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The Utility and Recent Advances in Self-Monitoring of Blood Glucose in Type 1 Diabetes

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ABSTRACT

Self-monitoring of blood glucose (SMBG) is a fundamental and effective principle in the management of type 1 diabetes mellitus (T1DM). SMBG is a precise and accurate clinical tool in the treatment of glycemia and facilitates tight glycemic control. Recent studies have shown that frequent SMBG improves metabolic control and can detect and predict hypoglycemia. The Diabetes Control and Complications Trial demonstrated that SMBG is a key component in achieving tight glycemic control and is associated with improvement in complications of diabetes. Despite the recommendations and benefits of frequent SMBG, it continues to be an underutilized tool, though adherence rates are steadily improving. Recent advances in glucose meters and SMBG data processing have revolutionized the clinical applicability of SMBG. However, several barriers to frequent SMBG have been identified and need to be addressed in order to realize the full potential of SMBG in patients with T1DM. In this review, we provide an overview of the epidemiology of SMBG, review the evidence supporting frequent SMBG, and discuss the recent advances in glucose monitoring and data technologies that support its use in effective diabetes management. We also discuss the potential barriers to the use of frequent SMBG, which continue to limits its applicability and require further study.

INTRODUCTION

Self-monitoring of blood glucose (SMBG) has become a principal component of intensive diabetes management. SMBG allows for rapid and accurate assessment and treatment of glycemia. SMBG is an effective tool that enables patients and healthcare providers to tailor therapy to maintain near-normal glycemia, minimizing hypo- and hyperglycemia, which is a fundamental element of diabetes care.

SMBG became a standard of care in 1993 when the Diabetes Control and Complications Trial (DCCT) demonstrated that intensive treatment to achieve meticulous glycemic control could prevent the onset and slow the progression of long-term microvascular complications.[1] Furthermore, several trials have shown that frequent SMBG is correlated with improvements in metabolic control.[2–4] Given the evidence in favor of tight glycemic control, the current practice guidelines recommend that SMBG be carried out at least three times per day in patients with type 1 diabetes mellitus (T1DM).[5,6]

Since the introduction of routine SMBG in clinical practice in 1978, several advances have

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been made to improve the performance, accessibility, use, and data handling of blood glucose monitoring devices. The mounting evidence supporting the use of SMBG and technological advances in glucose monitoring devices have been associated with increases in SMBG adherence in patients over the last 3 decades.[7,8] However, the use of SMBG in clinical practice still requires optimization at both the patient and provider levels.

In this review, we provide an overview of the current practices in SMBG, the evidence supporting the use of frequent SMBG, the methods and performance characteristics of glucose monitoring devices, alternative site testing (AST) of blood glucose, and the technologic advances in processing SMBG data, and finally we address barriers to SMBG.

CURRENT GUIDELINES FOR SMBG AND PATTERNS OF SMBG IN PATIENTS WITH T1DM

The American Diabetes Association (ADA) currently recommends SMBG three or more times daily in patients with T1DM. The goals of frequent monitoring include improved glycemic control, in addition to prevention of asymptomatic hyper- and hypoglycemia.[5] Similar testing recommendations are also made by the Canadian Diabetes Association (CDA).[6] In addition, both the ADA and CDA emphasize the importance of individualized frequency and timing of SMBG based on prandial needs, exercise, intercurrent illness, and pregnancy.

Despite the frequent testing advocated by the ADA and CDA, a significant number of patients do not meet the standard of care for SMBG. In 1997, a small study of 258 patients with T1DM demonstrated that 12% of patients were not testing at all. A significant proportion of patients (95.3%) had received counseling by their provider to check blood sugars, with the most common recommendation of three times per day.[9]

There is evidence that SMBG adherence is gradually improving across the United States. A large survey study of patients with both T1DM and type 2 diabetes mellitus using the National Health and Nutrition Examination Surveys (NHANES) and Behavioral Risk Factor Surveillance System (BRFSS) carried out in 1988–1995 (the 1990s) and again in 1999–2002 (the 2000s) demonstrated that 38.5% and 55.1% of patients reported testing at least once per day, respectively. The significant improvement in SMBG over the 10 years between the two studies was not associated with a significant change in mean hemoglobin A1c (HbA1c); however, there was a higher percentage of patients with an HbA1c between 6% and 8% in the 2000s (47.0%) compared to the 1990s (34.2%) surveys.[7] The BRFSS was updated in 2006 and demonstrated that 63.4% of patients reported testing at least once per day.[8] Analysis of NHANES 1999–2000, 2001–2002, and 2003–2004 demonstrated a progressive reduction in HbA1c with means of 7.82%, 7.47%, and 7.18%, respectively, over the 5-year interval.[10]

The use of SMBG is significantly increasing in the United States as its value in achieving improved glycemic control and overall health outcomes becomes more established and appreciated by both healthcare providers and patients alike. However, recent studies demonstrate that the use of SMBG continues to fall short of meeting the standard of care as outlined by the ADA.

SMBG IS ASSOCIATED WITH IMPROVEMENT IN LONG-TERM METABOLIC CONTROL

The evidence establishing the use of SMBG in the care of T1DM and its role in improving tight glycemic control and long-term metabolic control was demonstrated by the DCCT, clearly the most important randomized study assessing the role of glucose control and, albeit indirectly, SMBG in reducing the burden of microvascular complications in T1DM.[1] There have been several studies examining the relationship between frequency of SMBG and metabolic control. These studies have shown that increased frequency of testing is associated with improved metabolic control, as evidenced by decreases in HbA1c in T1DM.[2–4,11] To quantify this relationship further, a study of patients with T1DM demonstrated that there is an inverse relationship between frequency of SMBG and HbA1c levels that can be fit by a nonlinear curve equation:

$$\text{HbA1c} = 5.99 + 5.32/(\text{tests per day} + 1.39)$$

The nonlinear relationship suggests that there is no added benefit from testing more than 10 times per day with respect to HbA1c lowering.[12]

One of the main uses of SMBG is to detect asymptomatic hypoglycemia and to tailor therapies to avoid future hypoglycemia. A recent study examining SMBG data from the DCCT cohort illustrated that both mean blood glucose and glucose variability (measured by standard deviation) were independently able to predict the risk of hypoglycemia.[13] The risk of first hypoglycemic event increased 1.05-fold for each 18 mg/dL decrease in mean blood glucose and increased 1.07-fold for each 18 mg/dL increase in standard deviation. The mean blood glucose and standard deviation were able to predict hypoglycemia independent of HbA1c and were more predictive of daytime hypoglycemia as compared to nighttime hypoglycemia.

It is well accepted that increasing frequency of testing is associated with lowering of HbA1c and that SMBG is a useful tool in detecting and potentially predicting hypoglycemia. However, there has been no large randomized study directly examining whether increased frequency of testing is associated with a lowered risk of severe hypoglycemia.

SMBG AS A COMPONENT OF INTENSIVE THERAPY REDUCES MICRO- AND MACROVASCULAR COMPLICATIONS

The DCCT and Epidemiology of Diabetes Interventions and Complications (EDIC) studies provide evidence that SMBG, as an important component of intensive therapy, reduces the risk of micro- and macrovascular complications.[1,14–19] These studies did not examine the effect of SMBG in isolation, but rather as a component of an intensive therapy regimen that also included more frequent insulin dosing and tight glycemic control. However, they provide the only evidence studying the effects of frequent SMBG and associated HbA1c lowering and complication outcomes. More trials are required to evaluate the specific contribution of intensive SMBG in reducing these complications, as SMBG is a potentially inexpensive intervention that could offer tremendous morbidity and mortality benefit in patients with T1DM.

CAPILLARY BLOOD GLUCOSE ASSAYS AND PERFORMANCE CHARACTERISTICS

The development of SMBG replaced the use of urinary glucose measurement in the management of diabetes and has facilitated improved glycemic control.[20] Glucose meter measurement of capillary blood glucose offers a rapid, precise, and accurate tool that has facilitated frequent SMBG. There are currently more than 20 different glucose monitoring devices available, and this industry has burgeoned into a 3 billion dollar per year industry worldwide.[21] Over the last 20 years, there have been significant advances in developing glucose monitoring systems that have improved ease of use, portability, sample volume, testing time, cost, memory, and software enabling pattern recognition.[22]

Reflectance and electrochemical assays are employed in capillary blood glucose measurement. The reflectance assay couples oxidation of glucose to a chromogen system to generate a colorimetric readout. The newer electrochemical method couples glucose oxidation to the generation of a current proportional to the glucose concentration.[23] The electrochemical assay has largely replaced the reflectance assay and allows for more rapid testing with smaller sample volumes. Current glucose meters have test times varying between 5 and 15 s and require between 0.3 to 10 μL of sample.[22]

The performance of glucose meters has been well studied using a variety of methods.[22] In 1996, the ADA recommended that SMBG systems should achieve a total error (sum of both analytical and operator error) of less than 5%.[24] The error grid method is the most widely used method to evaluate the accuracy of glucose meter-based capillary blood glucose measurement and was first described in the mid-1980s (now referred to as the "Clarke error grid").[25] A recent study reported that 98.6% of blood glucose measurements using a variety of meters fell within a clinically acceptable range (error grid A and B zones). However, only 45% of the glucose meter readings were within 10% of the hexokinase reference method, which is well below current ADA recommendations.[26] The precision of glucose meters has been shown to be very high with both intra-assay and inter-assay coefficients of variation of less than 4% across a wide range of glucose concentrations.[27]

The accuracy and precision of capillary blood glucose measurement can also be affected by variables other than those specific to the glucose meter. These include extremes of hematocrit and glycemia, partial pressure of oxygen, altitude, ambient temperature, hypertriglyceridemia, drugs, and interfering substances, which must be taken into account when interpreting measurements.[28,29]

In summary, currently available glucose meters provide a rapid and easy method for SMBG and demonstrate high precision and clinically acceptable accuracy over a wide range of glucose concentrations. With advances in assay technology and meter calibration to reduce systematic bias, especially at the extremes of glycemia, we anticipate the performance characteristics to steadily improve.

AST OF BLOOD GLUCOSE

Currently, fingertip capillary blood sampling is the conventional method used in SMBG. However, the pain associated with the fingerstick during sampling can often be limiting. Repeated trauma to the fingers can also cause callus formation, resulting in inadequate sampling, necessitating multiple further attempts. These challenges in fingertip capillary blood glucose sampling have incited the development of new technologies to allow for sampling from alternative sites other than the finger. At present, there are several meters that are U.S. Food and Drug Administration-approved for use on the forearm, upper arm, palm, abdomen, thigh, and calf.[22]

Studies examining the efficacy of AST of blood glucose have shown that there is a strong positive correlation ($r > 0.95$) between fingertip and AST measurements, with the vast majority of patients (71–91%) expressing that AST resulted in no pain or less pain than the conventional methods of testing.[30,31] Despite the apparent advantages and accuracy of AST, there are several limitations. A recent study examining the accuracy of AST in prandial states and exercise suggests that the accuracy is compromised 1 h postprandially and immediately after exercise. The 1-h postprandial rise in blood glucose was blunted with AST as compared to conventional fingertip testing. Similarly, the drop in blood glucose expected with exercise exhibited a lag with AST, and glucose values were higher compared to fingertip testing. These differences are probably attributable to glucose lags in forearm capillaries as compared to fingertips, due to rapid changes in glucose (>2 mg/mL/min). This is further discussed by Heinemann and Koschinsky[32] in this supplement. However, at baseline and 90 min and 2 h postprandially, accuracy of AST was comparable to that of conventional SMBG.[22,33] Thus, AST appears to be most reliable in states of relative stable glycemia and should be used with caution in settings where hypoglycemia or hyperglycemia has developed rapidly.[33]

In patients with significant pain or difficulty with conventional fingertip capillary blood sampling, AST may offer an option for continued frequent monitoring that still allows for reasonable glycemic control. However, the overall applicability in T1DM is limited given that these patients are at increased risk of rapidly fluctuating glycemia.

ADVANCES IN SMBG DATA STORAGE AND INTERPRETATION

Frequent SMBG, facilitated through capillary blood glucose meters, generates a wealth of information that requires effective and efficient data processing and interpretation. The sheer volume and complexity of data can be overwhelming and time-consuming, to both patient and healthcare provider. Unless the provider has the time, willingness, and ability to process the data and translate them into thoughtful recommendations to optimize the patient's treatment regimen, the provider will miss an important opportunity to assist the patient. The problem is further compounded by the lack of studies and clear practice guidelines to assist in utilizing the data to their full potential in the clinical setting. SMBG data provide the opportunity to identify blood glucose patterns that can vary with basal and bolus insulin, meals, diurnal rhythm, activity level, acute illness, and menstrual cycle and enable the safe and efficacious prescription of insulin regimens.[34]

Glucose meter memory storage has revolutionized SMBG data processing. Studies examining glucose logbooks have shown that both accuracy and completeness are limiting.[35] The memory and software incorporated in contemporary meters allow for the storage of between 150 and 500 tests with time and date, depending on the meter. The meter software can compute the average blood glucose over a specified number of days and at specific times of day. Additional features include the option for manual input of insulin dosage, which provides the option of correlating insulin amounts with changes in glucose.[34]

Most glucose meters also have the capability for computer download, which can be implemented in the provider's office setting, in the patient's home, or more recently on the internet. Many providers find the latter two options attractive as they place the burden of the responsibility and time for downloading on the patient. The patient can print the results of the download at home or can review the data online in the provider's office. This also allows between-visit review of SMBG data should the need arise. Computer downloading allows for graphical display and statistical analysis of SMBG variation throughout the day, thereby facilitating the identification of trends in blood glucose. However, the glucose meter must be set correctly for time and date as the download will not occur if there is a discrepancy with the computer's time and date. We have noted that even in a clinic where downloading occurs with every patient, the time or date is not entered correctly approximately 25% of the time.[36] Furthermore, patients often forget to bring their meter or use more than one meter, which can make getting a comprehensive picture of SMBG trends difficult. There is software available that is capable of integrating and collating SMBG data from multiple meters, which we have found simplifies the confusing array of competing software and wires that would be required otherwise.[37]

Most glucose meter software programs provide the average number of blood glucose tests and their value over a specified number of days and at specific times of day, the proportion of readings above, below, and within the defined target range, and finally the standard deviation over a specified number of days or at specific times of day. The average glucose can be analyzed against the HbA1c to see whether correlation exists. It also provides an overview of specific times of day where glycemic control is outside the targeted range. The standard deviation can be used to assess the consistency of patterns in glycemic control, which is especially helpful in identifying patients or specific time periods in which there is considerable risk for clinically significant hyper- or hypoglycemia. The standard deviation can also be useful in identifying patients with poor matching of caloric intake and insulin, noncompliance with insulin doses, missed meals, gastroparesis, or erratic insulin absorption.[34] The frequency, average glucose values, and standard deviation can be used to identify periods that need further scrutiny of individual glucose values and to guide goals and changes in self-management and insulin therapy.

In summary, glucose meter memory and software advances in the last 3 decades have facilitated the use of frequent SMBG both for the patient and provider and allow for identification of trends and problems with glycemic control that can guide therapy more effectively and efficiently. However, the incorporation of these technologies by both patients and providers is still met with reluctance and requires further investment in education and studies to guide clinical application and illustrate and achieve its full potential. Finally, it is quite likely that since the only way to assess glucose control with real-time continuous glucose monitoring (rt-CGM) is by downloading onto a computer, there could be a "carry over" of glucose meter downloads as both patients and providers appreciate the advantages of this technology.

BARRIERS TO SMBG

Several barriers to the implementation of frequent SMBG limit its efficacy in achieving tight glycemic control and detecting asymptomatic hyper- and hypoglycemia.

Recent studies have shown that language barriers, higher out-of-pocket costs for test strips, male sex, older age, certain ethnic minorities including Asian/Pacific Islander and African-American ancestry, lower socioeconomic status, fewer daily insulin injections, smoking, less frequent HbA1c monitoring, higher HbA1c, and fewer physician visits were associated with less frequent SMBG.[38,39] The identification of these potential barriers to SMBG and improved glycemic control can help guide community-based diabetes education and health policy targeted to improve access to effective diabetes care in high-risk populations.

The cost of test strips has been identified as a major potential barrier to frequent SMBG. The cost of test strips is estimated around $1 per strip and, following current guidelines of testing at least three times per day, places the annual cost at approximately $1,460 for patients with T1DM. This number is almost double for our pump patients, who test on average 5.5 times daily.[40] As a result, there have been considerable efforts across the United States through state legislation to minimize cost as a barrier to SMBG. A recent study compared test strip use in a cohort of patients who initially incurred significant out-of-pocket costs for test strips, followed by a period in which free tests strips were provided. The provision of free test strips, which shifted cost from the patient to the health plan, however, was surprisingly not associated with any improvement in SMBG frequency. The reintroduction of copayments resulted in a slight decrease in SMBG practices. This suggests that SMBG practices are formed early, become habitual, and are often difficult to modify despite removing barriers of cost.[41] There have been a few smaller studies that have shown that provision of testing supplies improves SMBG and diabetes management.[42] Larger long-term studies are required to validate the efficacy of cost-sharing in improving overall diabetes management.

Another barrier to diabetes self-care is depression, which affects one in four patients with diabetes.[43,44] Depression has been associated with nonadherence with SMBG and poor glycemic control and has been thought to be potentially causal.[44,45] Furthermore, adolescents and women challenged with eating disorders and difficulties with body image often neglect SMBG and have worsening glycemic control. Further studies are required to fully elucidate the complex relationship among depression, self-care practices, and hyperglycemia. There have been no intervention studies to address whether treatment of depression ameliorates self-care or glycemic control.

CONCLUSIONS

SMBG is a fundamental and widely accepted principle in the management of patients with T1DM. There are considerable data to support that increased frequency of SMBG is associated with improvements in metabolic control, and more recently SMBG data itself have been shown to predict hypoglycemia. The DCCT and EDIC trials provide indirect evidence that SMBG has a role in preventing diabetes complications. Current recommendations support a SMBG frequency of at least three times daily in order to achieve tight glycemic control. Over the last 3 decades, with mounting evidence and education regarding the importance of SMBG and tremendous advances in meter technology and data interpretation, there has been an increase in adherence to SMBG. However, there is still considerable room for improvement in SMBG in patients with T1DM. Several studies have identified key barriers to SMBG, and the next step is to address these barriers with larger intervention trials that improve accessibility and efficacy of SMBG in this population.

The clinical efficacy of SMBG has been translated more recently into the development of rt-CGM, which exploits the benefits of SMBG with the added advantage of being relatively minimally invasive. We predict that frequent

SMBG in patients with T1DM (those testing more than four to six times daily) will largely be replaced with rt-CGM in the near future as the technology improves and cost becomes less prohibitive, and will provide all of the benefits with respect to metabolic control and prediction and prevention of hypoglycemia and may even potentially decrease complication rates.

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