Can Blood Glucose Monitoring be Simplified/Modified in Order to Achieve Better Diabetes Management—Perspectives for the Future

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Abstract

Self-monitoring of blood glucose (SMBG) with reflectance meters was heralded as a major advance in the management of diabetes and has been available to individuals with diabetes for home use since the late 1970s. This tool was put to use in the landmark Diabetes Control and Complications Trial (DCCT), which revolutionized care for individuals with type 1 diabetes, enabling these individuals to intensify their glucose control. SMBG has similar benefit in individuals with type 2 diabetes requiring insulin therapy. Its use in other individuals with type 2 diabetes treated with oral agents or non-insulin therapies is less clear. While SMBG is a potentially powerful tool to aid in the daily management of diabetes, to be used effectively, SMBG must be optimized to ensure the information derived from it can be acted on to modify physical activity, dietary intake, or medications to improve glycemic control. Recently, studies looking at this population have called into question the utility of SMBG in the management of individuals with type 2 diabetes treated with non-insulin therapies. However, these studies are lacking in the specifics of how such information was used to modify therapies. In addition to this, the lack of a universally accepted output for SMBG data significantly impedes its uptake and appropriate use by healthcare providers and patients. To maximize the effectiveness of SMBG, both patients and providers need to have a clear understanding of when and how to use SMBG data and, most importantly, act upon the data to effect a change in their diabetes management.

Keywords

Self monitoring blood glucose, glucose meters, glucose monitoring, capillary glucose testing, home glucose testing, reflectance meters, diabetes self-management

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The Development of Self-monitoring of Blood Glucose

The advent of home-based capillary self-monitoring of blood glucose (SMBG) was initially heralded as a major advance in the treatment of individuals with diabetes. There was much anticipation that this technology would revolutionize diabetes care, allowing for dramatic improvements in glucose control and a reduction in its devastating complications.

Urine Glucose Measurement

Early qualitative urine glucose testing was later followed by the development of semi-quantitative urine glucose measurement, first available for home use in the 1940s. This technique gave only a retrospective estimate of glycemic control over the preceding one to two days and even then only if control was poor, with the resultant blood glucose levels exceeding the renal threshold (~200mg/dl), resulting in glycosuria.[1]

Such information might have allowed the patient to avoid those circumstances in the future, but would do little to reinforce and encourage those practices that resulted in good glycemic control. Thus, diabetes care during this period was, by necessity, centered on the 'avoidance of the bad', rather than the promulgation and empowering potential of striving for 'good or ideal control'.

Semi-quantitative Whole Blood Glucose Measuring

Starting in the 1960s, a predominately office-based semi-quantitative method of measuring capillary whole blood glucose was developed. This technique utilized reagent strips to which a drop of blood was added, reacting with a glucose oxidase-based system to effect a colorimetric change. The resultant colorimetric reaction could then be compared to a standardized chart to estimate the blood glucose level. Eventually this method became available for limited home testing use, providing individuals with a more current, albeit 'estimated', glucose level on which to potentially take action.

Reflectance Meters

Initial reflectance meters used similar technology based on reagent strips and a light source, enabling the reflected light to be read by a photoelectric cell yielding an estimated glucose level. This was visualized by a range of values indicated a by swinging needle. The first reflectance meters for home patient use became available in the late 1970s and have seen continuing advancement in technologies, allowing for greater accuracy in glucose measurement with improved reagents and electrochemical glucose sensing. A trend toward increasing convenience has also occurred.

Over time these meters have continued to become smaller, require less capillary blood sampling, utilize easier and less painful lancing devices, and provide ever-faster reaction and reading times. Some units allow alternate site testing (forearm rather than finger-stick testing) and do not require coding (the entrance of the appropriate manufacturing or 'lot' number for the reagent testing strips to calibrate the meter).[2] Today, nearly 70% of all patients in the US with diabetes perform SMBG.[3]

The Importance of Tight Glycemic Control and the Role of Self-monitoring of Blood Glucose in Achieving It

The availability of the first SMBG actually preceded and made possible the landmark studies in both type 1 and type 2 diabetes. These studies have demonstrated the importance of improving glucose control in reducing the long-term microvascular complications of diabetes.

Long-term follow-up of participants in the Diabetes Control and Complications Trial (DCCT) definitively showed that improved glycemic control resulted in a dramatic reduction in microvascular complications.[4] This was achieved during the trial with intensive insulin management guided by frequent SMBG. A similar benefit in type 2 diabetes was demonstrated in the UK Prospective Diabetes Study (UKPDS).[5]

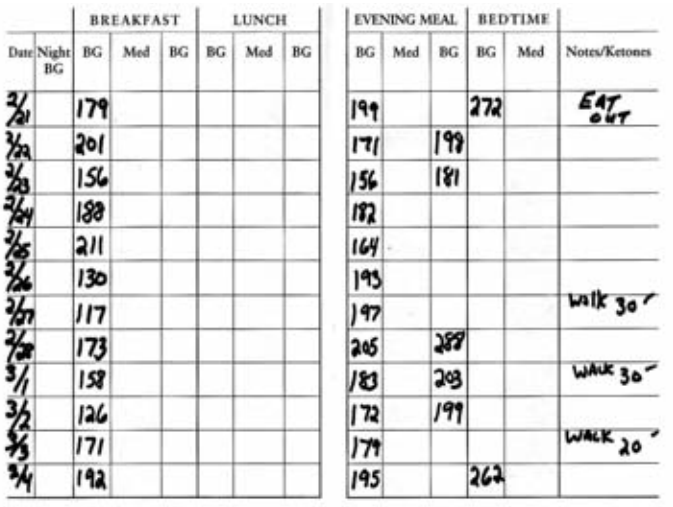
Longer-term follow-up of these trials was reported in the Epidemiology of Diabetes Interventions and Complications in type 1 diabetes[6] and the 10-year follow-up of the UKPDS in type 2 diabetes papers.[7] These provided clear evidence that the early and intensive control of hyperglycemia reduced the long-term risks of macrovascular complications in diabetes. The beneficial effects of good glycemic control—termed 'metabolic memory' or the 'legacy effect'—persists for years despite the subsequent inability of the intensively treated cohorts to maintain very tight glycemic control once the original trials ended.[4,6,7]

Despite more frequent SMBG performance by individuals in the intensified glycemic control groups in clinical trials, tight glycemic control resulted in a three-fold increased risk for severe hypoglycemia. This occurred in type 1 diabetes, as seen in the DCCT trial, as well as type 2 diabetes, as seen in the Action to Control Cardiovascular Risks in Diabetes (ACCORD) trial.[8,9] Interestingly, in this trial, individuals in the intensive glycemic control group with the highest risk for hypoglycemia were, somewhat counter-intuitively, the patients who failed to improve on their baseline glycated hemoglbin (HbA_{1C}) at study entry.[10] This phenomenon perhaps indicates a lack of comprehension, or inability to perform, good diabetes self-management practices, including the appropriate use of SMBG.

Table 1: Sample Self-monitoring of Blood Glucose Testing Schedule (Utilizing One Testing Strip per Day)

	Mon	Tue	Wed	Thu	Fri	Sat	Sun
Fasting or pre-breakfast	X						
Post-breakfast		X					
Pre-lunch			X				
Post-lunch				X			
Pre-dinner					X		
Post-dinner						X	
Bedtime							X

Figure 1: Typical Glucose Logbook



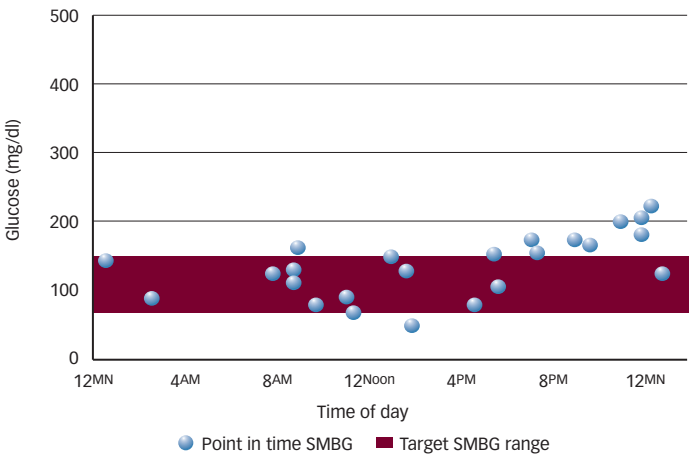
The available evidence would suggest that most patients with diabetes should maintain as 'tight' a glycemic control as safely possible, as early in the course of the disease as possible. Evidence also suggests that patients to keep this level of control as tight as possible[11] to maximally reduce their risks of micro- and macrovascular complications. For most patients this means targeting HbA_{1C} levels of <7.0% (American Diabetes Association [ADA] guidelines) or <6.5% (International Diabetes Federation [IDF] or American Association of Clinical Endocrinologists [AACE] guidelines).

As an adjunctive tool enhancing patients' diabetes self-management, SMBG can play a pivotal role if used appropriately. In addition to providing an overall picture of day-to-day glycemic control, SMBG can provide immediate feedback on the effects of nutrition, physical activity, and medications on blood glucose levels. It enables immediate determination of hypo- or hyperglycemia, allowing the patient to take action to improve glucose safely. The continual feedback of SMBG data can motivate individuals to make appropriate changes in activity patterns, diet, and medications to 'fine-tune' their glycemic control.

Self-monitoring of Blood Glucose in Type 1 Diabetes and Insulin-requiring Type 2 Diabetes Patients

The use of SMBG in patients with type 1 diabetes and in those with type 2 diabetes treated with intensive insulin therapies or multiple daily insulin injections is supported by clinical trial data and, thus, is not

Figure 2: Modal Day Analysis of Self-monitoring of Blood Glucose



SMBG = self-monitoring of blood glucose.

controversial. SMBG provides day-to-day information for adjusting insulin doses to optimize overall glucose control. Patients on pre-meal bolus insulin use their pre-meal SMBG values to adjust the dose of their bolus insulin. This corrects it for the amount of carbohydrate consumed and compensates for any deviation of their pre-meal glucose above or below the desired target range (the so-called corrective dose of insulin). Insulin titration schemes utilize pre-meal SMBG values as an actionable item to adjust the insulin dose before a meal so as to achieve tighter post-prandial glucose control.

Fasting SMBG values can guide the patient to appropriate adjustment in their basal insulin until targeted fasting glucose ranges are met. This concept was nicely emphasized in the DCCT, in which intensive insulin therapy improved glycemic control, reduced microvascular complications and was achieved by intensifying treatment regimens utilizing SMBG.[8]

SMBG can serve an important safety function, particularly in insulin-treated patients, in detecting hypoglycemia in those with diminished hypoglycemia awareness. The recommendation from the DCCT was to perform SMBG at least four times per day, but observational studies show most patients with type 1 diabetes fall well short of this recommendation.[12,13]

Self-monitoring of Blood Glucose in Non-insulin-requiring Type 2 Diabetes

SMBG has gained wide acceptance as a part of the management of patients with non-insulin-treated type 2 diabetes in many areas. Despite this, its efficacy and rationale has been called into question by recent studies, most prominently by the recent randomized controlled trial by Farmer et al. in the UK.[14,15]

The Diabetes Glycaemic Education and Monitoring (DiGEM) study was designed to test whether SMBG, used with or without instruction, in incorporating findings into self-care, could improve glycemic control in non-insulin-treated type 2 diabetes patients compared with standardized usual care.[14] A total of 453 patients were individually randomized in this RCT to one of three groups:

- standardized usual care with three-monthly measurement of HbA_{1c} levels (control group);
- SMBG with patient training focused on clinician interpretation of results in addition to usual care (less intensive self-monitoring); or
- SMBG with additional training of patients in interpretation and application of the results to enhance motivation and maintain adherence to a healthy lifestyle (more intensive self-monitoring).

There was no evidence of glycemic benefit between the three groups at the end of 12 months in the primary outcome, which was HbA_{1c} level, nor was there benefit when comparing subgroups of patients defined by duration of diabetes, therapy, and diabetes-related complications.[14] In fact, patients in the more intensive SMBG arm detected more hypoglycemia and had a negatively affected quality of life.[14] An economic analysis suggested that added SMBG resulted in extra healthcare costs and was unlikely to be cost-effective in routine use.[15] The potential clinical ramifications from this study have been significant, calling into question the utility, cost, and impact on quality of life of routine SMBG in individuals with type 2 diabetes who are not receiving insulin therapy.

Several criticisms have been leveled at this study's design. The study enrolled selected individuals who were either not SMBG at all or taking no more than a single measurement per week. Participants at baseline were treated with diet or oral agents alone. They had reasonably good glycemic control (mean HbA_{1c} 7.5%),[14] in part due to their recent onset and short duration of diabetes (median duration of three years). Thus, the study may have inadvertently selected a biased population; one behaviorally less geared toward, or less compliant with, SMBG and with potentially less to gain from improvements in glucose control given their recent onset of diabetes and modest hyperglycemia.

A specified action plan in response to the SMBG data was also lacking and not delineated for those who were to utilize the SMBG data to modify their lifestyle or medication. While there was a minimal decline in HbA_{1c} of 0.17 % in this group, it was not statistically significant.[13] It was far less than the decline reported from the majority of other RCT's evaluating the effect of SMBG. Despite these criticisms, the DiGEM study was a careful attempt to determine the value of SMBG in a population of non-insulin treated individuals with type 2 diabetes. Its aim was to make the case for proponents of SMBG and prove its worth in this population.

Much of the previously-established data in support of the efficacy of SMBG in non-insulin treated subjects with type 2 diabetes comes from observational, cross-sectional and retrospective studies. These indicate improved glycemic control in individuals who perform SMBG monitoring more frequently.[16–18]

The RCTs evaluating the potential beneficial effect of SMBG have been plagued by difficult-to-solve methodological issues. Recruiting biases can affect the outcomes if participants are not representative of the community population. Explanations as to how the SMBG values are used to modify treatment are often lacking or not clearly defined. Even in those randomized clinical trials that did show benefit in terms of HbA_{1c} reduction, the benefit was modest and most often in the range

of a 0.25–0.60%. It should be stated here that meta-analyses of various combinations of these RCTs tend to favor SMBG.

Large observational or epidemiological studies generally note improved glycemic control in individuals with diabetes who monitor more frequently. Despite this, such studies can only implicate an association between more frequent SMBG and improved glycemic control; not a causal relationship.[19] Contrary to this, some cross-sectional studies, such as the Fremantle Diabetes Study, do not show benefit in terms of glycemic control with SMBG.[20]

Finally, the Cochrane collaborative evidence-based review of SMBG use in patients with type 2 diabetes on non-insulin-based therapies also appears to favor SMBG, but noted that more evidence is needed.[21] Several groups have formed to attempt to outline the necessary components of a large-scale RCT to better evaluate the role and utility of SMBG in type 2 diabetes.[19,22]

Improving the Utility and Effectiveness of Self-monitoring of Blood Glucose

SMBG is s a useful tool, providing patients with information and feedback on their current glucose control. This allows them to take immediate steps to correct an ongoing active problem, such as treating hypoglycemia, or in response to hyperglycemia to acutely alter activity, caloric intake or, potentially, medication. SMBG data can also be reviewed over the course of days, weeks, or months to aid in 'glycemic pattern recognition'. This enhances self-management of diabetes over the longer term by giving feedback on continuing efforts to increase activity, reduce dietary intake, and achieve a weight reduction; all potentially helping to improve long-term glycemic control. If SMBG data are insufficient to demonstrate improvement in glucose control to with target ranges, then they should serve to inform the patient and their healthcare provider that therapeutic intensification is required. Such intensification includes increasing the dosage of current medications aimed at lowering blood glucose or adding a medication from a different therapeutic class.

Overcoming Barriers

It is important to remember that SMBG is but a tool, rather than a direct therapeutic intervention targeting glucose levels. There are multiple aspects of SMBG use of that must be in place for the information it generates to be used appropriately by the patient to improve glycemic control. Many important potential barriers exist in using SMBG appropriately. These include:

- proper technique;
- correct coding of the testing strips to calibrate the meters;
- correctly setting the time and date of the meter to aid in the review of downloaded meter data; and
- most importantly, the level of patient education, training, and understanding of SMBG use in their diabetes self-management.

The absolutely critical issue is that the data derived from SMBG be used to modify the patient's self-management. The information then becomes an actionable item leading to modification in therapy (behavioral change resulting in changes in diet or activity, or adjustment in medication).

Patient-driven Changes

To maximize the impact of SMBG, the changes in management should be patient-driven rather than simply periodically reviewed by their healthcare provider. SMBG should be used at various time points throughout the day to optimize management by uncovering behavioral modifications required in diet and activity, or uncovering evidence of the need for adjustment or intensification of medications. Regular SMBG monitoring should provide ongoing feedback for potential problematic periods of marked hyperglycemia or hypoglycemia. It should also provide the patient with an early detection of worsening overall glycemic control due to intercurrent illness, steroid usage, or the progressive nature type 2 diabetes itself. Such information can be used in titrating therapy to re-establish glycemic control in a timely manner.

Encouraging Alterations in Therapy

In order to advance the potential for the information provided by SMBG to be used in a more effective patient-driven manner, specific alteration algorithms are needed. These can instruct patients on what course of action to take in terms of altering their management or therapy in response high glucose values. Alterations in therapy need not just be medication related. In dealing with consistent post-prandial hyperglycemia following a specific meal-time each day (e.g. post-breakfast), behavioral modification may easily fix the problem. Diminishing the excessive carbohydrate content of the meal is one option. Simply shifting some of the carbohydrate content to a different meal (e.g. lunch), when the same quantity of carbohydrate may be better tolerated in terms of post-meal glycemic excursions, may be all that is required. Changes in the amount or timing of scheduled physical activity may have similar effects.

Getting the Best Results from Daily Self-monitoring of Blood Glucose

It is not uncommon for patients with type 2 diabetes treated with non-insulin therapies to be instructed to perform SMBG on a daily basis. Unfortunately these individuals frequently only check their fasting blood glucose every morning. Often there is documented good control of morning fasting blood glucose, but HbA_{1c} remains above target because it is likely that blood glucose values are higher at other time points throughout the day. It would be more useful to use those same seven weekly testing strips in a manner that was much more informative about the patient's overall daily glycemic pattern. This can be achieved by alternating the testing times between fasting, pre- and post-meal and bedtime to determine blood glucose levels. This is especially useful if it is also associated with the patient's record of any changes in typical dietary or activity patterns (see *Table 1*).

Patients educated and empowered as to how to use this information to make actionable changes in their diabetes management may encounter greater success in more quickly correcting any worsening of glycemic control. They do this is in part by becoming more active participants in their own care and improving adherence.

Reducing Technical Barriers

The technical aspects of glucose meters that may serve as subtle barriers to appropriate use of SMBG are continually being improved on. These include:

- eliminating the requirement for coding of the meter to match the manufacturing lot number of the testing strips will decrease errors;
- time and date stamping of SMBG values will become automated;
- meal markers, which will aid in interpreting fasting or pre-meal from post-prandial blood glucose values; and
- meters may inform the patient if the blood sample is inadequate for accurate testing.

Addressing Patient Education, Training, and Empowerment

Addressing the lack of patient education and training in diabetes self-management, including proper use of SMBG, may be a more challenging deficit than most to correct. Major fiduciary issues pertaining to re-imbursement for services and insufficient patient access to training remain major hurdles.

Patients often view the collection of their SMBG data primarily for 'presentation to their clinician at their next visit'. They are then frequently disappointed by their perception of the inadequate attention, review and discussion of this information within the visit to the clinician. Such current patterns would need to change. How physicians comfort patients, especially in primary care settings with patient-driven strategies (based on SMBG) for self-titration of therapies and alteration in diabetes self-management, may need to be addressed.

It is hoped that employing such a strategy, utilizing SMBG for patient-directed continuous surveillance and quality improvement, could serve to impact the clinical inertia currently seen in the health system. This system was initially designed and developed to manage acute illnesses, rather than chronic diseases such as diabetes. Brown et al.[23] have demonstrated how this inertia can result in a typical patient being exposed to eight to 10 years of significant hyperglycemia (with increased risk for complications). The exposure occurs while the patient's medical regimen is very slowly progressed through the different therapies available.

Patients should be empowered to act on their SMBG values and to contact their healthcare provider if they encounter problematic hyperglycemia that has not responded to their attempts at correction, as their medication may need to be advanced. This approach should allow therapies to be quickly optimized until glycemic targets are achieved rather than the patient waiting until the next office visit (often three to six months hence) before therapy is advanced.

Optimizing the Use of Physician Office Time

Another barrier inhibiting the optimal use of a patient's SMBG data in their diabetes management occurs in the physician's office. In today's environment, healthcare providers are often forced to complete the entire patient office visit within a span of 15–20 minutes. In these situations it may not be practical to expect the primary care physician or other provider to use the traditional glucose logbook to search for glycemic patterns from which to make therapeutic recommendations. This is because it could entail visually scanning many pages of often messy, hand-scribbled columns of individual glucose values in a time-consuming attempt to make sense of any emerging patterns (see *Figure 1*). To further complicate matters, these unverified values may be prone to transcriptional errors in transferring the results from the meter to logbook, incomplete recording of data, and, in some cases, selective or fictitious information.[24]

Unfortunately, no common format or universal output exists for SMBG data in contrast to another well-accepted diagnostic tool, the electrocardiogram, which has the same standardized universal output throughout much of the world. The ability to download and present verified aggregate glucose data in an organized fashion, along with basic statistical summaries, is an improvement.

Despite this, myriad competing proprietary software programs needed to download the data from each company's meter severely inhibits their broad generalizability and utility. Thus, while standard 12-lead electrocardiogram (ECG) tracing enjoys widespread adoption and common use in clinical practice, the use of downloaded SMBG data from specific meters remains most widely relegated to selected subspecialists. Continued use of a handwritten glucose logbook therefore predominates within general practice, where the majority of care is provided.

Lack of a standardized universal output for SMBG data also inhibits the ability to teach glycemic pattern recognition to patients and generalist clinicians. This further impedes the potential for SMBG to help shape therapeutic interventions and improve overall levels of glycemic control. The 'Modal Day' analysis was an attempt to have a more common data output from the many meters that allow data to be expressed in this form (see *Figure 2*). This form of data output yields a representation of all SMBG data, expressed as a single day (24-hour time course). Unfortunately the use of the Modal Day never became commonplace and it is not in widespread use, especially in general practice where it may be most useful.

Conclusion

There remains an ongoing need for properly designed, well-controlled RCTs to evaluate the potential benefit of SMBG in those individuals with type 2 diabetes treated with non-insulin therapies. Device manufacturers should strive to reach an agreement on an optional default download format, such as the Modal Day analysis, that could be used across a wide array of platforms. It remains to be seen how forward-reaching glycemic monitoring technologies, such a continuous glucose monitoring of subcutaneous interstitial fluid, might play a role in diabetes management in individuals with type 2 diabetes. It will be particularly interesting to gather the results of such technologies in terms of the generation of a comprehensive 24-hour glycemic profile amenable for analysis of overall glycemic patterns. ■

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