large vertically integrated service network in the Veterans Health Administration. Data were gathered for patients at a single Texas VA facility. Laboratory, inpatient, outpatient, and demographic data were obtained from the Veterans Health Administration Information Systems and Technology Architecture, a computer system with an integrated clinical database and electronic patient record that incorporates all patient-specific information at each VA facility into one database. All prescription information was obtained from the local pharmacy file. Approval from the institutional review board was obtained.

Sample. The study cohort was derived from patients receiving care at the single facility between October 1, 1999, and September 30, 2002. Patients eligible for VA benefits from October 1, 1999, with *International Classification of Disease, 9th Revision Clinical Modification* (ICD-9-CM) codes for diabetes (250.00 to 250.X0) for outpatient visits were identified.[12] A three-step filtering procedure was developed to ensure that patients with diabetes who were seen for three years continuously or received their care regularly from the VA facility were selected. To identify the latter patients, only patients having an assigned primary care provider, at least two outpatient visits at the primary care clinic, and at least one HbA_{1c} value recorded during each of three consecutive fiscal years (FYs) were included in the final cohort. Patients who did not have a prescription for diabetes medication (oral medication or insulin in FY 2000) were excluded. From this cohort, only those who were taking oral medications all three years were included in the final cohort.

The following data were collected: demographic characteristics (age and sex), HbA_{1c} values, height and weight (to calculate body mass index [BMI]), SMBG supplies, and ICD-9-CM codes from outpatient and inpatient visits (to calculate the case-mix score).

Duration of monitoring. Local pharmacy data were used to identify patients who received blood-glucose-monitoring strips. The cohort was assigned to four mutually exclusive groups according to the duration of SMBG, determined by using pharmacy records. Group 1 did not receive monitoring strips during the study period (control group), group 2 received strips in FYs 2002 only, group 3 received strips in FYs 2001 and 2002, and group 4 received strips during all three years. Patients who did not meet the criteria for any of the four groups (e.g., received strips during the first year only) were excluded from the analysis.

Frequency of monitoring. The frequency of monitoring was calculated by dividing the total amount of strips dispensed by the number of days for which they were supplied. For example, a box of 50 strips indicated as a 90-day supply would require the use of 0.56 strip/day.

Case-mix scores. To account for the presence of comorbidities, the Chronic Illness and Disability Payment System (CDPS), a case-mix measure, was employed. The CDPS is a diagnostic classification system that some states use for their Medicaid programs to make health-based cap-

itation payments for persons with disabilities and Temporary Assistance to Needy Families beneficiaries.[13] The CDPS incorporates ICD-9-CM codes to create diagnostic categories. The ICD-9-CM codes were extracted from inpatient and outpatient data. The program calculates case-mix scores by applying CDPS national weights, which are based on expenditure files for the Medicaid population. The mean score for this population is 1, and the score represents the number of diagnostic categories per patient.[14] There are 19 major diagnostic categories, most of which are further divided into subcategories according to the degree of increased expenditures associated with the diagnoses. CDPS assumes that the cost effects of different types of diagnoses should be added together to produce an accurate prediction of total expenditures.

Statistical analyses. Nonparametric statistics, such as the Kruskal-Wallis test, were used to compare the demographic and clinical characteristics of the four groups. Robust regression was used to analyze the relationship between SMBG and glycemic control in FY 2002. The dependent variable in the model was the mean HbA_{1c} value for FY 2002, and the independent variables included the following: baseline HbA_{1c} value (FY 2000), age, case-mix score, BMI, race, and duration of monitoring (based on group membership). A robust regression method was used to respect violation of the assumption of normality.[15] A least-squares analysis weighed each observation equally on obtaining parameter estimates. Robust methods enabled the observations to be weighted unequally. Sample size and power calculations were based on multivariate analysis. An a priori value of 0.05 was established as significant for all analyses. Data analyses were performed with Stata, version 8 (StataCorp, College Station, TX).

Results

Of the 1185 patients who received oral hypoglycemic medications during all three fiscal years, 976 patients met the criteria for inclusion in one of the four groups and were included in the analysis. The sample was predominantly male (97.4%). The mean ± S.D. age was 62.7 ± 10.7 years, and the mean ± S.D. BMI was 30.8 ± 5.6 kg/m^2 (Table 1). The mean ± S.D. case-mix score was 2.70 ± 1.24. (range, 0.99–13.86), suggesting that this population is more ill than the Medicaid population on which the national weights are based.

Almost half of the sample was Hispanic (48.1%), 38.4% were non-Hispanic white, 8% were non-Hispanic black, and the race of 5.5% was unknown or missing. The median usage of monitoring strips was 0.56 strip/day.

There were no significant differences among the four groups in baseline HbA_{1c} values, BMIs, or case-mix scores. Pairwise comparison showed that patients who did not receive strips at all (group 1) were older compared with those who received strips during FY 2002 only (group 2). Of the 106 Hispanic and 20 non-Hispanic black patients in groups 1 and 2, group 1 contained 90% of the non-Hispanic black patients and 60% of the Hispanic patients (χ^2 = 6.50, $p < 0.01$).

Results of robust regression showed that age and being Hispanic (compared with being white) were significant predictors of recorded HbA_{1c} in FY 2002 (controlling for baseline HbA_{1c}) ($F_{9, 906} = 49.77$, $p < 0.001$) (Table 2). The adjusted coefficient of multiple determination (R^2) was 0.278, which indicates that 28% of the variance in HbA_{1c} values in FY 2002 is explained by the independent

Table 1.
Characteristics of Study Patients by Use of Blood-Glucose-Monitoring Strips[a]

Variable	Median (Interquartile Range)			
	Group 1 (No Strips) (*n* = 161)	Group 2 (Strips in FY 2002 Only) (*n* = 75)	Group 3 (Strips in FYs 2001 and 2002) (*n* = 138)	Group 4 (Strips in FYs 2000–2002) (*n* = 602)
Age (yr)	66 (56–73)	59 (52–66)[b]	63.5 (53–71)	63 (53–71)
BMI (kg/m^2)	28.97 (26.18–33.30)	30.42 (27.7–33.52)	30.08 (27.02–33.42)	29.99 (27.03–33.74)
CDPS score	2.28 (1.78–3.35)	2.40 (1.88–3.13)	2.37 (1.72–2.98)	2.55 (1.85–3.32)
Hemoglobin A_{1c} value (%)				
FY 2000	7.10 (6.40–8.13)	7.00 (6.35–7.93)	7.03 (6.20–7.03)	7.13 (6.40–8.10)
FY 2001	6.87 (6.10–7.80)	7.25 (6.43–7.85)	6.68 (5.82–6.68)	6.70 (6.10–7.54)
FY 2002	6.80 (6.80–7.85)	7.23 (6.45–8.17)	6.60 (5.80–6.60)	6.79 (6.17–7.61)
Ethnicity[c]				
Non-Hispanic white	65 (40.4)	26 (34.7)	62 (44.9)	222 (36.9)
Hispanic	64 (39.8)	42 (56.0)[d]	56 (40.6)	307 (51.0)
Non-Hispanic black	18 (11.2)	2 (2.7)[d]	12 (8.7)	46 (7.6)
Data missing	14 (8.7)	5 (6.7)	8 (5.8)	27 (4.5)

[a]BMI = body mass index, CDPS = Chronic Illness and Disability Payment System, FY = fiscal year.
[b]Significantly different from result for group 1 ($p < 0.01$, pairwise comparison with Bonferroni adjustment).
[c]Reported as no. (%).
[d]Significantly different from result for group 1 ($p < 0.05$).

variables. Age was inversely related to HbA_{1c}. Hispanic patients, compared with white patients, have higher HbA_{1c} values and worse control. Duration of monitoring (including no monitoring at all) was not a significant predictor of recorded HbA_{1c} values for FY 2002. We determined that a sample size of 916 achieves 100% power to detect an R^2 of 0.28 attributed to nine independent variables using an F test, with a significance level of 0.05 for regression analysis. Power calculation was performed using PASS 2000 (NCSS Statistical Software, Kaysville, UT).

The Kruskal-Wallis test found no significant differences among the four groups in the number of laboratory blood glucose tests conducted, but there were significant differences in the number of HbA_{1c} tests conducted among the groups. The mean rank for the number of HbA_{1c} tests performed in FY 2002 was significantly higher for group 2 than group 1 ($z = -2.865$, $p < 0.05$). Mean rank for number of HbA_{1c} in FY 2002 was significantly higher in group 4 than group 1 ($z = -3.483$, $p < 0.05$). The median number of HbA_{1c} tests conducted was the same across all groups (median = 2). The median number of blood glucose tests performed was similar across groups. The median number of blood glucose tests conducted was 1 for FY 2000 and FY 2001 and 2 for FY 2002. Table 3 presents the descriptive statistics of the laboratory tests performed among the study groups.

Discussion

In this population of older veteran patients managed on oral medications, no significant association was found between the duration of SMBG and glycemic control. Our findings related to glycemic control are consistent with those of previous studies, bringing into question the utility and practicality of SMBG.[2-10] In addition, no significant differences were found in the age, BMI, or case-mix score between those who did not receive strips at all and those who did receive strips during all three years.

The number of blood glucose tests performed by the laboratory was independent of the study group. However, the number of HbA_{1c} values recorded in FY 2002 was greater in group 2 than group 1 and greater in group 4 than group 1. This relationship was not expected. A possible explanation for why the number of HbA_{1c} tests was higher in patients who self-monitored all three years (group 4) than those who did not self-monitor at all (group 1) is that group 4 patients or their physicians were very motivated in monitoring HbA_{1c} levels.

One possible explanation for the lack of association between SMBG and glycemic control is that our sample did not monitor blood glucose frequently enough to detect a significant difference. The median usage of monitoring strips was 0.56 strip/day (about four times per week). Karter et al.[10] found that managed-care patients with drug-treated type 2 diabetes mellitus exhibited an inverse relationship between HbA_{1c} levels and frequency of self-monitoring.

Another explanation for the lack of association between SMBG and glycemic control might be that these patients have overall good glycemic control. The median HbA_{1c} values at baseline (7.00–7.13%) indicated good control. Those veterans who do not follow up with their physician regularly may have poor glycemic control and were not included in the study. Patients with poor glycemic control may benefit more from SMBG than patients with good control. Among the factors possibly associated with glycemic control is physician management style, which may influence the degree and duration of SMBG.

Our finding that age and being Hispanic (compared with being white) were significant predictors of HbA_{1c} in FY 2002 is similar to other research with the VA population.[16]

There are limitations to our study that are related to its retrospective design and the use of administrative databases. There is the possibility that patients may be obtaining the SMBG strips on their own, since these products are available without a prescription; however, this may be unlikely because the strips are expensive and the VA medical center provides strips for a nominal copay. Another limitation is that we assumed that receiving strips implied that patients were performing SMBG as directed. In reality, patients who received strips may not have performed SMBG. We could not assess a number of other factors that may affect glycemic control, such as compliance with medications or SMBG.

Table 2.
Results of Robust Regression[a]

Variable	Coefficient	S.E.	*t*	*p*
Baseline hemoglobin A_{1c}	0.436	0.026	16.56	0.000
Age	–0.13	0.004	–3.50	0.000
CDPS score	–0.025	0.030	–0.85	0.395
BMI	0.005	0.007	0.74	0.460
Ethnicity[b]				
Hispanic	0.217	0.077	2.80	0.005
Black	0.132	0.135	0.97	0.330
Group 2[c]	–0.227	0.162	–1.40	0.161
Group 3[c]	0.124	0.126	0.99	0.324
Group 4[c]	–0.126	0.083	–1.51	0.132
Constant	4.46	0.438	10.17	0.000

[a]Dependent variable is hemoglobin A_{1c} value in fiscal year 2002. CDPS = Chronic Illness and Disability Payment System, BMI = body mass index.
[b]Reference group is white race.
[c]Reference group is group 1.

Table 3.
Mean ± S.D. No. Laboratory Tests Ordered in Study Groups

Test[a]	Group 1 (No Strips) (*n* = 161)	Group 2 (Strips in FY 2002 Only) (*n* = 75)	Group 3 (Strips in FYs 2001 and 2002) (*n* = 138)	Group 4 (Strips in FYs 2000–2002) (*n* = 602)
Hemoglobin A_{1c}				
FY 2000	2.18 ± 1.15	2.21 ± 1.06	2.04 ± 1.02	2.49 ± 1.13
FY 2001	2.24 ± 1.02	2.29 ± 1.01	2.54 ± 1.16	2.46 ± 1.15
FY 2002	2.28 ± 1.29	2.77 ± 1.33	2.53 ± 1.12	2.46 ± 1.28
Blood glucose				
FY 2000	1.22 ± 1.08	1.40 ± 1.38	1.19 ± 1.13	1.28 ± 1.18
FY 2001	1.45 ± 1.11	1.44 ± 1.23	1.57 ± 1.17	1.55 ± 1.20
FY 2002	1.65 ± 1.26	1.93 ± 1.35	1.88 ± 1.36	1.66 ± 1.27

[a]FY = fiscal year.

Also, we could not assess whether there were any treatment interventions or mitigating factors, such as diet and level of physical activity. Another limitation is that these results cannot be generalized to other VA populations; however, we believe that with the use of a control group, our conclusions are valid.

Further research is needed to determine the effectiveness and optimal frequency of SMBG in type 2 diabetes mellitus, and these studies should be conducted prospectively. A more rigorous design, such as a randomized control trial, may yield more specific recommendations for SMBG in patients with type 2 diabetes mellitus.

Conclusion

SMBG was not associated with glycemic control in VA patients with type 2 diabetes mellitus managed on oral hypoglycemic medications.

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