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CLINICAL GUIDELINE

Diabetes Technology: Review of the 2019 American Diabetes Association Standards of Medical Care in Diabetes

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Description: The American Diabetes Association (ADA) annually updates its Standards of Medical Care in Diabetes to provide clinicians, patients, researchers, payers, and other interested parties with evidence-based recommendations for the diagnosis and management of patients with diabetes.

Methods: The ADA Professional Practice Committee comprises physicians, adult and pediatric endocrinologists, diabetes educators, registered dietitians, epidemiologists, pharmacists, and public health experts. To develop the 2019 standards, the committee continuously searched MEDLINE through November 2018 to consider and review studies, particularly high-quality trials including persons with diabetes, for potential incorporation into recommendations. It also solicited feedback from the larger clinical community.

Recommendations: This synopsis focuses on selected guidance relating to use of diabetes technology in adults with diabetes. Recommendations address self-monitoring of blood glucose, continuous glucose monitors, and automated insulin delivery systems.

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In 2019, the American Diabetes Association (ADA) added a new section on diabetes technology to the Standards of Medical Care in Diabetes. Diabetes technology is the devices, hardware, and software that persons with diabetes use to help manage blood glucose levels. Such technology includes pens or pumps that administer insulin and meters or continuous glucose monitors that measure blood glucose. Recent evolutions addressed in this synopsis are devices that both monitor glucose and deliver insulin, and software that serves as a medical device by supporting diabetes self-management.

Guideline Development and Evidence Grading

The Professional Practice Committee of the ADA is an expert committee comprising physicians, diabetes educators, and others who have expertise in such areas as adult and pediatric endocrinology, public health, epidemiology, lipids and hypertension, pregnancy care, and preconception planning. Appointment to the Committee is based on excellence in research or clinical care. For the current revision, members systematically searched MEDLINE through November 2018 for studies that were related to each section and had been published since 15 October 2017. Recommendations were revised to incorporate new evidence, clarify the prior recommendation, or align the strength of the wording to that of the evidence. The standards were approved by the ADA's Board of Directors, which consists of health care professionals, scientists, and laypersons.

The recommendations are rated as A, B, C, or E. Those with an A rating are based on large, well-designed clinical trials or high-quality meta-analyses. Recommendations with lower-quality evidence may also be important and are based on well-conducted cohort studies (B rating) or uncontrolled studies (C rating). Recommendations are assigned an E rating when there is no evidence from clinical trials, clinical trials might be impractical, or evidence is conflicting.

The ADA funds development of the standards from its general revenues, with no industry involvement or support. Details on the methods, information about the committee members and their conflict-of-interest disclosures, and the complete standards can be downloaded at https://professional.diabetes.org/annals.

Self-Monitoring of Blood Glucose

Recommendations

Most patients using intensive insulin regimens (multiple daily injections or insulin pump therapy) should assess glucose levels using self-monitoring of blood glucose (SMBG) or continuous glucose monitoring (CGM) before meals and snacks; at bedtime; occasionally postprandially; before exercise; when they suspect low blood glucose; after treating low blood glucose until they are normoglycemic; and before critical tasks, such as driving. (Grade B recommendation)

For patients using less frequent insulin injections, SMBG may help guide treatment decisions as part of a broad educational program. (Grade B recommendation)

Patients should receive ongoing instruction and evaluation of technique, results, and their ability to use the data to adjust therapy. (Grade E recommendation)

Self-monitoring of blood glucose—a technology used in the major clinical trials of patients who receive insulin—is an integral part of therapy for such patients (1). Continuous glucose monitoring is an additional method that gives continuous readings of glucose levels, allowing patients to see how medications, meals, and exercise affect blood glucose. It provides complementary information to that obtained with SMBG. Both SMBG and CGM help show patients their individual responses to therapy, and the results must be integrated into the diabetes management program to be useful in adjusting medications, guiding nutrition and exercise recommendations, and preventing hypoglycemia.

Optimizing SMBG and Continuous Glucose Monitor Use

Patients' monitoring technique should be evaluated initially and at regular intervals. Optimal use of SMBG and CGM requires review and interpretation of data by both the patient and the provider. In patients with type 1 diabetes, more frequent use of these technologies has been associated with lower levels of hemoglobin A_{1c} (HbA_{1c}) (2, 3). However, many patients who report checking their blood glucose at least once daily also report taking no action when results are high or low (4). Patients should be taught how to use SMBG or CGM data to adjust food intake, exercise, and pharmacologic therapy. The need for and frequency of SMBG should be reevaluated at each visit to avoid overuse, particularly if SMBG is not being used effectively for self-management (4–6).

For Patients Using Intensive Insulin Regimens

Use of SMBG or CGM is most important for insulin-treated patients because it enables them to adjust therapy to minimize hypoglycemia and manage hyperglycemia. An observational study of almost 27 000 children and adolescents with type 1 diabetes showed that increased daily frequency of SMBG was significantly associated with lower HbA_{1c} levels (difference, −0.2 percentage points per additional test/d) and fewer acute complications (7).

For Patients Using Basal Insulin or Oral Agents

Evidence is insufficient to guide when to prescribe and how often to test SMBG for insulin-treated patients who are not using intensive insulin regimens. However, when fasting glucose monitoring is used to determine dose adjustments in patients using basal insulin, it results in lower HbA_{1c} levels (8, 9).

In patients with type 2 diabetes who are not using insulin, potential benefits of glucose monitoring include insight into the effects of diet, physical activity, and medication management. In addition, SMBG is useful in assessing hypoglycemia, glucose levels during intercurrent illness, and discrepancies between measured HbA_{1c} and glucose levels. Randomized trials, however, have raised questions about the clinical utility and cost-effectiveness of routine SMBG in non–insulin-treated patients (10–13). Reductions in HbA_{1c} levels were greater (change, −0.3 percentage points) in trials where structured SMBG data were used to adjust medications than in trials without such adjustment, where changes were not significant (14). In addition, SMBG does not itself lower blood glucose levels; rather, its utility depends on the way in which the information is used and integrated into the patient's diabetes management plan.

Glucose Meter Accuracy

Recommendation

Health care providers should be aware of medications and other factors that can interfere with glucose meter accuracy and choose appropriate devices for their patients on the basis of these factors. (Grade E recommendation)

The U.S. Food and Drug Administration (FDA) uses the following accuracy standard for glucose monitors intended for home use: 95% of readings need to be within 15% for all blood glucose results in the monitor's readable range, and 99% must be within 20% (15, 16). Accuracy varies among widely used systems for blood glucose monitoring. A recent study found that only 6 of the top 18 glucose meters met the defined accuracy standard (17). Detailed information on individual devices can be found at the Diabetes Technology Society Blood Glucose Monitoring System Surveillance Program Web site (www.diabetestechnology.org/surveillance.shtml).

Factors Limiting Accuracy

Glucose monitors use either glucose oxidase or glucose dehydrogenase in the reaction to determine glucose levels (18). Because glucose oxidase monitors depend on oxygen levels, these devices should be used only in patients whose oxygen saturation is normal. Higher oxygen tension (for example, from arterial blood readings or during oxygen therapy) can lead to falsely low glucose readings, and low oxygen tension (for example, at high altitude, during hypoxia, or from venous blood readings) can lead to falsely high readings. Glucose dehydrogenase monitors are not oxygen-dependent. Patients and physicians should also be aware of and avoid using counterfeit strips that have not been subject to quality control procedures because they may give inaccurate results.

CONTINUOUS GLUCOSE MONITORS

Recommendations

Sensor-augmented pump therapy can be considered for children, adolescents, and adults to improve glycemic control without increasing overall or severe hypoglycemia. Benefits correlate with ongoing consistent use of the device. (Grade A recommendation)

When CGM is prescribed, intensive diabetes education, training, and support are required for optimal implementation and ongoing use of a continuous glucose monitor. (Grade E recommendation)

Persons who have been successfully using continuous glucose monitors should have continued access across third-party payers. (Grade E recommendation)

Continuous glucose monitoring measures interstitial glucose (which correlates well with plasma glucose) through a small subcutaneous sensor. Devices are available as real-time devices that continuously report glucose levels and include alarms for both hyperglycemic and hypoglycemic excursions and intermittently scanned CGM (isCGM) devices, which are approved for adult use only. The latter devices (discussed in more detail under Use of Intermittently Scanned Continuous Glucose Monitors) neither communicate continuously nor provide real-time alarms, but they are less expensive than CGM systems with automated alerts. Although SMBG is required to make treatment decisions

with some CGM systems, the FDA has approved 2 CGM systems (Dexcom G5 and Dexcom G6) for decision making without a confirmatory SMBG check (19, 20).

Systems for CGM provide a significant amount of patient data that can be incorporated into clinical practice and can lead to better treatment decisions (21). Recommended glucose metrics to follow include average glucose level, percentage of time in hypoglycemia ranges (<3.00 mmol/L [<54 mg/dL] and 3.00 to 3.89 mmol/L [54 to 70 mg/dL]), percentage of time in the target range (3.89 to 10.0 mmol/L [70 to 180 mg/dL]), and percentage of time in the hyperglycemia range (>10.0 mmol/L [>180 mg/dL]) (22).

The HbA_{1c} test is an established marker of risk for diabetes complications. With the expanding use of CGM to facilitate diabetes management, patients and providers must understand how CGM metrics (such as mean glucose and HbA_{1c} levels) correlate. Estimated HbA_{1c} is a calculated measure that uses a formula to convert the mean glucose level from SMBG readings or CGM reports into an estimate of a simultaneously measured laboratory HbA_{1c} level. The formula was derived from glucose readings from a large population (23). Recently, estimated HbA_{1c} was renamed the glucose management indicator (24).

Real-Time Continuous Glucose Monitor Use in Adults

Recommendations

When used properly, real-time CGM in conjunction with intensive insulin regimens is a useful tool to lower HbA_{1c} levels in adults with type 1 diabetes who are not meeting glycemic targets. (Grade A recommendation)

Real-time CGM may be a useful tool in those with hypoglycemia unawareness or frequent hypoglycemic episodes. (Grade B recommendation)

Real-time CGM should be used as close to daily as possible for maximal benefit. (Grade A recommendation)

Sensor-augmented pump therapy with automatic low-glucose suspend can be considered for adults with type 1 diabetes at high risk for hypoglycemia to prevent episodes of hypoglycemia and reduce their severity. (Grade B recommendation)

Randomized controlled trials of CGM therapy for adults with type 1 diabetes include some studies with HbA_{1c} level as the primary outcome (25, 26) and some with hypoglycemia as the primary outcome (27–29). Several studies have included both adults and children, with a primary outcome of HbA_{1c} level (2, 30–32) or hypoglycemia. Several published studies have investigated CGM use in adults with type 2 diabetes (27, 28, 33).

Primary Outcome: HbA_{1c} Reduction

Large studies involving adults with type 1 diabetes who use multiple daily injections of insulin with CGM therapy showed reductions in HbA_{1c} level of 0.43 percentage points (25) and 0.6 percentage points (26). In the Juvenile Diabetes Research Foundation CGM study, a significant reduction of 0.53 percentage points was seen in a subset of adults primarily using continuous subcutaneous insulin infusion (2). Consistent CGM use seems to be an important factor in reduction of HbA_{1c} levels (2, 34).

In 1 study of 158 adults with type 2 diabetes mellitus using multiple daily insulin injections alone, CGM use reduced HbA_{1c} by an average of 0.3 percentage points (33). A study in persons using oral agents with or without insulin (27) and another in patients using either multiple daily injections or continuous subcutaneous insulin infusion (28) showed significant reductions in HbA_{1c} levels.

Primary Outcome: Hypoglycemia

Use of CGM reduced hypoglycemia in adults with type 1 diabetes using multiple daily injections or continuous subcutaneous insulin infusion (29–31). In a study of patients with high risk for hypoglycemia (32), CGM use reduced time in all levels of hypoglycemia. In adults with type 2 diabetes using oral medications with or without insulin, CGM did not reduce hypoglycemia rates (27, 28, 33). It may be most useful in insulin-dependent patients with hypoglycemic unawareness or those with frequent hypoglycemic episodes. Findings conflict regarding reduction in severe hypoglycemia (2, 32, 35).

Sensor-augmented pumps—an FDA-approved technology—suspend basal insulin when glucose is currently low or predicted to decrease below 3.89 mmol/L (70 mg/dL) in the next 30 minutes. The low-glucose suspend function reduced hypoglycemia over a 3-month period without raising HbA_{1c} levels in the ASPIRE (Automation to Simulate Pancreatic Insulin REsponse) study of 247 persons with type 1 diabetes and known nocturnal hypoglycemia (34). In another study, predictive low-glucose suspend decreased time spent with HbA_{1c} levels below 3.89 mmol/L (70 mg/dL) from 3.6% to 2.6% (3.2% in the control group) over 6 weeks without leading to rebound hyperglycemia (36).

Use of Intermittently Scanned Continuous Glucose Monitors: Recommendation

Use of an intermittently scanned continuous glucose monitor can be considered as a substitute for SMBG in adults with diabetes requiring frequent glucose testing. (Grade C recommendation)

In 2017, the FDA-approved isCGM (sometimes called "flash" CGM) for use in adults. The personal version of isCGM has a receiver that displays real-time glucose values with trend arrows when the patient scans it over the sensor. Data can be uploaded and reports created using software either at home or in the provider's office. In the professional version, data are blinded to the patient because he or she does not carry a receiver while wearing the sensor and are then downloaded in the provider's office. The sensor, which requires only a 1-hour start-up time, can be worn for up to 14 days. The isCGM device comes factory calibrated and does not require calibration with SMBG. Accuracy of isCGM is not affected by acetaminophen. The sensor measures glucose levels every minute, records a measurement

every 15 minutes, and can display up to 8 hours of data on the receiver. Unlike real-time CGM systems, isCGM provides no blood glucose alerts, but its direct costs are lower than those of real-time CGM. Both the consumer and professional versions are covered by most commercial insurance carriers and eligible Medicare programs.

Studies in adults show that isCGM has excellent accuracy compared with SMBG (37–39). However, accuracy is lower at high and low glucose levels (21, 40). Outcomes conflict regarding the accuracy of isCGM versus real-time CGM (40–42). In patients with type 1 (29) and type 2 (43) diabetes, isCGM may decrease hypoglycemia risk. Recent studies show both excellent performance and potential for benefit in several special populations of patients with diabetes, including pregnant women with diabetes (44) and persons with type 1 diabetes and hypoglycemia unawareness (45).

Several thorough reviews have studied isCGM (46–48). In 2017, the Norwegian Institute of Public Health reviewed isCGM and its clinical effectiveness, safety, and cost-effectiveness in persons with type 1 and type 2 diabetes (46). The authors reported that few quality data were available at the time of the report but that isCGM may increase time in range, reduce frequency of nocturnal hypoglycemia, and improve treatment satisfaction. In 2016, the Canadian Agency for Drugs and Technologies in Health reviewed isCGM's performance, accuracy, effect on HbA_{1c} levels and hypoglycemia, and patient satisfaction and quality of life and concluded that isCGM could replace SMBG in patients who require frequent SMBG testing (47).

AUTOMATED INSULIN DELIVERY

Recommendation

Automated insulin delivery systems can be considered in children (aged >7 years) and adults with type 1 diabetes to improve glycemic control. (Grade B recommendation)

Automated insulin delivery systems consist of an insulin pump, a continuous glucose sensor, and an algorithm that determines insulin delivery. These systems suspend, increase, or decrease insulin delivery on the basis of sensor glucose values. Recent studies suggest that these systems may have psychosocial benefits (25, 49–51) and may reduce exercise-induced hypoglycemia (26).

A 3-month, noncontrolled trial involving 124 patients aged 14 to 75 years with type 1 diabetes and regular in-home use of insulin found that a first-generation, hybrid, closed-loop system (in which the user must calculate a bolus dose for carbohydrates) showed safety (52) and improved HbA_{1c} levels in adolescents (from 7.7% [SD, 0.8] to 7.1% [SD, 0.6]; $n = 30$) and adult users (from 7.3% [SD, 0.9] to 6.8% [SD, 0.6]; $n = 94$) (53).

Future Systems

Many other automated systems for insulin delivery are under investigation, including those that use dual hormones (insulin plus glucagon or pramlintide). Some patients are choosing to create and build their own pancreas device systems out of FDA-approved devices using training modules from online communities. These systems do not have FDA approval, and the FDA recently warned of the risks of using unapproved or unauthorized devices for diabetes management (including CGM systems, insulin pumps, and automated insulin dosing systems) in the United States (54–58).

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