Self-Monitoring of Blood Glucose as Part of the Integral Care of Type 2 Diabetes

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Results from landmark diabetes studies have established A1C as the gold standard for assessing long-term glycemic control. However, A1C does not provide "real-time" information about individual hyperglycemic or hypoglycemic excursions. Real-time information provided by self-monitoring of blood glucose (SMBG) represents an important adjunct to A1C, because it can differentiate fasting, preprandial, and postprandial hyperglycemia; detect glycemic excursions; identify hypoglycemia; and provide immediate feedback about the effect of food choices, physical activity, and medication on glycemic control. The importance of SMBG is widely appreciated and recommended as a core component of management in patients with type 1 or insulin-treated type 2 diabetes, as well as in diabetic pregnancy, for both women with pregestational type 1 and gestational diabetes. Nevertheless, SMBG in management of non–insulin-treated type 2 diabetic patients continues to be debated. Results from clinical trials are inconclusive, and reviews fail to reach an agreement, mainly because of methodological problems. Carefully designed large-scale studies on diverse patient populations with type 2 diabetes with the follow-up period to investigate long-term effects of SMBG in patients with type 2 diabetes should be carried out to clarify how to make the best use of SMBG, in which patients, and under what conditions.

O ver the last 2 decades, it was firmly established that tight glycemic control is associated with a significant reduction in serious long-term diabetes-related complications. The Diabetes Control and Complications Trial demonstrated that treatment that maintains blood glucose levels near normal in type 1 diabetes delays the onset and reduces the progression of microvascular complications (1). In the U.K. Prospective Diabetes Study, each 1% reduction in A1C was associated with a 37% decrease in relative risk for microvascular complications and a 21% decrease in relative risk of any end point or death related to diabetes (2).

Assessing glycemia in the management of diabetes has always been a challenge. The urine glucose testing provided a noninvasive inexpensive proof of severe hyperglycemia; nevertheless, the method was seriously limited by being only semi-quantitative, retrospective, and signifi-

cantly dependent on the patient's individual threshold, detecting only concentrations above this threshold. In the 1970s and 1980s, self-monitoring of blood glucose (SMBG) and A1C testing became available. In the 1990s, the continuous measurement of glucose in subcutaneous tissue was introduced.

Glycosylated hemoglobin remains the gold standard marker for assessing long-term glycemic control. What still remains elusive is to which extent the retrospective reflection of the average glycemia of the past 100–120 days, as expressed by A1C, reflects, even within the normal range, a secure nondeleterious effect of hyperglycemic excursions or hypoglycemic nadir on organ targets. However, A1C does not provide "real-time" information about individual hyperglycemic or hypoglycemic excursions.

To the contrary, SMBG reveals the immediate hour-to-hour blood glucose, which in people without diabetes, varies

only ~50% throughout the day but may vary up to10-fold in patients with diabetes. Real-time information provided by SMBG represents an important adjunct to A1C, because it can track fasting and postprandial hyperglycemia, detect glycemic excursions and hypoglycemia, and ultimately provides on-the-spot information about the instant effects of food choice, physical activity, and medication on glycemic control. In fact, SMBG can aid in diabetes control by doing the following: facilitating the development of an individualized blood glucose profile, which can then guide doctors in treatment planning for an individualized diabetic regimen; offering patients with diabetes the ability to make appropriate day-to-day treatment choices in diet and physical activity as well as in insulin or oral hypoglycemic agents; and improving patient recognition of hypoglycemia. If the principle of data-driven feedback governs the treatment adaptation, SMBG could ultimately show effectiveness in significantly lowering A1C.

In pursuit of achieving near-euglycemia while avoiding hypoglycemia, the importance of SMBG is widely appreciated and recommended as a routine part of management in patients with type 1 or insulin-treated type 2 diabetes, as well as in diabetic pregnancy, for both women with pregestational type 1 and gestational diabetes (3). In patients with type 1 diabetes in the Diabetes Control and Complications Trial, it was clearly shown that SMBG in the context of multifactorial interventions is linearly correlated with reductions in A1C (1). Most authorities recommend subjects with type 1 diabetes using multiple insulin injections or insulin pump therapy to perform more than three capillary glucose determinations per day, but ideally four to six (3).

In patients with type 2 diabetes managed with noninsulin therapies or medical nutrition therapy, despite the lack of clear evidence linking SMBG to improved glycemic control, the adoption of this practice is quite common and constantly increasing. National guidelines unanimously recommend SMBG in insulin-treated type 2 diabetes; however, there is a lack of consensus on the value of SMBG

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in non–insulin-treated type 2 diabetes (NIT-DM) patients. Considering the increasing incidence of type 2 diabetes and the tremendous economic burden of the disease both in direct and indirect costs, but also the not neglectable cost of the supplies for performing SMBG, such a gap of a straightforward recommendation regarding SMBG applicability and the optimal frequency of measurements is at least query worthy.

This work focuses on the evidence from clinical trials regarding the impact of SMBG on the metabolic control and on diabetes-related morbidity and mortality for NIT-DM subjects. Attention is given to the question if there is evidence from the performed studies that SMBG produces a differential effect in a subpopulation of type 2 diabetic subjects, on the frequency and timing of SMBG. It reviews the current recommendations for use of SMBG in NIT-DM patients. Also reviewed are the available data about the cost and the cost-effectiveness of this practice. A general discussion of controversies is following.

EVIDENCE FOR THE OVERALL IMPACT OF SMBG ON METABOLIC CONTROL
— The results from numerous studies aimed to answer whether SMBG positively affects non–insulin-treated patient care are conflicting. And there is even opposite interpretation of these trials in copious reviews or meta-analysis attempting to evaluate the available data for the clinical utility of SMBG in this subset of patients.

A number of randomized controlled trials (RCTs) (4–8), reviews, and meta-analysis (9–11) of such trials reported no benefit of SMBG on A1C values for NIT-DM patients. More specifically, in an early meta-analysis carried out by Coster et al. (9), blood or urine monitoring was not found to have any significant effect on A1C. A following review including relative studies published until 1996 failed to locate significant evidence of benefit in type 2 diabetes, but the authors recognized the need for more studies (10). In a recent meta-analysis analyzing nine RCTs, Towfigh et al. (11) concluded that SMBG produces a statistically significant but clinically modest effect in controlling blood glucose levels in patients not treated with insulin.

Nonetheless, other studies show benefit to SMBG for patients with type 2 diabetes using non-insulin therapies. Several nonrandomized reports of SMBG, in the

late 1970s, were positive for SMBG (12–14). More than a few RCTs found beneficial results for A1C in favor of SMBG at the end of the study between the groups in NIT-DM patients (15–20), and at least two of them reported a significant effect of SMBG on A1C (18,19).

Sarol et al. (21) summarized eight RCTs of 1,307 patients and found a significant reduction in A1C of ~0.4% among patients who performed SMBG. Welschen et al. (22) scrutinizing the literature reached the conclusion that SMBG might be effective in improving glycemic control in patients with type 2 diabetes who are not using insulin. In a meta-analysis of 13 RCTs of SMBG versus no SMBG versus self-monitoring of urine glucose and SMBG with regular feedback versus monitoring without feedback, positive results on the effectiveness of interventions with SMBG in type 2 diabetes were found (23). In an elegant systematic review of the literature, which included cross-sectional, longitudinal, and RCTs from 1990 to 2006, of non–insulin-treated patients, the impact of SMBG on A1C levels from the cross-sectional and longitudinal studies was inconclusive, whereas the evidence from RCTs suggested that SMBG may lead to improvements in glucose control. In this search, it is noted that few studies examined potential mediators or moderators of SMBG on A1C levels (24).

Is there evidence from the performed studies that SMBG would produce a differential effect in a subpopulation of type 2 diabetic subjects? No statistically significant difference in A1C was reached after 1 year in a three-arm parallel group randomized trial between the two groups of SMBG with patient empowerment (group of SMBG with advice for patients to contact their doctor for interpretation of results and group with SMBG with additional training of patients in interpretation and application of the results) versus the control group in NIT-DM patients with baseline A1C values <7.5% (25).

In an effort to avoid selection bias introduced in previously performed studies in which patients with a previous diagnosis of type 2 diabetes who could have found SMBG helpful and beneficial were excluded, the Efficacy of Self-Monitoring of Blood Glucose in Patients With Newly Diagnosed Type 2 Diabetes (ESMON) study group recruited newly diagnosed patients who had not previously performed SMBG. No significant differences were noted between the self-monitoring

group versus no monitoring groups at 12 months in A1C, whereas the SMBG group presented with a 6% higher score on the depression subscale of the well-being questionnaire (26).

Nowadays, the paradigm for type 2 diabetes management has been shifting and insulin is no longer reserved as the last resort, but is increasingly combined with oral antidiabetic drugs at an earlier stage of the physical history of the disease. Few previous RCTs targeted to answer the question if SMBG is lowering A1C in this situation, although adjustment of basal bedtime insulin dosage is based on SMBG readings (27,28).

EVIDENCE FOR THE IMPACT OF SMBG ON DIABETES-RELATED MORBIDITY AND MORTALITY
— In a German epidemiological cohort study, which involved 3,268 patients with type 2 diabetes followed for a mean follow-up of 6.5 years, investigating the relationship of SMBG with disease-related morbidity and mortality, the total rate of fatal and nonfatal events was lower in SMBG patients than in non-SMBG patients (29).

However, conflicting results came from the Fremantle Diabetes Study, in which SMBG was not found to be independently associated with improved survival, but the authors concluded that inconsistent findings relating to the association of SMBG with cardiac death and retinopathy may be due to confounding incomplete covariate adjustment or chance (30).

FREQUENCY AND TIMING OF SMBG AMONG NIT-DM SUBJECTS
— The frequency of SMBG, especially for NIT-DM patients, differs from country to country, patient to patient, and apparently depends largely on the intensity of treatment and metabolic status, whereas cost and reimbursement issues apparently influence its use.

Data gathered between 1988 and 1994 from the Third National Health and Nutrition Examination Survey (NHANES III) showed that 65% of the patients treated with oral antidiabetic agents and 80% treated with diet alone had either never monitored or monitored less than once per month their blood glucose, whereas SMBG at least once per day was practiced by only 5–6% of those treated with oral agents or diet alone. The frequency of SMBG was not found to be related to glycemic control in this cross-

sectional study (31). The answer of how often and under which circumstances patients perform SMBG in real-life conditions in France comes from a national survey of people being treated for diabetes. It was found that 38% of the 2,689 people participating in the survey with NIT-DM perform SMBG testing regularly (six times a week on average), whereas in only 3% of subjects, the regular use of SMBG is not related to any special needs or events (such as insulin treatment, occurrence of severe hypoglycemia, or chronic complications) (32).

The frequency of SMBG is not consistent even among the various studies looking to see if there is a correlation of SMBG and metabolic control. Among the RCTs previously discussed to show benefit to A1C for SMBG users, the frequency varied between five and seven capillary assays a week. Data assessed from over 3,000 clinic visits of 228 patients with type 2 diabetes in a period of 3 years showed that regularly monitoring and consistently discussing blood glucose appeared to be positively associated with better glycemic control (33). In a large observational study of 24,312 patients with pharmacologically treated type 2 diabetes who performed at least daily self-monitoring, A1C levels were significantly lower than those who monitored less frequently (34). Adversely, in a multicenter analysis including 24,500 patients from 191 centers in Germany and Austria, no benefit of more frequent (e.g., two measurements per day) SMBG on metabolic control was found in patients with type 2 diabetes on oral antidiabetic agents or diet alone (35). Similarly, in a recently published study, no statistically significant difference on A1C was found among the one versus the four SMBG levels per week in NIT-DM patients, who were close to metabolic target (36).

There are no definitive clinical studies to answer which is the optimal frequency of SMBG for non–insulin-treated type 2 diabetic patients; still, substantial disparity exists among the recommendations on the frequency and timing of SMBG among international diabetes associations.

A group of experts from the U.K. reached a consensus opinion suggesting patients using oral antidiabetic drugs to monitor their blood glucose at least once daily, varying the time of testing between fasting, preprandial, and postprandial levels during the day (37). A global consensus conference on SMBG differentiated its recommendations based on the treatment and the metabolic status of the patients; accordingly, it was recommended that patients on intensified insulin therapy or insulin pump have more than three to four readings per day. The panel recommended that patients on oral antidiabetic agents or daily insulin who are above glycemic target perform SMBG more than twice per day and those at target perform SMBG more than once per day and collect pre- and postmeal glucose test results over the week. The panel recommended that individuals with diabetes treated with a combination of oral antidiabetic agents plus insulin perform more frequent profiles of pre- and postprandial glucose per week and suggested that patients with type 2 diabetes not receiving pharmacological therapy perform more than one profile per week (38). In the most recent clinical practice recommendations, the American Diabetes Association recognizes SMBG as an important element in adjusting or adding new interventions and, in particular, in titrating insulin doses. But it is stated that for patients on hypoglycemic regimens that do not include sulfonylureas or glinides (these patients are therefore not likely to suffer hypoglycemia), SMBG usually is not required. However, it is stated that SMBG may be used to determine whether therapeutic blood glucose targets are being achieved and to adjust treatment regimens without requiring the patient to have laboratory-based blood glucose testing. No specific recommendations with respect to frequency are provided (39).

COST-EFFECTIVENESS OF SMBG FOR NIT-DM PATIENTS —

In an era of scarce resources for health care, diabetes is associated with a substantial economic burden, and it has been estimated that people with diabetes have medical expenditures about 2.4 times higher than expenditures that would be incurred by the same group in the absence of diabetes. The total cost of diagnosed diabetes in the U.S. in 2007 was estimated to be $174 billion (40). An estimated conservative cost of SMBG in the U.S. is $0.5 billion/year (41). On the other hand, the competition among the suppliers to develop more and more convenient and/or sophisticated devices is the best indication for a multi-billion dollar blossoming market. In this environment, the question if SMBG in NIT-DM patients is cost-effective is no less than necessary.

An incremental cost utility analysis using the data from the Diabetes Glycaemic Education and Monitoring (DiGEM) trial reached the conclusion that SMBG with or without additional training in incorporating the results into self-care was associated with higher costs (42).

Responding to Davidson's counterpoint article (43) that claimed that SMBG in NIT-DM subjects is a waste of money, Neeser et al. (41) performed a cost-effectiveness analysis of SMBG using a Markov-state model of diabetes to assess the clinical impact and related costs when SMBG is provided to patients not on insulin therapy. They assumed a modest improvement in A1C of 0.39%. The results of the analysis showed a slight increase in life expectancy (0.083 years) and a reduced cost of complications, 70% of which was attributable to reductions in microvascular events. The cost per life-year gained was approximately $39,650, which is considered to be an acceptable cost-effective intervention from a health insurance perspective.

Using data from a Kaiser Permanente "real-world" study, cost-effectiveness of SMBG one and three times per day was modeled. For both SMBG frequencies, relative risks (versus no SMBG) were lower for most complications. Although not cost-saving, both SMBG frequencies showed good value. Incremental cost-effectiveness ratios were less than $8,000 per quality-adjusted life-year gained (44).

LIMITATIONS OF PRESENT EVIDENCE AND FUTURE PERSPECTIVES —

The data for the clinical utility of SMBG in NIT-DM patients are still conflicting, and the evidence fails to be conclusive.

A lot of methodological faults of studies performed so far are hampering the effort to reach a conclusion of the important question of, which is exactly the role of SMBG in patients with type 2 diabetes who are not receiving insulin, as has been already identified by others (11,22,24). A coherent question is if SMBG should be assigned either as an "intervention," or simply as a "tool for intervention." The definition of intervention is the act of intervening, interfering, or interceding with the intent of modifying the outcome, which in medicine is usually undertaken to help treat or cure a condition. In the studies performed so far, there is not a common or even an adequate definition for what exactly "SMBG intervention" refers to. Glucometers are just tools; and despite their value as tools to record and

present physiological data, they lack the ability to capture, or the behaviors that cause, fluctuations in blood glucose levels, or to modify activities. Instead, SMBG should be incorporated in the feedback process with meaningful responses to be necessary to generate a feedback effect, and ultimately to change A1C levels.

There is sound evidence that co-intervention with education on diet and lifestyle could result in better control (23,45). For future trials, appropriate action based on the readings of SMBG should be clearly defined for both interplayers of the feedback, the patient, and the health provider, and clear guidelines should be provided to modify food selection and physical activity level.

Vigorous attention should be paid in the future to the fact that previously conducted RCTs and systemic reviews of RCTs failed to give a clear answer at the interrogation as to whether SMBG is or is not influencing metabolic control in NIT-DM. Undoubtedly, a well-conducted RCT is the ideal study design for determining a causal relation between a health care intervention and its putative outcomes, and systemic reviews of RCTs provide the best evidence, graded level 1, on the effects of preventive, therapeutic, or other interventions in medicine. Then why can't the selected RCTs and reviews reach a conclusion about the utility of SMBG in this setting of patients? We should be cautious when interpreting the results, and a distinction between failure to demonstrate underlying effectiveness and good evidence of ineffectiveness is mandatory. Importantly, negative findings warrant vigilant reading to distinguish if the research failed to find an effect where one exists because of evaluation failure, or because there is no effect (program failure). In the case of program failure, it should be clarified if the failure is attributable to an inherent inadequacy in the intervention or is attributable to poor implementation. Furthermore, proper interpretation of the evidence depends on the availability of descriptive information on the intervention and its context, so that the transferability of the evidence can be determined. Study design per se is not an adequate marker of evidence quality in public health intervention evaluation (46).

As already reported by others (11,22,24), most of the RCTs mentioned in this work were insufficiently powered, with subsequent lack of confidence for concluding that an intervention is ineffective. Besides, heterogeneity of the studies

was another limiting factor. It is quite important at the study design stage that the characteristics of the target population and the degree of outcome heterogeneity be specified. It is quite expected, for example, that patients with A1C close to normal not show great change with SMBG. Similarly, in type 2 diabetic patients with very poor metabolic control on maximal dose and number of agents, initiation of insulin may be the only solution to improve glycemic control and SMBG (47).

Outcome measures should possibly be expanded in future research. Several recent studies have shown the respective role of fasting, preprandial, and postprandial glucose levels in overall diurnal hyperglycemia in type 2 diabetes and their respective contribution to the mean A1C level depending on how well blood glucose levels are controlled (48). Even at equivalent A1C levels, patients receiving intensive therapy (involving more frequent preprandial insulin injections) had a reduction in the risk of progression of retinopathy over time compared with patients receiving conventional treatment (1). There is substantial evidence supporting that postprandial glucose levels in diabetes provide better information about future cardiovascular risk—a fact that is emphasized in the European Society of Cardiology (ESC)/ European Association for the Study of Diabetes (EASD) guidelines (49). In this context, it is reasonable to speculate that a subpopulation of patients with type 2 diabetes close to the metabolic target might benefit if we were to intervene (e.g., with short-acting secretagogues—not available at the time of previous studies) to correct postprandial glucose levels.

Apart from glycemic control, quality of life, well-being, and patient satisfaction are issues poorly covered in previous studies. A survey came up with the conclusion that SMBG in NIT-DM patients was associated with higher A1C levels and higher psychological burden (50). Nevertheless, SMBG coupled with structured counseling in NIT-DM patients resulted in statistically significant differences in glycemic control, provided patients with a tool for taking on more self-control, and resulted in an improved outlook on life (51).

SMBG seems to be a logical tool for the management of a large proportion of type 2 diabetic patients, but it requires to be proposed in structured counseling educational programs adapted to the psy-

chological profile and social status of the patients. These programs must be evaluated by randomized controlled trials. There is a need for carefully designed high-quality large-scale studies on diverse patient populations with type 2 diabetes with the follow-up period to investigate long-term effects of SMBG in patients with type 2 diabetes, to come up with answers on how to make the best use of SMBG, in which patients, and under what conditions.

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