Self-Monitoring of Blood Glucose in Patients With Type 2 Diabetes Who Are Not Using Insulin

A systematic review

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A strict glycemic control reduces the risk of the development of micro- and macrovascular complications (1–3). In the U.K. Prospective Diabetes Study, each 1% reduction in HbA_{1c} was associated with a 37% decrease in risk for microvascular complications and a 21% decrease in risk for any end point or death related to diabetes (3). In clinical practice, a 3-monthly visit to the general practitioner is recommended for the assessment of glycemic control (4). There is now much debate on the effectiveness of self-monitoring of blood glucose (SMBG) as a tool in the self-management of diabetic patients (1,5,6).

SMBG aims at collecting information on blood glucose levels at different time points during the day and allows for the timely identification of high levels. SMBG has proven effective for patients with type 1 diabetes (7–9) and patients with type 2 diabetes who are using insulin (10–12) because the information about a patient's glucose level is useful to refine and adjust insulin dosages, resulting in an improved glycemic control. It has been suggested that patients with type 2 diabetes who are not using insulin might also benefit from SMBG (13). These patients might cope more independently with their disease when using SMBG, and they might achieve a better understanding about the factors that affect their disease and potentially a better perceived quality of life. SMBG might also improve adherence to pharmacological treatment and motivate patients to make appropriate lifestyle changes (10,14).

Until 2001, several reviews investigated the literature on the effectiveness of SMBG in patients with type 2 diabetes who are not using insulin and reported no clear effects of SMBG on HbA_{1c} (1,5,6, 15). Other outcome measures like quality of life were not discussed. Moreover, these reviews had some methodological limitations, and some reviews also included a study of insulin-using patients with type 2 diabetes, while the content and efficacy of self-management education and also SMBG is expected to depend on type of treatment (1,6,15). One review only searched Medline, and criteria for the methodological quality of the studies and data extraction methods were not clearly described (5). In another review, a meta-analysis was performed, but heterogeneity and poor quality of the included studies were reported (1,6).

The aim of our review was to assess the effects of SMBG relative to usual care without SMBG on glycemic control, quality of life and well-being, patient satisfaction, and hypoglycemic episodes in patients with type 2 diabetes who are not using insulin.

RESEARCH DESIGN AND METHODS

Identification of studies

This review was conducted within the Metabolic and Endocrine Disorders Review Group of the Cochrane Collaboration. We identified relevant trials by searching the Medline database of the National Library of Medicine (1966 to September 2004), The Cochrane Library (Issue 3, 2004), and EMBASE (1974 to September 2004). When searching both Medline and EMBASE, 90% of the randomized controlled trials available for the topic of the review can be identified (16). Furthermore, the Cochrane Central Register of Controlled Trials (CENTRAL) includes citations to reports of controlled trials that might not be indexed in Medline or EMBASE (17). By searching these three databases, we fulfilled the requirements of the Cochrane Collaboration, and we therefore consider our search to be as valid as possible.

Search strategies were adapted from the Cochrane Handbook (16,18) and The Cochrane Metabolic and Endocrine Disorders Review Group. The medical subject headings (MeSH) searched were "randomized controlled trial" combined with "diabetes mellitus, type II" and "blood glucose self-monitoring," including all subheadings. Additionally, we scanned the reference lists of the identified reviews and included studies for all other relevant publications. We did not search for unpublished trials, as this is extremely time consuming and will probably lead to selection bias, as not all researchers will answer. We did include articles in press, found by notifications of researchers in our network.

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Abbreviations: SMBG, self-monitoring of blood glucose; SMUG, self-monitoring of urine glucose.

Study selection

Two observers (L.M.C.W. and G.N.) independently inspected the titles and abstracts of the identified references to evaluate their potential eligibility. The full article was retrieved for clarification if the abstract did not provide enough information or was not available. We included studies investigating the effectiveness of SMBG compared with usual care in patients with type 2 diabetes who were not using insulin at baseline. Studies concerning the comparison between SMBG and urine glucose monitoring were also included. We selected randomized controlled trials only because these types of study designs are considered to be more valid in general and to give maximal power for causal inference (19). Furthermore, the studies to be considered for inclusion in the review should have used at least one of the following outcome measures: glycemic control measured by HbA_{1c} concentration and/or fasting plasma glucose level, hypoglycemic episodes, quality of life (e.g., with the SF-36 [36-item short-form health survey] [20]), well-being (e.g., by means of the well-being questionnaire [21]), and/or patient satisfaction (e.g., by means of the Diabetes Treatment Satisfaction Questionnaire [22]). No language restriction was applied. Studies were eliminated if both reviewers agreed that the study did not meet the criteria for including studies in the review. If necessary, a third party resolved differences in opinion (J.M.D.).

Methodological quality assessment

The methodological quality of the relevant trials was assessed independently by two reviewers (L.M.C.W. and E.B.) by means of a score list. We used the Maastricht-Amsterdam score list (23) for randomized trials, which includes all criteria of the lists by Jadad et al. (24) and Verhagen et al. (25). The original list consisted of 19 items. Commensurate with the recommendation of Van Tulder et al. (23), we only applied the 11 items pertaining to internal validity. Each item has a rating scale of "yes" if bias was unlikely, "no" if bias was likely, or "don't know" if information concerning the item was not available. Studies fulfilling ≥6 of the 11 quality criteria (>50%) were considered to be of "high quality." All studies scoring less than six criteria were rated as "low quality."

The initial level of agreement between the two reviewers (L.M.C.W. and E.B.) was reported as Cohen's κ (26). Item-level discrepancies were discussed, and if consensus could not be reached, a third reviewer (G.N.) made the final decision.

A pilot test, using two trials excluded from the review, preceded the quality assessment of the randomized controlled trials in order to assess the feasibility of using this scale. All items were clearly defined, and both authors could obtain consensus on each item in the list.

Data extraction

Data extraction from eligible trials was performed using the items from the Cochrane Metabolic and Endocrine Disorders Editorial base generic data extraction form that were considered relevant by two reviewers (L.M.C.W. and E.B.). The adapted data extraction form included information about the authors, randomization procedure, analyses, patients' characteristics, type of intervention(s), characteristics of methodological quality, and results. Two reviewers (L.M.C.W. and E.B.) independently performed data extraction and data entry. Any discrepancies between reviewers were resolved by discussion, and if consensus could not be reached, a third reviewer (G.N.) made the final decision.

A pilot test, based on the same two trials excluded from the review, preceded the data extraction of the selected randomized controlled trials in order to identify data that were not needed or missing. The test was performed to optimize the data extraction sheet and to obtain consensus between reviewers about the form.

Data analysis

We performed a meta-analysis with the HbA_{1c} values of all studies, which was the only outcome measure that was available in all studies. We did separate analysis of the two possible comparisons, SMBG versus usual care and SMBG versus self-monitoring of urine glucose (SMUG). The results of each study were plotted as point estimates with corresponding 95% CIs. The measures of effect for HbA_{1c} were the differences from baseline to end point in both groups. When the SDs for these differences were missing, they were estimated with the following formula. We used a conservative correlation coefficient of 0.4 (27).

$$SD_{\text{paired difference}} = \sqrt{(\text{SD}_{\text{baseline}})^2 + (\text{SD}_{\text{final}})^2 - (2 \times r \times \text{SD}_{\text{baseline}} \times \text{SD}_{\text{final}})}$$

Statistical heterogeneity was assessed by visual inspection of the CIs in the forest plot. Additionally, it was tested using the Z score and the χ^2 statistic, with significance set at $P < 0.10$. Quantification of the effect of heterogeneity was assessed by means of I^2, ranging from 0 to 100% and including its 95% CI. I^2 demonstrates the percentage of total variation across studies due to heterogeneity and was used to judge the consistency of evidence. The evidence of statistical heterogeneity was considered substantial if I^2 was >50% (28).

Clinical heterogeneity was assessed by comparing the data extraction forms of the studies. If studies are clinically homogeneous regarding study populations, interventions, and outcomes, a meta-analysis should use the fixed-effect model. However, since clinical heterogeneity was observed, it was unlikely that there was one "true" effect underlying the data, and thus a random-effects model was used.

The analyses were carried out by using the statistical module MetaView 4.2 in Review Manager 4.2 (Cochrane Collaboration, Oxford, U.K.).

RESULTS — The search of the computerized databases identified a total of 572 citations. After excluding titles clearly not related to the objective of our review, 97 studies were considered in the selection procedure. Screening of references resulted in another 15 citations. After reading the abstracts of the studies, if available, 36 full-text articles were retrieved for further examination. Only five eligible randomized controlled trials met all inclusion criteria and were included in this review (14,29–32). During the review process, we received the notification of an article in press that we also included in our review (33).

Four studies compared SMBG with usual care without monitoring (29,31–33), one study compared SMBG with urine glucose monitoring (30), and one study was a three-armed trial comparing all three interventions (14). Characteristics and results of the included trials are described in Table 1.

Methodological quality of included studies

Initial agreement between both reviewers on the overall methodological quality was 91%, and after the consensus meeting, no

Table 1—*Characteristics of randomized controlled trials on the effectiveness of SMBG in patients with type 2 diabetes who are not using insulin*

Study	Intervention	Patients (*n*)	Duration of study	Baseline characteristics (mean ± SD)	Outcomes (mean ± SD)	Changes between baseline and outcomes (mean ± SD)	Comments
Fontbonne (14), 1989, France	SMBG: measurements twice every other day. SMUG: measurements twice every other day. Control: regular HbA_{1c} determinations every 2 months at physician, no self-monitoring	SMBG 68, SMUG 72, control 68	6 months	SMBG: HbA_{1c} 8.2 ± 2.5%, BMI 27.1 ± 4.1 kg/m^2, age 54.5 ± 10.7 years, diabetes duration 12.2 ± 6.6 years; SMUG: HbA_{1c} 8.6 ± 2.5%, BMI 26.0 ± 3.4 kg/m^2, age 54.9 ± 10.2 years, diabetes duration 13.3 ± 6.8 years; control: HbA_{1c} 8.2 ± 2.5%, BMI 27.0 ± 4.1 kg/m^2, age 56.3 ± 9.1 years, diabetes duration 12.7 ± 0.8 years	SMBG: HbA_{1c} 7.84%; SMUG: HbA_{1c} 8.47%; control: HbA_{1c} 7.7%	SMBG: HbA_{1c} −0.36 ± 3.14%; SMUG: HbA_{1c} −0.13 ± 2.20%; control: HbA_{1c} −0.5 ± 1.54%	Withdrawals: 44 patients (21%) lost to follow-up (SMBG 12, SMUG 18, control 14). Compliance: expected number to be used = 182 (SMBG 91 strips, SMUG 79 strips, $P < 0.01$, poor compliance)
Allen (30), 1990, U.S.	SMBG: at least 36 blood glucose determinations/month, before each meal every other day. SMUG: at least 36 urine glucose determinations/month, before each meal every other day. Both groups: standardized treatment program including diet and exercise counseling. Use of an algorithm for treatment alterations by physician	SMBG 27, SMUG 27	6 months	SMBG: HbA_{1c} 12.4 ± 3.3%, FPG 12.0 ± 2.4 mmol/l, age 58.2 ± 9.7 years, diabetes duration 6.8 ± 6.5 years; SMUG, HbA_{1c} 11.7 ± 3.0%, FPG 12.0 ± 2.6 mmol/l, age 57.9 ± 10.7 years, diabetes duration 9.0 ± 10.3 years	SMBG: HbA_{1c} 10.4 ± 2.9%, FPG 10.6 ± 3.6 mmol/l; SMUG: HbA_{1c} 9.7 ± 2.6%, FPG 10.5 ± 3.0 mmol/l	SMBG: HbA_{1c} −2.0 ± 3.4%, FPG −1.4 ± 3.2 mmol/l; SMUG: HbA_{1c} −2.0 ± 2.4%, FPG −1.5 ± 2.8 mmol/l	Withdrawals: 7 patients. Compliance: records complete in 87% of visits for SMBG and in 90% of visits for SMUG. Attendance at monthly visits: 98% in both groups
Muchmore (29), 1994, U.S.	SMBG: individual and group teaching on carbohydrate counting and SMBG, measured six times daily for 4 weeks. Reduce to pre- and postprandial testing of a single meal per day for weeks 4–20. Beyond week 20, individual's election. Control: identical amount of attention, focus on general principles of diabetes nutrition	SMBG 12, control 11	28 weeks and follow-up until 44 weeks	SMBG: HbA_{1c} 10.29 ± 1.1%, BMI 35.1 ± 4.8 kg/m^2, age 57.3 ± 8.0 years, diabetes duration 5.7 ± 4.8 years, quality of life* satisfaction 3.1, impact 4, worry-diabetes related 4, worry-social/ vocational related 4.6; control: HbA_{1c} 10.45 ± 1.5%, BMI 33.3 ± 4.3 kg/m^2, age 60.1 ± 7.3 years, diabetes duration 5.2 ± 4.6 years, quality of life* satisfaction 3, impact 3.9, worry-diabetes related 4.1, worry-social/vocational related 4.3	SMBG: HbA_{1c} 8.75 ± 1.66%, quality of life* satisfaction 2.7, impact 4.1, worry-diabetes related 4.6, worry-social/ vocational related 4.6; control: HbA_{1c} 9.6 ± 2.09%, quality of life* satisfaction 2.7, impact 3.9, worry-diabetes related 4.5, worry-social/ vocational related 4.6	SMBG: HbA_{1c} −1.54 ± 1.46%, quality of life satisfaction −0.4, impact +0.1, worry-diabetes related +0.6, worry-social/ vocational related ±0; control: HbA_{1c} −0.85 ± 1.87%, quality of life satisfaction −0.3, impact ±0, worry-diabetes related +0.4, worry-social/vocational related +0.3	Withdrawals: 6 patients of 29 recruited dropped out prior to or at the time of randomization. Compliance: data ascertainment for HbA_{1c} was 96% complete. One control group individual did not complete group meetings. High compliance with carbohydrate counting. Average performance of testing blood glucose (4.67 times per week)

Schwedes (31), 2002, multicenter study in Germany and Austria	SMBG: measurements of blood glucose six times on 2 days per week and recordings of values obtained in a diary for blood glucose data and documentation of eating habits and state of well-being. Patients were seen every 4 weeks for counseling on use of the meter and regarding diet and lifestyle. Continual use of the glucose meter during the follow-up period. Control: nonstandardized counseling with a focus on diet and lifestyle	SMBG 113, control 110	6 months and 6 months of follow-up	SMBG: HbA_{1c} 8.47 ± 0.86%, BMI 31.0 ± 4.6 kg/m^2, age 58.7 ± 7.6 years, diabetes duration 5.5 ± 4.8 years, quality of life† general well-being 26.4 ± 5.4, satisfaction 27.6 ± 7.1; control: HbA_{1c} 8.35 ± 0.75%, BMI 31.9 ± 5.5 kg/m^2, age 60.5 ± 6.6 years, diabetes duration 5.2 ± 3.9 years, quality of life† general well-being 26.5 ± 5.9, satisfaction 27.0 ± 6.6	SMBG: HbA_{1c} 7.47 ± 1.27%, quality of life† general well-being 30.4, satisfaction 31.12; control: HbA_{1c} 7.81 ± 1.52%, quality of life† general well-being 28.5, satisfaction 30.6	SMBG: HbA_{1c} −1.0 ± 1.08%‡, quality of life general well-being +4.0, satisfaction +3.52; control: HbA_{1c} −0.54 ± 1.41%, quality of life general well-being +2.0, satisfaction +3.6	Withdrawals: 27 patients. Compliance: average number of weekly measurements 24.8 ± 3.9 per patient. Blood glucose/eating diary regularly used by 97.9% of the patients. During follow-up, 87% of the patients continued self-monitoring
Guerci (32), 2003, France	SMBG: SMBG in addition to the conventional laboratory work-up. Education on weight loss and physical activity; treatment alterations by physician. Measurements at least six times per week, on 3 different days, including weekends. Control: conventional laboratory work-up based solely on laboratory measurement of HbA_{1c} every 12 weeks. Education on weight loss and physical activity; treatment alterations by physician	SMBG 345, control 344	24 weeks	SMBG: HbA_{1c} 9.0 ± 1.3%, FPG 7.2 ± 5.1 mmol/l, BMI 30.4 ± 6.1 kg/m^2, age 60.9 ± 9.4 years, diabetes duration 7.7 ± 6.3 years; control: HbA_{1c} 8.9 ± 1.3%, FPG 7.5 ± 4.8 mmol/l, BMI 29.7 ± 4.8 kg/m^2, age 62.2 ± 9.1 years, diabetes duration 8.4 ± 6.6 years	SMBG: HbA_{1c} 8.1 ± 1.6%, FPG 6.66 ± 4.8 mmol/l, hypoglycemia 53 episodes‡; control: HbA_{1c} 8.4 ± 1.4%, FPG 6.9 ± 4.6 mmol/l, hypoglycemia 25 episodes	SMBG: HbA_{1c} −0.9 ± 1.54%‡, FPG −0.54 mmol/l; control: HbA_{1c} −0.5 ± 1.54%, FPG −0.6 mmol/l	Dropouts: SMBG 164 patients (48%), control 139 patients (40%). Compliance: not clear
Davidson (33), in press, U.S.	SMBG: before and between 1 and 2 h after eating meals 6 days a week; two breakfasts, two lunches, and two suppers. Recordings of what was eaten. Control: regular HbA_{1c} determinations every 2 months at physician, no self-monitoring. Both groups: five visits to dietician for education on nutrition. Support by nurse, unaware of SMBG status, according to detailed algorithms to make therapeutic decisions	SMBG 43, control 45	6 months	SMBG: HbA_{1c} 8.38 ± 2.12%, BMI 31.7 ± 6.7 kg/m^2, age 49.8 ± 11.2 years, diabetes duration 5.5 ± 4.7 years; control: HbA_{1c} 8.5 ± 2.2%, BMI 33.4 ± 7.0 kg/m^2, age 50.9 ± 11.0 years, diabetes duration 5.8 ± 5.8 years	SMBG: HbA_{1c} 7.53 ± 1.55%; control: HbA_{1c} 7.88 ± 1.5%	SMBG: HbA_{1c} −0.8 ± 1.6%; control: HbA_{1c} −0.6 ± 2.1%	Compliance: dietary visits: SMBG 4.0 ± 1.0, control 3.2 ± 0.9. SMBG averaged 129 of 288 readings (45%)

*Quality of life measured by the diabetes quality-of-life inventory used by the Diabetes Control and Complications Trial with a range of 0 (worst) to 5 (best score) (45). †Quality of life measured by the Patient Well-being Questionnaire, which has a four-item scale with a range of 0 (worst score) to 36 (best score) (21), and the Diabetes Treatment Satisfaction Questionnaire, which has a six-item scale with a range from 0 (very dissatisfied) to 36 (very satisfied) (22). ‡Statistically significant difference between groups ($P < 0.05$). FPG, fasting plasma glucose.

Table 2—*Results of the methodological quality assessment by use of the internal validity criteria of the Maastricht-Amsterdam list (23)*

Criteria	Fontbonne (14)	Allen (30)	Muchmore (29)	Schwedes (31)	Guerci (32)	Davidson (33)
Was the method of randomization adequate?	+	+	+	+	+	+
Was the treatment allocation concealed?	?	−	?	?	?	?
Were the groups similar at baseline regarding the most important prognostic indicators?	+	+	+	+	+	+
Was the patient blinded to the intervention?	NA	NA	NA	NA	NA	NA
Was the care provider blinded to the intervention?	NA	NA	NA	NA	NA	NA
Was the outcome assessor blinded to the intervention?	?	?	?	?	?	+
Were cointerventions avoided or comparable?	?	+	?	−	+	+
Was the compliance acceptable in both groups?	+	+	+	+	?	−
Was the withdrawal/drop-out rate described and acceptable?	+	+	+	+	−	+
Was the timing of the outcome assessment in all groups similar?	+	+	+	+	+	+
Did the analysis include an intention-to-treat analysis?	?	−	?	−	+	+
Total quality score	5	6	5	5	5	7

NA, not applicable for this type of intervention; +, criteria answered with "yes"; −, criteria answered with "no"; ?, criteria answered with "don't know".

disagreement persisted. The results of the methodological quality assessment are presented in Table 2. The studies of Allen et al. (30) and Davidson et al. (33) were considered to be of high quality by scoring positive for 6 and 7 out of 11 criteria, respectively. The studies of Schwedes et al. (31), Fontbonne et al. (14), Muchmore et al. (29), and Guerci et al. (32) scored positive for five criteria, a level we considered to be of low quality.

With respect to cointerventions, such as treatment with other medications or dietary advice, Allen et al. (30) and Guerci et al. (32) reported that these were avoided. Davidson et al. (33) provided the same information in both groups. We considered that the SMBG group in Schwedes et al. (31) did receive a cointervention by means of a structured counseling program every 4 weeks during the intervention period, whereas the control group received only a nonstandardized counseling. Furthermore, Muchmore et al. (29) provided individual and group teaching on the concept of carbohydrate counting for the intervention patients. However, because the control group received an identical amount of attention, although with a focus on the general principles of diabetes nutrition according to ADA practice guidelines, we did not consider a cointervention to have occurred in this study. This consideration was based on findings that more intention by care providers is associated with an improvement in HbA_{1c} levels (34). Fontbonne et al. (14) did not provide information on this item. Five studies (14,29–31,33) had an acceptable withdrawal/drop-out rate. Guerci et al. (32) reported a drop-out rate of >40%, which was considered nonacceptable. The item on concealment of treatment allocation was unclear or not done in all studies.

Outcomes

HbA_{1c}. In the meta-analysis, the overall effect was a statistically significant decrease of 0.39% in HbA_{1c} (95% CI −0.56 to −0.21) in favor of SMBG compared with the control group. The comparison between SMBG and SMUG showed a nonsignificant decrease of 0.17% (−0.96 to 0.61) in HbA_{1c} in favor of SMBG. There was no statistical heterogeneity, as indicated by visual inspection of the CIs, χ^2 statistic, or I^2, which was 0%. However, we found clinical heterogeneity between the studies because of differences in baseline data of the patients and type of interventions. Schwedes et al. (31) provided education in the SMBG group only, which we considered to be a cointervention. Results of the meta-analyses are shown in Fig. 1.

Fasting plasma glucose. Only two studies measured fasting plasma glucose levels. Both found a decrease as a result of SMBG, though not statistically significant (30,32).

Hypoglycemic episodes. Only Guerci et al. (32) investigated the effect of SMBG on the frequency of asymptomatic and symptomatic (capillary blood glucose <3 mmol/l) hypoglycemia. They found a significant difference in the number of patients who reported at least one episode of asymptomatic hypoglycemia during the study. We consider this to be an invalid result because it was not possible for the control group to measure this type of hypoglycemia. No serious episode of hypoglycemia was reported during this study.

Quality of life, well-being, and patient satisfaction. Muchmore et al. (29) found identical results in the SMBG and control group for the improvement in quality of life scales (satisfaction, impact, worry-social/vocational, and worry-diabetes related). Schwedes et al. (31) also found that well-being and treatment satisfaction improved to the same extent in both groups. Neither study found any statistically significant difference between the groups.

CONCLUSIONS

— In our review, six randomized controlled trials could be included to evaluate the effects of SMBG in patients with type 2 diabetes who are not using insulin. The overall effect of SMBG was a statistically significant decrease of 0.39% in HbA_{1c} compared with the control groups. This is considered clinically relevant. Based on the U.K. Prospective Diabetes Study, a decrease of 0.39% in HbA_{1c} is expected to reduce risk of microvascular complications by ~14% (3,35,36).

No difference was found between the SMBG and SMUG groups. Furthermore, there was little information on other outcomes, as only one study reported data on hypoglycemic episodes (32) and only two studies reported some data on quality of life and patient satisfaction (29,31).

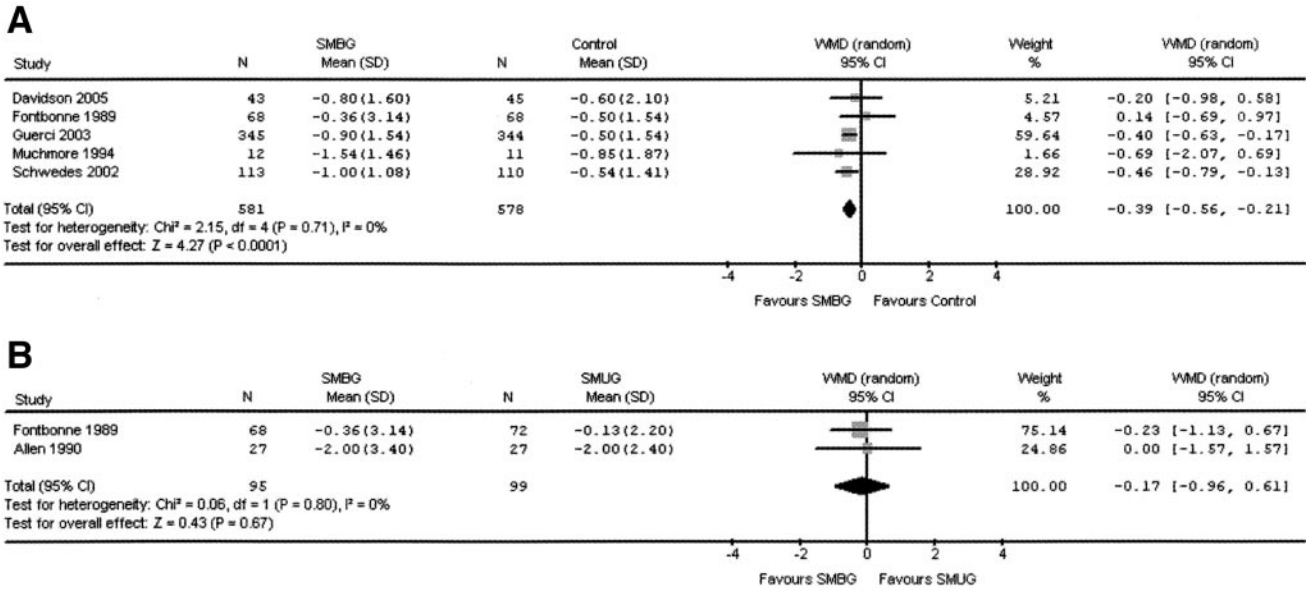

Figure 1—*Meta-analyses of HbA_{1c} values (measured in percent) of SMBG intervention trials with control groups* (A) *and SMUG groups* (B).

When assessing the studies individually, only two studies found a significant effect of SMBG on HbA_{1c} (31,32). There are several possible explanations. The two significant studies (Schwedes et al. [31] and Guerci et al. [32]) had 113 and 345 patients, respectively, in their intervention groups, whereas the other studies had 12–68 patients. In addition, the frequency of monitoring blood glucose differed between the studies, as did diabetes duration and HbA_{1c} level at baseline. Furthermore, participants in a randomized controlled trial might be motivated in both the intervention and control group to improve their behavior by the knowledge that outcome measures are being observed. This so-called Hawthorne effect could also have resulted in a underestimation of the efficacy of SMBG (34,37).

A limitation of three studies was that no standard instructions were given to the patients to adjust their behavior and change their lifestyle and medication to modify their glucose values. Davidson et al. (33) had the only blinded study, which guarantees that the education was the same in the groups. Supervision was provided in both groups by a dietician and a nurse who made therapeutic decisions according to detailed algorithms while unaware of the SMBG status of the patient. HbA_{1c} levels decreased 0.2% more in the SMBG group, but the change was not statistically significant. This might be due to the small number of patients included in the study or to the possibility that the mostly poorly educated minority population might not have adequately interpreted the information provided by the nurses. Also, Faas et al. (5) earlier described that education on how to change lifestyle habits is essential to show positive effects of SMBG on glycemic control. The control group should receive the same topics on lifestyle with the same intensity to evaluate the effect of SMBG.

Nonrandomized controlled trials

Because we only found six randomized controlled trials, we also briefly discuss nonrandomized controlled trials. We found seven studies that met all other criteria on the study population, intervention, and outcome measures.

Patrick et al. (38) studied patients who performed SMBG in a hospital clinic. Rindone et al. (39) selected medical records of patients of the previous 2 years and compared those who did receive a prescription for SMBG with those who did not receive a prescription. Both studies found no differences in the improvement in HbA_{1c} values in patients who did and did not use SMBG. Gallichan et al. (40) performed a survey by questionnaire of current self-monitoring preferences, attitudes, and practices of type 2 diabetic patients on oral hypoglycemic agents. The group that used urine glucose monitoring was selected for a 6-month trial, with one group continuing urine testing and the other starting SMBG. This study also did not find differences in fructosamine levels between groups. Miles et al. (41) compared home testing of blood and urine in newly diagnosed patients with type 2 diabetes in a randomized cross-over trial. After 3 months of testing, all patients were crossed-over to the other method of self-monitoring. The improvements in HbA_{1c} and quality of life score did not differ between the groups. Franciosi et al. (42) investigated the frequency of SMBG and its association with metabolic control and quality of life by use of a questionnaire. No association was found between a higher frequency of SMBG and a better glycemic control in patients with type 2 diabetes who are not using insulin. However, SMBG frequency of at least one time a day was significantly related to higher levels of distress, worries, and depressive symptoms. Distress and worries were also significantly related to a SMBG frequency of at least one time per week. Karter et al. (10) used a cohort design ($n = 17,601$) to assess the association between SMBG and glycemic control. They found that monitoring at the recommended frequency (at least daily) was associated with a better HbA_{1c} level of 0.4% ($P < 0.0001$) compared with less frequent monitoring. Because of the study design, it cannot be determined if the association between SMBG and glycemic control was causal, since we cannot exclude the possibility that more motivated subjects choose to

initiate SMBG. Soumerai et al. (43) evaluated a policy providing free blood glucose monitors, and they found that initiating SMBG was associated with a significant reduction in HbA_{1c} levels, although only in patients with a poor glycemic control at baseline (HbA_{1c} >10%) compared with patients with good or adequate glycemic control (HbA_{1c} <10.0%).

Thus, one of the seven described nonrandomized controlled trials found an improvement in HbA_{1c} levels as a result of monitoring at least daily compared with less frequent monitoring (10), and one trial found a significant decrease in HbA_{1c} levels in the patients with a poor glycemic control (43). No long-term information was available on the effects of SMBG, as most studies had a follow-up of only 6 months. Furthermore, there were very few data on the effects of SMBG on quality of life, well-being, patient satisfaction, and hypoglycemic episodes. Moreover, the role of education in SMBG could not be distinguished from the effect of SMBG.

Methodological issues

The conclusion from this review that SMBG has a beneficial effect on HbA_{1c} in patients with type 2 diabetes who are not using insulin should be interpreted with caution, as the methodological quality of the trials, as judged by an a priori determined cutoff on a score list, was limited in four of the six included studies (23). The fact that the concealment of treatment allocation was not clear in all studies is an important indication for selection bias. Schulz et al. found that trials with inadequate or unclear allocation concealment yielded exaggerated estimates of treatment effects (19).

In addition, the studies were clinically heterogeneous in their study populations and interventions. Because there was no statistical heterogeneity, we could still perform the meta-analysis; however, it is possible that some studies have influenced the overall effect. Schwedes et al. (31) provided education in the SMBG group only, and the decrease in HbA_{1c} may have been at least partly due to education. The baseline HbA_{1c} values of the studies were also varying from 12.4% in Allen et al. to 8.2% in Fontbonne et al., which might have influenced the results.

We performed an extensive literature search in three electronic databases that are considered to be of high quality; however, it is possible that we missed some relevant trials that were not published or not included in these databases. Furthermore, we did not include any unpublished trials. These issues might have caused an overestimated effect of SMBG due to publication bias (44).

Implications for practice and research

To answer the question if patients with type 2 diabetes who are not using insulin might benefit from SMBG, a large randomized controlled trial with a follow-up period to also investigate long-term effects should be carried out. It should fulfill all the methodological criteria of our checklist (Table 2). This trial should also measure quality of life, well-being, patient satisfaction, and hypoglycaemic episodes as well as glycemic control. Moreover, such a trial should also include a standardized treatment program on diet and lifestyle in both the intervention and control groups.

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