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Continuous Glucose Monitoring Versus Self-monitoring of Blood Glucose in Children with Type 1 Diabetes- Are there Pros and Cons for Both?

Susana R. Patton, PhD, CDE[1] and **Mark A Clements, MD, PhD**[2]
[1]University of Kansas Medical Center, Kansas City, KS 66160
[2]Children's Mercy Hospital, Kansas City, MO 64018

Abstract

Glucose monitoring is essential for modern diabetes treatment and the achievement of near-normal glycemic control. Monitoring provides the data necessary for patients to make daily management decisions related to food intake, insulin dose, and physical exercise and can enable patients to avoid potentially dangerous episodes of hypo- and hyperglycemia. Additionally, monitoring can provide health care providers with the information needed to identify glycemic patterns, educate patients, and adjust insulin. Presently, youth with type 1 diabetes can self-monitor blood glucose via home blood glucose meters or monitor glucose concentrations nearly continuously using a continuous glucose monitor. There are advantages and disadvantages to the use of either of these technologies. This review describes the two technologies and the research supporting their use in the management of youth with type 1 diabetes in order to weigh their relative costs and benefits.

Keywords

diabetes; type 1; children; monitoring; glycemic control

Introduction

Type 1 diabetes mellitus is a disease that affects about 150,000 youths in the United States (1, 2). It is a disease characterized by an absence of insulin production by the beta cells of the pancreas (1). Patients with type 1 diabetes must administer insulin either via injection or insulin pump, to achieve near-normal glucose metabolism and to avoid life-threatening ketoacidosis (1). Self-monitoring of blood glucose (SMBG) is a cornerstone of modern diabetes treatment (1). Monitoring provides the data necessary to make daily management decisions related to food intake, insulin dose, and physical exercise. In addition, monitoring enables patients to avoid acute complications of type 1 diabetes, namely hypo- and hyperglycemia, and diabetic ketoacidosis (1, 3, 4). Finally, health care providers (HCPs) utilize blood glucose data to identify glycemic patterns, to educate patients, and to adjust insulin (5). Monitoring of blood glucose has been made easier in modern diabetes therapy with the introduction of home blood glucose monitors which allow patients to check their glucose levels quickly and provide an accurate measure of capillary glucose concentrations. The recent introduction of continuous glucose monitors (CGM), which measure glucose concentrations subcutaneously in interstitial fluid, offers patients an alternative to traditional SMBG, the relative benefit of avoiding multiple finger sticks to measure glucose levels, and a wealth of glucose data. Both SMBG and CGM technologies offer clear advantages and disadvantages in diabetes management and both have empirical support demonstrating their efficacy related to promoting better long-term glycemic control (e.g., glycated hemoglobin) (6–8). The purpose of this review is to provide an overview of the technologies and the

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research supporting their use in the management of youth with type 1 diabetes in order to weigh their relative costs and benefits.

Self-Monitoring Blood Glucose (SMBG)

Models of home blood glucose meters available in the market today have come a long way from the visual blood glucose strip tests available approximately 35 years ago. Now SMBG technology uses test strips containing either hexokinase or glucose oxidase chemistry (9). After applying a small drop of blood (< 1 μl for some meters) and a series of chemical reactions, current home blood glucose meters yield a numerical measure of capillary glucose concentration either via colorimetry, photometry, or electrochemistry (9). Thirty home blood glucose meters are available in the market today. All of these models meet at least the minimum standard of accuracy as established by the US Food and Administration Agency (FDA), which is currently: 95% of tests fall within 15 milligrams of the test reference for values less than 75 or within 20% of the test reference for values of 75 or greater (9). Thus, the features that most distinguish among meters and may make them more or less appropriate for pediatric patients include: cost, insurance coverage, size of the meter, test time, size of the blood sample required, memory capabilities, and special features (i.e., no code strips, appearance) (3, 10). User error is still the number one barrier to accurate results in SMBG and user factors that can impact accuracy include improper patient training, use of damaged or expired test strips, an uncalibrated meter, an inadequate blood sample, and a contaminated blood sample (11, 12). The American Diabetes Association (ADA) and the International Society for Paediatric and Adolescent Diabetes (ISPAD) do not offer specific recommendations for the minimum daily frequency of SMBG tests in youth (1, 13), but it is generally accepted that at least three SMBG checks per day is the minimum standard for youth with type 1 diabetes.

Multiple lines of evidence support the efficacy of SMBG in youth as a tool to achieve better long-term glycemic control, as measured by HbA1c. In an early study recruiting 89 school-age and adolescent patients with type 1 diabetes, Anderson et al. (7) found that youths' HbA1c levels improved as the frequency of daily SMBG tests increased. Specifically, at zero or one check per day, youth had a mean HbA1c value of 9.9%±0.44%, while at four or more checks per day, youth had a mean HbA1c value of 8.3% ± 0.22%. More recently, Ziegler et al. (6), was able to replicate these findings in a larger sample and a broader age range of youth (0–18 years). Adjusting for age, gender, diabetes duration, year of treatment, insulin regimen, insulin dose, BMI, and treatment center, these researchers found that for each additional SMBG check per day, youth experienced a 0.20% decrease in their HbA1c level. It is expected that SMBG contributes to better HbA1c levels indirectly by increasing a patient's ability to modify insulin and carbohydrate intake to achieve more consistent and normal glucose levels. However, research specifically identifying this relation between SMBG and HbA1c has not yet been published.

To conclude, the advantages of SMBG are that it is relatively inexpensive, easy to train youth to complete, provides an accurate measure of capillary glucose concentrations, and available glucose meters can offer features including memory, downloading software, no coding strips, and small blood sample requirements (3, 10, 11, 14). Disadvantages are the impact of user error on test accuracy (11), the need for multiple finger-stick blood samples each day, and the limited data available (e.g., SMBG provides a single snap shot of glucose concentrations, not trending data). Efficacy studies support the use of SMBG in diabetes management in youth (6, 7), which suggests that it likely to remain the most common form of glucose monitoring practiced by youth today.

Continuous Glucose Monitoring (CGM)

CGM is increasing in use as an adjunct to SMBG or on its own. CGM technology includes blinded, retrospective models, which can be deployed by HCPs for short-term monitoring of patients and real-time monitors, which are more typically reserved for personal use. Presently, the US FDA has approved three models for use in diabetes, but only two systems are approved for children seven years and older. For very young children with type 1 diabetes (<7 years old), CGM represents off-label use (15). CGM technologies measure glucose subcutaneously, in the interstitial fluid. A sensor is placed just under the skin typically in the patients' buttocks, thighs, abdomen, or upper arm. The sensor is a glucose oxidase platinum electrode (16), which in the presence of glucose in the interstitial fluid, generates an electrical current. Individual CGM monitors measure the electrical current and generate an average glucose value every 5 minutes, which depending on the monitor, is either displayed in real-time or stored for downloading later (15, 16). In order to receive continuous glucose values, CGM's require daily calibration with SMBG. In addition, for the monitors to receive and either display or record glucose values, the units need to be fully charged and synchronized with the sensors. Studies have demonstrated adequate accuracy rates, especially when measuring glucose values within the normal range (17). However, CGM values may not always be identical to concurrent SMBG levels, which can raise some concern among families about their accuracy. While highly automated, CGM's remain vulnerable to user error. Common sources of user error include failure to complete an adequate number of calibration tests, poor SMBG technique, and insertion or sensor-related site problems (15, 16). Sensors may fall out if not adequately secured with additional tape or adhesives. This can be very upsetting to families, as sensors can cost as much as $70 each and once removed, cannot be reused. In some cases, health insurance will cover a portion of the cost for CGM use, but invariably there are still significant out-of-pocket expenses for families. In addition, youths may object to wearing a CGM because of the additional needle stick, infusion site, and monitor the CGM requires.

The most notable benefit of CGM is the wealth of time-series glucose data this technology provides. SMBG provides only snap-shots of blood glucose concentration, and is limited by the number of finger-sticks a patient is willing to perform per day. In contrast, CGM can report up to 288 glucose values per day and yield data revealing temporal trends and patterns in glucose control (16). With CGM, patients are better able to detect asymptomatic hypoglycemia (18). Indeed, with real-time CGM, patients can even set an alarm to sound if glucose levels are detected above or below a specific threshold, thus potentially allowing youths and parents to more readily treat these abnormal values (15, 18). In addition, the continuous datastream generated by CGM is better equipped to detect glycemic variability, which may be associated with the future risk for microvascular disease (5). For HCPs, CGM can theoretically provide a vast amount data to better inform insulin management and better educate youths and parents on the effects of food intake, insulin, and exercise (16), although data regarding the impact of CGM on insulin management and education by providers are currently lacking. The one pediatric study that did test the impact of CGM-guided insulin adjustment by providers suggested no additional benefit over SMBG-guided insulin adjustment with regard to glycemic control (19).

In a large randomized trial recruiting 322 youth and adults with type 1 diabetes on either insulin pump therapy or multiple daily injections (8), researchers found a significant reduction in HbA1c levels (0.53%) in comparison to controls for adult patients after 6 months of real-time CGM use. Unfortunately, for youth with type 1 diabetes, there was no difference in HbA1c between the control and CGM use groups after 6 months. However, follow-up examination suggests there may have been a dose effect, as 83% of adults reported CGM use at least 6 days per week, compared to 30% of young adults (15–24 years), and 50% of youth (8–14 years). This study did not find a difference in either time spent below the target glucose range or the frequency of severe hypoglycemic events for CGM users or controls, although other studies have shown CGM to be superior to SMBG in detecting episodes of severe hypoglycemia (18).

CGM use may be associated with unique psychological concerns (15). It can be highly frustrating and upsetting for parents and youth to experience false alarms for hypo- or hyperglycemia, although it may be possible to reduce the false alarm rate by adjusting the threshold values further from the normal range. CGM may give youth and parents false confidence that with the significant influx of new data specific to daily glucose values perfect control can be achieved, but this is unlikely given all of the factors that can affect glucose levels. Finally, youth may resent CGM if the technology is used by caregivers to detect and chastise them for every high or low blood glucose value (20).

To conclude, the main advantage of CGM is that it can provide a near-continuous read-out of interstitial glucose concentration, which adequately reflects blood glucose concentration and can help to identify trends and patterns in glucose control with only a single needle stick to place the sensor (15, 16). In addition, in the case of real-time CGM, monitors can be programmed to alarm for either high or low glucose values, thus allowing parents and youth to treat for these abnormal values and potentially reducing fear related to hypo or hyperglycemia (18). Disadvantages include the cost of CGM, lack of universal insurance coverage for this technology, limited FDA approval for CGM devices in youth, and cosmetic (e.g., additional infusion site/monitor) and psychological concerns (20) (e.g., frustration, helplessness if glucose control is not perceived as adequate). There is also limited evidence supporting use of CGM in youth with type 1 diabetes as a means of improving long-term glycemic control. One barrier to CGM use appears to be youths' willingness to accept and use this technology for diabetes management (8), a problem which likely will need to be addressed before it is possible to adequately examine for the efficacy of CGM use on glycemic control.

Glucose monitoring is an important component of type 1 diabetes treatment. Careful consideration of the advantages and disadvantages of SMBG and CGM can help providers identify the approach that best fits with youths' lifestyle and treatment goals. Further research is needed to compare the efficacy and cost effectiveness of each approach in pediatrics.

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