Patient Selection for Continuous Glucose Monitoring

James J. Chamberlain, MD, St. Mark's Hospital and St. Mark's Diabetes Center, Salt Lake City, UT

Identifying appropriate patients for continuous glucose monitoring (CGM) use is a vital component of therapy success. Potential candidates come from a diverse group of individuals with diabetes.

Many people with type 1 diabetes may be excellent candidates for CGM therapy. Studies of the Juvenile Diabetes Research Foundation (JDRF) showed improvement in A1C levels in children, adolescents, and adults with type 1 diabetes with the use of three different CGM systems (1,2). However, the improvement in glycemic control was significant only in the adult agegroup because of relatively poor sustained adherence to CGM therapy in children and adolescents. With improved adherence, all groups showed improved A1C. Benefits were also greater for people with higher baseline A1C levels. A recent re-analysis of JDRF study data showed statistically significant improvements in the important measures of time spent in hypoglycemia, hyperglycemia, and glycemic variability (3). People with type 1 diabetes on either continuous subcutaneous insulin infusion (CSII) or multiple daily injection (MDI) therapy have been shown to benefit from CGM therapy (4-6).

People with type 2 diabetes, particularly those using insulin, also may be candidates for CGM. In 2017, the U.S. Centers for Medicare & Medicaid Services (CMS) began covering the Dexcom G5 Mobile system for people with type 1 or type 2 diabetes on intensive insulin therapy, defined as three or more daily injections of insulin or CSII therapy. A recent trial involving 158 people with type 2 diabetes on MDI insulin therapy randomized patients to usual care versus Dexcom G4 Platinum CGM-guided therapy. After 6 months, mean A1C levels improved from 8.5 to 7.7% in the CGM-treated group versus 8.0% in the usual care group (P = 0.022) (7). CMS also covers the FreeStyle Libre (Abbott, Alameda, CA) flash CGM (FCGM) system in the same populations. Use of FCGM for 6 months in people with type 2 diabetes on intensive insulin therapy resulted in statistically significant reductions in rates of hypoglycemia below blood glucose levels of 70, 55, and 45 mg/dL by 55, 68, and 75%, respectively (8). People using FCGM also reduced test strip use by 90% and scanned the CGM sensor an average of 8.3 times per day.

Pregnant women with diabetes are strong candidates for CGM. The American Diabetes Association recommends an A1C target of <6% during pregnancy for women with preexisting type 1 or type 2 diabetes if this goal can be achieved without excessive hypoglycemia (9), an often-difficult accomplishment. Studies have demonstrated improvement in neonatal outcomes and significantly more time spent in target range during pregnancy with the use

of CGM therapy (10,11). Women with gestational diabetes mellitus (GDM) may benefit from CGM use as well. In a study of 340 Chinese women with GDM randomized to intermittent prospective CGM use versus SMBG testing seven times per day throughout pregnancy, those using CGM showed superior glycemic variability, had infants with a lower mean birth weight, and had a lower risk of preeclampsia and a lower rate of cesarean delivery (12).

Another group of people who are excellent candidates for CGM therapy are those with hypoglycemia unawareness or a significant fear of hypoglycemia. Hypoglycemia unawareness increases the risk of severe hypoglycemia sixfold in patients with type 1 diabetes and ninefold in patients with type 2 diabetes (13,14). The IMPACT study using the FreeStyle Libre system in 239 people with type 1 diabetes for 6 months demonstrated reductions of 40% in nocturnal hypoglycemia, 50% in serious hypoglycemia (<55 mg/dL), and 91% in routine fingerstick blood glucose measurements (15). A retrospective study of 35 people with type 1 diabetes and established hypoglycemia unawareness showed a significant reduction in episodes of severe hypoglycemia from a mean rate of 8.1 to 0.6 episodes/ patient-year (P = 0.005) over 1 year with multiple CGM systems (16). A subsequent retrospective study demonstrated an 86% reduction in risk for severe hypoglycemia requiring medical assistance in the first year of real-time CGM therapy (P = 0.0013) in people with type 1 diabetes who reported wearing their CGM system on an "almost daily" basis (17). There was also a strong trend toward a reduction in fear of hypoglycemia. More recently, a significant reduction in fear of hypoglycemia was shown in 20 people with type 1 diabetes after only 8 weeks of real-time CGM therapy (P = 0.01) (18).

It is important not to assess a person's eligibility for CGM based on superficial observation. In particular, those with dexterity problems or visual disability may be appropriate candidates for CGM therapy, as evidenced by a case report of a person with type 1 diabetes, complete blindness, frequent hypoglycemia, and hypoglycemia unawareness who was able to rapidly and dramatically improve glycemic control with real-time CGM by learning to respond more appropriately to high and low blood glucose alerts (19). This patient's average blood glucose decreased from 162 mg/dL during the first 4 days of CGM use to 138 mg/dL during the next 4 days, and there was also improvement in glycemic variability. The percentage of time spent in the high glucose range (>180 mg/dL) improved from 35 to 18%, and the percentage of time spent in the low glucose range (<80 mg/dL) improved from 9 to 3% with no episodes of severe hypoglycemia. People

with dexterity or visual loss may need the help of a family member or caregiver to assist with CGM sensor insertion and calibrations.

Obviously, there are individuals for whom CGM therapy may not be beneficial or appropriate. It is important for people with diabetes to understand the strengths and limitations of CGM systems as related to their individual needs. (See the article on p. 8 of this compendium for a description of available systems.) Some people have misconceptions about CGM therapy, believing incorrectly, for example, that they may never have to perform fingerstick blood glucose testing for systems requiring calibration, that the CGM system is going to automatically adjust all aspects of CSII therapy, or that they may be able to take a completely hands-off approach to managing their diabetes. Others experience emotional distress due to "information overload" from the amount of data available through CGM. Also, people with type 2 diabetes who are stable on oral medications have not been shown to benefit from CGM. Appropriately selected individuals will have the best chance of improving their glucose control and outcomes when they consult the device frequently and are taught to use continuous data to make informed and timely treatment decisions.

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