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REVIEW ARTICLE

Self-Monitoring of Blood Glucose in Type 2 Diabetes: Recent Studies

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Abstract

The increasing role for structured and personalized self-monitoring of blood glucose (SMBG) in management of type 2 diabetes has been underlined by randomized and prospective clinical trials. These include Structured Testing Program (or STeP), St. Carlos, Role of Self-Monitoring of Blood Glucose and Intensive Education in Patients with Type 2 Diabetes Not Receiving Insulin, and Retrolective Study Self-Monitoring of Blood Glucose and Outcome in Patients with Type 2 Diabetes (or ROSSO)-in-praxi follow-up. The evidence for the benefit of SMBG both in insulin-treated and non-insulin-treated patients with diabetes is also supported by published reviews, meta-analyses, and guidelines. A Cochrane review reported an overall effect of SMBG on glycemic control up to 6 months after initiation, which was considered to subside after 12 months. Particularly, the 12-month analysis has been criticized for the inclusion of a small number of studies and the conclusions drawn. The aim of this article is to review key publications on SMBG and also to put them into perspective with regard to results of the Cochrane review and current aspects of diabetes management.

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Introduction

Structured and personalized self-monitoring of blood glucose (SMBG) is a systematic approach to glucose monitoring that reveals significant patterns of glycemia occurring throughout the day.[1] Its role in management of diabetes is increasing. Self-monitoring of blood glucose is well established and a highly valuable approach for the daily management of type 2 diabetes mellitus (T2DM).[2,3] In addition, SMBG has been demonstrated to be a beneficial approach for the achievement of long-term glycemic control in patients with T2DM.[4] It also supports preventive strategies of acute and chronic complications of diabetes.[5] In particular, SMBG increases a patient's awareness of hypoglycemia[6,7] and

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Abbreviations: (BMI) body mass index, (DiGEM) Diabetes Glycaemic Education and Monitoring Trial, (DST) decision support tool, (HbA1c) glycosylated hemoglobin, (PRISMA) Prospective, Randomized Trial on Intensive Self-Monitoring of Blood Glucose Management Added Value in Non-Insulin-Treated Type 2 Diabetes Mellitus Patients, (ROSSO) Retrolective Study Self-Monitoring of Blood Glucose and Outcome in Patients with Type 2 Diabetes, (SMBG) self-monitoring of blood glucose, (STeP) Structured Testing Program, (T2DM) type 2 diabetes mellitus, (ZODIAC) Zwolle Outpatient Diabetes project Integrating Available Care

Keywords: blood glucose, diabetes, glycosylated hemoglobin, self-monitoring, self-monitoring of blood glucose, treatment

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therefore provides a potential strategy to trigger self-regulatory prevention of significant hypoglycemic episodes.[7,8] In T2DM, SMBG has been investigated across the spectrum of treatment options, and various schemes for SMBG have been suggested.[9–18]

The performance of postprandial SMBG has been observed to be beneficial in non-insulin-treated T2DM patients.[19] The result is of interest in view of a prospective 14-year follow-up of more than 500 T2DM patients, which demonstrated postprandial blood glucose levels but not fasting blood glucose to predict cardiovascular events and all-cause mortality.[20]

The importance of SMBG in T2DM is also underlined by growing evidence that glycemic variability independently increases the risk for endothelial dysfunction, cognitive impairment, vascular complications, and mortality.[21–24] It is currently hypothesized that glycemic variability contributes to diabetes complications independently of glycosylated hemoglobin (HbA1c) levels.[24–26] To assess diurnal glucose excursions, SMBG has also been established as a useful tool.[27,28]

In "Guidelines on Diabetes, Pre-Diabetes, and Cardiovascular Diseases: Executive Summary. The Task Force on Diabetes and Cardiovascular Diseases of the European Society of Cardiology (ESC) and of the European Association for the Study of Diabetes (EASD)," SMBG is acknowledged as a major part of comprehensive management to reduce cardiovascular risk in diabetes patients.[3]

Despite growing evidence supporting the beneficial potential of SMBG in diabetes management, some authors presented divergent observations.[17,29,30] In addition, SMBG is reported to be accompanied by an increase in challenges for the patients.[7] It has been hypothesized that consistently high blood glucose readings could increase levels of anxiety and self-blame.[7]

In January 2012, a Cochrane database review on SMBG in patients with T2DM who are not using insulin reported a "small" overall effect of SMBG on glycemic control up to 6 months after initiation, which was considered to subside after 12 months.[31] The Cochrane review, however, has been criticized, particularly with regard to the fact that many studies were excluded from the analysis, and some of the conclusions were based on very few studies.[32] Only two studies, the Diabetes Glycaemic Education and Monitoring Trial (DiGEM) trial and Zwolle Outpatient Diabetes project Integrating Available Care (ZODIAC)-17, were included in the 12-month follow-up Cochrane analysis. In the analysis, a nonsignificant decrease in HbA1c [-0.13% (-0.13 to -0.04)] was reported. Both the DiGEM trial and ZODIAC-17 had been characterized by several limitations. In the DiGEM trial, patients with a stable and relatively good metabolic control at entry into the study may have attenuated the need for a modification or intensification of treatment within any of the three groups. No specific algorithm for modification of treatment plans was mentioned. ZODIAC-17 is a small Dutch study in which only 22 patients were included in the SMBG group, of whom, 17 performed at least 80% of the requested glucose measurements. The authors of the study themselves mention in the discussion the sample size as an important limitation of the study. In the study, structured testing of blood glucose was not applied, and any information on modification of treatment is missing.

The fact that prospective and randomized studies that demonstrated benefits of structured SMBG approaches in non-insulin-treated T2DM, e.g., Structured Testing Program (STeP) study, were not or were insufficiently included in the Cochrane analyses further limited the conclusions.

The aim of the current review, therefore, is to present results of innovative studies and publications on SMBG in T2DM and also to discuss the results in light of the Cochrane analysis where applicable.

The Cochrane Review

The Cochrane review "Self-Monitoring of Blood Glucose in Patients with Type 2 Diabetes Mellitus Who Are Not Using Insulin" was long awaited.[31] The review pointed out three key results:

- mean HbA1c reduction of 0.3% at 6-month follow-up in T2DM patients with a history of >1 year,
- nonsignificant mean reduction of HbA1c (0.1%) at 12-month follow-up in T2DM patients with a history of >1 year, and
- significant mean reduction of HbA1c (0.5%) at 12-month follow-up in patients with newly diagnosed T2DM.

Several aspects, however, need to be considered:

1. The review is based on highly selective data. Out of 1153 citations, the review authors considered 32 studies to be potentially eligible.[31] Eventually, 6 new trials were included, while 26 studies were not considered,[31] among them, the STeP study.[9] Additionally, six trials from a previous Cochrane review[27] were included.

2. The reported mean HbA1c reduction of 0.3% at 6-month follow-up in patients with a T2DM history of >1 year is based on nine trials (2324 patients). Some of these trials, such as the Role of Self-Monitoring of Blood Glucose and Intensive Education in Patients with Type 2 Diabetes Not Receiving Insulin study, assessed structured SMBG with an educational and therapeutic component in response to blood glucose values.[15] Other ones did not publish details of training on how to respond to SMBG readings.[33–35] The mean HbA1c reduction found in the review ranged from 0.07% to 0.69%.[31] The mean reduction of 0.3% was classified as "small."[31] The result, however, is statistically significant and should be recognized and valued for the treatment of T2DM.[32] In the United Kingdom Prospective Diabetes Study, a 1% reduction in HbA1c was associated with a 37% decrease in risk for microvascular complications and a 21% decrease in the risk of any end point or death related to diabetes.[36]

3. The conclusion of a nonsignificant mean reduction of HbA1c (0.1%) at 12-month follow-up in T2DM patients with a history of >1 year is based on the assessment of two clinical trials (493 patients): DiGEM and ZODIAC-17.[37,38]

In the DiGEM trial, the relatively good metabolic control (HbA1c 7.41–7.53%) of the patients at entry may have attenuated the need for a modification of treatment within any of the three groups. Therefore, an increase in the utilization of oral antidiabetic agents was found only in less than one-third of the patients.[39] Additionally, the enrolled patients were a highly selected population (453 patients out of 2986 total eligibles).[39]

ZODIAC-17 included only 22 patients in the SMBG group, of whom, 17 performed at least 80% of the requested glucose measurements. The sample size is regarded as an important limitation of the study.[32] Structured SMBG was not applied, and any information on modification of treatment is missing.[37] It therefore may be considered that the conclusions given of the 12 months in Cochrane analysis are not warranted.[32]

Studies

Structured Testing Program

The STeP study is a randomized prospective trial that compared two strategies of SMBG in insulin-naïve patients. It demonstrated that structured SMBG significantly contributes to an improvement in glycemic control compared with patients not receiving structured SMBG.[9] In a primary care setting, 483 poorly controlled (mean HbA1c 8.9%), insulin-naïve patients with T2DM were randomized to a structured testing group or an active control group. Both groups received enhanced usual care, which was characterized by quarterly clinic visits. The care focused on diabetes management (free blood glucose meters and strips were included) and the performance of office point-of-care HbA1c. In addition, the structured testing group was instructed to perform a seven-point SMBG profile (fasting, preprandial/2 h postprandial at each meal, and bedtime) on three consecutive days prior to each scheduled study visit (months 1, 3, 6, 9, and 12). The SMBG patients also were required to document meal sizes and energy levels and to comment on their SMBG experiences.[9] At 1 year, in the SMBG group, a significantly greater mean reduction of HbA1c was registered (-1.2% versus -0.9%; $p = .04$). Per protocol, analysis revealed an even more pronounced mean HbA1c reduction among those SMBG patients who adhered to the intervention compared with controls (-1.3% versus -0.8%).[9]

Significantly greater improvements in diabetes self-confidence and autonomous motivation were observed in patients adherent to a structured, collaborative SMBG protocol than in patients receiving enhanced usual care.[16] The authors emphasize that significant attitudinal improvement was demonstrable only in patients actively adherent to the structured SMBG protocol. Patients who were not actively engaged showed results similar to control patients.[16]

Furthermore, routine availability of structured SMBG data encouraged primary care physicians to treat glycemia earlier, more frequently, and more effectively compared with settings with limited, unstructured, or unsystematic SMBG.[10] Significantly more patients of the structured SMBG group received recommendations for a treatment change as compared with control subjects.[10] In addition, early changes in treatment were associated with a more pronounced glycemic improvement than recommendations given at a later change.[10] These findings highlight the critical role of diligent and well-informed physicians when SMBG is being performed.[10]

The prospective, randomized STeP study has received widespread recognition.[40–43] It, however, was not included in Cochrane review because a non-SMBG group was missing.[31]

St. Carlos

In the prospective randomized St. Carlos study, an SMBG-based structured educational and pharmacological program was applied to analyze the achievement of nutritional and physical activity goals.[18] The study revealed that SMBG encourages physicians and patients to optimize therapy. In the 1-year study, 161 newly diagnosed patients with T2DM were allocated 2:1 to either an SMBG-based intervention or a HbA1c-based control group.[18] All patients received metformin (850 mg/day). During a 2 h consultation, individual lifestyle interventions were recommended, with reinforcement at each follow-up visit. In the intervention group (n = 99), SMBG was used as an educational tool supporting lifestyle changes and for the management of pharmacological treatment. The SMBG patients started with six-point profiles every 3 days. They conducted one profile every 1–2 weeks. In the control group (n = 66), however, treatment was adjusted every 3–6 months according to HbA1c values.[18]

After 1 year, the SMBG group showed significant reductions in median HbA1c (from 6.6% to 6.1%; $p < .05$) and body mass index (BMI; from 29.6 to 27.9 kg/m^2; $p < .01$) as compared with no change in the control group.[18] The St. Carlos study was included in the Cochrane analysis addressing newly diagnosed diabetes. The Cochrane review concluded that SMBG was beneficial in patients with newly diagnosed diabetes.[31]

Role of Self-Monitoring of Blood Glucose and Intensive Education in Patients with Type 2 Diabetes Not Receiving Insulin

This randomized controlled trial assessed SMBG plus intensive educational intervention (intervention) versus no monitoring plus standard education (control). It included 62 T2DM patients without insulin and with no SMBG experience in the previous 12 months.[15] The self-monitoring disease management strategy was primarily led by diabetes nurses and allowed a timely and efficient use of SMBG readings. The strategy was demonstrated to improve metabolic control, primarily through lifestyle modifications, leading to weight loss.[15]

Patients assigned to the intervention group received specific education addressing SMBG application, adjustment of nutrition and physical activity according to blood glucose levels, and the response to abnormal glucose values. The education was based on face-to-face encounters every 3 months and additional monthly telephone contact. The control group received standard counseling focusing on diet and lifestyle, with follow-up visits every 3 months.[15]

In the intervention group, a HbA1c reduction of 1.2% ± 0.1% was observed compared with 0.7% ± 0.2% in the control group, equaling a significant mean difference of 0.5%.[15] Of the patients assigned to the intervention group, 61.9% reached the HbA1c target <7.0% compared with only 20.0% of the control group. In addition, mean body weight reduction was significantly higher in the intervention group compared with the control group (-4.49 versus -0.50 kg).[15]

Retrolective Study Self-Monitoring of Blood Glucose and Outcome in Patients with Type 2 Diabetes-In-Praxi Follow-Up

The Retrolective Study Self-Monitoring of Blood Glucose and Outcome in Patients with Type 2 Diabetes (ROSSO)-in-praxi follow-up trial was conducted to assess longer-term effects of the short-term intervention assessed by the ROSSO-in-praxi trial.[44] In that trial, 405 patients with T2DM had received a 12-week structured SMBG-based lifestyle intervention, including seven-point blood glucose profiles every 4 weeks.[13] Significant improvements in HbA1c, quality of diet, level of physical activity, weight, and physical and mental health measurements had been demonstrated.[13]

In the follow-up trial, 228 ROSSO-in-praxi participants (70%) completed a mean follow-up of 2 years, demonstrating a stable mean weight (90.2 ± 15.7 = -2.4 kg) and BMI (31.5 ± 5.1 = -0.8 kg/m²) versus baseline.[44] In HbA1c, a marginal mean increase of 0.2% was observed from 3 months to the 2-year follow-up, translating into mean value of 6.6% ± 0.8% at 2 years.[44] A further mean reduction of HbA1c (0.28% ± 1.21%), however, was seen in 46 patients who had continued daily SMBG conduction of 2.0 ± 1.0 tests.[44] No significant correlation between SMBG performance and depression, as assessed with the validated Center for Epidemiologic Studies Depression Scale questionnaire,[45] was detected. Also, an absence of a relationship between mental-health-related quality of life, as assessed with the validated 36-Item Short-Form Health Survey questionnaire,[46] and SMBG was found.[44]

Delivering Early Care in Diabetes Evaluation Study

The potential of an automated decision support tool (DST), an educational DVD, or both to support structured SMBG was evaluated by the Delivering Early Care in Diabetes Evaluation study, in which virtual cases were assessed.[47] In this prospective, randomized, controlled, multicenter study, 30 patient cases (T2DM) were analyzed by 288 clinicians. Physicians were randomized to structured SMBG alone, structured SMBG with DST, structured SMBG with an educational DVD, and structured SMBG with DST and the educational DVD. Physicians using the support tools significantly performed better than those using SMBG alone when identifying the glycemic abnormality and selecting the most appropriate therapeutic option. Use of either the educational DVD or the DST showed to be equally effective in improving data interpretation and utilization. A DST, however, also provides a viable alternative when comprehensive education is not feasible. It may be integrated into medical practices with minimal training.[47]

Prospective, Randomized Trial on Intensive Self-Monitoring of Blood Glucose Management Added Value in Non-Insulin-Treated Type 2 Diabetes Mellitus Patients

Prospective, Randomized Trial on Intensive Self-Monitoring of Blood Glucose Management Added Value in Non-Insulin-Treated Type 2 Diabetes Mellitus Patients (PRISMA) is a 12-month, prospective, multicenter, open, parallel group, randomized, controlled trial to evaluate the added value of an intensive, structured SMBG regimen in T2DM patients on oral treatment and/or diet.[48] The intervention group received structured SMBG (four-point daily glucose profiles 3 days per week), comprehensive patient education, and clinician's adjustment of medication based on an algorithm targeting SMBG levels, HbA1c, and hypoglycemia. The active control group received discretionary, unstructured SMBG, comprehensive patient education, and treatment adjustment according to HbA1c levels and hypoglycemia.[48] Publication of the PRISMA results is expected shortly, yielding further evidence regarding the effects of structured SMBG, including changes in patient and physician attitudes and behaviors.[48]

Reviews and Meta-Analyses

Aberdeen Health Technology Assessment Group

A systematic review on 10 trials (published 1996–April 2009) comparing SMBG with no SMBG in patients with T2DM found a statistically significant reduction in HbA1c of 0.21% in favor of SMBG.[49] With appropriate education provided both for patients and for health care professionals, further improvement of glycemic control is considered to be possible. Prerequisites, however, are appropriate education addressing SMBG interpretation, adjustment of nutrition and physical activity according to measurements, and the response to abnormal values of blood glucose, both for patients and for health care professionals.[49]

Meta-Analysis of Individual Patient Data in Randomised Trials of Self-Monitoring of Blood Glucose in People with Non-Insulin-Treated Type 2 Diabetes

This meta-analysis compared treatment strategies using SMBG and strategies not using SMBG.[42] Based on 2552 patients from six trials, a significantly higher mean reduction of HbA1c levels in patients using SMBG was found.[42] At 3- and 6-month follow-up, the difference in mean reduction was 0.25%. At 12 months, a difference of 0.35% was found.[42] The difference in HbA1c levels was consistent across age, baseline HbA1c level, sex, and duration of diabetes.

Despite these significant improvements in glycemic control, the authors estimate that the evidence from their meta-analysis was "not convincing for a clinically meaningful effect" of SMBG in non-insulin-treated T2DM.[42] A mean HbA1c reduction of 0.35% at 12 months, however, should be recognized and valued for the treatment of T2DM.[32]

The meta-analysis's data indicate, although not significantly, that those who have used SMBG in the past may benefit less than a group newly exposed to the technology. According to the authors, SMBG is one component of a complex intervention aimed at improving overall glycemic control and quality of life.[42]

Self-Monitoring of Blood Glucose and Personalized Diabetes Management

Case-Based Recommendations for Self-Monitoring of Blood Glucose

Individualized SMBG management has also been proposed in a consensus document, which aimed at presenting typical clinical settings for SMBG.[50] The recommendations focused on nine clinical scenarios that address aspects of the daily clinical practice:

1. pediatric patients with type 1 diabetes,
2. patients with gestational diabetes,
3. T2DM patients with elevated postprandial blood glucose levels,
4. patients with lack of motivation and adherence,
5. T2DM patients at risk of hypoglycemia unawareness,
6. obese T2DM patients with oral glucose-lowering agents and initiation of insulin therapy,
7. T2DM patients presenting with coronary artery disease,
8. T2DM patients with nephropathy, and
9. elderly patients (≥80 years of age) with T2DM.[50]

Due to the consensus document, individual glycemic targets should always be agreed upon between patient and health care professional. The authors emphasize that optimal frequency and patterns of SMBG always depend on a range of factors such as type of diabetes, treatment regimen, individual targets of HbA1c, as well as preprandial and postprandial blood glucose values.[50]

Personalizing Treatment in Type 2 Diabetes

Despite an association between improved glycemic control and the prevention of complications, tight glycemic control does not always translate into a benefit for every patient.[51–55] To achieve optimal efficacy, safety, and adherence, a group from Italy proposed the implementation of individualized treatment targets.[51] Five different algorithms for patients with T2DM were presented:[51]

1. No antidiabetic drug therapy, severe hyperglycemic episodes (HbA1c ≥ 9%), in the presence or absence of symptoms;

2. Normal weight or overweight (i.e., BMI < 30 kg/m²) and mild/moderate hyperglycemia (i.e., HbA1c 6.5–<9%);

3. Obesity (i.e., BMI ≥ 30 kg/m²) and mild/moderate hyperglycemia (i.e., HbA1c 6.5–<9%);

4. Presence of occupational risks potentially related to hypoglycemia and mild/moderate hyperglycemia (i.e., HbA1c 6.5–<9%); and

5. Chronic renal failure and mild/moderate hyperglycemia (i.e., HbA1c 6.5–< 9%).

The algorithms are available as an interactive online tool.[56] Performance of structured SMBG is emphasized to contribute essentially to the best possible outcome of diabetes management.[51]

Consensus Reports

"The Current Role of Self-Monitoring of Blood Glucose in Non-Insulin-Treated Type 2 Diabetes"

This consensus report was compiled by the Coalition for Clinical Research Self-Monitoring of Blood Glucose Scientific Board, which was organized by Diabetes Technology Society.[43] The core statements were formulated as follows:

1. Most of the earlier studies did not include an educational and therapeutic intervention in response to blood glucose values. In contrast, many trials following an expert panel recommendation published in November 2008[57] did incorporate an educational and a therapeutic component in response to blood glucose values. Consistently, many of these trials could demonstrate significant reductions in HbA1c.

2. In order to optimize its efficacy, SMBG should be implemented in a structured and standardized approach. Information obtained from SMBG measurement has to be used to manage treatment.

3. Both patients and health care professionals require education on how to respond to the results of SMBG measurement.[43]

As emphasized in the consensus report, in most studies contributing to relatively poor SMBG results in meta-analyses, SMBG was not performed in a structured approach. The SMBG values were not permitted to influence treatment strategies. Additionally, further trials are reported to be affected by small sample size, low baseline HbA1c levels, or poor study design.[43]

Several potential benefits of SMBG beyond HbA1c reduction were suggested: reduction of glycemic variability and hypoglycemia, improvements in lifestyle and medication adherence, and accelerated medication adjustment.[43]

The consensus highlights that HbA1c will remain the primary end point for future studies on SMBG. Secondary end points could include hypoglycemic and hyperglycemic events, weight or lipid changes, time to achieve target goals, or combined end points.[43] It was recommended that end points take into account educational and therapeutic components in response to blood glucose values.[43]

"Addressing Schemes of Self-Monitoring of Blood Glucose in Type 2 Diabetes: A European Perspective and Expert Recommendation"

In 2010, the need to educate diabetes caregivers and patients on SMBG was suggested in European recommendations.[40] The performance based on two schemes of varying intensity across the T2DM continuum was suggested.[42] Scheme 1 is assigned to less intensive testing (**Figure 1**) while scheme 2 is intended for intensive testing (**Figure 2**). The selection of the adequate scheme as well as the lengths of the testing periods should be oriented on the individual situations. The two schemes are considered as a starting point, which could be applied as an intermittent or continuous approach.[40]

	Breakfast		Lunch		Dinner		
	pre	post	pre	post	pre	post	night
Mon	×	×					
Tue			×	×			
Wed					×	×	
Thur	×	×					
Fri			×	×			
Sat					×	×	
Sun	×	×					

Figure 1. Less intensive SMBG testing to be applied temporarily or continuously.[40]

	Breakfast		Lunch		Dinner		
	pre	post	pre	post	pre	post	night
Mon	×	×	×	×	×	×	×
Tue	×	×	×	×	×	×	×
Wed	×	×	×	×	×	×	×
Thur	×	×	×	×	×	×	×
Fri	×	×	×	×	×	×	×
Sat	×	×	×	×	×	×	×
Sun	×	×	×	×	×	×	×

Figure 2. Intensive SMBG testing to be applied temporarily.[40]

Guidelines

International Diabetes Federation Guideline for Self-Monitoring of Blood Glucose in Non-Insulin-Treated Type 2 Diabetes

This guideline, published in 2009 by the International Diabetes Federation, is considered to be the first guideline providing global recommendations for SMBG.[58] The guideline differentiates three levels of diabetes care, depending on the regions where they are applied: minimal care, standard care, and comprehensive care. In standard care, SMBG is recommended for all newly diagnosed people with T2DM as an integral part of self-management education.[58] Furthermore, SMBG should be available on an ongoing basis in all patients on insulin treatment.

In non-insulin-treated patients, SMBG is recommended on an ongoing basis to provide information on hypoglycemia, glucose excursions due to intercurrent illness, and changes in medication or lifestyle.[58] In addition, the guideline underlines the need for an annually structured assessment of self-monitoring skills, the quality of measurements, the response to blood glucose values, and the equipment.[58]

International Diabetes Federation Guidelines for the Management of Postmeal Glucose

Updated guidelines report that 2 h postmeal plasma glucose should not exceed postprandial targets of <9.0 mmol/liter (≤160 mg/dl). They propose a time frame of 1–2 h after a meal as long as hypoglycemia is avoided.[59] The target for monitoring slightly above the normal range of <7.8 mmol/liter (≤140 mg/dl) is recommended due to the fact that near-normal glycemic control is frequently associated with an increased risk of hypoglycemic events.[59] Self-monitoring of blood glucose is emphasized to be the most practical method for monitoring of postmeal glycemia. Both clinicians experienced in adjusting treatment following SMBG data and patients trained to perform SMBG, interpret measurement results, and appropriately adjust treatment are emphasized to be an indispensable need for the potential benefits of SMBG.[59]

American Diabetes Association Position Statement 2012: Further Standards of Medical Care in Diabetes

The American Diabetes Association's position statement highlights the role of SMBG in T2DM.[60] In patients using less-frequent insulin injections, non-insulin therapies, or medical nutrition therapy alone, SMBG is considered as a useful guide to management. Proper interpretation of the data is emphasized as a prerequisite for optimal use of SMBG.[60]

Summary and Outlook

Overall, studies and recommendations largely contribute to a more complete picture on the effects and potentials of SMBG in T2DM.[3,9,15,18,43,58,59] Glycosylated hemoglobin reduction, improvement of glycemic variability, visualization of

hypoglycemic episodes, and improvements in lifestyle and medication adherence have been demonstrated. A key learning is that SMBG needs to be performed in a structured setting. Personalized approaches of SMBG are a prerequisite for its success in T2DM.[9,15,43,44] Both patients and health care providers are required to interact and to embed SMBG in diabetes management plans.

Further studies, however, are required to create additional information on glucose meters, e.g., their accuracy, the role of software-based approaches to visualize glucose values, and telemedical approaches. Noninvasive testing may have a future role in T2DM and will need to be studied extensively once it may become available.

Currently, novel strategies of diabetes treatment, e.g., glucagon-like peptide-1-based approaches or sodium–glucose transporter-2 inhibitors, should also be further studied in conjunction with SMBG.

These studies will be important steps on the way to further shape the role for SMBG in the management of T2DM.

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References:

1. Parkin CG, Hinnen DA, Tetrick DL. Effective use of structured self-management of blood glucose in type 2 diabetes: lessons from the STeP study. Clin Diabetes. 2011;29(4):131–8.
2. Abraira C, Colwell JA, Nuttall FQ, Sawin CT, Nagel NJ, Comstock JP, Emanuele NV, Levin SR, Henderson W, Lee HS. Veterans Affairs Cooperative Study on glycemic control and complications in type II diabetes (VA CSDM). Results of the feasibility trial. Veterans Affairs Cooperative Study in Type II Diabetes. Diabetes Care. 1995;18(8):1113–23.
3. Rydén L, Standl E, Bartnik M, Van den Berghe G, Betteridge J, de Boer MJ, Cosentino F, Jönsson B, Laakso M, Malmberg K, Priori S, Ostergren J, Tuomilehto J, Thrainsdottir I, Vanhorebeek I, Stramba-Badiale M, Lindgren P, Qiao Q, Priori SG, Blanc JJ, Budaj A, Camm J, Dean V, Deckers J, Dickstein K, Lekakis J, McGregor K, Metra M, Morais J, Osterspey A, Tamargo J, Zamorano JL, Deckers JW, Bertrand M, Charbonnel B, Erdmann E, Ferrannini E, Flyvbjerg A, Gohlke H, Juanatey JR, Graham I, Monteiro PF, Parhofer K, Pyörälä K, Raz I, Schernthaner G, Volpe M, Wood D; Task Force on Diabetes and Cardiovascular Diseases of the European Society of Cardiology (ESC); European Association for the Study of Diabetes (EASD). Guidelines on diabetes, pre-diabetes, and cardiovascular diseases: executive summary. The Task Force on Diabetes and Cardiovascular Diseases of the European Society of Cardiology (ESC) and of the European Association for the Study of Diabetes (EASD). Eur Heart J. 2007;28(1):88–136.
4. Allemann S, Houriet C, Diem P, Stettler C. Self-monitoring of blood glucose in non-insulin treated patients with type 2 diabetes: a systematic review and meta-analysis. Curr Med Res Opin. 2009;25(12):2903–13.
5. Kovatchev BP, Otto E, Cox D, Gonder-Frederick L, Clarke W. Evaluation of a new measure of blood glucose variability in diabetes. Diabetes Care. 2006;29(11):2433–8.
6. Schnell O, Alawi H, Battelino T, Ceriello A, Diem P, Felton A, Grzeszczak W, Harno K, Kempler P, Satman I, Vergès B. Consensus statement on self-monitoring of blood glucose in diabetes: a European perspective. Diab Metab Heart. 2009;18(4):285–9.
7. Peel E, Parry O, Douglas M, Lawton J. Blood glucose self-monitoring in non-insulin-treated type 2 diabetes: a qualitative study of patients' perspectives. Br J Gen Pract. 2004;54(500):183–8.
8. UK Prospective Diabetes Study (UKPDS) Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). Lancet. 1998;352(9131):837–53.
9. Polonsky WH, Fisher L, Schikman CH, Hinnen DA, Parkin CG, Jelsovsky Z, Petersen B, Schweitzer M, Wagner RS. Structured self-monitoring of blood glucose significantly reduces A1C levels in poorly controlled, noninsulin-treated type 2 diabetes: results from the Structured Testing Program study. Diabetes Care. 2011;34(2):262–7.
10. Polonsky WH, Fisher L, Schikman CH, Hinnen DA, Parkin CG, Jelsovsky Z, Axel-Schweitzer M, Petersen B, Wagner RS. A structured self-monitoring of blood glucose approach in type 2 diabetes encourages more frequent, intensive, and effective physician interventions: results from the STeP study. Diabetes Technol Ther. 2011;13(8):797–802.
11. Martin S, Schneider B, Heinemann L, Lodwig V, Kurth HJ, Kolb H, Scherbaum WA. Self-monitoring of blood glucose in type 2 diabetes and long-term outcome: an epidemiological cohort study. Diabetologia. 2006;49(2):271–8.

12. Khamseh ME, Ansari M, Malek M, Shafiee G, Baradaran H. Effects of a structured self-monitoring of blood glucose method on patient self-management behavior and metabolic outcomes in type 2 diabetes mellitus. J Diabetes Sci Technol. 2011;5(2):388–93.

13. Kempf K, Kruse J, Martin S. ROSSO-in-praxi: a self-monitoring of blood glucose-structured 12-week lifestyle intervention significantly improves glucometabolic control of patients with type 2 diabetes mellitus. Diabetes Technol Ther. 2010;12(7):547–53.

14. Karter AJ, Parker MM, Moffet HH, Spence MM, Chan J, Ettner SL, Selby JV. Longitudinal study of new and prevalent use of self-monitoring of blood glucose. Diabetes Care. 2006;29(8):1757–63.

15. Franciosi M, Lucisano G, Pellegrini F, Cantarello A, Consoli A, Cucco L, Ghidelli R, Sartore G, Sciangula L, Nicolucci A; ROSES Study Group. ROSES: role of self-monitoring of blood glucose and intensive education in patients with type 2 diabetes not receiving insulin. A pilot randomized clinical trial. Diabet Med. 2011;28(7):789–96.

16. Fisher L, Polonsky WH, Parkin CG, Jelsovsky Z, Petersen B, Wagner RS. The impact of structured blood glucose testing on attitudes toward self-management among poorly controlled, insulin-naive patients with type 2 diabetes. Diabetes Res Clin Pract. 2012;96(2):149–55.

17. Farmer A, Wade A, Goyder E, Yudkin P, French D, Craven A, Holman R, Kinmonth AL, Neil A. Impact of self monitoring of blood glucose in the management of patients with non-insulin treated diabetes: open parallel group randomised trial. BMJ. 2007;335(7611):132.

18. Durán A, Martín P, Runkle I, Pérez N, Abad R, Fernández M, Del Valle L, Sanz MF, Calle-Pascual AL. Benefits of self-monitoring blood glucose in the management of new-onset type 2 diabetes mellitus: the St Carlos Study, a prospective randomized clinic-based interventional study with parallel groups. J Diabetes. 2010;2(3):203–11.

19. Shiraiwa T, Takahara M, Kaneto H, Miyatsuka T, Yamamoto K, Yoshiuchi K, Sakamoto K, Matsuoka TA, Matsuhisa M, Yamasaki Y, Shimomura I. Efficacy of occasional self-monitoring of postprandial blood glucose levels in type 2 diabetic patients without insulin therapy. Diabetes Res Clin Pract. 2010;90(3):e91–2.

20. Cavalot F, Pagliarino A, Valle M, Di Martino L, Bonomo K, Massucco P, Anfossi G, Trovati M. Postprandial blood glucose predicts cardiovascular events and all-cause mortality in type 2 diabetes in a 14-year follow-up: lessons from the San Luigi Gonzaga Diabetes Study. Diabetes Care. 2011;34(10):2237–43.

21. Rizzo MR, Marfella R, Barbieri M, Boccardi V, Vestini F, Lettieri B, Canonico S, Paolisso G. Relationships between daily acute glucose fluctuations and cognitive performance among aged type 2 diabetic patients. Diabetes Care. 2010;33(10):2169–74.

22. Buscemi S, Re A, Batsis JA, Arnone M, Mattina A, Cerasola G, Verga S. Glycaemic variability using continuous glucose monitoring and endothelial function in the metabolic syndrome and in type 2 diabetes. Diabet Med. 2010;27(8):872–8.

23. Brownlee M, Hirsch IB. Glycemic variability: a hemoglobin A1c-independent risk factor for diabetic complications. JAMA. 2006;295(14):1707–8.

24. Nalysnyk L, Hernandez-Medina M, Krishnarajah G. Glycaemic variability and complications in patients with diabetes mellitus: evidence from a systematic review of the literature. Diabetes Obes Metab. 2010;12(4):288–98.

25. Monnier L, Mas E, Ginet C, Michel F, Villon L, Cristol JP, Colette C. Activation of oxidative stress by acute glucose fluctuations compared with sustained chronic hyperglycemia in patients with type 2 diabetes. JAMA. 2006;295(14):1681–7.

26. Kohnert KD, Augstein P, Heinke P, Zander E, Peterson K, Freyse EJ, Salzsieder E. Chronic hyperglycemia but not glucose variability determines HbA1c levels in well-controlled patients with type 2 diabetes. Diabetes Res Clin Pract. 2007;77(3):420–6.

27. Welschen LM, Bloemendal E, Nijpels G, Dekker JM, Heine RJ, Stalman WA, Bouter LM. Self-monitoring of blood glucose in patients with type 2 diabetes mellitus who are not using insulin. Cochrane Database Syst Rev. 2005;(2):CD005060.

28. Hirsch IB, Bode BW, Childs BP, Close KL, Fisher WA, Gavin JR, Ginsberg BH, Raine CH, Verderese CA. Self-monitoring of blood glucose (SMBG) in insulin- and non-insulin-using adults with diabetes: consensus recommendations for improving SMBG accuracy, utilization, and research. Diabetes Technol Ther. 2008;10(6):419–39.

29. Tengblad A, Grodzinsky E, Lindstrom K, Molstad S, Borgquist L, Ostgren CJ. Self-monitoring of blood glucose and glycaemic control in type 2 diabetes. Scand J Prim Health Care. 2007;25(3):140–6.

30. Simon J, Gray A, Clarke P, Wade A, Neil A, Farmer A; Diabetes Glycaemic Education and Monitoring Trial Group. Cost effectiveness of self-monitoring of blood glucose in patients with non-insulin treated type 2 diabetes: economic evaluation of data from the DiGEM trial. BMJ. 2008;336(7654):1177–80.

31. Malanda UL, Welschen LM, Riphagen II, Dekker JM, Nijpels G, Bot SD. Self-monitoring of blood glucose in patients with type 2 diabetes mellitus who are not using insulin. Cochrane Database Syst Rev. 2012;1:CD005060.

32. Schnell O, Alawi H, Battelino T, Ceriello A, Diem P, Felton A, Grzeszczak W, Harno K, Hummel M, Kempler P, Satman I, Vergès B. Self-monitoring of blood glucose in patients with type 2 diabetes mellitus who are not using insulin: letter to the editor. Cochrane Database Syst Rev. 2012;1:CD005060.

33. Fontbonne A, Billault B, Acosta M, Percheron C, Varenne P, Besse A, Eschwege E, Monnier L, Slama G, Passa P. Is glucose self-monitoring beneficial in non-insulin-treated diabetic patients? Results of a randomized comparative trial. Diabete Metab. 1989;15(5):255–60.

34. Guerci B, Drouin P, Grangé V, Bougnères P, Fontaine P, Kerlan V, Passa P, Thivolet Ch, Vialettes B, Charbonnel B; ASIA Group. Self-monitoring of blood glucose significantly improves metabolic control in patients with type 2 diabetes mellitus: the Auto-Surveillance Intervention Active (ASIA) study. Diabetes Metab. 2003;29(6):587–94.

35. Davidson MB, Castellanos M, Kain D, Duran P. The effect of self monitoring of blood glucose concentrations on glycated hemoglobin levels in diabetic patients not taking insulin: a blinded, randomized trial. Am J Med. 2005;118(4):422–5.

36. Stratton IM, Adler AI, Neil HA, Matthews DR, Manley SE, Cull CA, Hadden D, Turner RC, Holman RR. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. BMJ. 2000;321(7258):405–12.

37. Kleefstra N, Hortensius J, Logtenberg SJ, Slingerland RJ, Groenier KH, Houweling ST, Gans RO, van Ballegooie E, Bilo HJ. Self-monitoring of blood glucose in tablet-treated type 2 diabetic patients (ZODIAC). Neth J Med. 2010;68(1):311–6.

38. Farmer A, Wade A, French DP, Goyder E, Kinmonth AL, Neil A. The DiGEM trial protocol--a randomised controlled trial to determine the effect on glycaemic control of different strategies of blood glucose self-monitoring in people with type 2 diabetes [ISRCTN47464659]. BMC Fam Pract. 2005;6:25.

39. Schnell O, Heinemann L. Self-monitoring of blood glucose in noninsulin-treated patients with type 2 diabetes: a never ending story? J Diabetes Sci Technol. 2007;1(5):614–6.

40. Schnell O, Alawi H, Battelino T, Ceriello A, Diem P, Felton A, Grzeszczak W, Harno K, Kempler P, Satman I, Vergès B. Addressing schemes of self-monitoring of blood glucose in type 2 diabetes: a European perspective and expert recommendation. Diabetes Technol Ther. 2011;13(9):959–65.

41. Stephens JW, Carman JE, Brooks CJ, Lyons RA, Ford DV, Price DE, Bain SC. Comment on: Polonsky et al. Structured self-monitoring of blood glucose significantly reduces A1C levels in poorly controlled, noninsulin-treated type 2 diabetes: results from the structured testing program study. Diabetes Care 2011;34:262-267. Diabetes Care. 2011;34(5):e57; author reply e58.

42. Farmer AJ, Perera R, Ward A, Heneghan C, Oke J, Barnett AH, Davidson MB, Guerci B, Coates V, Schwedes U, O'Malley S. Meta-analysis of individual patient data in randomised trials of self monitoring of blood glucose in people with non-insulin treated type 2 diabetes. BMJ. 2012;344:e486.

43. Klonoff DC, Blonde L, Cembrowski G, Chacra AR, Charpentier G, Colagiuri S, Dailey G, Gabbay RA, Heinemann L, Kerr D, Nicolucci A, Polonsky W, Schnell O, Vigersky R, Yale JF; Coalition for Clinical Research-Self-Monitoring of Blood Glucose Scientific Board. Consensus report: the current role of self-monitoring of blood glucose in non-insulin-treated type 2 diabetes. J Diabetes Sci Technol. 2011;5(6):1529–48.

44. Kempf K, Kruse J, Martin S. ROSSO-in-praxi follow-up: long-term effects of self-monitoring of blood glucose on weight, hemoglobin a1c, and quality of life in patients with type 2 diabetes mellitus. Diabetes Technol Ther. 2012;14(1):59–64.

45. Radloff LS. The CES-D scale: a self-report depression scale for research in the general population. Appl Psychol Measure. 1977;1:385–401.

46. Brazier JE, Harper R, Jones NM, O'Cathain A, Thomas KJ, Usherwood T, Westlake L. Validating the SF-36 health survey questionnaire: new outcome measure for primary care. BMJ. 1992;305(6846):160–4.

47. Rodbard HW, Schnell O, Unger J, Rees C, Amstutz L, Parkin CG, Jelsovsky Z, Wegmann N, Axel-Schweitzer M, Wagner RS. Use of an automated decision support tool optimizes clinicians' ability to interpret and appropriately respond to structured self-monitoring of blood glucose data. Diabetes Care. Apr 2012;35(4):693–8.

48. Scavini M, Bosi E, Ceriello A, Giorgino F, Porta M, Tiengo A, Vespasiani G, Bottalico D, Marino R, Parkin C, Bonizzoni E, Cucinotta D. Prospective, randomized trial on intensive SMBG management added value in non-insulin-treated T2DM patients (PRISMA): a study to determine the effect of a structured SMBG intervention. Acta Diabetol. 2011. Epub ahead of print.

49. Clar C, Barnard K, Cummins E, Royle P, Waugh N; Aberdeen Health Technology Assessment Group. Self-monitoring of blood glucose in type 2 diabetes: systematic review. Health Technol Assess. 2010;14(12):1–140.

50. Schnell O, Alawi H, Battelino T, Ceriello A, Diem R, Felton A, Grzeszczak W, Hämo K, Kempler P, Satman I, Verges B. A consensus of clinical cases on self-monitoring of blood glucose: a European perspective. Diab Metab Heart. 2010;19(5):3–25.

51. Ceriello A, Gallo M, Armentano V, Perriello G, Gentile S, De Micheli A; Associazione Medici Diabetologi. Personalizing treatment in type 2 diabetes: a self-monitoring of blood glucose inclusive innovative approach. Diabetes Technol Ther. 2012;14(4):373–8.

52. Action to Control Cardiovascular Risk in Diabetes Study Group, Gerstein HC, Miller ME, Byington RP, Goff DC Jr, Bigger JT, Buse JB, Cushman WC, Genuth S, Ismail-Beigi F, Grimm RH Jr, Probstfield JL, Simons-Morton DG, Friedewald WT. Effects of intensive glucose lowering in type 2 diabetes. N Engl J Med. 2008;358(24):2545–59.

53. ADVANCE Collaborative Group, Patel A, MacMahon S, Chalmers J, Neal B, Billot L, Woodward M, Marre M, Cooper M, Glasziou P, Grobbee D, Hamet P, Harrap S, Heller S, Liu L, Mancia G, Mogensen CE, Pan C, Poulter N, Rodgers A, Williams B, Bompoint S, de Galan BE, Joshi R, Travert F. Intensive blood glucose control and vascular outcomes in patients with type 2 diabetes. N Engl J Med. 2008;358(24):2560–72.

54. Duckworth W, Abraira C, Moritz T, Reda D, Emanuele N, Reaven PD, Zieve FJ, Marks J, Davis SN, Hayward R, Warren SR, Goldman S, McCarren M, Vitek ME, Henderson WG, Huang GD; VADT Investigators. Glucose control and vascular complications in veterans with type 2 diabetes. N Engl J Med. 2009;360(2):129–39.

55. Del Prato S. Megatrials in type 2 diabetes. From excitement to frustration? Diabetologia. 2009;52(7):1219–26.

56. Working Group on Personalised Therapy in Type 2 Diabetes; Italian Association of Medical Diabetologists. Personalization of therapy in type 2 diabetes. *http://www.aemmedi.it/algoritmi/intro-inglese.html*.

57. Klonoff DC, Bergenstal R, Blonde L, Boren SA, Church TS, Gaffaney J, Jovanovic L, Kendall DM, Kollman C, Kovatchev BP, Leippert C, Owens DR, Polonsky WH, Reach G, Renard E, Riddell MC, Rubin RR, Schnell O, Siminiero LM, Vigersky RA, Wilson DM, Wollitzer AO. Consensus report of the Coalition For Clinical Research-Self-Monitoring of Blood Glucose. J Diabetes Sci Technol. 2008;2(6):1030–53.

58. International Diabetes Federation. IDF guideline on self-monitoring of blood glucose in non-insulin treated type 2 diabetes. *http://www.idf.org/guidelines/self-monitoring*.

59. International Diabetes Federation. Guideline for management of postmeal glucose in diabetes 2011. *http://www.idf.org/2011-guideline-management-postmeal-glucose-diabetes*.

60. American Diabetes Association. Standards of medical care in diabetes--2012. Diabetes Care. 2012;35 Suppl 1:S11–63.