Self-monitoring of Blood Glucose Levels in Patients With Type 2 Diabetes Mellitus Not Taking Insulin: A Meta-analysis

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Objective: To perform a meta-analysis of randomized controlled trials (RCTs) and systematic reviews evaluating the efficacy of self-monitoring of blood glucose (SMBG) levels among patients with diabetes mellitus (DM).

Study Design: Meta-analysis of RCTs among patients with DM not taking insulin comparing patients with SMBG versus those without SMBG and reporting results as change in glycosylated hemoglobin (A1C) values.

Methods: Prior systematic reviews and a PubMed search were used to identify studies. Data were extracted by trained physician reviewers working in duplicate. Trials were classified according to duration of the intervention, and random-effects meta-analysis was used to pool results.

Results: Three trials of SMBG of 3 months' duration were too heterogeneous to pool. Nine other trials were identified. Five trials of SMBG of 6 months' duration yielded a pooled effect estimate of a decrease in mean A1C values of –0.21% (95% confidence interval [CI], –0.38% to –0.04%). Four trials that reported outcomes of 1 year or longer yielded a pooled effect estimate of a decrease in mean A1C values of –0.16% (95% CI, –0.38% to 0.05%). Three trials reported hypoglycemic outcomes, which were increased in the patients using SMBG, although this mostly involved asymptomatic or mild episodes.

Conclusions: At most, SMBG produces a statistically significant but clinically modest effect in controlling blood glucose levels in patients with DM not taking insulin. It is of questionable value in helping meet target values of glucose control.

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For author information and disclosures, see end of text.

According to the World Health Organization,[1] at least 180 million people worldwide have diabetes mellitus (DM). The National Diabetes Information Clearinghouse estimates that DM costs $132 billion in the United States every year.[2] Given these estimates along with the projection that the worldwide incidence of DM will double in the next 20 years,[1] research into better management of this chronic disease is important.

Glucose control along with blood pressure and lipid control is a main goal of DM management. In addition to pharmaceutical agents, an advocated method to achieve better glucose control is self-monitoring of blood glucose (SMBG) levels. For patients with DM taking insulin, SMBG has generally been accepted as necessary to help monitor the effect of insulin on daily blood glucose levels, with adjustments in dosage made in response to SMBG values. However, evidence supporting the use of SMBG for patients with DM not requiring insulin is not as clear. Self-monitoring of blood glucose levels is postulated to have a beneficial effect on glucose levels in patients not taking insulin by promoting dietary and lifestyle changes that a patient may make as a response to feedback provided by blood glucose results.[3-6]

Prior trials and systematic reviews have reached conflicting results, with 6 trials[4,5,7-10] and 3 reviews[11-13] reporting benefits and 3 trials[3,6,14] and 3 reviews[15-17] reporting no benefits. With an estimated cost of $466 million for Medicare alone, establishing the efficacy or lack of efficacy of SMBG represents an important goal for providers and payers interested in optimizing management of this condition. Because new larger and better-quality trials of SMBG continue to appear, we undertook a meta-analysis to provide the best current estimate of the efficacy of SMBG in patients with type 2 DM not taking insulin.

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METHODS

Search Strategy

We first identified prior systematic reviews and meta-analyses on this topic. We identified 6 reviews.[11-13,15-17] We judged the search strategy and inclusion and exclusion criteria of the review by Welschen et al,[12] which included studies published from 1996 to September 2004, to be comprehensive and acceptable as the basis to begin our review. We updated this review by

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searching PubMed from the end date of the prior search to July 2007. We searched PubMed for the following terms: *randomized controlled trial* AND *diabetes mellitus*, as well as *type 2* AND *blood glucose self-monitoring*. In addition to our PubMed search and screening of references from prior reviews, we performed reference mining of retrieved articles and received articles from experts. During this process, another review[13] became available, and we reference mined this review as well.

Study Selection

Two trained researchers (AT, MR), both general internists with a special interest in DM, reviewed the list of titles and selected articles for further review. Each article retrieved was reviewed using a brief screening form. To be included in our analysis, a study had to measure the efficacy of SMBG alone or as part of a multicomponent intervention, measure glycosylated hemoglobin (A1C) level as an outcome, and have a follow-up duration of 12 weeks or longer. Eligible study designs included randomized controlled trials (RCTs) and controlled clinical trials. Observational studies, case reports, nonsystematic reviews, letters to the editor, and other similar contributions were excluded. Systematic reviews were reference mined.

Data Abstraction

Data were independently abstracted by 2 general internists (AT, MR) trained in critical reading of the literature, with consensus resolution. The following data were abstracted from included trials: design; randomization and appropriateness; blinding and appropriateness; withdrawals and dropouts described; sample size enrolled and followed up; characteristics of the population, including percentage of women and race/ethnicity; mean, median, and range of ages; body mass index and duration of DM; reported comorbidities; sample size, intervention, and exposure data for each arm of the study (intervention and exposure data included components of the intervention, total number of visits, frequency of SMBG, number of days per week monitored, duration of treatment, and cotherapies); outcomes measured; intervals in which the outcomes were measured; and adverse events.

The mean (SD) A1C level was recorded by treatment arm for each reported follow-up point. For trials that reported a mean outcome but no standard deviation, we estimated the standard deviation by taking the weighted mean standard deviation across all other trials that reported standard deviations for the A1C level.[18]

Quality Assessment

To assess internal validity of the eligible trials, we used the Delphi list.[19] We abstracted data on treatment allocation; method of randomization; similarity at baseline regarding the most important prognostic indicators; specified eligibility criteria; blinding of outcome assessor, care provider, and patient; presentation of point estimates and measures of variability; and intent-to-treat analysis. Work performed by the Cochrane Collaboration Back Review Group supports these items individually as being associated with bias and the use of a threshold of half the items for distinguishing "high-quality" versus "low-quality" studies (M. Suttorp, MS, written communication, 2006).

Data Synthesis

We synthesized data among the articles that were determined to be clinically eligible. Duration of follow-up and frequency of SMBG were reviewed across studies to see if they were comparable.

Since the outcome of interest was the same across all trials, a mean difference was calculated for each time point that reported statistical data. The mean difference is the difference between the follow-up mean A1C level for the SMBG group and the follow-up mean A1C level for the control group. A negative mean difference indicates that the SMBG group has a lower mean A1C score than the control group. For our main analysis, we did not control for the baseline mean A1C level for each group (a difference of differences estimate) because there is evidence that this approach is susceptible to bias.[20] We present results controlling for the baseline as a sensitivity analysis.

A pooled estimate was calculated by follow-up duration in the following categories: 3 to 6 months, 6 to 11 months, and 12 months or longer. The pooled estimate was calculated using the DerSimonian and Laird[21] random-effects model. In addition, we calculated a pooled estimate stratified by high-quality and low-quality trials.

Meta-regression analyses[22] were performed to individually examine the effect of treatment frequency, quality score, and mean baseline A1C level on the mean difference. For trials with more than 1 follow-up duration, the long-term estimates were used.

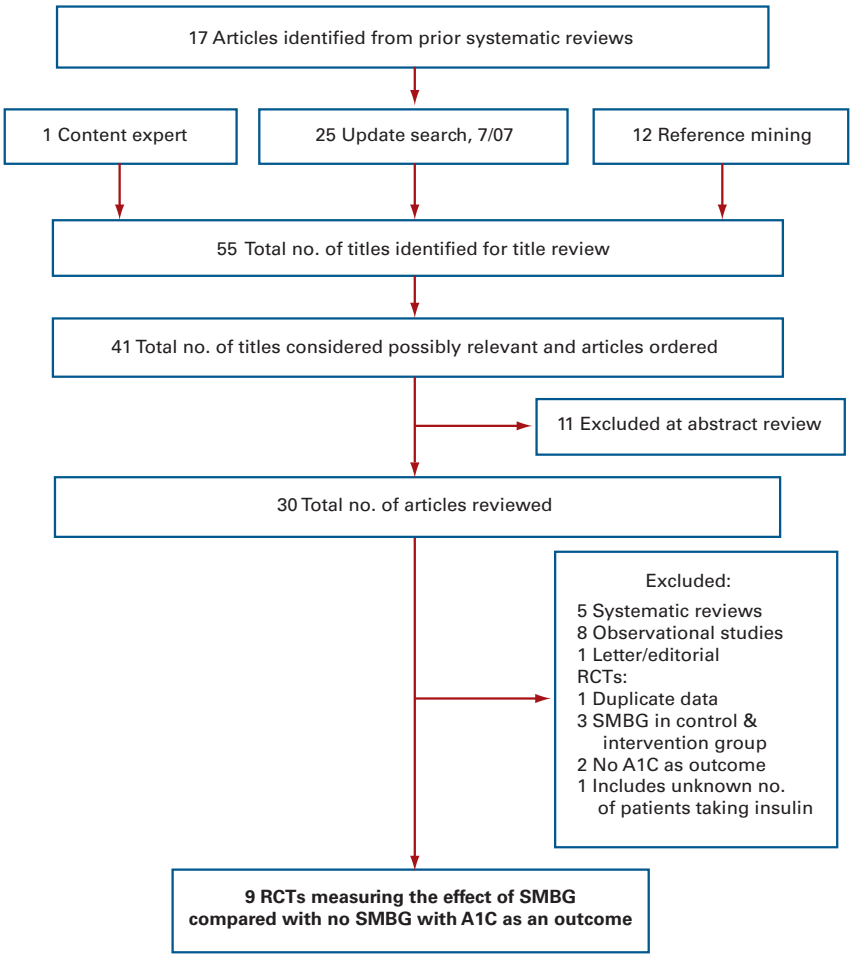
Test of heterogeneity was performed using the I^2 statistic.[23] I^2 values close to 100% represent very high degrees of heterogeneity. Publication bias was examined using Begg rank correlation[24] and Egger regression asymmetry test.[25] All analyses were conducted in STATA 9 (Stata Corp LP, College Station, Texas).[26]

RESULTS

Literature Flow

In total, we examined 55 titles. Seventeen titles were identified from prior systematic reviews. The electronic update search identified 25 titles. An additional 12 titles were identi-

Figure 1. Self-monitoring of Blood Glucose (SMBG) Levels Literature Flow



A1C indicates glycosylated hemoglobin; RCTs, randomized controlled trials.

fied through reference mining. One was identified by a content expert (JEW). Of the titles identified through our electronic literature search, 14 were rejected as irrelevant to the project. This left 41 from all sources. Eleven articles were excluded at abstract review.

In total, we reviewed 30 articles. Initial screening of the articles resulted in 16 RCTs that measured the effect of SMBG with at least 3 months of follow-up. Seven were excluded, 1 because the trial presented duplicate data, 2 because they did not report A1C levels as an outcome, 1 because the trial included an unknown number of patients taking insulin, and the other 3 because the trials compared a control group of patients with SMBG versus an intervention group of patients with SMBG plus other components (Figure 1).

Description of the Evidence

The 9 RCTs ranged in size from 29 to 988 subjects. All patients had type 2 DM, with mean durations of 3 to 13 years. All trials but 1 included only patients treated without insulin.

The mean ages of patients ranged from 50 to 66 years. Almost all trials included counseling and education with SMBG in the intervention group, but other components of the intervention varied (Table 1). All trials measured A1C level as an outcome; 5 trials assessed this at 6 months, and 4 trials assessed this at 1 year or later. Three other trials assessed this at 3 months but were too heterogeneous to pool. The quality of trials varied; most trials scored positively on less than half of the criteria on the Delphi list.[19] Details of each trial are given in Table 2 (quality criteria are available in an online table [eAppendix Table; available at **www.ajmc.com**]).

Improving Glycemic Control

We grouped trials based on the duration of the intervention. The individual and pooled results are shown in Figure 2.

We identified 3 trials[6,9,27] that reported A1C outcomes at 3 months. The trials reported variable results. We did not pool the results of these 3 trials because their results were too heterogeneous, with an I^2 statistic of 67%.

We identified 5 trials[3-5,14,27] that reported outcomes at 6 months. One trial[4] reported a statistically significant improvement in A1C level, although a second trial[5] yielded a statistically significant result after adjusting for baseline differences. The random-effects pooled effect estimate of these 5 trials was a change in mean A1C values of –0.21% (95% confidence interval [CI], –0.38% to –0.04%). The I^2 statistic for heterogeneity was 0%.

We identified 4 trials[6-8,27] that reported outcomes at 1 year or longer. No study reported a statistically significant difference between groups in the mean A1C values, although one study[7] reported statistically significant benefits after adjusting for baseline differences in A1C values. The random-effects pooled effect estimate of these 4 trials was a change in mean A1C values of –0.16% (95% CI, –0.38% to 0.05%). The I^2 statistic for heterogeneity was 0%.

Table 1. Components of Each Arm of the 9 Randomized Controlled Trials

	Study Arm	SMBG	Counseling and Education	Dietician	Exercise	Carbohydrate Counting	Financial Incentive		Patient Control
							Weight	SMBG	
Wing et al, 1986[6]	Control		X				X	X	
	Intervention	X	X				X	X	
Fontbonne et al, 1989[3]	Control		X						
	Intervention	X	X						
Rutten et al, 1990[7]	Control		X						
	Intervention	X							
Muchmore et al, 1994[8]	Control		X	X					
	Intervention	X	X	X		X			
Jaber L et al, 1996[9]	Control								
	Intervention	X	X		X				
Schwedes et al, 2002[5]	Control		X						
	Intervention	X	X						
Guerci et al, 2003[4]	Control		X						
	Intervention	X	X						
Davidson et al, 2005[14]	Control		X	X					
	Intervention	X	X	X					
Farmer et al, 2007[27]	Control								
	Intervention 1	X							
	Intervention 2	X							X

SMBG indicates self-monitoring of blood glucose.

We performed several additional analyses. We compared studies scoring 5 or more Delphi items positively (which we called high quality) with those scoring fewer than 5 items positively (low quality). The pooled results showed no statistically significant differences between high-quality and low-quality studies.

We repeated our primary analysis using as the outcome the difference in A1C levels between groups adjusted for baseline A1C levels (whether to do such adjusting in the results of an RCT is controversial). When analyzed this way, there was much greater heterogeneity between studies, with I^2 statistics of 49% and 73% for studies with 6-month and 12-month outcomes, respectively. However, despite this, our primary pooled results were remarkably similar, with a modest effect on A1C levels at 6 months of −0.23% (95% CI, −0.48% to 0.02%) (compared with a pooled result of 0.21% in the main analysis) and a nonsignificant effect at 12 months of −0.26% (95% CI, −1.00% to 0.48%). In the difference of differences analysis, high-quality studies reported lower estimates of effect than low-quality studies, an observation seen in other conditions.[28]

Meta-regression analysis on baseline A1C levels showed differential effectiveness ($P = .06$), with higher baseline A1C levels being associated with lesser efficacy of SMBG. Each 1% increase in A1C level was associated with a 0.19% decrease in efficacy of SMBG. Therefore, indirect evidence suggests that SMBG results in a smaller percentage of A1C level change for patients with higher baseline A1C values.

We attempted to identify other components of the intervention or characteristics of the patients associated with greater effectiveness. The trials did not have sufficient dissimilarity in intervention components to permit a meta-regression analysis (Table 1). Almost all studies included SMBG and counseling and education, rendering an assessment of the effect of one without the other impossible, and other intervention components were too sparsely distributed to support meta-regression analysis. Meta-regression analysis using the quality assessment (as a continuous variable or dichotomous variable at a threshold value of 5) also did not demonstrate differences between results.

The funnel plot did not support the existence of publication bias. Neither Begg correlation rank nor Egger asymmetry test yielded evidence of publication bias.

Hypoglycemia

We identified 3 trials that reported hypoglycemia as an outcome. In a trial by Jaber et al,[9] there were 17 reported hypogly-

Table 2. Randomized Controlled Trials Evaluating the Self-monitoring of Blood Glucose of Patients With Diabetes Not Requiring Insulin

Source	Duration of Diabetes Mellitus, y	Age Mean, y	Weight Mean, kg/BMI[a]	Women, %	Arm or Group: Sample Size Entering/ Follow-up	Arm or Group: No. of Visits	Arm or Group: Frequency of SMBG, per Week	Arm or Group: Duration of Treatment	Outcome	Adverse Events
Wing et al, 1986[6]	NR	54	98/NR	78	25/22 25/23	20 20	— 5.4	62 wk 62 wk	A1C, fasting glucose, BMI/weight loss	NR
Fontbonne et al, 1989[3]	13	55	73/27	42	68/54 68/56	4 4	— 7.5	6 mo 6 mo	A1C, BMI/weight loss	NR
Rutten et al, 1990[7]	8.1	63	75/NR	65	83/72 66/55	NA Variable	— NR	1 y 1 y	A1C, BMI/weight loss	NR
Muchmore et al, 1994[8]	5	59	99/34	61	14/11 15/12	8 2	— —	44 wk 44 wk	A1C, BMI/weight loss, HRQOL	NR
Jaber et al, 1996[9]	6	62	90/33	70	22/22 23/17	2 NR	— 8	4 mo 4 mo	A1C, fasting glucose, HRQOL	Hypo-glycemia, other
Schwedes et al, 2002[5]	5.3	60	89/31	48	NR/110 NR/113	6 6	— 12	24 wk 24 wk	A1C, BMI/weight loss, HRQOL	NR
Guerci et al, 2003[4]	8.1	62	83/30	45	NR/344 NR/345	5 5	— 6	6 mo 6 mo	A1C, fasting glucose	Hypo-glycemia, other
Davidson et al, 2005[14]	5.6	50	82.3/32.5	74	45/NR 43/NR	13 13	— 36	6 mo 6 mo	A1C, BMI/weight loss	NR
Farmer et al, 2007[27]	3	66	NR/31.3	43	152/NR 150/NR 151/NR	NR NR NR	— 6 NR	12 mo 12 mo 12 mo	A1C, BMI/weight loss	Hypo-glycemia

A1C indicates glycosylated hemoglobin; BMI, body mass index; HRQOL, health-related quality of life; NA, not applicable; NR, not reported or described.
[a]Calculated as weight in kilograms divided by height in meters squared.

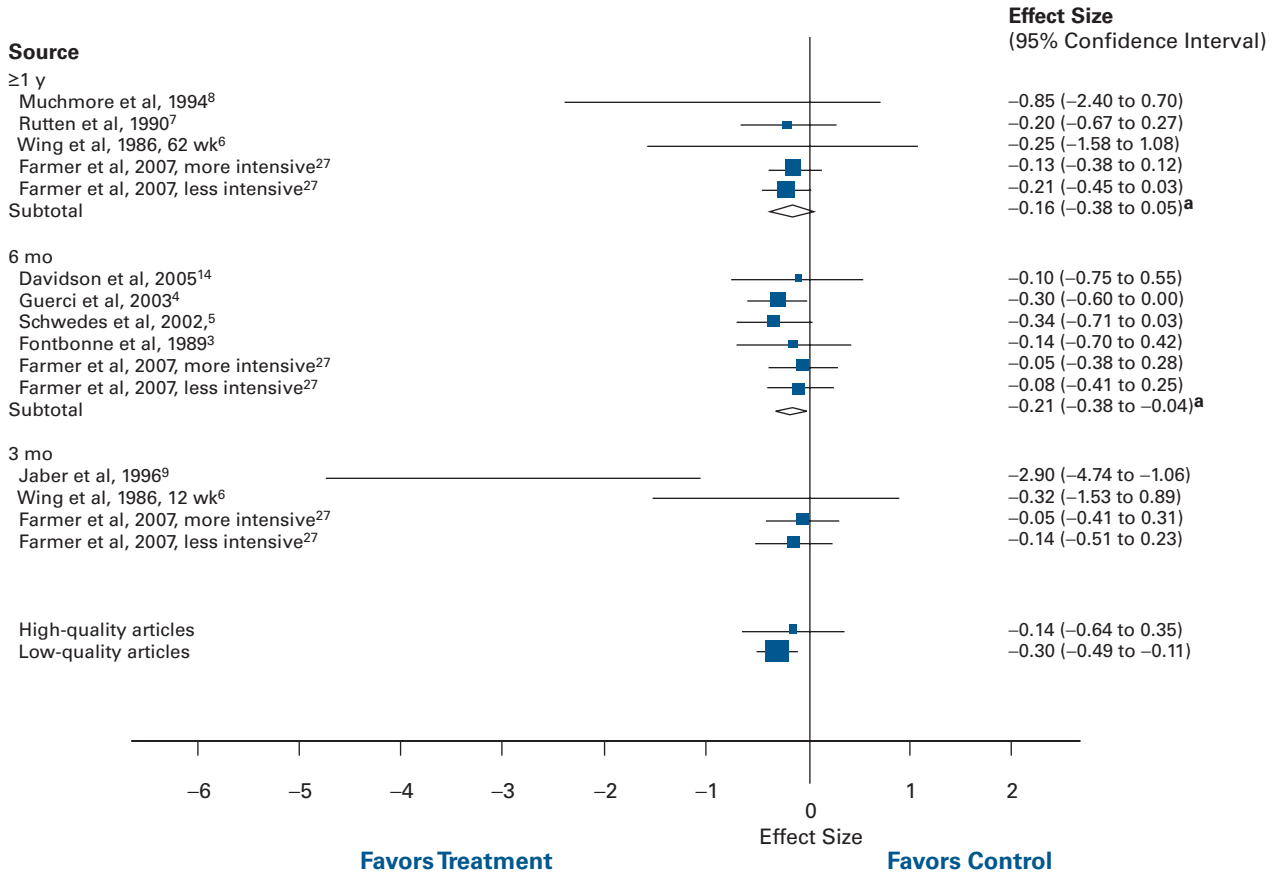
cemic reactions in the intervention group and 2 in the control group. All were rated as mild to moderate and were successfully self-treated. In the trial by Guerci et al,[4] 78 patients reported at least 1 episode of hypoglycemia, either symptomatic or asymptomatic, including 53 patients (10%) in the SMBG group and 25 patients (5%) in the control group. These proportions were significantly different because of asymptomatic hypoglycemia alone (P = .001). There was no serious episode of hypoglycemia reported. Last, in the recent trial by Farmer et al,[27] 14 patients in the control group had at least 1 grade 2 hypoglycemia episode (mild symptoms) compared with 33 patients in the less intensive intervention group and 43 patients in the more intensive intervention group (P <.001). One patient in the control group had a grade 3 hypoglycemic episode (moderate symptoms requiring immediate third-party intervention).

Therefore, the limited evidence available indicates that SMBG increases the frequency of recognized hypoglycemia. This is associated with an increase in asymptomatic low blood glucose readings and an increase in mild-to-moderate symptomatic episodes. There is scant evidence about the effect of SMBG on more clinically significant hypoglycemia.

DISCUSSION

The principal finding of our meta-analysis was a modest but statistically significant improvement in A1C level at 6

Figure 2. Analysis of Mean Differences Between Control and Self-monitoring of Blood Glucose Level Groups at Follow-up



[a]Subtotal does not include Farmer et al[27] 2007 less intensive self-monitoring arm.

months in patients with type 2 DM not requiring insulin when SMBG and education were added to management. The 3-month trials showed variability in results, leaving little to conclude. Similar though slightly smaller reductions in A1C level were found when pooling the 12-month trials. Although the pooled effect estimate at 12 months had a 95% CI that just crossed the null value, the effect estimate was not statistically different from the pooled effect estimate at 6 months.

The efficacy of SMBG has been studied previously. In one such review published by Welschen et al,[12] 6 RCTs were evaluated and were found to show an overall statistically significant effect of SMBG in decreasing A1C levels by 0.39% (95% CI, –0.56% to –0.21%). All but 1 of the trials in the review were also included in our meta-analysis (the study[29] excluded from our analysis compared SMBG with urine testing of glucose levels). In a systematic review published for Agency for Healthcare Research and Quality, Balk et al[13] included 5 RCTs and some nonrandomized cohort studies and found results similar to our meta-analysis, specifically a trend toward statistically significant but clinically modest reductions in A1C levels. In contrast, a recent cost-effectiveness analysis estimated that SMBG in a mixed population of patients with type 2 DM resulted in improved quality of life and a cost-effectiveness ratio of less than $10,000 per quality-adjusted life-year.[30] However, this analysis was based on data from an observational cohort and did not include more recent RCT data reporting limited effectiveness of SMBG in primary care populations.

Two additional factors suggest that SMBG may be of little importance as a glucose control intervention in patients with type 2 DM not receiving insulin. First, our meta-regression findings suggest that the efficacy of SMBG may be lower as the baseline A1C level is higher. This means that SMBG may be least effective for the patients who need it most. Second, in the study[27] that most closely approximates the use of

Take-away Points

Self-monitoring of blood glucose (SMBG) levels is proven effective at helping control glucose levels in patients with diabetes mellitus (DM) taking insulin. The usefulness of SMBG in patients with DM not taking insulin is unclear.

- Our meta-analysis of 9 randomized controlled trials of SMBG found a statistically significant improvement in glycosylated hemoglobin outcomes at 6 months of –0.21%. Results at 3 months or 12 months were not significant.
- At best, SMBG is an intervention of modest efficacy in patients with DM not taking insulin.

SMBG in a community-based primary care practice, there was no effect found.

To help interpret the significance of the effect of SMBG on A1C levels demonstrated in our review, it needs to be put in the context of other interventions to control blood glucose levels. In an exhaustive review,[31] investigators concluded that many oral DM medications as monotherapy (thiazolidinediones, second-generation sulfonylureas, metformin, and repaglinide) had reductions in A1C levels of about 1.0%. This is about 5 times the effect produced by SMBG in our pooled estimate. Lower A1C reductions have been seen for other classes of hypoglycemic agents (0.5%-0.8% for alpha-glucosidase inhibitors, 0.8% for dipeptidyl peptidase IV inhibitors, and 0.3%-0.45% for amylin analogues), but these are still greater than our findings for SMBG. More comparable may be DM education. Norris et al[32] performed a meta-analysis on the effect of DM self-management education on A1C level and found an overall 0.26% reduction in A1C levels a few months after the intervention. Some of the trials included in the meta-analysis involved SMBG along with education, which renders the individual effect of either intervention difficult to separate. Still, SMBG is closer to DM self-management in terms of the effect size than it is to most pharmaceuticals.

Our study has several limitations. An important limitation common to systematic reviews is the quality of the original studies. The sensitivity analysis of our main result did not yield any suggestion that the quality of the trials influenced our findings in a significant way. Another limitation is the heterogeneity of the studies. While there were some differences in the populations being assessed, the most important heterogeneity in this meta-analysis was the differing intervention components added to SMBG and the difference in the recommendations for frequency of SMBG, provider interaction or algorithm to adjust medications, and intensity of education. In addition, because education and counseling were invariably included with SMBG in the various intervention groups, the effect of SMBG alone was impossible to distinguish. Although our literature search procedures were extensive and included all articles identified in prior reviews plus additional articles, publication bias is a limitation. Our formal tests for publication bias did not indicate the presence of possible publication bias, but such tests do not exclude the possibility that such bias exists.

In conclusion, our analysis showed a statistically significant but clinically modest overall reduction in A1C levels when using SMBG in patients with type 2 DM not taking insulin. The results of our meta-regression analysis and the findings by Farmer and colleagues[27] further limit the likelihood that SMBG is a particularly useful intervention. Patients, providers, and health plans will need to look elsewhere for interventions that have the kind of effects needed to bring A1C levels down to target values.

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