

Effects of Structured Versus Unstructured Self-Monitoring of Blood Glucose on Glucose Control in Patients With Non-insulin-treated Type 2 Diabetes: A Meta-Analysis of Randomized Controlled Trials

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Abstract

Background: The use of self-monitoring of blood glucose (SMBG) in patients with non-insulin-treated type 2 diabetes is debated. Meta-analyses of randomized clinical trials (RCTs) suggest a small reduction of HbA1c in patients using SMBG, without considering potential confounders, such as SMBG regimen and use of SMBG data to adjust diabetes medications.

Methods: A meta-analysis was performed including RCTs in patients with non-insulin-treated type 2 diabetes, with an intervention of ≥ 24 weeks and HbA1c as the primary endpoint, to verify the effect of SMBG (vs no monitoring), structured SMBG (vs unstructured), and of SMBG-driven therapy adjustments.

Results: In RCTs ($n = 8$) comparing SMBG with no SMBG (1277 and 1072 patients, respectively), SMBG reduced HbA1c by -0.17% (95% CI -0.25 to -0.09% , $P < .003$). The reduction in HbA1c was greater in RCTs ($n = 3$) in which SMBG data were used to adjust diabetes medications (HbA1c decrease: -0.3% [95% CI -0.49 to -0.1%]) than in RCTs ($n = 6$) where SMBG data were not used for this purpose (HbA1c decrease: -0.1% [95% CI -0.2 to 0.0%]) ($P < .005$). In the RCTs comparing structured and unstructured SMBG (757 and 750 patients, respectively), in which structured SMBG data were also used to adjust diabetes medications, the HbA1c difference between groups at study end was -0.27% (95% CI -0.49 to -0.04% , $P < .018$).

Conclusions: In RCTs performed in non-insulin-treated patients with type 2 diabetes, SMBG is associated with a significant, although small, reduction in HbA1c. HbA1c reduction was greater with structured SMBG and when structured SMBG data were used to adjust diabetes therapy.

Keywords

meta-analysis, non-insulin treated, type 2 diabetes, self-monitoring of blood glucose, treatment algorithms

Self-monitoring of blood glucose (SMBG) is an established component of diabetes management in patients with type 1 diabetes or insulin-treated type 2 diabetes.^{1,2} By contrast, patients on diabetes medications other than insulin do not usually monitor capillary glucose to modify the prescribed dose of diabetes medications in response to the glucose levels detected by SMBG. Furthermore, patients on oral diabetes medications other than sulfonylureas or glinides do not monitor capillary glucose to detect excessive lowering of glucose levels since their risk of hypoglycemia is generally very low. On the other hand, measurements of capillary glucose in patients with non-insulin-treated type 2 diabetes may increase the awareness of the effects of different type and amount of food and the benefit of physical exercise on glucose control, thus promoting positive and sustained lifestyle modifications. Documenting daily

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glucose patterns may also enable physicians to tailor an individualized diabetes treatment plan for each patient,^{2,4} through prescription of diabetes drugs having a preferential effect on fasting or postprandial glucose levels. Indeed, the International Diabetes Federation (IDF) recommends to evaluate postprandial glucose levels, which can be effectively assessed only through SMBG, among the key therapeutic targets in type 2 diabetes, regardless of insulin treatment prescription.⁵

Several meta-analyses and systematic reviews, exploring the effects of SMBG on glucose control in patients with non-insulin-treated type 2 diabetes, estimated a reduction of glycated hemoglobin A1c (HbA1c) levels ranging from 0.2% to 0.4% in patients using SMBG compared with control groups not using SMBG.⁶⁻¹² The reported size of HbA1c reduction may be perceived as small and may be influenced by some characteristics of the study participants, including baseline HbA1c and type of prescribed diabetes medications. In a meta-analysis by the Cochrane Collaboration,¹⁰ it was concluded that the effect of SMBG on glycemic control in patients with type 2 diabetes who are not using insulin is small, especially after 12 months of follow-up, and that the evidence that SMBG affects patient satisfaction, general well-being or general health-related quality of life is modest. However, this study examined trials until 2011.

The SMBG regimen tested in a specific randomized clinical trial (RCT) may also affect the magnitude of HbA1c reduction. It has been reported that structured SMBG, that is, an SMBG regimen with clearly defined timing and frequency of glucose measurements, is more effective than unstructured SMBG, where timing and frequency of measurements are at the discretion of patients and/or health care providers.¹³ In the recent guidelines on SMBG use, the IDF supported structured SMBG as an integral component of diabetes care also in patients with non-insulin-treated type 2 diabetes.² Moreover, the effect of SMBG on glycemic control may be greater when SMBG data are used by physicians to adjust the prescription of diabetes medications. The potential confounding effect of the SMBG regimen and use of SMBG data was not properly accounted for in previous meta-analyses.

The aim of the present study was to assess by a meta-analysis of published articles the effect of SMBG on HbA1c in patients with non-insulin-treated type 2 diabetes, documenting the impact of confounders, such as the predefined schedule for glucose measurements and use of SMBG data by physicians for the adjustment of diabetes medications.

Methods

This meta-analysis is reported according to the statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions.¹⁴

Data Sources and Searches

An extensive Medline, Embase, and Cochrane database search for “self-monitoring blood glucose [MeSH Terms]

AND diabetes mellitus, Type 2 [MeSH Terms]” was performed to identify all published randomized clinical trials conducted in humans and published in the English language after January 1, 2000, and up to December 31, 2015. The www.clinicaltrials.gov website was also searched, using the same keywords, for unpublished trials. The identification of relevant abstracts, the selection of studies based on the criteria described above, and the subsequent data extraction were performed independently by two of the authors (EM and AA) and conflicts were resolved by discussion.

Study Selection

A meta-analysis was performed including all randomized clinical trials (RCTs) with a duration of at least 24 weeks, enrolling patients with non-insulin-treated type 2 diabetes, comparing SMBG with no SMBG, or structured SMBG with unstructured SMBG. RCTs enrolling patients with insulin-treated type 2 diabetes or patients with type 1 diabetes were excluded, unless separate data analyses for patients with non-insulin-treated type 2 diabetes were provided. The review protocol for these analyses was not published elsewhere.

Data Extraction and Quality Assessment

For all published RCTs (including the primary trial publications, and all subsequent reviews and/or pooled analyses reporting data on an individual RCT), the results reported in published manuscript(s) were the primary source of information. Information from the www.clinicaltrials.gov website was used to complete the results of published RCTs, when not reported in publications. Structured SMBG was defined as an SMBG regimen in which timing and frequency of capillary glucose measurements were specified in the study protocol, as opposed to unstructured SMBG in which timing and frequency of SMBG were at the discretion of patients and/or investigators. For all the RCTs included in our analysis, we also verified whether prescription of diabetes medications to participants was adjusted on the basis of SMBG data according to an algorithm defined in the study protocol.

The quality of the RCTs was assessed using some of the criteria proposed by Jadad et al.¹⁵ The derived score was not used as a criterion for including an RCT in this meta-analysis, and some items were used only for descriptive purposes.

Data Synthesis and Analysis

The principal outcome of this analysis was the effect of SMBG versus no SMBG, or of structured SMBG versus unstructured SMBG, on HbA1c. Subgroup analyses were performed for RCTs using structured SMBG or unstructured SMBG versus no SMBG, and for RCTs with or without adjustment of diabetes treatment according to an algorithm versus no SMBG, whenever more than one RCT was available. Heterogeneity was quantified by using I^2

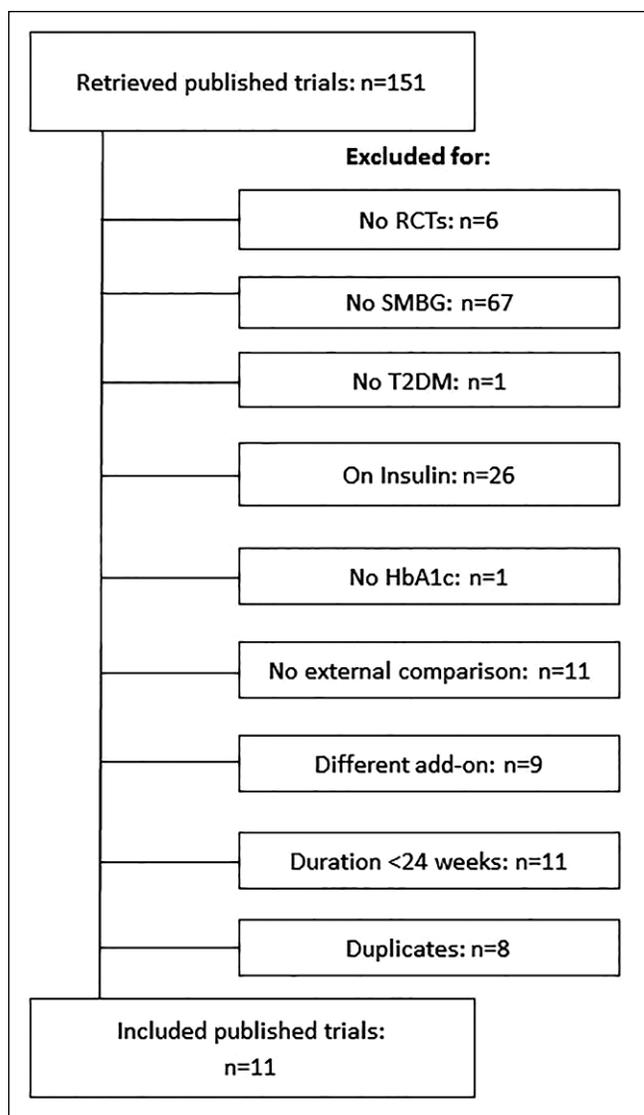


Figure 1. RCT flow diagram.

statistics and tested using the Cochran's Q test. Even when a low heterogeneity was detected, a random-effects model was applied, because the validity of the tests for heterogeneity can be limited when the number of RCTs included in the analysis is small. To estimate possible publication/disclosure bias we used funnel plots and the Begg's adjusted rank correlation test.^{16,17} Mean differences with 95% confidence intervals (95% CI) were calculated for HbA1c, generally on an intention-to-treat basis. All analyses were performed using the Meta package of the statistical software R, version 4.3.

Results

Retrieved Trials

The RCTs flow diagram is reported in Figure 1. A total of 11 trials fulfilling the inclusion criteria were identified.¹⁸⁻²⁹ Of

these, 8 compared SMBG with no SMBG,¹⁸⁻²⁵ and 3 structured with unstructured SMBG.²⁶⁻²⁹ The trial by Farmer et al²¹ compared SMBG with no SMBG and included two intervention groups, one trained to perform SMBG and to contact the doctor for interpretation of SMBG results (less intensive SMBG) and one trained to perform SMBG and self-interpret and apply the results to diet, physical activity, and drug adherence (more intensive SMBG). The two intervention groups were considered separately in this meta-analysis. The characteristics of the retrieved RCTs (including variables documenting trial quality) are reported in Table 1. The RCTs comparing SMBG with no SMBG included 1277 and 1072 patients, respectively; weighted mean duration of the intervention was 33.7 weeks. The mean age of participants was 59 years, baseline HbA1c was 8.3%, and baseline BMI was 30.8 kg/m². The 3 RCTs comparing structured SMBG with unstructured SMBG included 856 and 812 patients, respectively; the duration of the intervention was 52 weeks in two RCTs and 26 weeks in one RCT. The mean age of participants was 59 years, baseline HbA1c was 7.9%, and BMI was 32.1 kg/m².

Trials Comparing SMBG with no SMBG

In the RCTs comparing SMBG with no SMBG, I^2 was 13.2% [0.0%, 55.1%], and the Cochran's Q test was 9.22 ($P = .3243$). No evidence of publication bias was detected by funnel plot analysis (data not shown) or Begg's adjusted rank correlation test ($P = .6767$).

Use of SMBG was associated with a significant reduction of HbA1c in comparison with no SMBG use (Figure 2). In all RCTs except one,¹⁹ SMBG was structured, that is, timing and frequency of measurements were defined in the study protocol; when this RCT using unstructured SMBG was excluded from the analysis, the results (HbA1c change: -0.2% [-0.3 to -0.1], $P = .003$) were similar to those obtained in the full dataset (HbA1c change: -0.17% [-0.25 to -0.09], $P = .003$). In 3 RCTs, SMBG data were used by physicians to adjust diabetes medications in the intervention group according to an algorithm detailed in the study protocol. When SMBG data were used to adjust diabetes medications, the effect of SMBG on HbA1c change was greater (-0.3% [-0.4 to 0.1], $n = 3$ RCTs) than that observed in RCTs in which diabetes therapy was not consistently modified on the basis of SMBG data (-0.1% [-0.2 to 0.0], $n = 6$ RCTs) ($P = .005$).

Trials Comparing Structured SMBG with Unstructured SMBG

In the RCTs comparing structured with unstructured SMBG,²⁶⁻²⁹ the structured SMBG regimen produced a significantly greater reduction in HbA1c levels compared to the unstructured SMBG arm (-0.27% [-0.49 to -0.04], $P = .018$). In these RCTs, the results of SMBG were used by physicians to adjust diabetes treatment according to an algorithm only in the intervention arm of the study.

Table 1. Characteristics of the Studies Included in the Meta-Analysis.

Author, year	Structured SMBG	SMBG used for adjusting diabetes treatment	Duration of intervention (weeks)	Randomization	Allocation	Dropouts	Population analyzed	Number of patients	Baseline HbA1c control group ^a	Baseline HbA1c intervention group ^a
Comparisons of SMBG versus no SMBG										
Schwedes, 2002 ¹⁸	Yes	No	24	A	NAD	NAD	PP	223	8.4 (0.75)	8.5 (0.86)
Guerci, 2003 ¹⁹	No	No	24	NAD	NAD	A	Practical ITT	689	8.9 (1.3)	9.0 (1.3)
Davidson, 2005 ²⁰	Yes	No	26	NAD	NAD	A	ITT	88	8.5 (2.2)	8.4 (2.1)
Farmer ^{1, b} , 2007 ²¹	Yes	No	52	A	A	A	ITT	302	7.5 (1.09)	7.4 (1.02)
Farmer ^{2, b} , 2007 ²¹	Yes	Yes	52	A	A	A	ITT	303	7.5 (1.09)	7.5 (1.12)
O'Kane, 2008 ²²	Yes	No	52	A	A	A	ITT	184	8.6 (2.3)	8.8 (2.1)
Barnett, 2008 ²³	Yes	Yes	27	A	NAD	A	ITT	610	8.1 (0.84)	8.1 (0.89)
Kleefstra, 2010 ²⁴	Yes	No	52	A	A	A	Practical ITT	40	7.7 (0.4)	7.5 (0.5)
Franciosi, 2011 ²⁵	Yes	Yes	26	A	A	A	Practical ITT	62	7.9 (0.6)	7.9 (0.6)
Comparisons of structured versus unstructured SMBG										
Duran, 2010 ²⁶	Yes	Yes	52	A	NAD	A	Practical ITT	161	6.6 (6.4-7.1)	6.6 (5.8-7)
Polonsky, 2011 ²⁷	Yes	Yes	52	A	A	A	Yes	483	8.9 (1.2)	8.9 (1.2)
Bosi, 2013 ^{28,29}	Yes	Yes	52	A	A	A	Practical ITT, PP	1024	7.3 (6.9-7.8)	7.4 (6.9-7.8)

A, adequately reported; ITT, intention-to-treat analysis; NAD, not adequately reported.

^aData are expressed as mean % (SD) or median % (P25-P75).

^bFarmer 1 refers to the comparison between the less intensive SMBG group and the control group; Farmer 2 refers to the comparison between the more intensive SMBG group and the control group.

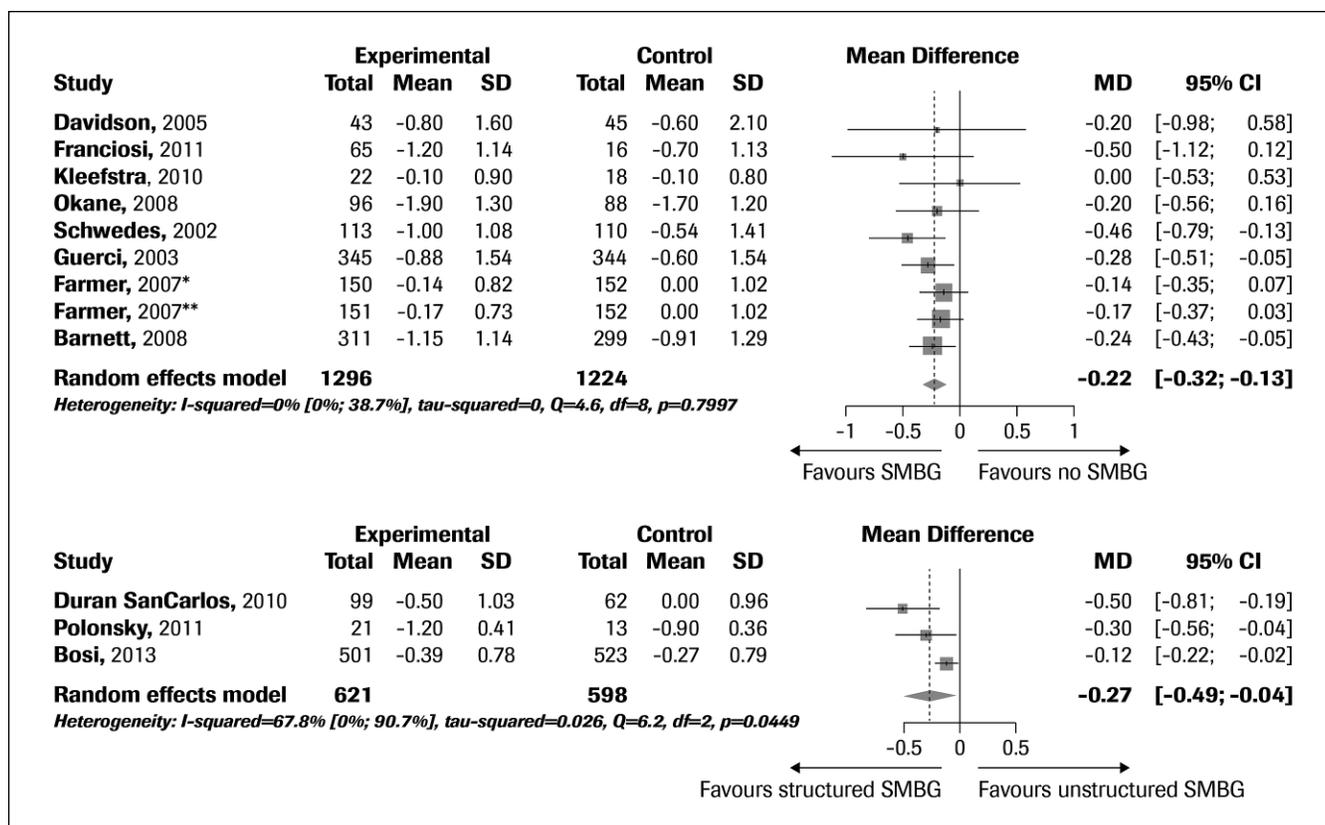


Figure 2. Forest plot of mean HbA1c differences in studies comparing SMBG vs no SMBG (upper panel) or structured SMBG vs unstructured SMBG (lower panel).

Discussion

In the RCTs included in this meta-analysis, SMBG produced a small but significant reduction in HbA1c, in line with previous meta-analyses or systematic reviews.⁶⁻¹² Our meta-analysis is, however, the first to consider the SMBG regimen and use of SMBG data to adjust diabetes medications, which represent potential confounders of the effect of SMBG on glucose control.

It has been hypothesized that structured SMBG, in which timing and frequency of capillary glucose measurements are clearly defined, is more effective in reducing HbA1c than unstructured SMBG. The 3 RCTs aimed at testing this hypothesis have both confirmed the superiority of structured SMBG over unstructured SMBG,²⁶⁻²⁹ with an effect on glucose control of similar magnitude as that observed when comparing SMBG with no SMBG. On the other hand, while most of the RCTs comparing SMBG versus no SMBG were performed using structured SMBG regimens, the only RCT comparing unstructured SMBG with no SMBG¹⁹ reported a much smaller effect on HbA1c than the RCTs comparing structured SMBG with no SMBG.^{18,20-25}

It is conceivable that the significant, albeit small, reduction of HbA1c associated with SMBG in RCTs conducted in non-insulin-treated patients with type 2 diabetes is due to

modifications of either lifestyle or pharmacological therapy triggered by the SMBG results. Indeed, greater improvements in HbA1c were observed in those RCTs in which structured SMBG data were used by physicians to adjust the type and dose of diabetes medications according to a pre-specified algorithm.^{21,23,25} Notably, in the 3 RCTs comparing structured SMBG and unstructured SMBG, and showing the superiority of the former, the study protocol also included algorithms with various pharmacological/lifestyle treatment strategies to be used in response to the specific glucose patterns identified through the SMBG.²⁶⁻²⁹ In the studies with structured SMBG in which an analysis was carried out to evaluate patients who adhered to the protocol (per-protocol analysis), greater HbA1c reductions were generally observed compared to the intention-to-treat dataset,^{21,27,29} underscoring the importance of adhering to the study procedures for achieving clinical outcomes.

Unlike earlier systematic reviews or meta-analysis,⁶⁻¹² we did not include studies conducted prior to 2000, when glucose meters were less accurate and user-friendly than nowadays and lacked the ability to store capillary glucose results for downloading by health professionals during outpatient visits. As pointed out for insulin pumps, the progress of diabetes-related technologies should be considered when compiling studies for systematic reviews or meta-analysis of

SMBG.³⁰ Indeed, after 2013 no further studies have been published comparing SMBG versus no SMBG, suggesting that SMBG is beginning to be considered as standard care in the management of non-insulin-treated type 2 diabetes. The three more recent studies²⁶⁻²⁹ have indeed compared unstructured SMBG with structured SMBG, the latter being included in the management of non-insulin-treated type 2 diabetes in the IDF guidelines.²

We acknowledge that an undetected bias may be present in our analysis, because funnel plots and the Begg's adjusted rank correlation test have a low statistical power when the number of RCTs included in the analysis is small. Therefore, our findings should be interpreted with caution, considering the small number of RCTs on this topic in patients with non-insulin-treated type 2 diabetes that met the criteria for being included in this meta-analysis. Furthermore, the potential for a publication bias favoring positive results cannot be excluded, although there is no evidence of such a bias in the specific analyses we conducted. Last, the between-group differences in HbA1c reductions are apparently of modest magnitude and may be perceived as clinically non-significant. However, in some studies,^{21,24-26,29} baseline HbA1c was not elevated (ie, <7.5%), and this may have explained the relatively modest changes in HbA1c levels upon intervention. Nevertheless, since any reduction in HbA1c reduces the risk of complications,¹ treatment strategies in addition to medications that help patients achieve their glucose goals, such as structured SMBG, should be pursued.

Conclusions

In patients with non-insulin-treated type 2 diabetes, the benefits of using SMBG on glucose control are more evident with structured SMBG and when SMBG data are used by physicians to adjust the prescription of diabetes medications according to an algorithm. It should be considered that some of the most recent algorithms for the pharmacological treatment of type 2 diabetes, including those proposed by the IDF,² recommend to prescribe different diabetes drugs on the basis of the glucose patterns documented using a structured SMBG regimen. Further studies are needed to verify whether diabetes treatment algorithms based on structured SMBG data are superior in terms of HbA1c reduction or risk of hypoglycemia to algorithms which do not use SMBG data.

Abbreviations

IDF, International Diabetes Federation; RCT, randomized clinical trial; SMBG, self-monitoring of blood glucose.

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Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: EM has received speaking fees from Roche Diagnostics, and consulting fees from Abbott and Lifescan. AA has no competing financial interest to disclose. FG has received speaking and consulting fees from Roche Diagnostics. MS has received consulting fees from Roche Diagnostics.

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