



Q/ Does use of continuous or flash glucose monitors decrease hypoglycemia episodes in T2D?

EVIDENCE-BASED ANSWER

A / **NO.** In adults with insulin-treated type 2 diabetes (T2D), continuous glucose monitoring (CGM) and flash glucose monitoring (FGM) do not decrease symptomatic hypoglycemia episodes (strength of recommendation [SOR], **B**) but do lower time in hypoglycemia (SOR, **C**; disease-oriented evidence).

CGM, in which glucose levels are sent automatically in numeric and graphic format to a patient's smart device for their potential action, did not change the hypo-

glycemic event rate (SOR, **B**; 2 prospective studies). CGM significantly reduced hypoglycemia duration in an 8-month randomized controlled trial (RCT; SOR, **C**) but not in a 1-year prospective study (SOR, **C**).

FGM, in which glucose levels are sent on demand to a device, did not significantly reduce hypoglycemic episodes (SOR, **B**; 1 small RCT and 1 prospective study). Hypoglycemia duration was reduced significantly with FGM in a 6-month RCT (SOR, **B**) but not in a 1-year prospective study (SOR, **B**).

Evidence summary

Continuous glucose monitoring:

Nonsignificant reductions in event rates

A 2021 multicenter RCT (N = 175) evaluated CGM effectiveness in patients with basal insulin-treated T2D.¹ Patients (mean age, 57 years; mean A1C, 9.1%) wore a blinded CGM device for baseline glucose measurement (minimum of 168 hours) before being randomly assigned to either CGM (n = 116) or traditional blood glucose monitoring (BGM; n = 59). At 8-month follow-up, patients in the BGM group again had blinded sensors placed. A significant reduction in hypoglycemia duration was observed for the CGM group vs the BGM group at 8 months for glucose values < 70 mg/mL (adjusted mean difference [aMD] = -0.24%; 95% CI, -0.42 to -0.05) and < 54 mg/dL (aMD = -0.10%; 95% CI, -0.15 to -0.04). A nonsignificant decrease in severe hypoglycemic events requiring resuscitative assistance occurred for BGM (2%) vs CGM (1%) patients. Study limitations included

virtual visits due to COVID-19 and a short follow-up period.

A 2022 multicenter prospective study (N = 174) examined CGM effects on hypoglycemia frequency and severity in adults with T2D.² Patients with insulin-requiring T2D (mean age, 61 years; mean A1C, 8.0%) participated in a 12-month study with 6 months of self-monitored blood glucose (SMBG) followed by 6 months of CGM use. The primary outcome was the rate of severe hypoglycemic events. A nonsignificant decrease was observed in the CGM group compared to the SMBG group for hypoglycemic event rate, per participant per 6-month period (relative risk [RR] = 0.43; 95% CI, 0.07-2.64). Four moderate hypoglycemic adverse events occurred in the SMBG phase vs 2 in the CGM phase. Financial support by the study sponsor decreases the study's validity.

A 2021 prospective study (N = 90) evaluated the use of CGM to improve glycemic control.³ Patients younger than 66 years with

Frances K. Wen, PhD;
Simone Bigelow, DO;
Kimberly Crosby, PharmD;
Raye Reeder, MD, MPH
Department of Family and
Community Medicine,
University of Oklahoma School
of Community Medicine, Tulsa

Toni Hoberecht, MA, MLIS,
AHIP; Emrys Moreau, MFA,
MLIS
Schusterman Library, University
of Oklahoma-Tulsa

DEPUTY EDITOR

Rick Guthmann, MD, MPH
Advocate Health Care Illinois
Masonic Medical Center
Program, Chicago

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Continuous glucose monitoring and flash glucose monitoring do not decrease symptomatic hypoglycemia episodes but do lower time in hypoglycemia.

insulin-treated T2D and an A1C > 7.5% participated in a 7-day blinded CGM cycle every 4 months for 1 year. A nonsignificant decrease in hypoglycemia duration was observed for glucose values < 70 mg/dL and < 54 mg/dL at 12 months. No change in hypoglycemic event rate was seen with the use of CGM. Funding by the device manufacturer was a limitation of this study.

Flash glucose monitoring:

Mixed results on hypoglycemia events

A 2019 open-label RCT (N = 82) assessed the effectiveness of FGM on diabetes control.⁴ Patients with insulin-treated T2D were randomly assigned to the intervention or standard-care groups. The intervention group (n = 46; mean age, 66 years; mean A1C, 8.3%) used the FGM system for 10 weeks, while the standard-care group (n = 36; mean age, 70 years; mean A1C, 8.9%) maintained use of their glucometers. Both groups received similar types and duration of counseling. Treatment satisfaction was the primary outcome; total hypoglycemic events was a secondary outcome. No significant difference in the number of hypoglycemic episodes was observed between the intervention and control groups at 55 to 70 mg/dL (RR = 0.79; 95% CI, 0.44-1.4) or < 54 mg/dL (RR = 1.27; 95% CI, 0.38-4.2). No adverse events of severe hypoglycemia occurred during the study. Funding by the device manufacturer was a limitation of this study.

A 2017 open-label, multicenter RCT (N = 224) assessed FGM efficacy.⁵ Adults (mean age, 59 years; mean A1C, 8.8%) with T2D on intensive insulin therapy were randomized to FGM (n = 149) or SMBG (n = 75) after a 14-day masked baseline period. The 6-month treatment phase was unblinded. The duration of hypoglycemic events (glucose values < 70 mg/dL and < 55 mg/dL) was obtained from the sensors. Compared to the SMBG group, the FGM group spent 43% less time at < 70 mg/dL (aMD = -0.47 ± 0.13 h/d; P = .0006) and 53% less time at < 55 mg/dL (aMD = -0.22 ± 0.068 h/d; P = .0014). Hypoglycemic event rates significantly decreased by 28% (aMD = -0.16 ± 0.065; P = 0.016) and 44% (aMD = -0.12 ± 0.037; P = .0017) for glucose levels < 70 mg/dL and < 55 mg/dL,

respectively. A nonsignificant difference occurred in severe hypoglycemic events requiring third-party assistance for the FGM (2%) vs control (1%) groups. Involvement of the device manufacturer and unblinded group allocations are study limitations.

A 2021 single-arm, multicenter prospective study looked at the impact of FGM on glycemic control in adults with insulin-treated T2D (N = 90; mean age, 64 years; mean A1C, 7.5%).⁶ After a 14-day baseline period consisting of masked sensor readings paired with self-monitored fingerstick tests, participants were followed for 11 weeks using the sensor to monitor glucose levels. The primary outcome was amount of time spent in hypoglycemia (< 70 mg/dL), with secondary outcomes including time and events in hypoglycemia (< 70, < 55, or < 45 mg/dL). No significant decrease in hypoglycemia duration or hypoglycemic event rates at < 70, < 55, or < 45 mg/dL was observed for FGM compared to baseline. Adverse events were observed in 64% of participants; 94% of the events were hypoglycemia related. Serious adverse events were reported for 5.3% of participants. The single-arm study format, lack of generalizability due to the single-race study population, and sponsor support were study limitations.

Editor's takeaway

This reasonably good evidence shows a decrease in measured or monitored hypoglycemia, a disease-oriented outcome, but it did not reach statistical significance for symptomatic hypoglycemia (1% vs 2%), a patient-oriented outcome. Nevertheless, in patients reporting symptomatic hypoglycemia, a continuous or flash glucose monitor may allow for more aggressive glucose control. **JFP**

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■ **Dermatomyositis** is a rare disorder of inflammation in both the skin and muscles. Symptoms include rash, muscle aches, and weakness. Lab abnormalities include elevated creatine kinase levels and ANA. Muscle biopsy confirms the diagnosis.

■ **Erythema multiforme** is an immunologic-mediated rash consisting of firm targetoid erythematous papules distributed symmetrically on the extremities, including palms/soles. It typically appears after a viral infection, immunization, or new medications (eg, antibiotics, nonsteroidal anti-inflammatory drugs, or phenothiazines) initiated 1 to 3 weeks prior to the appearance of the rash. History and appearance inform the diagnosis.

■ **Polymorphic light eruption** is a rash of variable appearance on sun-exposed areas that results from a sensitivity to sunlight after lack of exposure for a period of time. Symptoms include burning and itching.

Treatment and outcome

Treat patients with SLE with hydroxychloroquine (200-400 mg/d) to suppress inflammation and with low-dose oral steroids such as prednisone (7.5 mg/d) for intermittent exacerbations. Higher steroid doses are sometimes needed for signs of organ inflammation. Patients with increased disease activity will require immunosuppressive therapy with disease-modifying antirheumatic drugs, such as methotrexate (7.5-25 mg/wk), mycopheno-

late (2-3 g/d), azathioprine (1.5-2.5 mg/kg/d), and biologic infusions.⁴ Additionally, in 2021, the US Food and Drug Administration approved anifrolumab (Saphnelo) and voclosporin (Lupkynis) for the treatment of SLE.⁴

■ **Our patient** was admitted for further evaluation. A lumbar puncture was performed because of his balance issues; it showed an elevated protein level, but further work-up did not find an infectious or malignant source. Balance improved with hydration. The patient remained hospitalized for 9 days, during which his fever subsided. His pain improved after initiation of hydroxychloroquine 400 mg/d. Follow-up with Rheumatology was arranged for further care. **JFP**

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CLINICAL INQUIRIES

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