

The Evidence Base for Continuous Glucose Monitoring

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Twenty-seven published randomized controlled trials (RCTs) assessing outcomes of continuous glucose monitoring (CGM), involving a total of 3,826 patients, have been published to date. Although the number of patients in each study has been small compared to drug trials, cumulative evidence indicates a benefit of CGM for patients treated with either continuous subcutaneous insulin infusion (CSII) or a multiple daily injection (MDI) insulin regimen. Additionally, some data suggest that CGM may benefit people with type 2 diabetes who do not use insulin therapy.

Overall, RCTs have shown improved glucose control in patients with higher initial A1Cs (often in the range of 7.8–8.8%) using CGM compared to self-monitoring of blood glucose (SMBG). People who wear their CGM device most consistently derive the most benefit. Time spent in the designated hypoglycemia range (usually <70 mg/dL) was reduced in some studies, particularly in those with patients selected for having a higher risk of hypoglycemia. These patients tended to have lower baseline A1Cs (in the range of 6.5–7.5%). Rates of severe hypoglycemia generally have not differed between CGM and non-CGM groups, and these rates have been low across all studies.

Studies fall into a few basic categories: adults with type 1 diabetes (8 trials, 698 patients), adults with type 2 diabetes (4 trials, 547 patients), children with type 1 diabetes (2 trials, 227 patients), adults plus children with type 1 diabetes (7 trials, 1,084 patients), adults with type 1 or type 2 diabetes (3 trials, 655 patients), and women during pregnancy with either type 1 diabetes or gestational diabetes mellitus (GDM) (3 trials, 585 patients). Table 1 lists general findings from all of these trials. It is important to note that some trials used A1C or time in

range as the primary endpoint, whereas others used time in a hypoglycemic range as the primary outcome. Readers should also be aware that Table 1 is not a meta-analysis per se, but rather includes studies identified through a literature search of PubMed and Ovid MEDLINE, as well as all prior reviews and studies in their reference lists. Only RCT data are included; observational studies and extension phases of RCTs also have been performed but are not represented here.

The first trials, from the early 2000s, used intermittent CGM. Some used “professional” CGM, in which patients were blinded to the CGM data (see the article on p. 8 of this compendium), and others followed an intermittent use schedule. As time progressed, the trials reflected evolving use of CGM to the current day. That is, earlier studies began to suggest that CGM could improve outcomes, but lack of access to real-time data limited benefit. More recent studies of real-time CGM, in which around-the-clock data are available, have shown more benefit in terms of reduction in both A1C and time spent in a hypoglycemic range.

A major impediment to interpreting CGM studies is that no uniform standard has been employed for teaching people with diabetes how to use continuous data, and no standard follow-up is provided to ensure that dose adjustments are made. In some trials, written instructions were provided to patients regarding insulin dose adjustments, but in many others, targeted education was not provided beyond how to use the device. Additionally, rapid advances in technology are not well represented in the literature, although data from newer systems, such as the Dexcom G5 Mobile (Dexcom, San Diego, CA) and the FreeStyle Libre (Abbott, Alameda, CA), are becoming available.

TABLE 1 Summary of CGM Research Studies

Study	Design	Primary Outcome / Type of CGM	A1C Outcomes	Hypoglycemia Change/Other
ADULTS WITH T1D: A1C PRIMARY OUTCOME				
Beck et al. (1,2)	<ul style="list-style-type: none"> ▶ Adults with T1D on MDI ▶ <i>n</i> = 158 ▶ Baseline A1C: ~8.6% ▶ Parallel arms, 24 weeks 	A1C reduction / Dexcom G4 Platinum	−0.6%, <i>P</i> < 0.001	<ul style="list-style-type: none"> ▶ Time <70 mg/dL was 43 vs. 80 min/day, <i>P</i> = 0.002 ▶ No difference in severe lows
Lind et al. (3)	<ul style="list-style-type: none"> ▶ Adults with T1D on MDI ▶ <i>n</i> = 161 ▶ Baseline A1C: 8.6% ▶ Crossover, 26-week arms 	A1C reduction / Dexcom G4 Platinum	−0.43, <i>P</i> < 0.001	<ul style="list-style-type: none"> ▶ Numerically less time in a hypoglycemic range with CGM
Sequeira et al. (4)	<ul style="list-style-type: none"> ▶ Underserved adults with T1D MDI ▶ <i>n</i> = 25 ▶ Baseline A1C: 8.5% ▶ Crossover, 28-week arms 	A1C reduction / Dexcom SEVEN	No significant difference between groups	<ul style="list-style-type: none"> ▶ No change in rates of hypoglycemia

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Study	Design	Primary Outcome / Type of CGM	A1C Outcomes	Hypoglycemia Change/Other
Tumminia et al. (5)	<ul style="list-style-type: none"> Adults with T1D on MDI or CSII $n = 20$ Baseline A1C: $\sim 8.65\%$ Crossover, 24-week arms 	A1C reduction / Medtronic Guardian REAL-Time	Only analyzed 14 patients who used CGM $\geq 40\%$ of the time; in these patients, there was a significant reduction in A1C ($P < 0.05$)	Risk for hypoglycemia was reduced (time spent < 70 mg/dL/day), $P < 0.05$
ADULTS WITH T1D: HYPOGLYCEMIA PRIMARY OUTCOME				
Bolinder et al. (6)	<ul style="list-style-type: none"> Adults with T1D on MDI or CSII $n = 241$ Baseline A1C: 6.7% Parallel arms, 6 months 	Change in time in hypoglycemic range (< 70 mg/dL) / Abbott FreeStyle Libre	NS	<ul style="list-style-type: none"> Overall, 38% reduction in time in hypoglycemia (-1.24 hours/day, $P < 0.0001$) Time in range (3.9–10.0 mmol/L [70–180 mg/dL]; mean difference) improved by 1.0 ± 0.30 hour, $P = 0.0006$
Hermanns et al. (7)	<ul style="list-style-type: none"> Adults with T1D, most on MDI $n = 41$ Baseline A1C: 8.2% Crossover design, 5-day arms; patients were free-living within inpatient research setting 	Proportion of time spent hypoglycemic / Dexcom SEVEN PLUS	N/A	Reduction in time in hypoglycemic range: 125 ± 89 vs. 181 ± 125 min/day, $P = 0.005$
van Beers et al. (8)	<ul style="list-style-type: none"> Adults with T1D on MDI or CSII with a Gold score ≥ 4 $n = 52$ Baseline A1C: 7.5% Crossover, 16-week arms 	Mean difference in time in range (4–10 mmol/L [72–180 mg/dL]) / Medtronic Enlite with a MiniMed Paradigm Veo system (used as a monitor)	NS	<ul style="list-style-type: none"> Reductions in hypoglycemia (≤ 3.9 mmol/L [70.2 mg/dL]) -4.7%, $P < 0.0001$ Severe hypoglycemia: 14 events with CGM vs. 34 events with SMBG, $P = 0.033$ Time in range (mean difference) improved by 9.6%, $P = 0.0001$
ADULTS AND CHILDREN WITH T1D: A1C/TIME IN RANGE PRIMARY OUTCOME				
Battelino et al. (9)	<ul style="list-style-type: none"> Adults and children with T1D on CSII $n = 153$ Baseline A1C: 8.1% for adults, 8.6% for children Crossover, 6-month arms 	A1C reduction / Medtronic Guardian REAL-Time	A1C difference -0.43% in favor of sensor on, $P < 0.001$	<ul style="list-style-type: none"> Time spent < 3.9 mmol/L (70.2 mg/dL) was 19 vs. 31 min/day, $P = 0.009$ Four severe hypoglycemic episodes in sensor on mode, two in sensor off mode
Deiss et al. (10)	<ul style="list-style-type: none"> Adults and children with T1D on MDI or CSII $n = 156$ Baseline A1C: 9.5% in arm 1, 9.7% in arm 2 Three parallel arms: continuous CGM (arm 1) vs. biweekly 3-day CGM (arm 2) vs. control for 3 months 	A1C reduction / Medtronic Guardian REAL-Time	Arm 1: -0.6% , $P = 0.003$; Arm 2: no difference in A1C	One episode of severe hypoglycemia in each arm
JDRF CGM Study Group (11)	<ul style="list-style-type: none"> Adults and children with T1D on MDI or CSII $n = 322$ Three age-groups: ≥ 25 years ($n = 98$), 15–24 years ($n = 110$), and 8–14 years ($n = 98$) Baseline A1C: ≥ 25 years, 7.6%; 15–24 years, 7.9–8.0%; and 8–14 years, 7.9–8.0% Parallel arms, 26 weeks 	A1C reduction / DexCom SEVEN, Medtronic MiniMed Paradigm REAL-Time insulin pump and CGMS, and Abbott FreeStyle Navigator	<ul style="list-style-type: none"> A1C difference: in those ≥ 25 years of age, -0.53%, $P < 0.001$; in those < 25 years of age, no difference A1C response related to use of CGM 	No difference in time spent in a hypoglycemic range or in number of severe hypoglycemic episodes

Study	Design	Primary Outcome / Type of CGM	A1C Outcomes	Hypoglycemia Change/Other
O'Connell et al. (12)	<ul style="list-style-type: none"> Adults and adolescents with T1D on CSII $n = 55$ Baseline A1C 7.3% for intervention group, 7.5% for control group Parallel arms, 3 months 	Time in range during the 3-month study period / Medtronic MiniMed Paradigm REAL-Time insulin pump and CGMS	<ul style="list-style-type: none"> No difference in primary outcome A1C was -0.43% lower in the CGM group, $P = 0.009$ Greater reduction in group with more use 	No difference in time in range, variability, or hypoglycemia
ADULTS AND CHILDREN WITH T1D: HYPOGLYCEMIA PRIMARY OUTCOME				
JDRF CGM Study Group (13)	<ul style="list-style-type: none"> Adults and children with T1D on MDI or CSII $n = 129$ Baseline A1C: 6.4% for CGM group, 6.5% for control group Parallel arms, 26 weeks 	Change in time ≤ 70 mg/dL / DexCom SEVEN, MiniMed Paradigm REAL-Time insulin pump and CGMS, and Abbott FreeStyle Navigator	A1C treatment difference favoring CGM, $P < 0.001$	<ul style="list-style-type: none"> Time ≤ 70 mg/dL numerically less frequent (54 vs. 91 min/day) but not significant, $P = 0.16$ Median time with blood glucose ≤ 60 mg/dL was 18 vs. 35 min/day, $P = 0.05$ Severe hypoglycemia 10 and 11% for CGM and control groups, respectively, $P = 1.0$
Battelino et al. (14)	<ul style="list-style-type: none"> Adults and children with T1D on MDI or CSII $n = 120$ Baseline A1C: 6.9% Parallel arms, 26 weeks 	Time spent in hypoglycemic range / Abbott FreeStyle Navigator	A1C treatment difference favoring CGM: -0.27% , $P = 0.008$	<ul style="list-style-type: none"> Time spent < 63 mg/dL shorter in CGM group; ratio of means 0.49, $P = 0.03$ No severe hypoglycemia
Heinemann et al. (15)	<ul style="list-style-type: none"> Adults and children with T1D on MDI with a history of impaired hypoglycemia awareness or severe hypoglycemia $n = 149$ Baseline A1C: 7.3% for control group, 7.6% for CGM group Parallel arms, 26 weeks 	Baseline-adjusted hypoglycemia events (glucose ≤ 3.0 mmol/L [54 mg/dL] for ≥ 20 minutes) / Dexcom G5 Mobile	No difference in A1C	Adjusted between-group difference in low glucose events: 0.28, $P < 0.0001$
CHILDREN WITH T1D				
Ludvigsson et al. (16)	<ul style="list-style-type: none"> Children with T1D on MDI or CSII $n = 27$ Baseline A1C: $\sim 7.7\%$ Cross-over, 12-week arms; wore CGM for 3 days every 2 weeks 	A1C reduction / Medtronic CGMS	A1C difference at 12 weeks during open vs. blind CGM: $\sim -0.39\%$, $P = 0.011$	No significant differences in hypoglycemia
Chase et al. (17)	<ul style="list-style-type: none"> Children with T1D $n = 200$ Baseline A1C: 8.0% Parallel arms, 6 months 	A1C reduction / GlucoWatch G2 Biographer	No significant change in A1C	Sensor use declined from 2.1 to 1.5 times/week because of skin irritation and other issues
ADULTS WITH T2D				
Beck et al. (18)	<ul style="list-style-type: none"> Adults with T2D on MDI $n = 158$ Baseline A1C: 8.5% Parallel arms, 24 weeks 	A1C reduction / Dexcom G4 Platinum with an enhanced algorithm	Adjusted mean A1C difference: -0.3% , $P = 0.022$	No change in hypoglycemia
Ehrhardt et al. (19)	<ul style="list-style-type: none"> Adults with T2D not on prandial insulin (half on oral medication alone) $n = 100$ Baseline A1C: 8.2% for SMBG group, 8.4% for CGM group Parallel arms, 2 weeks on/1 week off, 4 cycles over 12 weeks 	A1C reduction / Dexcom SEVEN	Difference in A1C: -0.6% , $P = 0.002$	<ul style="list-style-type: none"> Hypoglycemia data NA Most improvement in people who used CGM per protocol

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Study	Design	Primary Outcome / Type of CGM	A1C Outcomes	Hypoglycemia Change/Other
Haak et al. (20)	<ul style="list-style-type: none"> Adults with T2D on prandial-only insulin on MDI or CSII $n = 224$ Baseline A1C: 8.74% in intervention group, 8.88% in control group Parallel arms, 2:1 randomization, 6 months 	A1C reduction / Abbott FreeStyle Libre	No difference in A1C overall; difference in A1C if <65 years of age, $P = 0.03$	Time in hypoglycemia (<70 mg/dL) was reduced by 43%, $P = 0.0006$
Yoo et al. (21)	<ul style="list-style-type: none"> Adults with T2D on oral agents or insulin $n = 65$ Baseline A1C: 8.7% in SMBG group, 9.1% in CGM group Parallel arms, real-time CGM for 3 days once per month for 12 weeks 	A1C reduction / Medtronic Guardian REAL-Time	Improvement in A1C greater in CGM group, $\sim 0.5\%$, $P = 0.004$ (CGM: from 9.1 ± 1.0 to $8.0 \pm 1.2\%$, $P < 0.001$; SMBG: from 8.7 ± 0.7 to $8.3 \pm 1.1\%$, $P = 0.01$)	<ul style="list-style-type: none"> No significant changes in hypoglycemia In real-time CGM, reduced caloric intake, weight, BMI, and postprandial glucose level; increased physical activity
ADULTS WITH T1D OR T2D				
Garg et al. (22)	<ul style="list-style-type: none"> Adults with T1D or T2D on insulin $n = 91$ Baseline A1C: 7.6% in control group, 8.0% in CGM group Parallel arms, 3-day CGM for three consecutive 72-hour periods 	Time spent in high, low, and target glucose zones / Dexcom STS sensor	<ul style="list-style-type: none"> 23% less time in hyperglycemia (≥ 240 mg/dL) 26% increase in time in range (81–140 mg/dL) $P < 0.001$ for each comparison 	CGM group spent 21% less time in hypoglycemia (<55 mg/dL), $P < 0.0001$
New et al. (23)	<ul style="list-style-type: none"> Adults with T1D or T2D on MDI or CSII $n = 160$ Baseline A1C: 8.2% Parallel arms, 100 days 	Time spent outside of target range / Abbott FreeStyle Navigator; 1/3 CGM with no alarm, 1/3 CGM with alarm, 1/3 SMBG	No difference in A1C or time spent outside of target range	Less time in hypoglycemia range in group with alarms compared to SMBG group, $P = 0.03$
Cooke et al. (24)	<ul style="list-style-type: none"> Adults with T1D or T2D treated with at least twice-daily insulin injections $n = 404$ Baseline A1C: 9.1% Parallel arms, 18 months; GlucoWatch group wore device at least four times in the first 3 months and then as needed; Medtronic group wore device for 72 hours three times during first 3 months and on three more occasions thereafter 	A1C reduction / GlucoWatch G2 Biographer vs. Medtronic MiniMed CGMS (blinded)	No significant difference in A1C reduction	No reduction in hypoglycemia; possibly an increase
PREGNANT PATIENTS WITH T1D, T2D, OR GDM				
Feig et al. (25)	<ul style="list-style-type: none"> Adult women with T1D on MDI or CSII who were pregnant or planning pregnancy $n = 325$ (215 pregnant, 110 planning pregnancy) Baseline A1C: 6.83% in CGM group and 6.95% in control group (pregnant) and 7.57% in both CGM and control group (planning pregnancy) Parallel arms, to 34 weeks in pregnant women; for 24 weeks in those planning pregnancy 	A1C reduction / Medtronic Guardian REAL-Time or MiniMed MiniLink	A1C difference -0.19% , $P = 0.0207$ in pregnant women; no A1C difference in women planning pregnancy	<ul style="list-style-type: none"> Comparable severe hypoglycemia events (18 vs. 21) and time spent hypoglycemic (3 vs. 4%) Neonatal health outcomes: fewer LGA babies, fewer neonatal ICU stays for >24 hours, and fewer neonatal hypoglycemia events
Secher et al. (26)	<ul style="list-style-type: none"> Adult women with T1D or T2D who were pregnant $n = 154$ Baseline A1C: 6.6% in CGM group, 6.8% in control group Parallel arms, 6 days of CGM at 8, 12, 21, 27, and 33 weeks vs. routine care 	LGA babies / Medtronic Guardian REAL-time CGM with Sof-Sensor	No difference in A1C	<ul style="list-style-type: none"> No difference in number of LGA babies No difference in hypoglycemia

Study	Design	Primary Outcome / Type of CGM	A1C Outcomes	Hypoglycemia Change/Other
Wei et al. (27)	<ul style="list-style-type: none"> ▶ Adult women with GDM at 24–28 weeks of pregnancy ▶ $n = 106$ ▶ Baseline A1C: 5.8% in SMBG group, 5.7% in CGM group ▶ Parallel arms; women were asked to wear CGM intermittently early (second trimester) or late (third trimester) or perform SMBG 	Prenatal or obstetrical outcomes / Medtronic Gold CGMS	No significant reduction in A1C	<ul style="list-style-type: none"> ▶ No difference in obstetrical outcomes ▶ Some reduction in maternal weight gain

JDRF, Juvenile Diabetes Research Foundation; LGA, large-for-gestational-age; NA, not applicable; NS, non-significant; T1D, type 1 diabetes; T2D, type 2 diabetes.

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