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Glucose Self-Monitoring in Non–Insulin-Treated Patients With Type 2 Diabetes in Primary Care Settings
A Randomized Trial

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IMPORTANCE The value of self-monitoring of blood glucose (SMBG) levels in patients with non–insulin-treated type 2 diabetes has been debated.

OBJECTIVE To compare 3 approaches of SMBG for effects on hemoglobin A_{1c} levels and health-related quality of life (HRQOL) among people with non–insulin-treated type 2 diabetes in primary care practice.

DESIGN, SETTING, AND PARTICIPANTS The Monitor Trial study was a pragmatic, open-label randomized trial conducted in 15 primary care practices in central North Carolina. Participants were randomized between January 2014 and July 2015. Eligible patients with type 2 non–insulin-treated diabetes were: older than 30 years, established with a primary care physician at a participating practice, had glycemic control (hemoglobin A_{1c}) levels higher than 6.5% but lower than 9.5% within the 6 months preceding screening, as obtained from the electronic medical record, and willing to comply with the results of random assignment into a study group. Of the 1032 assessed for eligibility, 450 were randomized.

INTERVENTIONS No SMBG, once-daily SMBG, and once-daily SMBG with enhanced patient feedback including automatic tailored messages delivered via the meter.

MAIN OUTCOMES AND MEASURES Coprimary outcomes included hemoglobin A_{1c} levels and HRQOL at 52 weeks.

RESULTS A total of 450 patients were randomized and 418 (92.9%) completed the final visit. There were no significant differences in hemoglobin A_{1c} levels across all 3 groups ($P = .74$; estimated adjusted mean hemoglobin A_{1c} difference, SMBG with messaging vs no SMBG, −0.09%; 95% CI, −0.31% to 0.14%; SMBG vs no SMBG, −0.05%; 95% CI, −0.27% to 0.17%). There were also no significant differences found in HRQOL. There were no notable differences in key adverse events including hypoglycemia frequency, health care utilization, or insulin initiation.

CONCLUSIONS AND RELEVANCE In patients with non–insulin-treated type 2 diabetes, we observed no clinically or statistically significant differences at 1 year in glycemic control or HRQOL between patients who performed SMBG compared with those who did not perform SMBG. The addition of this type of tailored feedback provided through messaging via a meter did not provide any advantage in glycemic control.

TRIAL REGISTRATION clinicaltrials.gov Identifier: NCT02033499

Editor's Note

Author Video Interview and JAMA Report Video

Supplemental content

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Group Information: A complete list of the Monitor Trial Group members is provided in at the end of the article.

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The value of self-monitoring of blood glucose (SMBG) for patients with non–insulin-treated type 2 diabetes mellitus (T2DM) has been debated,[1-7] yet over 75% perform regular SMBG.[8] Several trials showed significant benefit from SMBG on glycemic control,[9-12] while others found no evidence of benefit.[7,13-16] Proponents postulate that testing promotes better awareness of glucose levels, leading to improvements in diet and lifestyle. However, harms from routine SMBG in patients with non-insulin-treated T2DM are possible.[17,18]

Studies of enhanced SMBG, where patients and/or clinicians were educated to better interpret SMBG values, found hemoglobin A_{1c} reductions close to 0.5%,[3,10,19,20] compared with simple SMBG, where levels were reduced by 0.2%, an amount that was statistically significant but of doubtful clinical significance.[3,21] This pattern suggests that, for SMBG to be an effective self-management tool in non-insulin-treated T2DM, the patient and physician must actively engage in performing, interpreting, and acting on the SMBG values.

Our goal was to answer the following question: Is SMBG effective for people with non-insulin-treated T2DM in terms of improving either hemoglobin A_{1c} levels or health-related quality of life (HRQOL)?

Key Points

Question Is self-monitoring blood glucose levels effective for people with non–insulin-treated type 2 diabetes in terms of improving either hemoglobin A_{1c} levels or health-related quality of life (HRQOL) in primary care practice?

Findings In this pragmatic randomized clinical trial that included 450 patients randomized to 1 of 3 groups: no self-monitoring of blood glucose (SMBG), once-daily SMBG, and once-daily SMBG with enhanced patient feedback. There were no significant differences in glycemic control across all groups, nor were there significant differences found in HRQOL.

Meaning Routine self-monitoring of blood glucose levels does not significantly improve hemoglobin A_{1c} levels or HRQOL for most patients with non–insulin-treated type 2 diabetes; patients and clinicians should consider the specifics of each clinical situation as they decide whether to test or not to test.

Methods

Trial Design

We performed this pragmatic trial across 15 primary care practices in central North Carolina. The trial was funded by the Patient-Centered Outcomes Research Institute Diabetes stakeholders provided input during grant design, implementation, and dissemination.[22] The trial protocol (Supplement 1) was reviewed and approved by the University of North Carolina institutional review board. Written informed consent was obtained and participants were compensated with $50 for filling out baseline and follow-up surveys. Participants in the testing arms also received a meter and test strips. Patients with non–insulin-treated T2DM were randomly assigned to 1 of 3 arms: (1) no SMBG; (2) standard once-daily SMBG consisting of glucose values immediately reported to the patient through the meter; and (3) enhanced once-daily SMBG consisting of glucose values immediately reported to the patient plus automated, tailored messaging delivered to the patient through a Telcare meter. The messaging algorithm accounted for blood glucose value, time of day, and relationship to food intake. Messages were intended to educate and motivate patients (eTable 2 in Supplement 2). Time- and date-stamped data uploaded from the meters allowed the study team to monitor daily meter use in the SMBG arms. Following randomization, primary care clinicians guided participants' routine diabetes management. Clinicians received summaries of SMBG data and potential treatment options based on American Diabetes Association Standards of Care[1] through the electronic health record for patients in both testing arms. The recommendations were not prescriptive and clinicians were encouraged to use them based on clinical situation. Participants were reassessed at 52 weeks following randomization.

Patients

Eligibility criteria included: (1) T2DM, (2) 30 years or older, (3) established patient at a participating practice, (4) hemoglobin A_{1c} levels between 6.5% and 9.5% within 6 months preceding screening, and (5) willing to be randomly assigned to a study group. Patients were excluded if they planned to see an endocrinologist in the upcoming year, currently or planned to use insulin during study period, planned to become pregnant or relocate in the next year, or had other conditions that would put them at risk in following study protocol. Patients were not excluded if they had prior SMBG experience.

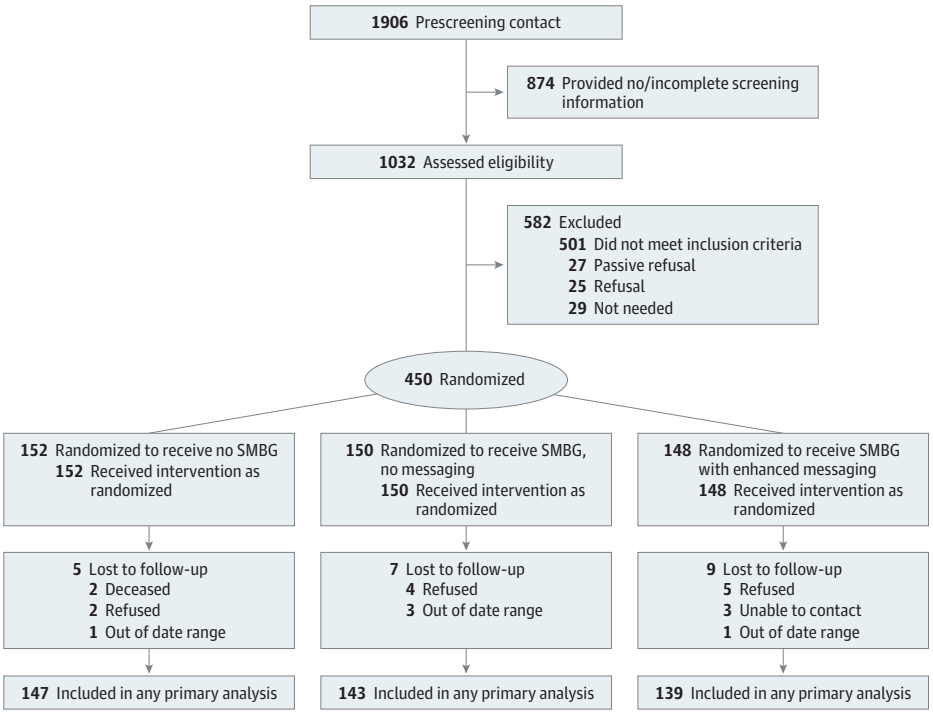
Baseline Procedures

After study field staff obtained written informed consent, patients completed an interview that included demographic, health history, and patient-reported measures. Patients had a hemoglobin A_{1c} blood test and height and weight were recorded. The field coordinator then opened a numbered, opaque randomization envelope containing group assignment. Randomization was stratified by practice and used randomly permuted blocks of sizes 15 and 18 generated by a biostatistics research assistant not otherwise involved in the study. The field coordinator taught patients randomized to the testing groups how to use the meter. All participants received educational brochures describing blood glucose goals and symptoms of hypoglycemia and hyperglycemia.

Outcomes

The 2 primary outcomes were change in hemoglobin A_{1c} levels and in HRQOL. Hemoglobin A_{1c} levels were measured at baseline and again at a mean (SD) 52 (6) weeks from baseline visit. For the first 40 patients enrolled, baseline hemoglobin A_{1c} levels were measured by total glycated hemoglobin; glycosylated hemoglobin was calculated using a published formula by the processing laboratory. The remainder of patients had their hemoglobin A_{1c} levels measured by glycosylated hemoglobin by a single laboratory at baseline and follow up visits. Intermediate hemoglobin A_{1c} values were captured passively from the electronic health record. We assessed HRQOL

Figure 1. The Monitor Trial CONSORT Flow Diagram



SMBG, self-monitoring of blood glucose.

using physical and mental component scores of the Short-Form 36 (SF-36).[23] Secondary outcomes included Problem Areas In Diabetes,[24] Diabetes Symptoms Checklist,[25] and Diabetes Empowerment Scale[26] to assess diabetes-specific HRQOL and self-efficacy. We examined diabetes self-care through the Summary of Diabetes Self-Care Activities measure.[27] Treatment satisfaction and provider-patient communication were assessed through the Diabetes Treatment Satisfaction Questionnaire[28] and the Communication Assessment Tool.[29]

Preidentified potentially study-related adverse events (AEs) included finger stick infections and severe hypoglycemia. Emergency department and hospitalizations alerts from the electronic health record allowed review of intrastudy events, which were adjudicated by committee. At follow-up, participants were queried regarding any urgent care, emergency department visit, hospitalization, finger stick infection, and hypoglycemic episode over the past 52 weeks.

Statistical Analysis

We calculated power for the 2 *df* overall tests comparing our primary outcomes across all 3 groups. Assuming a common standard deviation for change in hemoglobin A_{1c} levels of 0.8% and no more than 10% loss to follow-up, randomizing 150 patients per group would provide at least 90% power to detect a mean difference of −0.325% between the SMBG and no SMBG groups at the .05 significance level. Assuming a HRQOL standard deviation of 10 points, this sample size would provide at least 80% power to detect an overall difference between groups if the mean difference between the highest and lowest groups was at least 4 points on either component of the HRQOL scale at the .025 level (Bonferroni-corrected for 2 components).

For primary analyses, all randomized patients were analyzed according to their group regardless of the extent to which they performed SMBG (intention-to-treat, ITT). The statistician remained blinded to treatment groups until after finalization of programming for primary comparisons. Missing 52-week outcome data were ignored for primary analyses. We compared change in hemoglobin A_{1c} levels from baseline through 52 weeks across the 3 randomization groups using an analysis of covariance (ANCOVA) conducted at the .05 significance level. This model controlled for site, baseline hemoglobin A_{1c} levels, whether baseline hemoglobin A_{1c} levels were directly measured or calculated, use of SMBG at baseline, duration of diabetes, baseline use of antihyperglycemic treatment (sulfonylurea or glinide), age, race/ethnicity, health literacy, and number of comorbidities. Had the overall test been rejected, we planned to compare each SMBG group to the no testing group separately using the Dunnett-Tamhane Step-Up procedure.[30] We also conducted a contrast test comparing the average of the 2 SMBG groups to the no SMBG group at the .05 level. ANCOVA similar models were used to compare groups for change in HRQOL component scores as well as listed secondary outcomes; besides the covariates listed above, each of these models controlled for corresponding baseline scale score. Additionally, we explored potential for effect modification by each baseline variable included in the models by adding appropriate interaction terms to the ANCOVA model 1 at a time.

We conducted 3 prespecified sensitivity analyses for the hemoglobin A_{1c} comparison. First, we repeated ITT analysis using

Table 1. Baseline Characteristics

Characteristic	Randomization Group			
	No SMBG (n = 152)	SMBG, No Messaging (n = 150)	SMBG With Messaging (n = 148)	Total (n = 450)
Age, median (range), y	61 (31-89)	63 (32-82)	61 (35-92)	61 (31-92)
Sex, No. (%)				
Male	74 (48.7)	67 (44.7)	66 (44.6)	207 (46.0)
Female	78 (51.3)	83 (55.3)	82 (55.4)	243 (54.0)
Race, No. (%)				
Black	42 (27.6)	55 (36.7)	51 (34.5)	148 (32.9)
White	104 (68.4)	89 (59.3)	86 (58.1)	279 (62.0)
Other	6 (3.9)	6 (4.0)	11 (7.4)	23 (5.1)
Ethnicity, non-Latino Hispanic, No. (%)	148 (97.4)	147 (98.7)	146 (98.6)	441 (98.2)
Education, No. (%)				
<High school	6 (4.0)	10 (6.7)	9 (6.1)	25 (5.6)
High school/some college	95 (62.9)	87 (58.0)	89 (60.1)	271 (60.4)
College or higher	50 (33.1)	53 (35.3)	50 (33.8)	153 (34.1)
BMI, median (range)	33 (22-58)	33 (21-62)	34 (21-75)	33 (21-75)
Low health literacy, No. (%)[a]	62 (40.8)	54 (36.5)	55 (37.2)	171 (38.2)
Years with diabetes, median (range)	6 (0-45)	6 (0-44)	6 (0-50)	6 (0-50)
Diabetes 1 y or less, No. (%)	25 (16.4)	27 (18.0)	14 (9.5)	66 (14.7)
No. of comorbidities, median (range)	3 (0-9)	3 (0-10)	3 (0-8)	3 (0-10)
Use of SMBG, No. (%)				
Current	114 (75.0)	108 (72.0)	116 (78.4)	338 (75.1)
Ever	138 (90.8)	135 (90.0)	143 (96.6)	416 (92.4)
Testing preference, No. (%)				
Any SMBG	63 (41.4)	56 (37.3)	59 (39.9)	178 (39.6)
No SMBG	31 (20.4)	34 (22.7)	32 (21.6)	97 (21.6)
Uncertain	2 (1.3)	1 (0.7)	1 (0.7)	4 (0.9)
No preference	56 (36.8)	59 (39.3)	56 (37.8)	171 (38.0)
Diabetes medications, No. (%)[b]				
Metformin	123 (80.9)	115 (76.7)	120 (81.1)	358 (79.6)
Sulfonylurea or glinide	51 (33.6)	50 (33.3)	60 (40.5)	161 (35.8)
Thiazolidinedione	8 (5.3)	3 (2.0)	10 (6.8)	21 (4.7)
GLP-1 agonist	5 (3.3)	2 (1.3)	10 (6.8)	17 (3.8)
DPP-4 inhibitor	12 (7.9)	11 (7.3)	17 (11.5)	40 (8.9)

Abbreviation: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); SMBG, self-monitoring of blood glucose.

[a] Scoring less than 4 on Newest Vital Sign.[31]

[b] Other diabetes medications were less than 5%.

a per-protocol population that excluded participants who initiated insulin use during the study or who were not sufficiently compliant with their assigned treatment. In the testing arms, we excluded participants who uploaded a meter reading fewer than 80% of their days in the study, and in the no testing arm we excluded participants who admitted to ever testing with any regularity during the study. Second, we repeated the ANCOVA model using linear mixed models that included all intermediate hemoglobin A_{1c} values captured from the electronic health record, excluding any following initiation of insulin use. This model included fixed effects for linear and quadratic time trends and time-by-treatment group interactions, as well as random intercepts and slopes for each patient. As a final sensitivity analysis, we used last observation carried forward to impute the 52-week hemoglobin A_{1c} value for any patient who was lost to follow-up or who initiated insulin during the study.

Results

Overview of Trial Conduct

A total of 450 patients underwent randomization from January 2014 to July 2015 (**Figure 1**). A total of 92.9% of patients completed the final visit and provided data on both outcomes (hemoglobin A_{1c} levels and HRQOL). The demographic and clinical characteristics were similar among groups (**Table 1**). The mean age was 61 years old, patients had diabetes an average of 8 years, 75% were performing SMBG at baseline, and 38% had low health literacy (less than 4 on the Newest Vital Sign).[31] Patient testing preference at baseline was similar among groups with 22% preferring no SMBG and 40% preferring to self-monitor. The majority were taking metformin (80%), followed by sulphonylurea (35%).

Table 2. Summary of Primary Outcomes by Randomization Group

Variable	Randomization Group: No SMBG No.	No SMBG Mean (SD)	SMBG, No Messaging No.	SMBG, No Messaging Mean (SD)	SMBG With Messaging No.	SMBG With Messaging Mean (SD)	*P* Value: Overall[a]	*P* Value: Contrast[b]
Hemoglobin A_{1c}, %								
Baseline	152	7.52 (1.12) 58.70 (12.24)	150	7.55 (1.10) 59.06 (12.07)	148	7.61 (0.97) 59.65 (10.64)		
Follow-up	147	7.55 (1.24) 59.01 (13.56)	141	7.49 (1.12) 58.41 (12.23)	139	7.51 (1.13) 58.55 (12.34)	.74	.48
Change	147	0.04 (1.12) 0.41 (12.27)	141	−0.05 (1.00) −0.57 (10.89)	139	−0.10 (1.14) −1.04 (12.42)		
Health-Related Quality of Life, SF-36								
Physical score								
Baseline	152	48.72 (8.00)	150	47.27 (8.40)	148	46.22 (10.13)		
Follow-up	143	48.47 (7.21)	142	47.42 (9.03)	135	46.44 (9.68)	.48	.50
Change	143	−0.43 (6.86)	142	0.07 (6.77)	135	−0.35 (6.95)		
Mental score								
Baseline	152	53.52 (9.29)	150	52.94 (8.77)	148	53.43 (9.58)		
Follow-up	143	53.39 (10.55)	142	52.04 (9.57)	135	52.57 (10.39)	.90	>.99
Change	143	−0.94 (7.46)	142	−0.71 (7.72)	135	−1.39 (6.85)		

Abbreviation: SMBG, self-monitoring of blood glucose. Conversion factor: to convert percent of total hemoglobin to proportion of total hemoglobin, multiply by .01.

[a] Test comparing all 3 groups from ANCOVA model controlling for site, baseline hemoglobin A_{1c}, prior use of SMBG, duration of T2DM, baseline anti-hyperglycemic treatment, age, race/ethnicity, health literacy, and number of baseline comorbidities; for health-related quality of life scores, we also controlled for baseline score, and for hemoglobin A_{1c} we also controlled for how hemoglobin A_{1c} was measured at baseline.

[b] Contrast test from same ANCOVA model comparing average of SMBG groups with no SMBG group.

Primary Outcomes

At 1 year, we found no evidence that SMBG led to improved glycemic control (estimated adjusted mean hemoglobin A_{1c} difference: SMBG with messaging vs no SMBG, −0.09%; 95% CI, −0.31% to 0.14%; SMBG vs no SMBG, −0.05%; 95% CI, −0.27% to 0.17%; average over SMBG arms vs no SMBG, −0.07%; 95% CI, −0.26% to 0.12%) (**Table 2**). There were also no significant differences found in HRQOL (estimated adjusted mean difference for SF-36 Physical score: SMBG with messaging vs no SMBG, −0.83 points; 95% CI, −2.33 to 0.67; SMBG vs no SMBG, −0.05 points; 95% CI, −1.54 to 1.44; average over SMBG arms vs no SMBG, −0.44 points; 95% CI, −1.73 to 0.85; estimated adjusted mean difference for SF-36 Mental score: SMBG with messaging vs no SMBG, −0.19 points; 95% CI, −1.82 to 1.44; SMBG vs no SMBG, 0.19 points; 95% CI, −1.43 to 1.81; average over SMBG arms vs no SMBG, 0 points; 95% CI, −1.40 to 1.40).

Secondary Outcomes

We did not find significant differences in patient-reported outcomes by the Problem Areas in Diabetes, Diabetes Symptom Checklist, Diabetes Empowerment Scale, Diabetes Treatment Satisfaction, or the Communication Assessment Tool (**Table 3**). There were significant differences in the Summary of Diabetes Self-Care Activities (mean change 0.01 points, 0.51 points, and 0.45 points, in the no SMBG, SMBG, and SMBG with messaging, respectively; overall, $P < .001$). However, this was owing to the influence of the SMBG intervention (blood glucose testing subscale mean change, −1.46 points, 2.94 points, 2.81 points in the no SMBG, SMBG, and SMBG with messaging, respectively; overall, $P < .001$). Among the arms, there were no significant differences in insulin initiation (8.6%, 4.0%, 5.4% in the no SMBG, SMBG, SMBG with messaging, respectively; overall, $P = .23$). Patients in the SMBG groups taking a GLP-1 agonist at baseline were significantly more likely to increase their dose compared with patients in the no SMBG group ($P = .02$), but the numbers were small (eTable 1 in Supplement 2). In addition, patients in the SMBG with messaging group were significantly more likely to start using thiazolidinedione ($P = .01$), but again the numbers were small. No other comparisons of medication use differed significantly between groups.

Sensitivity Analyses

In per-protocol and last observation carried forward analyses, results were not notably different from those in the primary analyses. We did find evidence that mean hemoglobin A_{1c} values differed across groups over time. At 6 months, the estimated mean hemoglobin A_{1c} difference between the testing arms and the no testing arm was −0.33% (95% CI, −0.54% to -0.12%; $P = .002$). By 12 months, the mean differences between groups are similar to the primary analysis and do not show a significant difference. (**Figure 2**A).

Effect Modification

In analyses exploring potential for effect modification of prespecified subgroups (prior experience using SMBG, T2DM duration, baseline glycemic control, baseline insulin secretagogue use, age, race/ethnicity, health literacy, and number of baseline comorbidities), there were no significant interactions for glycemic control. For the HRQOL physical component score, we did identify a significant interaction by race ($P = .02$); African Americans in the SMBG with messaging group

Table 3. Secondary Outcomes by Randomization Group Diabetes Mellitus Patient-Reported Outcomes

	Randomization Group						*P* Value	
	No SMBG		SMBG, No Messaging		SMBG With Messaging			
Variable	No.	Mean (SD)	No.	Mean (SD)	No.	Mean (SD)	Overall[a]	Contrast[b]
Problem areas in diabetes (PAID)								
Baseline	152	13.12 (15.53)	150	12.54 (14.89)	148	13.67 (18.16)		
Follow-up	143	11.06 (15.45)	142	8.96 (13.90)	135	9.04 (14.54)	.21	.08
Change	143	−1.97 (15.44)	142	−4.01 (12.16)	135	−3.84 (13.53)		
Diabetes symptoms checklist (DSC)								
Baseline	152	19.04 (19.56)	150	21.55 (21.88)	148	20.73 (22.62)		
Follow-up	143	21.43 (23.73)	142	19.46 (20.10)	135	19.80 (21.42)	.06	.06
Change	143	2.15 (14.37)	142	−2.36 (15.37)	135	0.53 (14.78)		
Diabetes empowerment scale (DES-SF)								
Baseline	152	4.35 (0.48)	149	4.33 (0.50)	148	4.27 (0.58)		
Follow-up	143	4.43 (0.49)	142	4.42 (0.47)	135	4.46 (0.49)	.28	.28
Change	143	0.08 (0.53)	141	0.11 (0.50)	135	0.20 (0.49)		
Summary of diabetes self-care activities (total score)								
Baseline	152	3.42 (1.32)	150	3.64 (1.42)	148	3.46 (1.34)		
Follow-up	143	3.39 (1.23)	142	4.12 (1.30)	135	3.87 (1.32)	<.001	<.001
Change	143	0.01 (1.00)	142	0.51 (1.14)	135	0.45 (1.67)		
Summary of diabetes self-care activities (blood sugar subscale)								
Baseline	152	2.54 (2.62)	149	2.65 (2.77)	148	2.64 (2.87)		
Follow-up	143	0.95 (2.00)	142	5.60 (2.29)	135	5.39 (2.30)	<.001	<.001
Change	143	−1.46 (2.83)	141	2.94 (3.23)	135	2.81 (3.30)		
Diabetes Treatment Satisfaction								
Baseline	149	31.74 (5.52)	147	31.71 (4.92)	148	31.89 (4.96)		
Follow-up	135	31.66 (6.27)	141	32.21 (4.89)	135	31.74 (5.90)	.48	.48
Change	133	−0.16 (6.26)	138	0.67 (4.95)	135	−0.28 (5.89)		
Communication assessment tool								
Baseline	152	4.53 (0.69)	150	4.35 (0.70)	148	4.49 (0.76)		
Follow-up	141	4.57 (0.68)	142	4.52 (0.74)	134	4.53 (0.71)	.68	.45
Change	141	0.03 (0.68)	142	−0.02 (0.65)	134	0.01 (0.75)		

Abbreviation: SMBG, self-monitoring of blood glucose.

[a] Test comparing all 3 groups from ANCOVA model controlling for site, baseline scale score, baseline hemoglobin A_{1c}, prior use of SMBG, duration of T2DM, baseline antihyperglycemic treatment, age, race/ethnicity, health literacy, and number of baseline comorbidities.

[b] Contrast test from same ANCOVA model comparing average of testing groups with no testing group.

reported significantly lower HRQOL than the no testing group, but the same was not true for the SMBG without messaging group (estimated adjusted mean differences of SF-36 physical component score for African Americans: SMBG with messaging vs no SMBG, −2.91 points; 95% CI, −5.69 to −0.13; SMBG vs no SMBG, 0.78 points; 95% CI, −1.91 to 3.47) (eFigures 1-3 in Supplement 2).

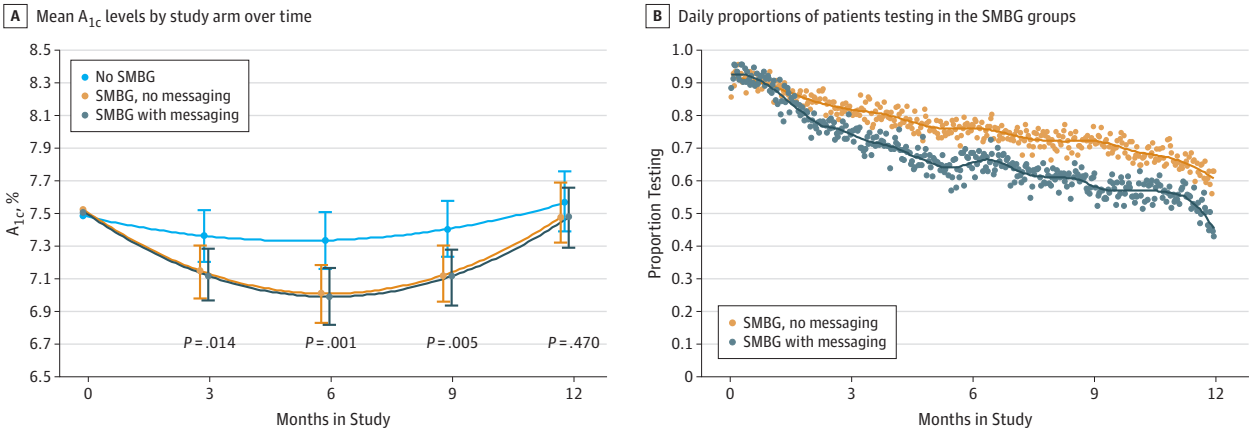
Testing Compliance

Compliance dropped consistently in both SMBG groups, with a larger initial decrease after 1 month in the SMBG with messaging arm (Figure 2B). In the no SMBG arm, 36 (23.7%) patients reported that they tested a few times per month or more, 2 (1%) tested once per month, and 13 (8.5%) tested less than once per month during the study.

Safety and Adverse Events

The following adverse events occurred during the study: 0 fingerstick infections, 1 severe hypoglycemia (secondary to urosepsis, recurrent bladder neoplasm, and acute kidney injury), 62 hospitalizations (no difference by arm), and 2 deaths (1 during cardiac surgery and 1 owing to amyotrophic laterals sclerosis). None of the adverse events were adjudicated to be study-related.

Figure 2. Mean Hemoglobin A_{1c} by Study Arm Over Time and Daily Proportions of Patients Testing in the SMBG Groups



A, Model-estimated mean hemoglobin A_{1c} values obtained by fitting a quadratic polynomial regression with linear mixed models using all observed hemoglobin A_{1c} values, including those at interim visits, but excluding any following insulin use. The model included 1875 total hemoglobin A_{1c} measurements from 450 patients; only 10 patients contributed no interim hemoglobin A_{1c} measurements and the median number was 4. The intervals represent pointwise 95% CIs for each group, and the *P* values compare the average of the SMBG groups with the no SMBG group. B, Daily proportions of patients in the SMBG groups uploading a result with the meter on each study day. Lines represent locally weighted smoothing using local quadratic polynomials across the observed proportions. SMBG Indicates self-monitoring of blood glucose.

Discussion

After 1 year, we identified no clinically or statistically significant differences in glycemic control or HRQOL between patients who performed once-daily SMBG compared with those who did not perform SMBG. The addition of instant tailored feedback messages via a meter did not improve glycemic control. This null result occurred despite training participants and primary care clinicians on the use and interpretation of the meter results. These findings align with earlier studies and a group that reinforce the limited utility of SMBG in patients with non-insulin-treated T2DM.[4,5,7,13-16,32] Surprisingly, SMBG has remained a cornerstone in the clinical management of non-insulin-treated T2DM, in part fueled by other studies and groups supporting glycemic control with SMBG.[9-12,33-35] As the first large pragmatic US trial of SMBG, our findings provide evidence to guide patients and clinicians making important clinical decisions about routine blood glucose monitoring. Health care clinicians are typically divided on this issue; most universally either do or do not recommend SMBG monitoring.[1,32] In addition, patient testing preferences are variable; in our study, patient testing preference at baseline was split. Based on these findings, patients and clinicians should engage in dialogue regarding SMBG with the current evidence suggesting that SMBG should not be routine for most patients with non-insulin-treated T2DM. Our study was not powered to determine effectiveness in certain clinical situations, such as initiation of new medication or medication dose changes. Patients and clinicians should consider each situation as they determine whether to test or not to test.

Patients were drawn from primary care practices; where most patients with T2DM receive their care. Most were on uncomplicated medical therapies including metformin (80%) and sulphonylureas (36%) and carried the diagnosis of T2DM for a median of 6 years. Given that only 66 (15%) patients had T2DM for a year or less, it is not surprising that most were experienced with SMBG (338, 75%) at baseline. In addition, compliance with testing showed progressive attrition in both SMBG monitoring groups. Although not a primary outcome, this may explain the statistically significant improvements in hemoglobin A_{1c} levels initially seen between the testing and non-testing arms in the early months, but no significance at the primary outcome of 12 months. It is possible that the intervention was off putting in some way causing user fatigue or provided false reassurance.

Proponents of routine SMBG have cited evidence that this testing approach is useful for patients with newly diagnosed diabetes or patients with poorer glycemic control.[10] Although disease duration, experience using SMBG, baseline glycemic control, antihyperglycemic treatment, age, race, health literacy, and number of comorbidities made no discernable difference in glycemic control at 52 weeks, absence of evidence is not evidence of absence. This trial was not powered for secondary analyses. Only race was significant by interaction testing for HRQOL physical component score; African Americans in the SMBG with messaging group had significantly lower scores. Given multiple comparisons across groups, the finding may be spurious.

Incorporating technology into self-management activities has been touted as potentially transformative for patients, and to date some smaller studies[36,37] support this notion. However, our findings do not. It is possible that the enhancement of SMBG with one-way messaging back to the patient does not adequately engage patients. This notion is supported by the sensitivity analyses that showed that over the first 6 months glycemic control improved for all patients engaging in SMBG regardless of messaging type. However, dur-

ing months 6 through 12, improvements in glycemic control regressed back to baseline. A more interactive approach or the use of 2-way messaging between the patient and physician may improve the durability of this approach.

Although designed with an eye toward the real-world clinical setting, our study team did not engage with the patients beyond the baseline visit. Clinicians likewise had minimal interaction with the study team. Thus, we do not have data on what the clinicians did with the summary of blood glucose results. More active engagement of both patients and clinicians may have improved patient outcomes, although this would have diminished the pragmatic nature of this study. Most (338, 75%) patients had some experience with SMBG at baseline and 161 (36%) were taking oral hypoglycemics. Prior trials of SMBG were heterogeneous; many did not describe SMBG use at baseline.

Limitations

Although our resultant population is more of a test of continuing monitoring, rather than initiating monitoring, the question remains equally relevant. The population included were willing to be randomized; this may not reflect the typical population of patients with T2DM. In addition, not all patients adhered to the group to which they were assigned; however, per-protocol analyses were not notably different from the intent-to-treat analyses. There is also a possibility that those participating might be generally good at self-care, so an automated system may add less than in other populations. Because our population included patients with T2DM not using insulin, these results cannot be generalized to insulin users. Furthermore, participating primary care practices were affiliated with a single health care system, though patients were typical of those found in primary care nationally.[38]

Conclusions

In patients with non-insulin-treated T2DM, there were no clinically or statistically significant differences at 1 year in glycemic control or HRQOL between patients who performed SMBG compared with those who did not perform SMBG. These findings suggest that glucose monitoring in patients with non-insulin-treated T2DM should not be routine.

ARTICLE INFORMATION

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