DOTTORE HO UNA BELLA NOTIZIA…

CGM per tutte?

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Dichiarazione Conflitto d'Interessi

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Sara Belcastro, MD PhD

Acta Diabetologica
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POSITION STATEMENT

The use of technology in diabetes in pregnancy: a position statement of expert opinion from the association of medical diabetologists (AMD), the Italian society of diabetology (SID) and the interassociative diabetes and pregnancy study group

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Table 1 Glycemic targets in pregnancy by national and international guidelines

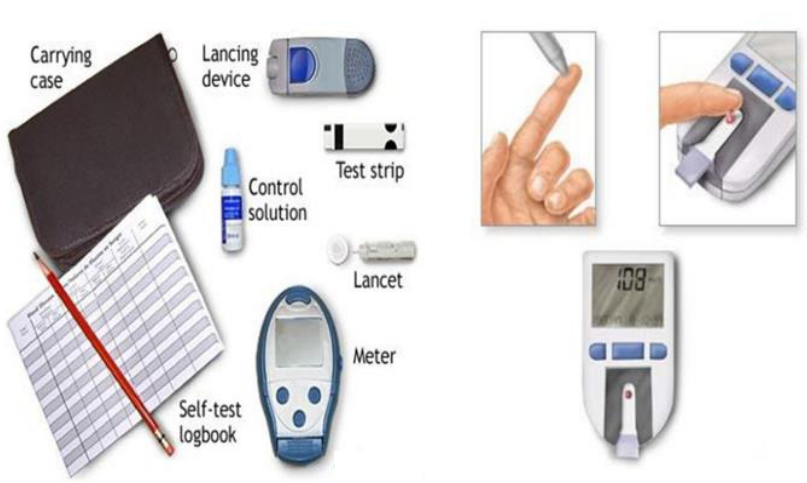
	SID-AMD [9]	ADA [6]		ACOG [10]	NICE [11]
		T1D or T2D and GDM insulin treated	GDM not insulin treated		
Fasting (mg/dL)	≤90	70–95*	<95	70–95	≤95^
1 h post-prandial (mg/dL)	≤130	110–140	<140	110–140	≤140
2 h post-prandial (mg/dL)	≤120	100–120	<120	100–120	≤115

*Lower glucose limits do not apply to individuals with type 2 diabetes treated with nutrition alone

^For women on insulin therapy, the minimum capillary glucose value is 72 mg/dL

Self Blood Glucose Monitoring in pregnancy

SBGM



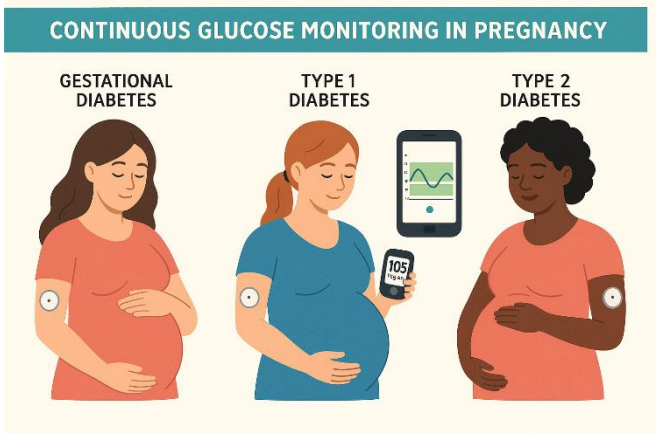
The **2018 Italian Standards for Diabetes Care** recommend <u>frequent SBGM for pregnant women</u>:

- For women undergoing dietary management: 75 measurements/month are suggested/recommended;

- For women on insulin therapy: 100–250 measurements/ month are suggested/recommended, depending on clinical circumstances.

Glucose Continuous Monitoring in pregnancy

CGM



- very useful for both the patient and the clinician in analysing **daily glucose trends** and making adjustments to **ongoing** insulin therapy;
- Is-CGM systems are also approved for use in pregnancy, but caution is advised because they report *longer* times below range (% TBR (<63 mg/dL) compared with rt-CGM, especially overnight, in pregnant women with T1D.

Resi V. et al Acta diabetologica 2025
https://doi.org/10.1007/s00592-025-02592-2

SBGM vs CGM

Aspect	SMBG	CGM
Measurement Type	Single-point glucose snapshots	Continuous glucose data (24/7)
Trend Information	*Not available*	Provides **trends** and rate of change
Detection of Hypo/Hyperglycaemia	Limited to the moment of testing	Real-time detection, **alarms available**
User Burden	Requires multiple daily fingersticks	Less frequent calibration and manual intervention
Patient Adherence	Often poor due to repeated checks	Generally better adherence
Glycaemic Metrics	Basic values (pre/post meals)	Time in Range, variability, patterns
Clinical Decision Support	Limited	Stronger support due to richer data
Cost	**Low**	Higher
Reimbursement (Italy)	**Uniformly** reimbursed by SSN	Variable across regions
Ease of Use	Simple but invasive	Easy to use, **minimally invasive**
Limitations	No trends, snapshot only	Sensor cost, regional reimbursement variability

Resi V. et al Acta diabetologica 2025
https://doi.org/10.1007/s00592-025-02592-2

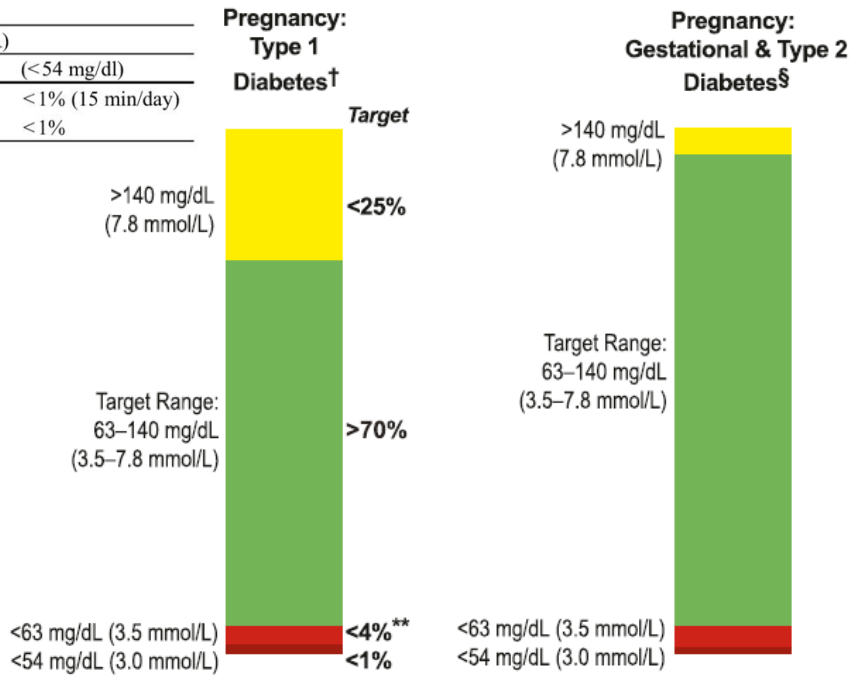
Clinical CGM targets for assessment of glycemic control during pregnancy

Table 3 Target values for continuous glucose monitoring [30]

	Time in range (TIR) (63–140 mg/dl)	Time above range (TAR) (>140 mg/dl)	Time below range (TBR) (<63 mg/dl)	Time below range (TBR) (<54 mg/dl)
Type 1 diabetes	>70% (>16 h 48 min/day)	<25% (<6 h/day)	<4% (<1 h/day)	<1% (15 min/day)
Type 2 diabetes^	≥90%	<5%	<4%	<1%

^For T1D target values are recommended, for T2D target values are suggested

Remember to set correct metrics on a CGM in pregnancy!



Resi V. et al Acta diabetologica 2025
https://doi.org/10.1007/s00592-025-02592-2

Battelino T. Diabetes Care 2019;42(8):1593-1603

HbA1c

HbA1c in pregnancy

In pregnancy → RBC turnover, iron deficiency/supplementation, alteration of plasma proteins, rapid change in metabolic compensation

In addition, because HbA1c is an average of glucose levels, **it may not adequately reflect postprandial hyperglycemia**, which is associated with outcomes such as macrosomia.

Therefore, HbA1c is used as a ***secondary measure*** of glycemic outcomes in pregnancy (*only* in DMT1).

HbA1c target is <6 –6.5% (42–48 mmol/mol); lower HbA1c—6% (42 mmol/mol) is optimal if it can be achieved **without significant hypoglycemia**.

Resi V. et al Acta diabetologica 2025
https://doi.org/10.1007/s00592-025-02592-2

CGM in pregnant women with type 1 diabetes

The CONCEPTT study

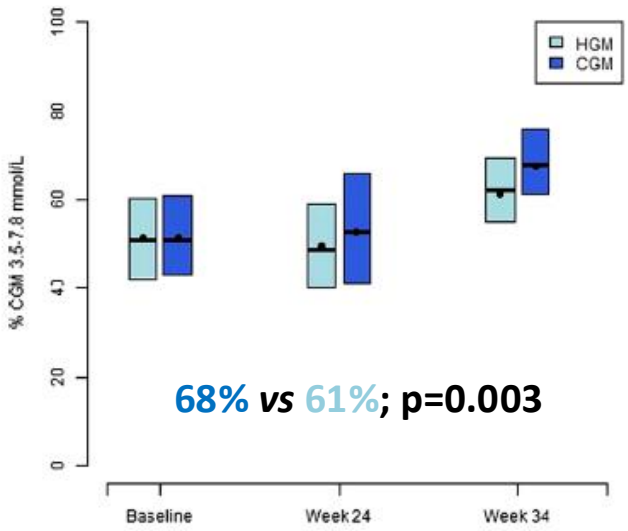
Open-label, multicentre, randomised controlled study

3 years follow-up 2013-2016

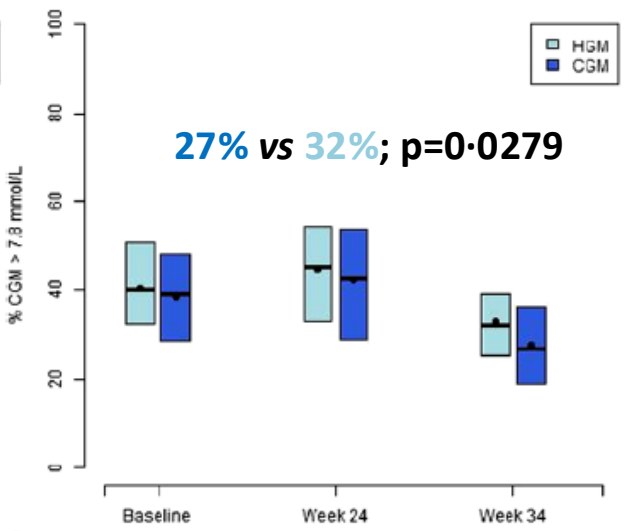
325 women with type 1 diabetes:
- 215 pregnant
- 110 planning pregnancy

→ CGM
→ SBGM

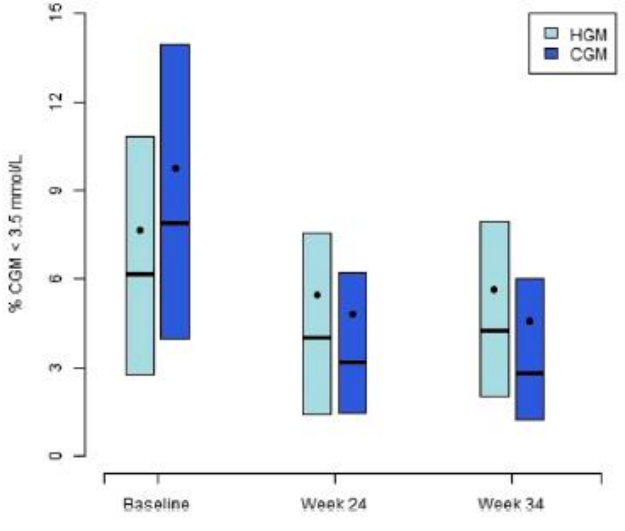
Time in range (63-140 mg/dl)



Time above range (>140 mg/dl)



Time below range (<63 mg/dl)



Feig DS. Lancet 2017; 390: 2347–59 - Murphy HR. Curr Diab Rep 2018;18(1):4

CGM in pregnant women with type 1 diabetes

The CONCEPTT study

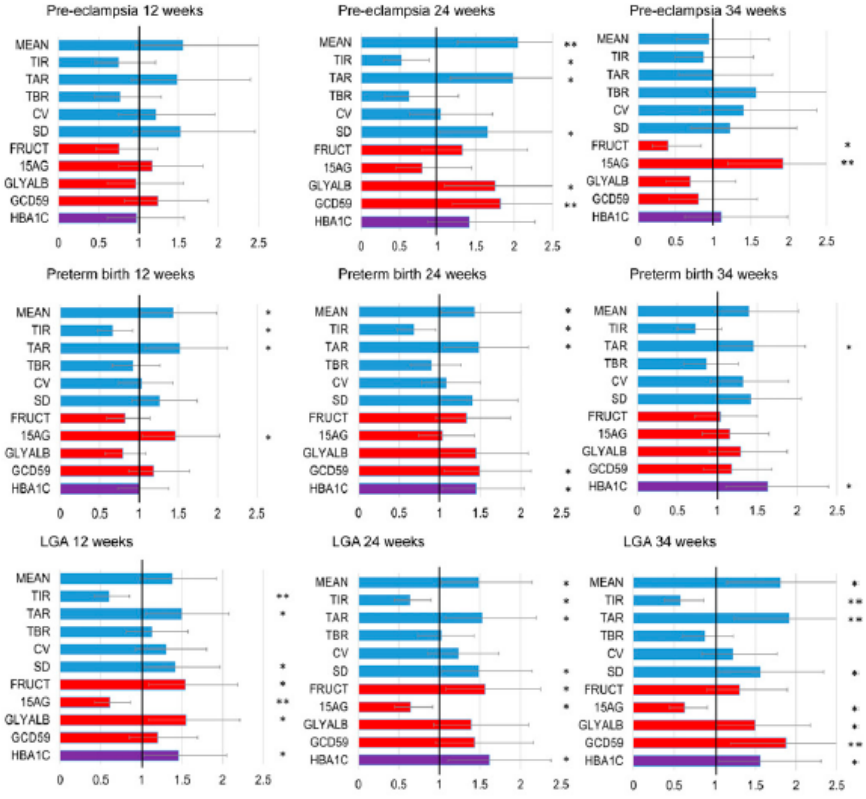
	CGM	Control	p value
Neonatal outcomes			
Preterm births			
Number assessed	100	102	..
Preterm <37 weeks	38 (38%)	43 (42%)	0·57
Early preterm <34 weeks	5 (5%)	11 (11%)	0·19
Gestational age at delivery‡	37·4 (36·7–38·1)	37·3 (36·0–38·0)	0·50
Birthweight			
Number assessed	100	100	..
Birthweight (g)	3545·4 (649·0)	3582·(777·0)	0·37
Median customised centile§	92 (68–99)	96 (84–100)	0·0489
Small for gestational age (<tenth centile)	2 (2 %)	2 (2%)	1·0
Large for gestational age (>90th centile)	53 (53%)	69 (69%)	0·0210
Extremely large for gestational age (>97·7th centile)	36 (36%)	44 (44%)	0·31
Macrosomia (≥4000 g)	23 (23%)	27 (27%)	0·62

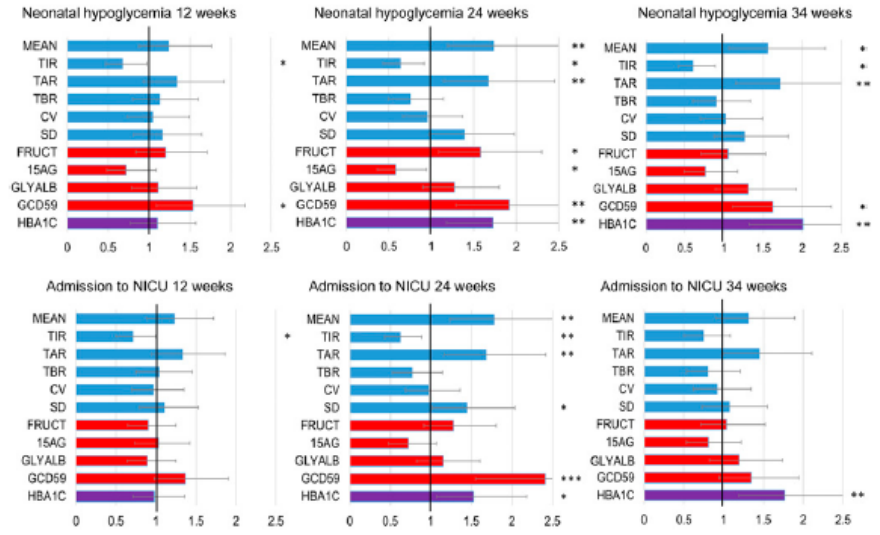
	CGM	Control	p value
Neonatal outcomes			
Neonatal complications			
Number assessed	100	100	..
Birth injury	1 (1%)	0	1·0
Shoulder dystocia	1 (1%)	0	1·0
Neonatal hypoglycaemia requiring intravenous dextrose	15 (15%)	28 (28%)	0·0250
Hyperbilirubinaemia	25 (25%)	31 (31%)	0·43
Respiratory distress	9 (9%)	9 (9%)	1·0
High-level neonatal care (NICU) >24 h	27 (27%)	43 (43%)	0·0157
Infant length of hospital stay	3·1 (2·1–5·7)	4·0 (2·4–7·0)	0·0091
Composite neonatal outcome¶	45 (42·9%)	56 (52·8%)	0·17

Feig DS. Lancet 2017; 390: 2347–59

CGM metrics in pregnant women with DMT1 and clinical outcomes

The CONCEPTT study





- ✓ HbA_{1c} is still an **important biomarker** for obstetric and neonatal outcomes in type 1 diabetes pregnancy.
- ✓ Other CGM metrics **did not** substantially increase the prediction of pregnancy outcomes compared with widely available HbA_{1c}, TIR and TAR.

Meek CL. Diabetes Care 2021;44(3):681-689

Accuracy of GMI and pregnancy outcomes in type 1 diabetes

- The CONCEPTT study -

Example:
HbA_{1c} 8.1% Conception
GMI: 8.4% 12 weeks
GMI: 7.7% 20 weeks
GMI: 7.6% 36 weeks

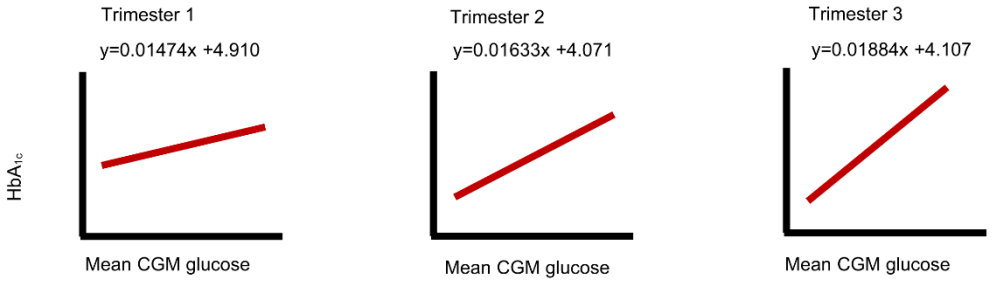
Existing evidence suggests:

50% GMI values show ≥0.5% error (bias) in HbA_{1c} assessment.

These changes may be due to chance alone.

Bias rates in pregnancy are highest in 1st and 3rd trimester.

Would pregnancy-specific equations help?
Relationship between mean CGM glucose and HbA_{1c} changes in each trimester.



Glucose monitoring options most strongly associated with outcomes in pregnancy

CGM
TIR
TAR
~~GMI~~

HbA_{1c}

GMI:
- Less accurate in pregnancy
- Many changes due to chance alone
- Offers no prognostic benefit over other options
- Potentially misleading

Meek CL. Diabetes Care 2025 Apr 2:dc242494

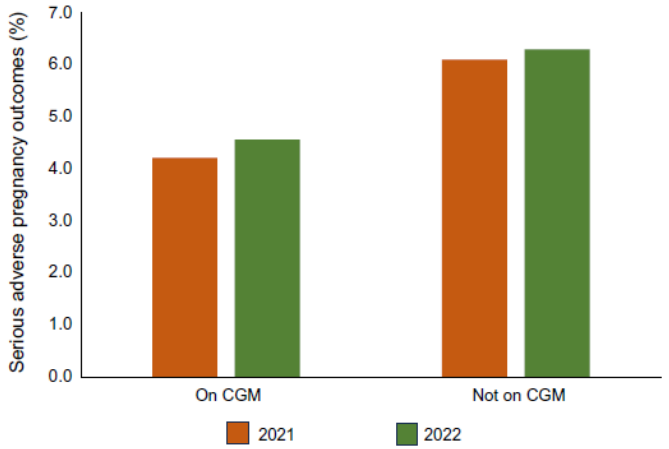
Real-world data for type 1 DM pregnancies according with CGM use in the UK

National population-based cohort study

Follow-up 2 years

2400 type 1 diabetes pregnancies using rt-CGM:
- 995 in 2021
- 1445 in 2022

Pregnancy outcomes[a]	CGM users	Non-CGM users
Target HbA_{1c} <48 mmol/mol (6.5%) during early pregnancy	25.5%	22.4%
Target HbA_{1c} <43 mmol/mol (6.1%) after 24 weeks' gestation	35.1%	25.3%
Maternal hospital admission for diabetic ketoacidosis (DKA) events	2.2%	2.9%
Preterm births <37 weeks' gestation	39.5%	43.9%
LGA babies	45.6%	53.5%
Neonatal care unit admissions	44.8%	48.5%
Major congenital anomaly	2.9%	3.8%
Perinatal deaths	1.7%	2.6%
Serious adverse pregnancy outcomes	4.4%	6.2%

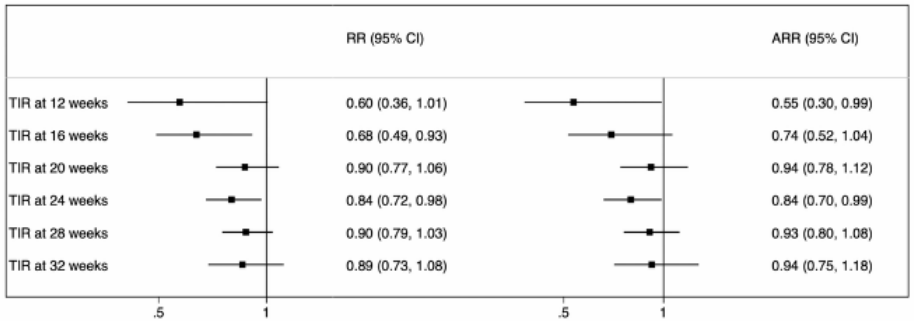


National Pregnancy in Diabetes Audit 2021 and 2022 – McLean Diabetologia 2024

CGM Metrics and Pregnancy Outcomes in women with preexisting Diabetes

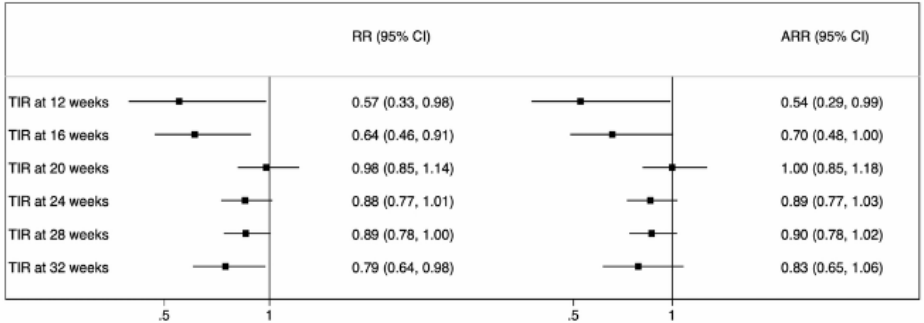
Multicenter retrospective cohort study	Since 2020 Up to 2022	91 pregnant women with type 1 diabetes using real-time CGM

Preeclampsia



Every 5% increase in TIR at 12 weeks was associated with a 45% reduction in the risk of preeclampsia.

Large for Gestational Age (LGA)



Every 5% increase in TIR at 12 weeks was associated with a 46% reduction in the risk of LGA.

Sobhani NC. Am J Obstet Gynecol 2024;231(4):467.e1-467.e8

Clinical Care/Education/Nutrition/Psychosocial Research
ORIGINAL ARTICLE

The Effect of Real-Time Continuous Glucose Monitoring in Pregnant Women With Diabetes

A randomized controlled trial

Anna L. Secher, md[1,2,3]
Lene Ringholm, md, phd[1,2]
Henrik U. Andersen, md, dmsc[4]
Peter Damm, md, dmsc[1,3,5]
Elisabeth R. Mathiesen, md, dmsc[1,2,3]

OBJECTIVE—To assess whether intermittent real-time continuous glucose monitoring (CGM) improves glycemic control and pregnancy outcome in unselected women with pregestational diabetes.

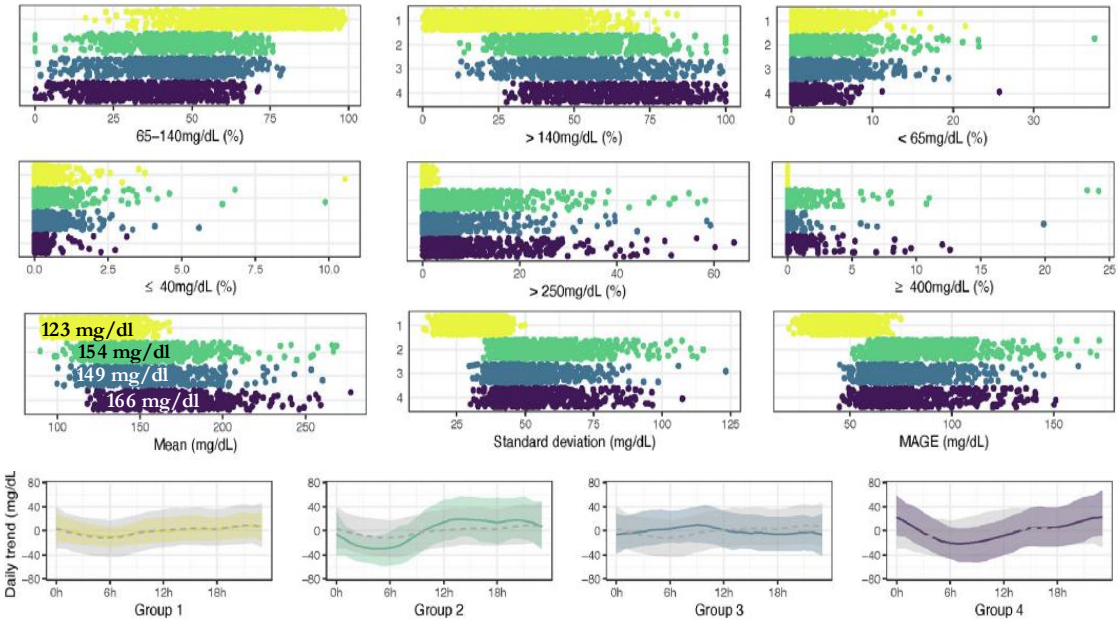
RESEARCH DESIGN AND METHODS—A total of 123 women with type 1 diabetes and 31 women with type 2 diabetes were randomized to use real-time CGM for 6 days at 8, 12, 21, 27, and 33 weeks in addition to routine care, including self-monitored plasma glucose seven times daily, or routine care only. To optimize glycemic control, real-time CGM readings were evaluated by a diabetes caregiver. HbA_{1c}, self-monitored plasma glucose, severe hypoglycemia, and pregnancy outcomes were recorded, with large-for-gestational-age infants as the primary outcome.

RESULTS—Women assigned to real-time CGM ($n = 79$) had baseline HbA_{1c} similar to that of women in the control arm ($n = 75$) (median 6.6 [range 5.3–10.0] vs. 6.8% [5.3–10.7]; $P = 0.67$) (49 [34–86] vs. 51 mmol/mol [34–93]). Forty-nine (64%) women used real-time CGM per protocol. At 33 weeks, HbA_{1c} (6.1 [5.1–7.8] vs. 6.1% [4.8–8.2]; $P = 0.39$) (43 [32–62] vs. 43 mmol/mol [29–66]) and self-monitored plasma glucose (6.2 [4.7–7.9] vs. 6.2 mmol/L [4.9–7.9]; $P = 0.64$) were comparable regardless of real-time CGM use, and a similar fraction of women had experienced severe hypoglycemia (16 vs. 16%; $P = 0.91$). The prevalence of large-for-gestational-age infants (45 vs. 34%; $P = 0.19$) and other perinatal outcomes were comparable between the arms.

CONCLUSIONS—In this randomized trial, intermittent use of real-time CGM in pregnancy, in addition to self-monitored plasma glucose seven times daily, did not improve glycemic control or pregnancy outcome in women with pregestational diabetes.

Glucose profiles identified using CGM in pre-gestational diabetes during pregnancy

Retrospective cohort study	Since January 2019 up to August 2023	175 pregnant women using CGM • Type 1 diabetes: 90 • Type 2 diabetes: 85	Glucose profiles based on weekly CGM metrics



Well controlled

Suboptimally controlled with high variability, fasting hypoglycemia, and daytime hyperglycemia

Suboptimally controlled with minimal circadian variation

Poorly controlled with peak hyperglycemia overnight

Battarbee AN. Am J Obstet Gynecol 2024;231(1):122.e1-122.e9

Glucose profiles identified using CGM and adverse pregnancy outcomes

Outcome	well controlled	suboptimally controlled with high variability	suboptimally controlled with minimal circadian variation	poorly controlled with peak hyperglycemia overnight
Preterm birth	Ref	0.97 (0.36–2.57)	2.59 (1.10–6.24)	2.18 (0.87–5.54)
Spontaneous preterm birth	Ref	0.53 (0.07–2.96)	0.53 (0.09–2.59)	0.98 (0.18–4.38)
Cesarean delivery	Ref	1.53 (0.57–4.34)	2.76 (1.09–7.46)	1.70 (0.65–4.69)
Preeclampsia	Ref	2.00 (0.77–5.28)	2.06 (0.88–4.94)	2.54 (1.02–6.52)
LGA neonate	Ref	3.34 (1.15–9.89)	1.66 (0.59–4.70)	3.72 (1.37–10.4)
Neonatal hypoglycemia	Ref	2.14 (0.80–5.90)	1.63 (0.68–4.00)	3.53 (1.37–9.71)
NICU admission	Ref	1.18 (0.44–3.19)	4.08 (1.58–11.4)	3.15 (1.20–9.09)

Battarbee AN. Am J Obstet Gynecol 2024;231(1):122.e1-122.e9

CGM in pregnant women with DMT1 and DMT2

The role and use of CGM is **well established in type 1 diabetes** also may be considered in women with T2D treated with MDI, both during pregnancy planning and during pregnancy to improve glycaemic control.

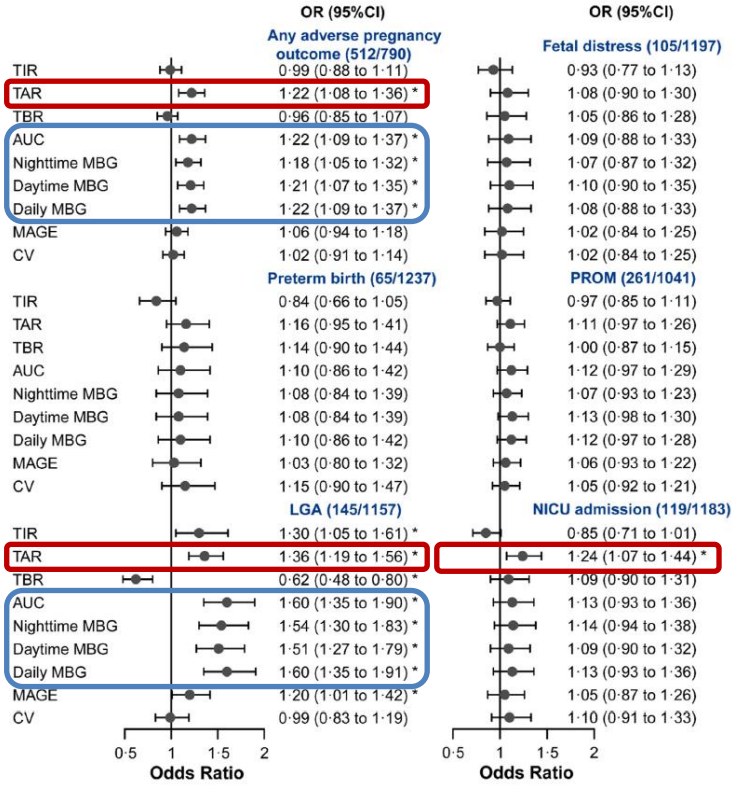
CGM may also facilitate follow-up via telemedicine where appropriate, thereby increasing patient engagement in diabetes care.

Bahrami J, Tomlinson G, Murphy HR, Feig DS. Diabet Med. 2022
Chan CB, Popeski N, Hassanabad MF, Sigal RJ, O'Connell P, Sargious P. Can J Diabetes 2021

CGM-derived glycemic metrics and adverse pregnancy outcomes among women with GDM

- Prospective cohort study
- Since August 2019 up to October 2022
- 1302 pregnant women with GDM
- CGM readings were blind to participants during wearing.

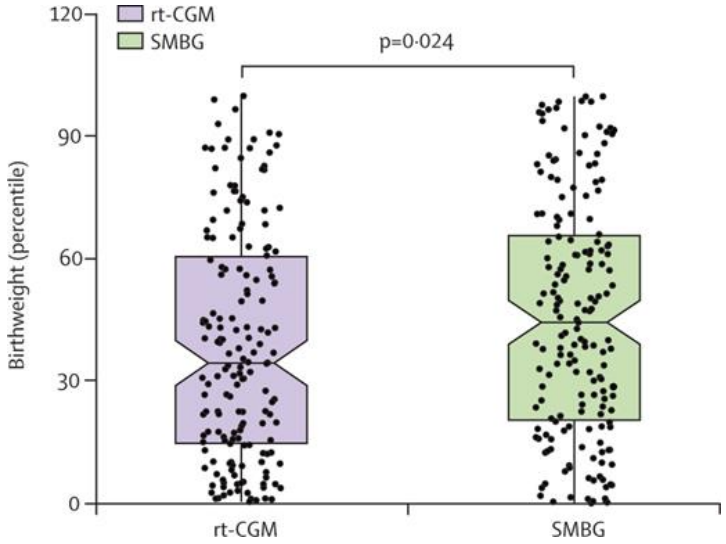
CGM-derived metrics	
TIR, %	92.8 (85.4, 96.7)
TAR, %	1.1 (0.3, 2.6)
TBR, %	4.0 (0.9, 12.3)
AUC, mmol/L·h	112.8 (105.0, 120.6)
Nighttime MBG, mmol/L	4.1 (3.7, 4.4)
Daytime MBG, mmol/L	4.9 (4.6, 5.3)
Daily MBG, mmol/L	4.7 (4.4, 5.1)
MAGE, mmol/L	2.3 (1.9, 2.7)
CV, %	20.1 (17.4, 23.0)



Liang X. The Lancet Regional Health -Western Pacific 2023;39: 100823

Glycaemic control and pregnancy outcomes with rt-CGM in GDM
The GRACE study

- Open-label, multicentre, randomised controlled study
- 375 pregnant women
  - CGM (190 pz)
  - SBGM (185 pz)
- Since August 2020 to May 2024 in Austria, Germany, Switzerland
- GDM diagnosis by OGTT after 24 weeks' gestation



- ✓ rt-CGM use in women with gestational diabetes **reduced LGA births**, without differences in serious adverse events.
- ✓ The higher-than-expected overall prevalence of SGA infants, possibly related to the tight glycaemic control in our cohort, requires further research.

Tina Linder et al. The GRACE study Lancet Diabetes Endocrinol 2025

Glycaemic control and pregnancy outcomes with real-time continuous glucose monitoring in gestational diabetes (GRACE): an open-label, multicentre, multinational, randomised controlled trial

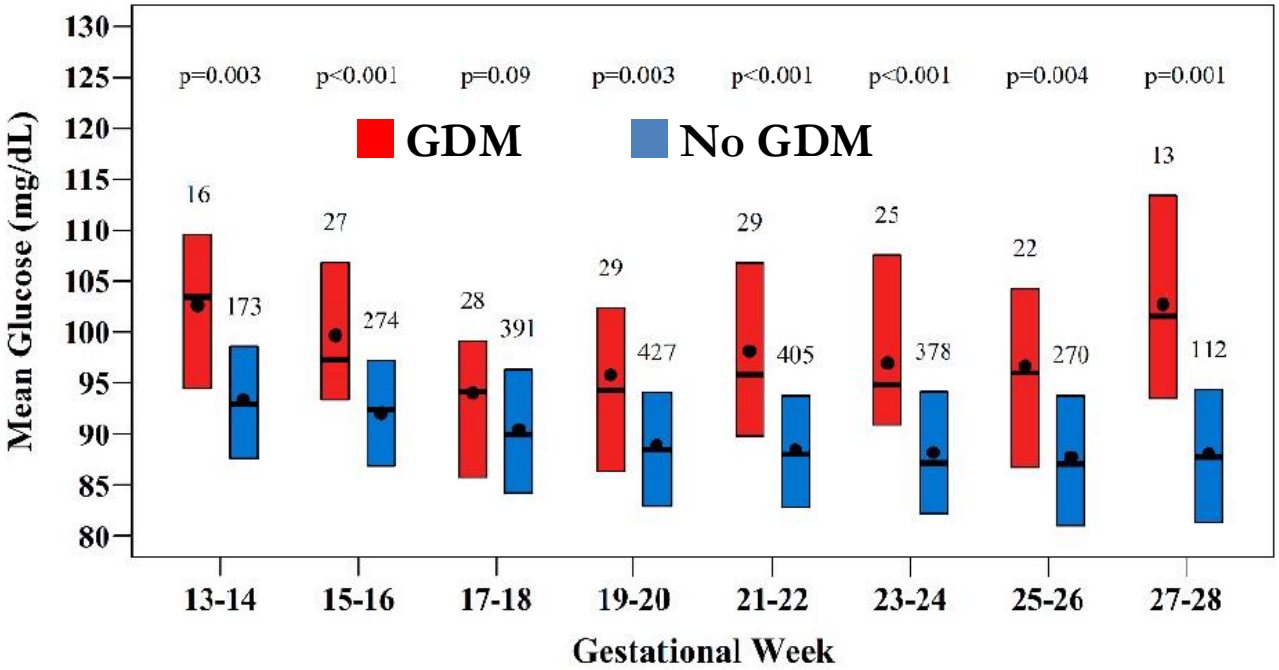
Tina Linder, Iris Dressler-Steinbach, Silke Wegener, Karen Schellong, Saskia Schmidt, Daniel Eppel, Cécile Monod, Florian Heinzl, Katharina Redling, Bettina Winzeler, Beatrice Mosimann, Friederike Weschenfelder, Tanja Groten, Martina Mittlböck, Johan Jendle, Wolfgang Henrich, Micaela Morettini, Latife Bozkurt, Andrea Tura, Christian Göbl, the GRACE study collaborative group

- …reduction in the proportion of LGA neonates might potentially be accompanied by **an increased risk of SGA**.
- Rt-CGM use also led to **increased administration of rapid-acting insulin** and modest enhancement in time in range.
- Consequently, until glycaemic targets for CGM use in gestational diabetes are better defined, **rt-CGM could be considered for selected patients under the supervision of an experienced care team**.

	n	rt-CGM	n	SMBG	p value	Effect size (95% CI)
Primary outcome						
Large for gestational age (>90th percentile)	170	6 (4%)	175	18 (10%)	0·014	0·32 (0·10 to 0·87)
Secondary obstetric outcomes						
Gestational age at delivery, weeks	170	38·9 (1·3)	175	38·8 (1·5)	0·56	0·09 (−0·21 to 0·39)
Preterm birth (<37 weeks)	170	8 (5%)	175	11 (6%)	0·52	0·74 (0·25 to 2·07)
Induction of labour	163	57 (35%)	165	45 (27%)	0·13	1·43 (0·87 to 2·36)
Caesarean section	170	77 (45%)	172	92 (53%)	0·13	0·72 (0·46 to 1·13)
Shoulder dystocia	169	0	170	0	..	..
Maternal birth injuries (all)	89	61 (69%)	75	52 (69%)	0·91	0·96 (0·47 to 1·97)
Perineal laceration >grade 2	89	1 (1%)	75	2 (3%)	0·46	0·42 (0·01 to 8·16)
Hypertensive disorder	167	8 (5%)	166	9 (5%)	0·79	0·88 (0·29 to 2·64)
Length of hospital stay, days	167	4·0 (3·0–5·0)	167	4·0 (3·1–5·0)	0·33	0·47 (0·41 to 0·53)
Secondary neonatal outcomes						
Birthweight, g	170	3242 (447)	175	3287 (483)	0·37	−45·13 (−143·72 to 53·46)
Birth length, cm	170	51·0 (2·6)	173	50·8 (3·0)	0·49	0·21 (−0·39 to 0·80)
Birthweight, customised percentile	170	38·6 (28·0)	175	45·6 (29·0)	0·024	−6·96 (−13·00 to −0·92)
Birthweight, national percentile	169	40·1 (25·9)	172	46·5 (26·8)	0·028	−6·30 (−11·92 to −0·68)
Birthweight >4000 g	170	9 (5%)	175	8 (5%)	0·76	1·17 (0·39 to 3·57)
Small for gestational age (<10th percentile)	170	33 (19%)	175	23 (13%)	0·11	1·59 (0·86 to 2·99)
Extreme small for gestational age (<5th percentile)	170	20 (12%)	175	14 (8%)	0·24	1·53 (0·71 to 3·41)
Umbilical cord pH	166	7·25 (0·07)	168	7·25 (0·08)	0·73	0·00 (−0·01 to 0·02)
Umbilical cord pH <7·2	166	34 (20%)	168	34 (20%)	0·96	1·01 (0·58 to 1·79)
Cord blood glucose, mg/dL	48	75·4 (19·3)	43	81·8 (24·2)	0·17	−6·40 (−15·61 to 2·80)
Cord blood C-peptide, pmol/L	40	1·6 (1·2)	45	1·7 (1·2)	0·64	−0·12 (−0·64 to 0·39)
Apgar score						
1 min	167	9 (9–9)	168	9 (9–9)	0·39	0·52 (0·47 to 0·57)
5 min	168	10 (10–10)	171	10 (9–10)	0·13	0·54 (0·49 to 0·58)
10 min	168	10 (10–10)	171	10 (10–10)	0·19	0·52 (0·49 to 0·56)
Newborn glucose, mg/dL	154	58 (15)	152	59 (15)	0·42	−1·39 (−4·77 to 2·00)
Newborn hypoglycaemia	153	5 (3%)	152	2 (1%)	0·26	2·51 (0·40 to 26·75)
NICU admission	170	6 (4%)	172	14 (8%)	0·07	0·41 (0·13 to 1·18)
NICU length of stay, days	6	4·0 (2·3–8·0)	14	4·5 (1·3–8·3)	0·85	0·53 (0·19 to 0·87)
Newborn jaundice	166	4 (2%)	170	2 (1%)	0·39	2·07 (0·29 to 23·17)
Stillbirth	170	0	175	0	..	..
Further secondary outcomes						
Large for gestational age (according to national percentile)	169	5 (3%)	172	9 (5%)	0·29	0·55 (0·14 to 1·88)
Small for gestational age (according to national percentile)	169	19 (11%)	172	18 (10%)	0·82	1·08 (0·52 to 2·28)
Maternal weight gain, kg*	155	10·8 (5·8)	150	10·3 (5·4)	0·42	0·51 (−0·74 to 1·77)
HbA_{1c} at 36^{+0} to 38^{+6} weeks, %	132	5·3 (0·4)	130	5·3 (0·3)	0·70	0·02 (−0·07 to 0·11)
HbA_{1c} at 36^{+0} to 38^{+6} weeks, mmol/mol	132	34·4 (4·4)	130	34·2 (3·8)	0·70	0·19 (−0·81 to 1·19)

CGM metrics in early pregnancy and risk of GDM
The GLAM study

- Prospective cohort study
- 768 pregnant women <17 gestational week
- Participants wore a CGM as much as tolerated across gestation
- GDM diagnosis by OGTT after 24 weeks' gestation



Durnwald C. Diabetes Care 2024;47:1333–1341

CGM in pregnant women with GDM

Current evidence is ***insufficient*** to recommend CGM routine use for clinical and diagnostic purposes (detecting early gestational diabetes and predicting the development of GDM). However, the use of CGM could be considered for women with **GDM on insulin therapy** to achieve better glycaemic control and improve certain outcomes.

Glycemic targets

- psTIR (63–140 mg/dL): ≥90%.
- psTAR (>140 mg/dL): <5%.
- psTBR (<63 mg/dL): <4%.
- psTBR (<54 mg/dL): <1%.

Resi V. et al Acta diabetologica 2025
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What about the Guidelies?

Guideline	T1D in Pregnancy	T2D in Pregnancy/GDM
Canada 2018	Recommended to improve glycaemic and neonatal outcomes	No indication
Italy AMD/SID 2018	rt-CGM recommended + SMBG	No indication
UK ABCD-DTN / NICE 2015–2020	rt-CGM for all; isCGM if rt-CGM not accepted	No indication
AACE (US) 2021	Recommended for T1D on intensive insulin therapy	Recommended only for T2D on intensive insulin therapy
ADA 2025	CGM + SMBG recommended to reduce LGA + neonatal hypoglycaemia	No indication
Endocrine Society / ESE 2025	No specific indication	CGM or SBGM may be used in T2D

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Clinical Practice Guideline

Preexisting Diabetes and Pregnancy: An Endocrine Society and European Society of Endocrinology Joint Clinical Practice Guideline

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Importantly, the guideline does not support **simplifying glucose targets to a single 24-h CGM target of < 140 mg/dL**; rather, it recommends maintaining the standard pregnancy glucose targets based on fasting and post-prandial values:

- fasting < 95 mg/dL
- 1-h post-meal < 140 mg/dL
- 2-h post-meal < 120 mg/dL

Conclusions

- SBGM has been the gold standard for blood glucose monitoring in pregnancy for many years and remains an excellent solution for patients managed on diet alone.
- CGM is now a cornerstone of care in type 1 diabetes during pregnancy and has a growing role in type 2 diabetes and gestational diabetes mellitus (GDM).
- Realtime CGM (rtCGM) offers greater benefit than intermittent scanning (isCGM), particularly for insulin-treated patients.
- Pregnancy-specific glycaemic targets remain difficult to achieve, particularly fasting and postprandial goals.
- Moreover, CGM-derived metrics may be useful in early pregnancy for predicting GDM.
- RCTs to further define glycemic targets in pregnancy and refinement of emerging technology to achieve those targets can lead to significant reduction of harm and in the burden of diabetes care

Grazie per l'ascolto!