The Impact of Self-monitoring of Blood Glucose on a Behavioral Weight Loss Intervention for Patients With Type 2 Diabetes

Purpose

The purpose of the study was to examine the association of self-monitoring of blood glucose (SMBG) to weight loss and A1C among participants in a behavioral weight loss intervention.

Methods

Multivariate analyses were employed to evaluate the relationship between SMBG and changes in patient weight and A1C levels. Bootstrapping was used to determine whether there was an indirect effect of SMBG on weight loss through diet adherence and an indirect effect of SMBG on A1C through weight loss.

Results

The relationship between increased SMBG and greater weight loss was mediated by better adherence to diet. The relationship of increased SMBG and greater reductions in A1C were mediated by greater weight loss.

Conclusions

Results of the study were consistent with the hypothesis that SMBG leads to an increased adherence to dietary recommendations. For patients who are taught to use their diet to lose weight, increased adherence to dietary

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Acknowledgments: The authors thank Bhavna Abbi, MHS, for her comments on this manuscript.

DOI: 10.1177/0145721712449434

recommendations is associated with increased weight loss and subsequently better glucose control. SMBG may be of value as an adjunctive intervention in behavioral programs for type 2 diabetes.

Diabetes is the sixth leading cause of death in the United States[1] and is associated with increased rates of depression,[2] retinopathy,[3] and renal disease. In order to improve diabetic outcomes, patients are recommended to maintain A1C levels below 7%. Modification of diet and exercise to lose weight is the first approach recommended to improve A1C levels.[4] Weight loss improves glycemic control,[5–8] reduces complications, improves quality of life, and decreases mortality rates.[9]

While behavioral weight loss interventions are effective at facilitating weight loss,[10–16] weight loss behaviors are not maintained over time. For this reason, there is a need to improve weight loss interventions.[12,17] One mechanism to improve adherence relies on giving patients immediate feedback based on results of their behaviors.[18] It has been posited that the self-monitoring of blood glucose (SMBG) can serve as a feedback function by helping patients connect eating behaviors to glucose levels.[19,20] SMBG provides patients concrete evidence of the biological effect of specific dietary choices and consequently may increase adherence to dietary recommendations. This hypothesis is consistent with the common-sense model of self-regulation, which suggests that patients in part manage their disease based on symptoms.[21–23] Since changes in glucose control provide few reliable symptoms, patients need objective measures of glucose control to manage their diabetes.

Previous studies on the efficacy of SMBG on improving glucose control have found mixed results. Systematic reviews and meta-analyses have concluded that SMBG leads to small improvements in A1C levels of 0.22% to 0.31%,[24–29] leading to long-term reductions in macrovascular complications and reductions in costs.[30–32] However, in one of the best designed SMBG trials to date, Farmer et al did not find statistically significant improvement in A1C levels for individuals with type 2 diabetes not on insulin.[33]

These inconsistent results can be understood by examining the impact of SMBG on weight loss behaviors. A patient can make changes to diet or exercise in response to SMBG, but these changes will only improve A1C if correct and effective changes are made. SMBG trials have infrequently taught patients how to change their diet and physical activity to achieve weight loss and glucose control.[34] The few studies that have provided a dietary and exercise component have not consistently shown improvement in weight loss, suggesting that these interventions have not targeted weight loss or did not use empirically based strategies.[35,36]

It is hypothesized that SMBG leads to improvements in dietary adherence. Patients who use empirically based strategies to change their diet to achieve weight loss will achieve greater weight loss and improve their A1C levels. To test the hypothesis, the impact of SMBG on dietary adherence in a weight loss intervention for patients with type 2 diabetes not on insulin was examined. A specific aim of the study was to examine if SMBG would lead to improved adherence to dietary recommendations, thereby improving weight loss and ultimately, glycemic control. Primary results of the weight loss intervention have been published and have demonstrated that a portion control diet results in greater weight loss than a diabetes support and education intervention.[37]

Methods

Design. The parent trial used a crossover design that compared a portion-controlled weight loss intervention (N = 35) to a diabetes support and education program (N = 34). There were no significant baseline differences between the two arms.[38] After 3 months, individuals in the support and education arm crossed over to the portion-controlled weight loss intervention, while individuals in the portion-controlled weight loss intervention continued receiving biweekly weight loss instruction. Therefore, individuals in both arms received 3 months of the weekly portion-controlled weight loss intervention.

The current study focuses on the data obtained while participants from both arms were in the portion-controlled weight loss intervention phase of the study. For the current study, all participants were compared immediately before they started the weekly portion-controlled weight loss intervention (either at month 0 or month 3) and 3 months after starting this intervention (either at month 3 or month 6). This allowed the examination of the effect of SMBG on weight loss. For ease of reporting, in this study, month 0 will indicate the time immediately before the portion-controlled weight loss intervention was started and month 3 will indicate the time immediately after the 3-month portion-controlled weight loss intervention was completed.

Sample. The population of the parent weight loss study consisted of 69 individuals with type 2 diabetes not on insulin.[39] All participants provided informed consent prior to participation in the study.[40] Participants were obese individuals (ages 21-75) recruited from the community and through physician referrals. Participants were eligible to participate if they had a BMI between 30 to 50 kg/m^2 and A1C level ≥ 6. Patients were excluded if they: were pregnant or lactating, had a serious medical condition, took medication that could affect their body weight, such as lipid-lowering medications, or diabetes medications other than metformin, thiazolidinediones, and sulfonylureas. Participants were randomly assigned to study arms by using a random number generated by the study statistician. Group assignment was made by the research coordinator and the primary outcomes were weight loss and A1C.

Outcome measures. *Frequency of SMBG* and *adherence to a diabetic diet* were our primary dependent variables. Both are subscales of the Summary of Diabetes Self-Care Activities measure.[41] The Summary of Diabetes Self-Care measure is frequently used in diabetes research and is responsive to change.[42–44] It consists of an 11-item questionnaire that asks participants to indicate during "how many of the last seven days" they completed diabetes self-care behaviors such as exercising, adhering to a diabetic diet, reporting fat intake and fruit and vegetable intake, and SMBG. Interitem correlations within scales were high (mean = .47) and test-retest correlations (mean =.40) were moderate. In addition, two items on the questionnaire asked about SMBG, overall diet adherence, and exercise. *Weight* was measured using a calibrated scale (Detecto, Cardinal Scale Manufacturing Company, Webb City, MO), while *A1C* was assessed from fasting blood samples and assays were performed in a commercial laboratory (Quest Diagnostics, Horsham, PA; http://www.questdiagnostics.com/hcp/qtim/testMenuSearch.do).

Intervention. During the portion-controlled weight loss intervention, all participants met weekly in groups and were given standard instruction on behavioral weight loss skills (ie, cognitive restructuring, identifying triggers to overeating, etc).[45] Portion-controlled meals were provided and participants added conventional foods to these meals for a total of 1250 kcal/day for women and 1550 kcal/day for men. Participants were asked to self-monitor their food intake and increase their duration of physical activity. They were also asked to self-monitor their blood glucose levels twice a day and consult their physician if they had either low glucose levels (hypoglycemia) or consistently elevated glucose levels. During this time, participants were provided with behavioral instruction on achieving weight loss; however, they were not given instructions on how to make changes to their diet or exercise regimen in response to high glucose readings.

Data analyses. Data were analyzed using SPSS version 16.0.1 for Windows. The current study examined all participants before they started the portion-controlled weight loss intervention (month 0) and immediately after completing the portion-controlled weight loss intervention (month 3). As a result of an administrative delay, the first 9 participants did not receive the questionnaire packet at baseline and were thus not included in the analyses (n = 60). The following variables were examined for normality: SMBG at month 3, diet at month 3, A1C level at months 0 and 3, and change in A1C levels (month 3 – month 0), which were found to be skewed. A log-based 10 transformation was applied to these variables to improve the normality of the distributions for all data analyses unless otherwise specified. Change scores (month 3 – month 0) were calculated and used in the correlation analyses. For the remaining analyses, the month 3 variable was used (eg, kg at month 3) after controlling for the effect of the month 0 variable (eg, kg at month 0) to estimate change.

Descriptive statistics were examined, including mean and standard deviations of diabetes behaviors at month 0 and month 3 (for interpretability, the nontransformed means and standard deviations were reported). Dependent *t* tests were conducted to detect improvements in diabetes behaviors from month 0 to month 3. Pearson's correlation analyses were conducted to determine associations between diabetes-specific behaviors with weight loss and diabetes-specific behaviors with A1C.

Two multivariate regression analyses were conducted to determine the relationship of SMBG to weight and A1C, respectively. Subsequently, a bootstrapping technique based on 5000 bootstraps and a 95% confidence interval (CI) was used to determine the effect of the mediation variables (http://www.comm.ohio-state.edu/ahayes/SPSS%20programs/indirect.htm).[46,47]

Bootstrapping techniques are beneficial in determining mediation and indirect effects, since they do not require the sampling distribution to be normally distributed.[48,49] For this reason, nontransformed variables were used in the bootstrapping analyses. Age, gender, and exercise were found to not be related to weight loss or A1C, and thus were not used as control variables in the regression or bootstrapping analyses. Instead, patient randomization to a study arm, as well as self-identification as African American, were used as control variables, since these variables were related to weight loss and/or A1C levels.

In the first multivariate regression analysis, the effect of SMBG on weight at month 3 was examined. In step 1, the independent variable (SMBG at month 3) and control variables (weight at month 0 and SMBG at month 0) were added. In the second step, the mediating variables were added (adherence to diet at months 0 and 3). The bootstrapping technique was then used to determine if there was an indirect (mediation) effect of SMBG on weight loss through the proposed mediator diet adherence.

In a second multivariate regression analysis, the direct effect of SMBG on A1C at month 3 was examined. In step 1, the independent variable (SMBG at month 3) and the control variables (A1C at month 0 and SMBG at month 0) were added. In the second step, the mediating variables (weight at month 0 and 3) were added. The bootstrapping technique was then used to determine if there was an indirect effect of SMBG on A1C through the proposed mediator, weight.

Table 1

Mean and Standard Deviations of Diabetes Behaviors

	Month 0 Mean (SD)	Month 3 Mean (SD)
Exercise[a]	4.04 (3.77)	8.36 (3.73)
Dietary adherence	7.33 (3.70)	12.22 (1.74)
SMBG	7.05 (4.94)	11.83 (3.61)

Abbreviation: SMBG, self-monitoring of blood glucose.
[a]Diabetes behaviors were each measured with 2 questions. Each question asked the number of days in the past week the participant completed the behavior. The behaviors reported in this table are the sum of these 2 questions (range, 0-14 days).

Results

Participants were on average 52.2 ± 9.5 years old, weighed 111.2 ± 21.3 kg, and had an average BMI of 39.0 ± 6.2 kg/m^2 and A1C of 7.5% ± 1.6%. Participants were primarily female (71.0%) and racially diverse: White (40.6%), African American (52.2%), American Indian/Alaska Native (2.9%), other/more than one race (4.3%).[50] The rates of diabetes behaviors at month 0 and month 3 are reported in Table 1. Dependent *t* test demonstrated that participants reported significantly increasing their exercise, dietary adherence, and SMBG as a consequence of the intervention.

The bivariate correlations of the change scores (baseline to month 3) and month 3 scores among SMBG, weight, A1C, and dietary adherence are reported in Table 2. Greater weight loss (negative change in weight, kg) was correlated with greater increases in SMBG (positive change in SMBG) (r = –.43) and a greater adherence to diet at month 3 (r = –.42). Reductions in A1C (negative change in A1C) were associated with greater adherence to diet at month 3 (r = –.31). Greater increases in SMBG (positive change in SMBG) were correlated with greater dietary adherence (r = .32). Self-reported exercise was not related to either weight or A1C.

Multivariate regression analyses were used to examine the direct impact of SMBG at month 3 (controlling for SMBG at month 0) on weight at month 3 (controlling for weight at month 0) (see Table 3). At step 1, not self-identifying as African American (β = .06), greater SMBG at month 3 (β = –.08), and a trend toward being in the initial portion controlled intervention arm (β = .06) were related to lower weight at month 3 (controlling for weight at month 0). In step 2, the addition of diet adherence completely accounted for the effect of SMBG on weight. In other words, lower weight at month 3 (controlling for weight at month 0) was related to greater adherence to diet at month 3 (β = –.08), and there was no longer an effect of SMBG at month 3 on weight. Finally, the bootstrapping technique verified that diet at month 3 (controlling for diet at month 0) mediated the effect of SMBG at month 3 (controlling for SMBG at month 0) on weight at month 3 (controlling for weight at month 0) (point estimate of –.1566; 95% CI, –.4691 to –.0296). The mediator is considered significant when the confidence interval of the point estimate does not include zero.

Multivariate regression analyses were also used to examine the impact of SMBG at month 3 (controlling for

Table 2

Correlation Matrix With Weight, A1C, SMBG, Dietary Adherence, and Exercise

	ΔA1C	ΔSMBG	ΔDiet	ΔExercise	Kg 3M	A1C 3M	SMBG 3M	Diet 3M	Exercise 3M
ΔKg	.29[a]	–.43[a]	.05	–.00	–.10	.41[a]	–.26	–.42[a]	.18
ΔA1C		–.11	.03	–.25	.15	.05	–.18	–.31[a]	–.04
ΔSMBG			.29[a]	.10	.08	–.12	.37[a]	.32[a]	–.11
ΔDiet				–.02	.14	.15	–.25	.12	–.23
ΔExercise					.11	.20	–.18	–.20	.48[a]
Kg 3M						–.02	.02	–.10	–.10
A1C 3M							–.18	–.19	.08
SMBG 3M								.51[a]	.00
Diet 3M									–.14

Abbreviations: Kg, kilogram; SMBG, self-monitoring of blood glucose; Δ, change; 3M, month 3 minus baseline.
[a]$P \leq .05$.

Table 3

Summary of Regression Analysis for Variables Predicting Weight (kg) at Month 3

	Model 1			Model 2		
Variables	**B**	**SE**	**Beta**	**B**	**SE**	**Beta**
Arm-PCD	2.15	1.09	.06	2.90	1.03	.08[a]
African American	3.89	1.08	.11[a]	3.45	1.01	.09[a]
Kg baseline	.98	.03	1.00[a]	.96	03	.98[a]
SMBG baseline	.27	.12	.07[b]	.26	.12	.07[b]
SMBG month 3	–3.68	1.52	–.08[b]	–.23	1.74	–.01
Diet baseline				–.28	.17	–.06
Diet month 3				–5.21	2.07	–.08[b]
R^2	.97					
F	241.94					
ΔR^2	.01					
ΔF	5.38					

Abbreviations: Arm-PCD, originally being randomized to the portion controlled arm; Kg, kilogram; SMBG, self-monitoring of blood glucose.
[a]$P < .01$.
[b]$P < .05$.

SMBG at month 0) on A1C at month 3 (controlling for A1C at month 0) (see Table 4). In step 1, not identifying as African American (β = .24) and a trend toward being associated with greater SMBG at month 3 (β = –.19) were related to lower A1C at month 3 (controlling for A1C at month 0). In step 2, the addition of weight completely accounted for the effect of SMBG on A1C. In other words, a lower A1C at month 3 (controlling for A1C at month 0) was related to lower weight at month 3 (β = 1.07), and there was no longer an effect of SMBG at

Table 4

Summary of Regression Analysis for Variables Predicting A1C at Month 3

	Model 1			Model 2		
Variables	B	SE	Beta	B	SE	Beta
Arm-PCD	.00	.01	.01	–.01	.01	–.06
African American	.03	.01	.24[a]	.02	.02	.13
HbA1c baseline	.54	.08	.65[b]	.54	.08	.64[b]
SMBG baseline	.00	.00	.03	.00	.00	–.04
SMBG month 3	–.03	.02	.19	–.02	.02	–.11
Diet baseline				–.00	.00	–1.05[a]
Diet month 3				.00	.00	1.07[a]
R^2	.60					
F	12.92					
ΔR^2	.04					
ΔF	2.34					

Abbreviations: Arm-PCD, originally being randomized to the portion controlled arm; Kg, kilogram; SMBG, self-monitoring of blood glucose.
[a] $P < .05$.
[b] $P < .01$.

month 3 on A1C. Finally, the bootstrapping technique demonstrated that although there was not a significant direct effect of SMBG on A1C, there was an indirect effect through the proposed mediator of weight loss (point estimate of –.0238; 95% CI, –.0776 to –.0003). In other words, SMBG indirectly led to improved A1C by increasing weight loss.

Discussion

Increased frequency of SMBG predicted greater weight loss in a weight loss behavioral intervention for patients with type 2 diabetes not on insulin. The relationship of SMBG to weight loss was mediated by improved dietary adherence. This is consistent with the hypothesis that SMBG would lead to improvements in adherence to diet, leading to improvements in weight loss. In addition, SMBG was shown to be indirectly associated with lower A1C through greater weight loss.

Results were consistent with the conceptual model, common-sense model of self-regulation.[21,51,52] The common-sense model of self-regulation suggests that individuals use their symptoms to understand their illnesses and evaluate treatments. For patients with relatively well-controlled diabetes, fluctuations in glucose will lead to few reliable symptoms. SMBG may be used to provide direct feedback to the patient on the effects of their behaviors.

Clinical trials of SMBG have been designed to examine the direct impact of SMBG on A1C. Our data are consistent with the hypothesis that SMBG is best used to motivate adherence to dietary recommendations and self-management behaviors by providing meaning to the value of these behaviors. However, if the patient is not taught empirically based strategies to improve glucose levels through diet, exercise, or medication, the effects of SMBG on A1C will be minimal. Although some SMBG interventions have included instruction on how to modify diet, exercise, and/or medication, the efficacy of the dietary and exercise instructions is unclear and may lead to the continued inconsistent findings in these trials.

In reviewing the literature, Kempf and colleagues concluded that "most RCTs of SMBG in type 2 diabetes do not provide a sufficiently detailed description of the SMBG-disease management strategy used, even though it is this intervention strategy that is analyzed in the trial."[53] In this study, we examined an alternative intervention approach—the use of SMBG within a proven behavioral intervention. Results suggest that adding SMBG to improve adherence within a proven behavioral intervention program may be beneficial in improving dietary adherence and weight loss and may lead to improved glycemic control.

This recommendation is consistent with other literature that demonstrates the importance of self-monitoring of behaviors.[54] A recent meta-analysis found that prompting self-monitoring of behavior (eg, diet diary, monitoring exercise) was the largest predictor of improvement in behavior.[55] Consistent with the hypotheses, dietary and exercise interventions that targeted prompting self-monitoring of behavior and at least one other self-regulatory technique (eg, provide feedback, goal setting) were more effective than interventions that did not include these skills.[56]

In this study, self-reported exercise was not related to A1C or weight. This is consistent with the findings of the American College of Sports Medicine, which found that moderate-intensity exercise, like that prescribed to participants in this study, has been found to be only modestly associated with weight loss.[57] Moderate-intensity exercise does improve health outcomes and prevent weight gain.[58]

Limitations

Participants in the study were not randomized to receive instruction on SMBG. As a result, one cannot exclude the alternative explanation that improvements in dietary adherence lead to more frequent SMBG. However, we are not aware of theoretical models that would suggest this alternative explanation. We also cannot exclude the possibility that conscientious participants were more likely to show improvements in SMBG and diet adherence and subsequently lose more weight. When we examined the relationship of SMBG to the other diabetes-related behaviors, change in SMBG was not related to changes in foot care, fruit and vegetable intake, or exercise. Since the study was not designed as an SMBG intervention, patients learned behavioral skills to achieve weight loss. Participants did not receive instruction on how to make dietary or physical activity changes in response to high glucose readings. Future studies should examine if added instruction on how to change diet and exercise in response to high glucose readings provides additional benefit. These studies should also examine the direct effect of dietary adherence on glucose control. Other limitations included a small sample size using a self-report measure of SMBG rather than meter results and not having a longer-term follow-up.

Conclusion and Implications

Results of the study were consistent with the hypothesis that SMBG would lead to an increased adherence to dietary recommendations and weight loss. This trial should be replicated in a larger sample—randomized to SMBG in the context of an effective behavioral weight intervention with a longer follow-up. Diabetes educators should be aware that SMBG may help patients adhere to dietary recommendations. This may be especially relevant for patients who are taught empirically based weight loss strategies. This study has implications for understanding the mechanisms through which SMBG can improve glycemic control and the health of patients with type 2 diabetes.

Declaration of Conflicting Interests

The authors declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Gary D. Foster, PhD, is a consultant to NutriSystem, Inc.

Funding

The authors disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This study was funded by a research grant from NutriSystem to Temple University (Clinicaltrials.gov identifier NCT00593476). The sponsor had input into the design but not the analyses or interpretation of the parent study. The sponsor did not have any input into the design, analyses, or interpretation of the study reported in this article. A portion of this material is the result of work supported with resources and the use of facilities at the Department of Veterans Affairs, New Jersey Health Care System. The contents do not represent the views of the Department of Veterans Affairs or the United States Government.

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