SID 60 Società Italiana di Diabetologia 1964-2024

SLOG

DIABETES PREGNANCY and TECHNOLOGY in Lombardy - 2024

SESSIONE 4: LA GRAVIDANZA E' SEMPRE PIU' TECNOLOGIA

IL MONITORAGGIO GLICEMICO IN CONTINUO

Dott.ssa Elisabetta Lovati
Resp. Ambulatorio Diabetologia
Fond. IRCCS Policlinico San Matteo di Pavia

8 GIUGNO 2024 - BERGAMO - OSPEDALE PAPA GIOVANNI XXIII

Il /la dr./sa Lovati Elisabetta dichiara di NON aver ricevuto negli ultimi due anni compensi o finanziamenti da Aziende Farmaceutiche e/o Diagnostiche

Dichiara altresì il proprio impegno ad astenersi, nell'ambito dell'evento, dal nominare, in qualsivoglia modo o forma, aziende farmaceutiche e/o denominazione commerciale e di non fare pubblicità di qualsiasi tipo relativamente a specifici prodotti di interesse sanitario (farmaci, strumenti, dispositivi medico-chirurgici, ecc.).

IL 12% DELLE GRAVIDANZE E’ COMPLICATO DA UNA FORMA DI IPERGLICEMIA

MACROSOMIA E LGA SONO LE COMPLICANZE MAGGIORMENTE RAPPRESENTATE NELLA GRAVIDANZA CON DIABETE

CLINICAL RESEARCH ARTICLE

Association Between Maternal Normal Range HbA1c Values and Adverse Birth Outcomes

Jianing Bi,[1] Cunwei Ji,[2] Yuntao Wu,[2] Mingyang Wu,[1] Yunyun Liu,[1] Lulu Song,[1] Shikha Upadhyaya Khatiwada,[1] Senbei Yang,[1] Bing Li,[2,*] Youjie Wang,[1] and Li Wu[2,*]

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2023
023.110589

International Journal of Epidemiology, 2022, 759–768
https://doi.org/10.1093/ije/dyab270
Advance Access Publication Date: 5 January 2022
Original article

IEA International Epidemiological Association

OXFORD

Prenatal Exposures

Glycated haemoglobin (HbA1c) in mid-pregnancy and perinatal outcomes

Ellen Ø Carlsen,[1,2] Quaker Harmon ,[3] Maria C Magnus,[1,4,5] Helle M Meltzer,[6] Iris Erlund,[7] Lars C Stene,[8] Siri E Håberg ,[1]* Allen J Wilcox[3]

Hong et al. BMC Pregnancy and Childbirth (2022) 22:679
https://doi.org/10.1186/s12884-022-05000-7

BMC Pregnancy and Childbirth

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The association between maternal HbA1c and adverse outcomes in gestational diabetes

Marie Parfaite Uwimana Muhuza[1†], Lixia Zhang[1†], Qi Wu[1], Lu Qi[2], Danqing Chen[1] and Zhaoxia Liang[1,2*]

The Journal of Clinical Endocrinology & Metabolism, 2022, Vol. 107, No. 3, e1117–e1125
https://doi.org/10.1210/clinem/dgab769
Clinical Research Article

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HbA1c at term delivery and adverse pregnancy outcome

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Cc Jesrine Gek Shan Hong, Mohd Yahaya Noor Fadzleeyanna, Siti Zawiah Omar and Peng Chiong Tan*

Epub 2018 Nov 30.

Clinical Research Article

Association Between HbA1c Levels on Adverse Pregnancy Outcomes During Pregnancy in Patients With Type 1 Diabetes

Madleen Lemaitre,[1,2] Camille Ternynck,[3,4] Julien Bourry,[1,2] Florence Baudoux,[1] Damien Subtil,[2,5] and Anne Vambergue[1,2,6]

Early Pregnancy Hemoglobin A1C and Pregnancy Outcomes: A Population-Based Study

Lu Chen [1], Gaia Pocobelli [1], Onchee Yu [1], Susan M Shortreed [1 2], Sarah S Osmundson [3], Sharon Fuller [1], Paige D Wartko [1 2], David Mcculloch [4], Susan Warwick [4], Katherine M Newton [1], Sascha Dublin [1 2]

Epidemiology/Health Services/Psychosocial Research
ORIGINAL ARTICLE

Outcomes in Type 1 Diabetic Pregnancies

A nationwide, population-based study

Dorte M. Jensen, phd[1]
Peter Damm, dmsc[2]
Lars Moelsted-Pedersen, dmsc[3]
Per Ovesen, dmsc[4]
Jes G. Westergaard, dmsc[5]
Margrethe Moeller, md[6]
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Cite this article as: BMJ, doi:10.1136/bmj.38856.692986.AE (published 16 June 2006)

Research

BMJ

Perinatal mortality and congenital anomalies in babies of women with type 1 or type 2 diabetes in England, Wales, and Northern Ireland: population based study

Mary C M Macintosh, Kate M Fleming, Jaron A Bailey, Pat Doyle, Jo Modder, Dominique Acolet, Shona Golightly, Alison Miller

Articles

Diabetologia (2002) 45:1484–1489
DOI 10.1007/s00125-002-0958-7

Macrosomia despite good glycaemic control in Type I diabetic pregnancy; results of a nationwide study in The Netherlands

I. M. Evers[1], H. W. de Valk[2], B. W. J. Mol[1], E. W. M. T. ter Braak[2], G. H. A. Visser[1]

[1] Department of Obstetrics, [2] Department of Internal Medicine and Endocrinology, University Medical Centre, Utrecht, The Netherlands

Glycaemic control during pregnancy. Second and third trimester HbA_{1c} and mean HbA_{1c} during pregnancy were higher in the women with a macrosomic infant. Glycaemic control was excellent (i.e. within the non-diabetic range) in 40%, good in 44% and not optimal in 16% of the pregnancies. In 79% of the pregnancies with a macrosomic infant and in 89% of the pregnancies with a non-macrosomic infant glycaemic control was excellent or good (p=0.03). Mean HbA_{1c} early in pregnancy measured in a central laboratory, was higher in the women with a macrosomic infant (6.8±0.7% vs 6.5±0.7%; p=0.01).

Analysis of Continuous Glucose Monitoring in Pregnant Women With Diabetes: Distinct Temporal Patterns of Glucose Associated With Large-for-Gestational-Age Infants

Graham R. Law,[1] George T.H. Ellison,[1] Anna L. Secher,[2] Peter Damm,[2] Elisabeth R. Mathiesen,[2] Rosemary Temple,[3] Helen R. Murphy,[4] and Eleanor M. Scott[1]

Diabetes Care 2015;38:1

Table 1—Number of women available in the analysis and number of measurements in the study

	England	Denmark	Total
Number of women in analysis			
Eligible	61	71	132
Excluded	12	3	15
Included	49	68	117
Type 1 diabetes	35	54	89
Type 2 diabetes	14	14	28
Trimester 1	31	64	95
Trimester 2	44	52	96
Trimester 3	30	50	80
LGA infant	23/49 (46.9%)	31/68 (45.6%)	54/117 (46.1%)
Number of measurements	256,640	1,423,706	1,680,346
Number of measurement episodes	171	588	759

were clinically well controlled, and there was no significant difference in mean HbA_{1c} levels among mothers with LGA infants (46 mmol/mol [95% CI 44–48]) and

Table 2—Comparison of standard summary measures of CGM data among women who delivered LGA infants and those who did not, by trimester

	Trimester 1			Trimester 2			Trimester 3		
	LGA	No LGA	Student *t* test[1]	LGA	No LGA	Student *t* test[1]	LGA	No LGA	St *t*
	Mean (SD)	Mean (SD)	t^2, *P*	Mean (SD)	Mean (SD)	t^3, *P*	Mean (SD)	Mean (SD)	t^4, *P*
Mean glucose (mmol/L)	**7.0 (1.8)**	**7.1 (2.1)**	**16.21, <0.01**	**7.0 (1.8)**	**6.7 (1.8)**	**27.43, <0.001**	**6.5 (1.6)**	**6.4 (1.7)**	**10.61, <0.01**
Proportion of time									
In target[5]	0.63 (0.1)	0.64 (0.2)	0.75, 0.46	**0.63 (0.1)**	**0.71 (0.2)**	**−3.17, <0.01**	0.69 (0.1)	0.73 (0.1)	−1.15, 0.25
Below target[5]	0.04 (0.0)	0.05 (0.0)	0.80, 0.43	0.06 (0.1)	0.05 (0.1)	0.12, 0.91	0.07 (0.1)	0.06 (0.1)	0.18, 0.86
Above target[5]	0.33 (0.1)	0.32 (0.2)	0.41, 0.68	**0.33 (0.1)**	**0.25 (0.2)**	**3.13, <0.01**	0.25 (0.1)	0.22 (0.1)	0.80, 0.43
Area under the curve (mmol/L per 5 min)									
>7.8 mmol/L	21,298 (14,599)	22,288 (16,761)	1.04, 0.30	**25,204 (19,303)**	**20,382 (16,360)**	**2.34, 0.02**	16,765 (11,822)	14,770 (12,174)	1.26, 0.21
>6.7 mmol/L	27,038 (16,348)	27,980 (17,430)	0.90, 0.37	**32,085 (20,748)**	**26,122 (17,347)**	**2.56, 0.01**	23,321 (14,017)	20,613 (18,136)	1.47, 0.14
<3.5 mmol/L	21,513 (8,127)	22,025 (8,728)	0.52, 0.60	23,810 (8,151)	23,527 (7,768)	0.29, 0.77	21,848 (7,727)	22,525 (8,539)	−0.15, 0.88
<2.8 mmol/L	17,346 (6,553)	17,735 (7,052)	0.50, 0.62	19,174 (6,541)	18,957 (6,270)	0.09, 0.93	17,623 (6,222)	18,179 (6,907)	−0.15, 0.88
SD (mmol/L)	**2.4 (0.7)**	**2.6 (1.0)**	**2.84, <0.01**	2.4 (0.8)	2.4 (0.9)	0.71, 0.48	2.2 (0.6)	2.1 (0.6)	1.00, 0.32
M-value	2,193.5 (401.4)	2,257.2 (384.8)	1.72, 0.09	**2,246.7 (348.9)**	**2,114.7 (352.5)**	**2.83, <0.01**	2,094.1 (276.2)	2,013.2 (375.5)	1.28, 0.23
LI	**1.4 (0.7)**	**1.9 (1.7)**	**3.16, <0.01**	1.5 (1.0)	1.4 (1.0)	1.26, 0.21	**1.3 (1.1)**	**1.0 (0.6)**	**2.88, <0.01**
J-index	**29.2 (8.5)**	**32.4 (15.2)**	**2.65, <0.01**	29.9 (11.4)	27.7 (11.6)	1.88, 0.06	25.0 (7.5)	23.8 (9.0)	0.94, 0.35
ADRR RLBG	1.6 (0.4)	1.5 (0.3)	−0.39, 0.70	1.6 (0.4)	1.6 (0.3)	0.34, 0.73	1.6 (0.3)	1.6 (0.3)	0.80, 0.43
ADRR RHBG	1.6 (0.4)	1.7 (0.5)	1.95, 0.05	1.6 (0.4)	1.5 (0.5)	0.65, 0.52	1.5 (0.4)	1.4 (0.4)	1.21, 0.23
MAGE+	**3.5 (1.4)**	**4.3 (2.7)**	**2.47, 0.02**	3.6 (1.6)	3.4 (1.7)	0.25, 0.81	3.3 (1.4)	2.9 (1.1)	1.14, 0.26
MAGE−	3.9 (1.9)	3.5 (1.7)	0.28, 0.78	3.5 (1.5)	3.9 (2.6)	−1.69, 0.09	3.7 (2.0)	3.0 (1.1)	1.86, 0.07
GRADE	3.9 (2.1)	3.9 (2.8)	0.59, 0.56	**3.8 (2.3)**	**3.3 (2.4)**	**2.78, <0.01**	2.9 (1.4)	2.8 (1.4)	0.58, 0.56
MAG	2.4 (0.7)	3.5 (6.0)	2.02, 0.05	**2.5 (0.8)**	**2.4 (0.9)**	**3.16, <0.01**	2.2 (0.8)	2.1 (0.7)	1.91, 0.06

[1]Comparing the difference in means to zero using a Student *t* test reporting the *t* value, and *P* value (boldface text indicates $P < 0.05$). Model adjusted for study and type of diabetes. [2]209 degrees of freedom. [3]297 degrees of freedom. [4]241 degrees of freedom. [5]3.5–7.8 mmol/L.

Analysis of Continuous Glucose Monitoring in Pregnant Women With Diabetes: Distinct Temporal Patterns of Glucose Associated With Large-for-Gestational-Age Infants

Graham R. Law,[1] George T.H. Ellison,[1] Anna L. Secher,[2] Peter Damm,[2] Elisabeth R. Mathiesen,[2] Rosemary Temple,[3] Helen R. Murphy,[4] and Eleanor M. Scott[1]

Diabetes Care 2015;38:1319–1325 | DOI: 10.2337/dc15-0070

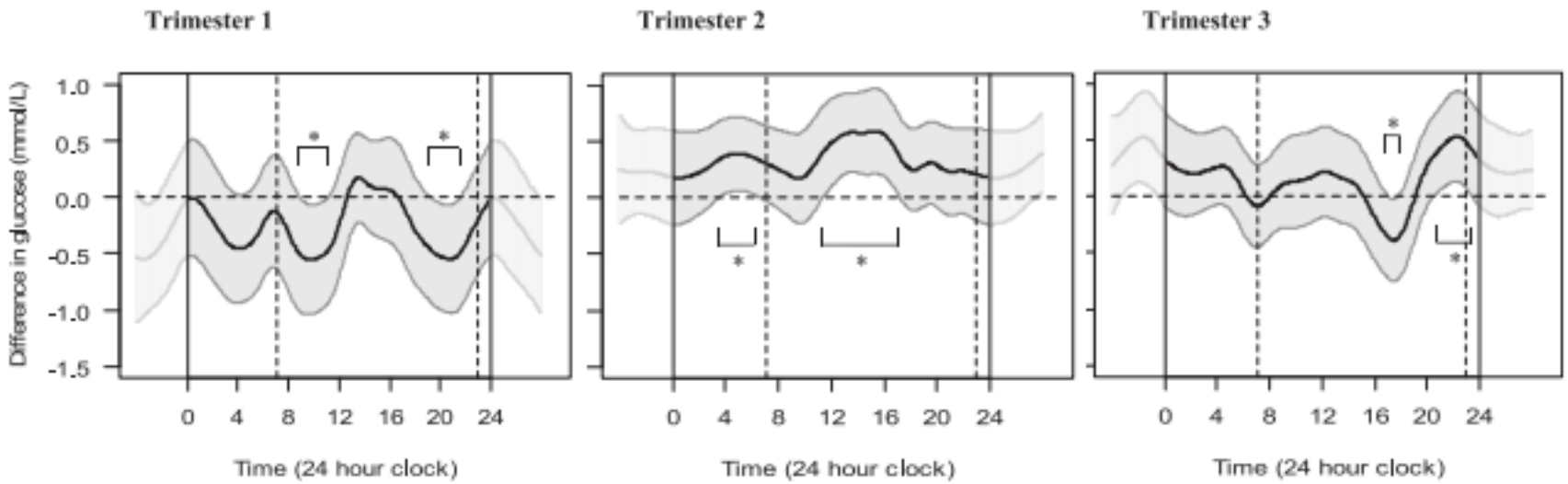


Figure 1—Difference in glucose levels between non-LGA (represented by the horizontal zero level) and LGA (dark line) with 95% pointwise CIs (gray section) (significant differences, using 95% CIs, are highlighted by *) stratified by trimester from the regression model (adjusted for study and type of diabetes). Dashed vertical lines represent 0700 h and 2300 h.

Diabetologia (2019) 62:1143–1153
https://doi.org/10.1007/s00125-019-4850-0

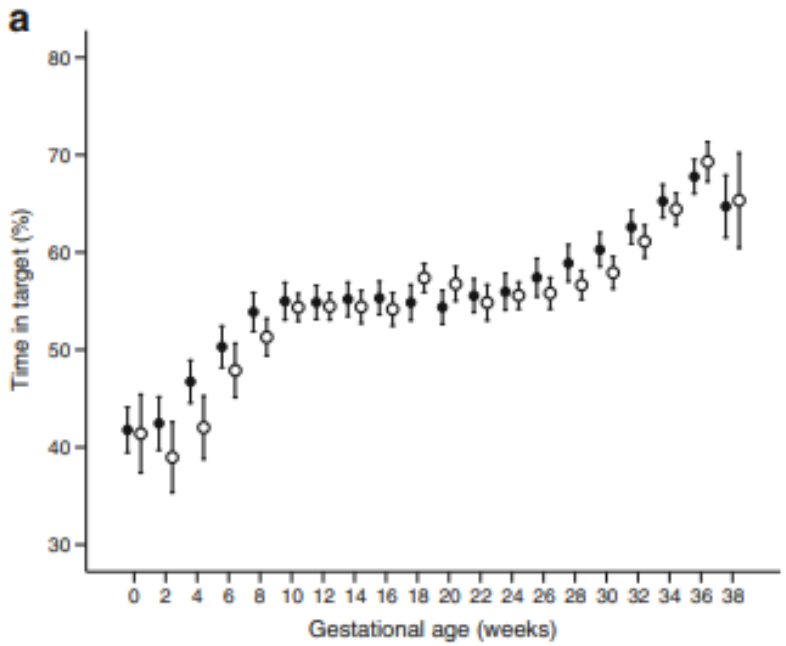
ARTICLE

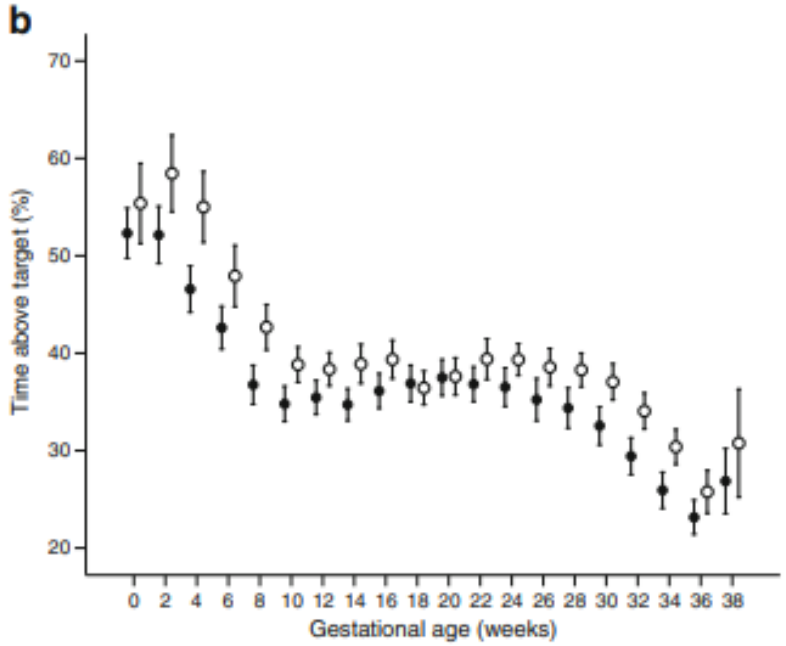
Continuous glucose monitoring in pregnant women with type 1 diabetes: an observational cohort study of 186 pregnancies

Karl Kristensen[1,2,3] · Linda E. Ögge[4,5] · Verena Sengpiel[4,5] · Karin Kjölhede[4,5] · Annika Dotevall[5,6] · Anders Elfvin[5,7] · Filip K. Knop[8,9] · Nana Wiberg[1,3] · Anastasia Katsarou[10,11] · Nael Shaat[10,11] · Lars Kristensen[2] · Kerstin Berntorp[10,11]

Outcome	Total cohort (n = 186)	rtCGM (n = 92)	iCGM (n = 94)	*p* value
Pre-eclampsia/PIH	34 (18)	15 (16)	19 (20)	0.47
Caesarean section	87 (47)	46 (50)	41 (44)	0.38
Gestational age (weeks)	38 (27–40)	38 (27–40)	38 (29–40)	0.47
Preterm birth (<37 weeks)	52 (28)	24 (26)	28 (30)	0.57
Female infant	87 (47)	48 (52)	39 (41)	0.14
Birthweight, g	3823 ± 711	3812 ± 678	3834 ± 747	0.84
LGA infant	98 (53)	48 (52)	50 (53)	0.89
Macrosomia (>4500 g)	30 (16)	14 (15)	16 (17)	0.74
5 min Apgar score <7	6 (3)	1 (1)	5 (5)	–
Shoulder dystocia	5 (3)	3 (3)	2 (2)	–
Neonatal hypoglycaemia[a]	45 (24)	19 (21)	26 (28)	0.27
NICU admission >24 h	60 (32)	27 (29)	33 (35)	0.40
NCO[b]	83 (45)	37 (40)	46 (49)	0.23

Results are given as *n* (%), mean ± SD or median (range)





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ARTICLE

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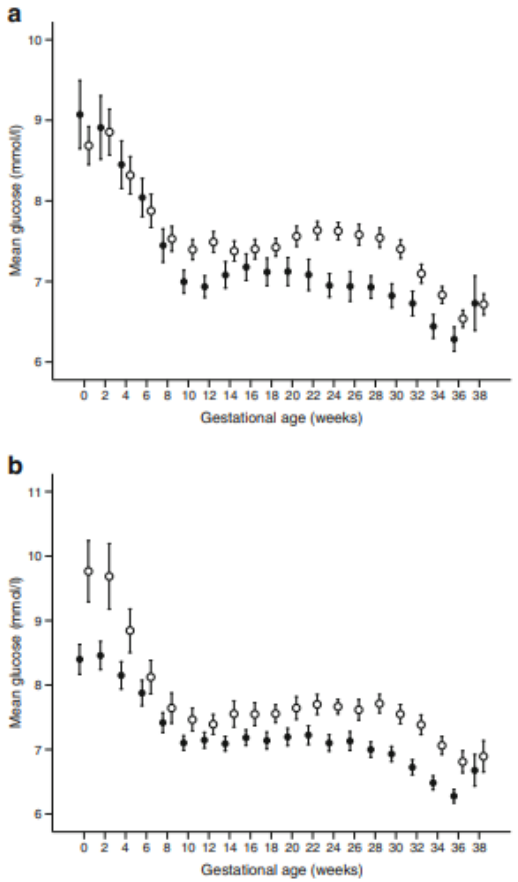

Fig. 2 (a) Mean ± SEM of interstitial glucose levels during pregnancy in women with (white) and without (black) fetal overgrowth (LGA). (b) Mean ± SEM of interstitial glucose levels during pregnancy in women with (white) and without (black) short-term neonatal complications

LGA

NEONATAL COMPLICATIONS

Table 3 Results of the binary logistic regression analysis of variables tested for associations with LGA

Variable	All (n = 186)	LGA (n = 98)	No LGA (n = 88)	Crude data		Adjusted data	
				OR (95% CI)	*p* value	OR (95% CI)	*p* value
Trimester 1 (*n* = 155)							
HbA$_{1c}$, mmol/mol[a]	52.4 ± 10.5	54.1 ± 1.0	50.4 ± 9.5	1.04 (1.00, 1.07)	0.03	1.04 (1.00, 1.08)	0.02*
HbA$_{1c}$, %	6.9 ± 1.0	7.1 ± 1.0	6.8 ± 0.9				
Mean glucose, mmol/l	7.8 ± 1.4	7.9 ± 1.3	7.7 ± 1.5	1.12 (0.88, 1.41)	0.35	1.16 (0.91, 1.49)	0.24
SD, mmol/l	3.2 ± 0.9	3.2 ± 0.8	3.2 ± 0.9	1.07 (0.74, 1.55)	0.71	1.09 (0.73, 1.62)	0.67
CV%	40.5 ± 7.2	40.5 ± 7.2	40.6 ± 7.3	1.00 (0.95, 1.04)	0.90	0.99 (0.95, 1.04)	0.77
Time in target, %[a]	50.0 ± 14.1	48.2 ± 13.6	51.9 ± 14.5	0.98 (0.96, 1.00)	0.10	0.98 (0.95, 1.00)	0.07
Time above target, %	43.0 ± 15.5	44.8 ± 14.6	40.9 ± 16.3	1.02 (0.99, 1.04)	0.11	1.02 (1.00, 1.04)	0.07
Time below target, %	7.0 ± 5.0	7.0 ± 5.1	7.2 ± 5.0	0.99 (0.93, 1.06)	0.81	0.98 (0.92, 1.05)	0.60
MAGE	7.7 ± 2.0	7.8 ± 1.8	7.5 ± 2.1	1.08 (0.92, 1.27)	0.37	1.09 (0.92, 1.30)	0.33
HBGI	5.5 ± 3.7	5.6 ± 3.4	5.3 ± 4.1	1.02 (0.94, 1.11)	0.60	1.04 (0.94, 1.13)	0.46
LBGI	2.6 ± 1.6	2.6 ± 1.6	2.7 ± 1.6	0.97 (0.79, 1.18)	0.74	0.94 (0.76, 1.16)	0.54
Trimester 2 (*n* = 165)							
HbA$_{1c}$, mmol/mol	45.2 ± 7.9	46.4 ± 7.4	43.7 ± 8.3	1.05 (1.00–1.09)	0.03	1.05 (1.01–1.10)	0.02*
HbA$_{1c}$, %	6.3 ± 0.7	6.4 ± 0.7	6.1 ± 0.8)				
Mean glucose, mmol/l	7.4 ± 1.2	7.6 ± 1.0	7.1 ± 1.3	1.48 (1.10, 1.98)	<0.01	1.53 (1.12, 2.08)	<0.001*
SD, mmol/l	2.8 ± 0.7	2.9 ± 0.6	2.7 ± 0.7	1.58 (0.98, 2.56)	0.06	1.65 (1.00, 2.74)	<0.05*
CV%	37.7 ± 6.3	37.8 ± 5.9	37.7 ± 6.7	1.00 (0.95, 1.05)	0.92	1.00 (0.95, 1.06)	0.93
Time in target, %[a]	54.7 ± 13.7	51.8 ± 12.3	57.9 ± 14.4	0.96 (0.94, 0.99)	<0.01	0.96 (0.94, 0.99)	<0.01*
Time above target, %	38.1 ± 14.9	41.9 ± 12.8	34.0 ± 15.9	1.04 (1.02, 1.06)	<0.001	1.04 (1.02, 1.07)	<0.001*
Time below target, %	7.2 ± 5.1	6.4 ± 4.5	8.0 ± 5.7	0.94 (0.88, 0.99)	0.04	0.93 (0.87, 0.99)	0.02*
MAGE	6.8 ± 1.5	7.0 ± 1.4	6.6 ± 1.6	1.21 (0.98, 1.48)	0.07	1.22 (0.98, 1.52)	0.06
HBGI	4.0 ± 2.9	4.4 ± 2.4	3.6 ± 3.3	1.11 (0.98, 1.24)	0.08	1.12 (0.99, 1.26)	0.07
LBGI	2.7 ± 1.6	2.4 ± 1.4	3.0 ± 1.8	0.80 (0.66, 0.97)	0.02	0.77 (0.62, 0.94)	0.01*
Trimester 3 (*n* = 167)							
HbA$_{1c}$, mmol/mol	45.7 ± 7.6	47.2 ± 6.7	44.0 ± 8.2	1.06 (1.02, 1.11)	<0.01	1.06 (1.02, 1.11)	<0.01*
HbA$_{1c}$, %	6.3 ± 0.7	6.5 ± 0.6	6.2 ± 0.8				
Mean glucose, mmol/l	7.1 ± 1.1	7.3 ± 1.1	6.8 ± 1.1	1.57 (1.13, 2.16)	<0.01	1.57 (1.12, 2.19)	<0.001*
SD, mmol/l	2.6 ± 0.6	2.6 ± 0.6	2.5 ± 0.6	1.58 (0.93, 2.68)	0.08	1.60 (0.92, 2.77)	0.09
CV%	36.0 ± 5.8	35.9 ± 5.5	36.1 ± 6.2	0.99 (0.94, 1.05)	0.83	0.99 (0.94, 1.05)	0.84
Time in target, %[a]	59.8 ± 13.3	57.6 ± 12.8	62.2 ± 13.4	0.97 (0.95, 1.00)	0.02	0.97 (0.95, 1.00)	0.04*
Time above target, %	33.7 ± 14.8	37.0 ± 13.5	30.2 ± 15.3	1.03 (1.01, 1.06)	<0.01	1.03 (1.01, 1.06)	<0.01*
Time below target, %	6.5 ± 5.6	5.4 ± 4.4	7.6 ± 6.4	0.93 (0.87, 0.98)	<0.01	0.92 (0.86, 0.98)	<0.01*
MAGE	6.2 ± 1.4	6.3 ± 1.4	6.0 ± 1.5	1.16 (0.93, 1.44)	0.18	1.16 (0.92, 1.45)	0.20
HBGI	3.3 ± 2.5	3.6 ± 2.7	2.9 ± 2.3	1.15 (1.00, 1.34)	0.04	1.15 (1.00, 1.34)	0.05
LBGI	2.6 ± 1.7	2.3 ± 1.4	2.9 ± 1.9	0.78 (0.63, 0.94)	<0.01	0.76 (0.61, 0.94)	<0.01*

Results are given as mean ± SD

Received: 18 February 2018 | Revised: 22 March 2018 | Accepted: 25 March 2018
DOI: 10.1111/dom.13310

WILEY

ORIGINAL ARTICLE

Continuous glucose monitoring during diabetic pregnancy (GlucoMOMS): A multicentre randomized controlled trial

Daphne N. Voormolen PhD[1] | J. Hans DeVries PhD[2] | Rieneke M. E. Sanson PhD[3] |

TABLE 1 Baseline characteristics

	CGM (n = 147)	Standard treatment (n = 153)
Age (y)	33 (29-36)	32 (29-36)
Gestational age (d)	173 (109-198)	170 (86-197)
Type 1 diabetes Type 2 diabetes Gestational diabetes	50 (34.0) 40 (27.2) 54 (36.7)	56 (36.6) 41 (26.8) 54 (35.8)
Duration of diabetes (y)[a]	6 (2-13)	5 (3-12)
Preconception HbA1c (mmol/mol)[a]	51 (42-57)	53 (46-61)
Microvascular complication	11 (7.5)	11 (7.2)
Insulin pump	28 (19.0)	27 (17.6)
Gestational age of diagnosis[b] (d)	144 (104-170)	143 (100-176)
Body mass index (kg/m^2)	28 (24-34)	29 (25-34)
Ethnicity White European	95 (64.6)	97 (63.4)
Primiparous	61 (41.5)	59 (38.6)
Folic acid use	69 (46.9)	77 (50.3)

Data are presented as median (IQR) or n (%)

	CGM (n = 143)	Standard treatment (n = 147)	RR, HR (95% CI)
Primary outcome			
Macrosomia, n (%)	44 (31.0)	42 (28.4)	RR 1.08 (0.76-1.54)
Maternal outcomes			
Severe glycaemic dysregulation, n (%)	6 (4.2)	3 (2.0)	RR 2.06 (0.52-8.06)
Pregnancy induced hypertension, n (%)	18 (12.3)	27 (18.4)	RR 0.72 (0.42-1.24)
Preeclampsia, n (%)	5 (3.5)	17 (11.6)	RR 0.30 (0.12-0.80)
HELLP syndrome, n (%)	0	4 (2.7)	RR 0.11 (0.01-1.2)
Onset of labour, n (%)			
Spontaneous	20 (14.0)	24 (16.3)	
Induction	90 (62.9)	87 (59.2)	
Primary caesarean section	33 (23.1)	36 (24.5)	
Route of delivery, n (%)			
Vaginal	71 (65.7)	77 (67.0)	
Instrumental	14 (13.0)	12 (10.4)	
Caesarean section	23 (21.3)	26 (22.6)	
Foetal outcomes			
GA at delivery (d), median (IQR)	266 (259-269)	266 (259-269)	HR 1.09 (0.86-1.37)
Male, n(%)	90 (53.9)	77 (46.1)	RR 1.19 (0.98-1.46)
Birth weight (gr), mean (SD)	3356 (721)	3429 (610)	−72 (−226-82)
Extremely LGA	32 (22.4)	31 (21.1)	RR 1.06 (0.69-1.64)
SGA	4 (2.8)	7 (4.8)	RR 0.59 (0.18-1.96)
Neonatal admission (MC or NICU), n (%)	29 (22.1)	30 (21.9)	RR 1.01 (0.65-1.59)
Neonatal hypoglycaemia, n (%)	60 (44.8)	58 (41.7)	RR 1.07 (0.82-1.41)
Severe neonatal hypoglycaemia, n (%)	25 (17.5)	25 (17.0)	RR 1.03 (0.62-1.70)
Prematurity, n (%)	31 (21.7)	34 (23.1)	RR 0.94 (0.61-1.44)
Shoulder dystocia, n (%)	7 (4.9)	4 (2.7)	RR 1.79 (0.54-5.97)
Neonatal death, n (%)	1 (0.7)	1 (0.7)	RR 1.02 (0.06-16.17)
Major congenital malformation, n (%)	5 (3.5)	4 (2.7)	RR 1.28 (0.35-4.66)

Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicentre international randomised controlled trial

*Denice S Feig, Lois E Donovan, Rosa Corcoy, Kellie E Murphy, Stephanie A Amiel, Katharine F Hunt, Elizabeth Asztalos, Jon F R Barrett, J Johanna Sanchez, Alberto de Leiva, Moshe Hod, Lois Jovanovic, Erin Keely, Ruth McManus, Eileen K Hutton, Claire L Meek, Zoe A Stewart, Tim Wysocki, Robert O'Brien, Katrina Ruedy, Craig Kollman, George Tomlinson, Helen R Murphy, on behalf of the CONCEPTT Collaborative Group**

PRIMARY OUTCOME:

- DIFFERENZA DI HbA1c DALLA RANDOMIZZAZIONE ALLA 34wk NEL GRUPPO GRAVIDANZA

- DIFFERENZA DI HbA1c ALLA 24wk O AL CONCEPIMENTO NEL GRUPPO PROGRAMMAZIONE

	CGM	Control	p value
Baseline	6·83% (0·67)	6·95% (0·66)	–
24 weeks' gestation	6·23% (0·53)	6·40% (0·68)	–
Change from baseline to 24 weeks	−0·67 (0·58)	−0·52 (0·55)	0·0374
34 weeks' gestation	6·35% (0·57)	6·53% (0·70)	–
Change from baseline to 34 weeks	−0·54 (0·62)	−0·35 (0·65)	0·0372
Achieved HbA$_{1c}$ <6·5% (48 mmol/mol) at 34 weeks	63/95 (66%)	48/92 (52%)	0·0601

Data are mean percentage (SD). Assessed in 99 participants in the CGM group and 96 participants in the control group at baseline, and in 95 participants in the CGM group and 92 participants in the control group at baseline and 34 weeks' gestation. Percentage point changes are either cross-sectional on participants with data for baseline, week 24, and week 34 values, or summaries of change on participants with data at the relevant timepoints. p values are from linear regression (HbA$_{1c}$) or logistic regression (HbA$_{1c}$ <6·5%) on available data, controlling for baseline HbA$_{1c}$ and method of insulin delivery. CGM=continuous glucose monitoring. HbA$_{1c}$=glycated haemoglobin.

Table 2: **Glycaemic control of pregnancy trial participants based on available HbA$_{1c}$ data**

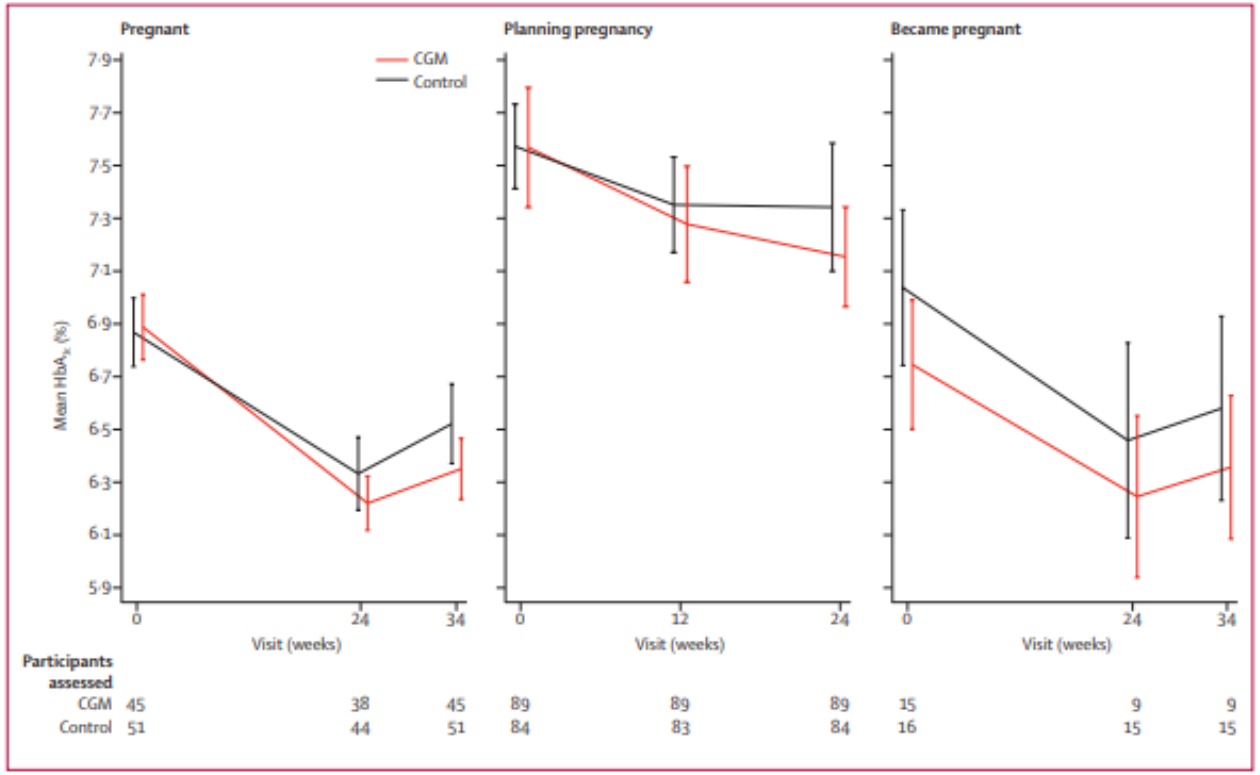

Figure 2: **Primary glycaemic outcome showing participants' HbA$_{1c}$ levels according to pregnancy status**
Mean HbA$_{1c}$ (95% CI) is shown at each assessment time for participants who had data at baseline and the time of the outcome assessment (24 and 34 weeks' gestation in the pregnancy trial and at 12 and 24 weeks from randomisation or at time of confirmed pregnancy in the pregnancy planning trial). Data are also shown for participants in the planning pregnancy trial who conceived before 24 weeks and stayed in the trial during pregnancy. CGM=continuous glucose monitoring. HbA$_{1c}$=glycated haemoglobin.

Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicentre international randomised controlled trial

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	CGM	Control	p value
Baseline	6·83% (0·67)	6·95% (0·66)	..
24 weeks' gestation	6·23% (0·53)	6·40% (0·68)	..
Change from baseline to 24 weeks	−0·67 (0·58)	−0·52 (0·55)	0·0374
34 weeks' gestation	6·35% (0·57)	6·53% (0·70)	..
Achieved HbA_{1c} ≤6·5% (48 mmol/mol) at 34 weeks	63/95 (66%)	48/92 (52%)	0·0601

Data are mean percentage (SD). Assessed in 99 participants in the CGM group and 96 participants in the control group at baseline, and in 95 participants in the CGM group and 92 participants in the control group at baseline and 34 weeks' gestation. Percentage point changes are either cross-sectional on participants with data for baseline, week 24, and week 34 values, or summaries of change on participants with data at the relevant timepoints. p values are from linear regression (HbA_{1c}) or logistic regression (HbA_{1c} <6·5%) on available data, controlling for baseline HbA_{1c} and method of insulin delivery. CGM=continuous glucose monitoring. HbA_{1c}=glycated haemoglobin.

Table 2: Glycaemic control of pregnancy trial participants based on available HbA_{1c} data

	Baseline		34 weeks' gestation		p value*
	CGM	Control	CGM	Control	
Direct CGM measures†					
Hours per week‡	158 (143–168)	150 (139–165)	159 (143–177)	156 (143-166)	..
Glucose	7·3 (1·2)	7·6 (1·1)	6·7 (0·9)	7·0 (1·1)	0·14
Time in target	52% (13)	52% (14)	68% (13)	61% (15)	0·0034
Time >7·8 mmol/L	39% (28–49)	40% (32–51)	27% (19–37)	32% (25–39)	0·0279
High blood glucose index	4·2 (2·3–6·2)	4·6 (2·8–6·7)	1·8 (1·1–2·8)	2·3 (1·5–3·4)	0·067
Time <3·5 mmol/L	8% (4–14)	6% (3–11)	3% (1–6)	4% (2–8)	0·10
Low blood glucose index	2·8 (1·6–4·6)	2·4 (1·5–3·6)	1·7 (1·1–2·8)	2·1 (1·4–2·8)	0·18
Hypoglycaemia§	0·8 (0·6–1·0)	0·7 (0·4–0·9)	0·5 (0·3–0·8)	0·5 (0·3–0·8)	0·73
Glucose variability measures					
Coefficient of variation	42% (38–47)	42% (36–47)	32% (28–37)	34% (29–39)	0·058
SD (mmol/L)	3·1 (2·6–3·6)	3·1 (2·6–3·8)	2·2 (1·8–2·5)	2·4 (2·0–2·8)	0·0359
Mean amplitude of glucose excursion (mmol/L)	6·0 (5·1–7·1)	6·4 (5·5–7·8)	4·2 (3·5–4·9)	4·6 (3·9–6·0)	0·0455
Rate of change mmol/L per h	2·15 (1·88–2·52)	2·17 (1·89–2·46)	2·02 (1·70–2·26)	1·63 (1·31–1·96)	<0·0001
Severe hypoglycaemia¶					
Number of women	7 (7%)	4 (4%)	11 (11%)	12 (12%)	1·0
Number of episodes‡	11	5	18	21	..
Diabetic ketoacidosis during study	..	..	2 (2%)	2 (2%)	1·0
Changed to insulin pump during study	..	..	1 (1%)	3 (3 %)	0·62
Total insulin dose (U/kg per day)	0·69 (0·25)	0·76 (0·31)	0·99 (0·41)	1·07 (0·42)	0·14

Values are mean (SD) and median (IQR) as appropriate. *p value for between-group difference at 34 weeks' gestation. †CGM data were obtained 1 week after completion of the 34 week visit using real-time sensors in the CGM group and masked sensors in the control group. Assessed in 107 participants in the CGM group and 107 participants in the control group at baseline, and in 77 participants in the CGM group and 77 participants in the control group at 34 weeks' gestation. ‡Not study outcomes. §Hypoglycaemia events are defined as CGM levels <3·5 mmol/L for at least 20 min. Distinct events were counted only if separated by at least 30 min. ¶Severe hypoglycaemia was defined as an episode requiring third-party assistance; assessed in 107 participants in the CGM group and 107 participants in the control group at baseline, and in 103 participants in the CGM group and 104 participants in the control group at 34 weeks' gestation.

Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicentre international randomised controlled trial

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	Baseline		34 weeks' gestation		p value*
	CGM	Control	CGM	Control	
Direct CGM measures†					
Hours per week‡	158 (143–168)	150 (139–165)	159 (143–177)	156 (143–166)	..
Time in target	52% (13)	52% (14)	68% (13)	61% (15)	0·0034
Time >7·8 mmol/L	39% (28–49)	40% (32–51)	27% (19–37)	32% (25–39)	0·0279
High blood glucose index	4·2 (2·3–6·2)	4·6 (2·8–6·7)	1·8 (1·1–2·8)	2·3 (1·5–3·4)	0·067
Low blood glucose index	2·8 (1·6–4·6)	2·4 (1·5–3·6)	1·7 (1·1–2·8)	2·1 (1·4–2·8)	0·18
Hypoglycaemia§	0·8 (0·6–1·0)	0·7 (0·4–0·9)	0·5 (0·3–0·8)	0·5 (0·3–0·8)	0·73
Glucose variability measures					
Coefficient of variation	42% (38–47)	42% (36–47)	32% (28–37)	34% (29–39)	0·058
SD (mmol/L)	3·1 (2·6–3·6)	3·1 (2·6–3·8)	2·2 (1·8–2·5)	2·4 (2·0–2·8)	0·0359
Mean amplitude of glucose excursion (mmol/L)	6·0 (5·1–7·1)	6·4 (5·5–7·8)	4·2 (3·5–4·9)	4·6 (3·9–6·0)	0·0455
Rate of change mmol/L per h	2·15 (1·88–2·52)	2·17 (1·89–2·46)	2·02 (1·70–2·26)	1·63 (1·31–1·96)	<0·0001
Severe hypoglycaemia¶					
Number of women	7 (7%)	4 (4%)	11 (11%)	12 (12%)	1·0
Number of episodes‡	11	5	18	21	..
Diabetic ketoacidosis during study	..	..	2 (2%)	2 (2%)	1·0
Changed to insulin pump during study	..	..	1 (1%)	3 (3%)	0·62
Total insulin dose (U/kg per day)	0·69 (0·25)	0·76 (0·31)	0·99 (0·41)	1·07 (0·42)	0·14

Values are mean (SD) and median (IQR) as appropriate. *p value for between-group difference at 34 weeks' gestation. †CGM data were obtained 1 week after completion of the 34 week visit using real-time sensors in the CGM group and masked sensors in the control group. Assessed in 107 participants in the CGM group and 107 participants in the control group at baseline, and in 77 participants in the CGM group and 77 participants in the control group at 34 weeks' gestation. ‡Not study outcomes. §Hypoglycaemia events are defined as CGM levels <3·5 mmol/L for at least 20 min. Distinct events were counted only if separated by at least 30 min. ¶Severe hypoglycaemia was defined as an episode requiring third-party assistance; assessed in 107 participants in the CGM group and 107 participants in the control group at baseline, and in 103 participants in the CGM group and 104 participants in the control group at 34 weeks' gestation.

Table 3: **Glycaemic and adverse outcomes of pregnancy trial participants**

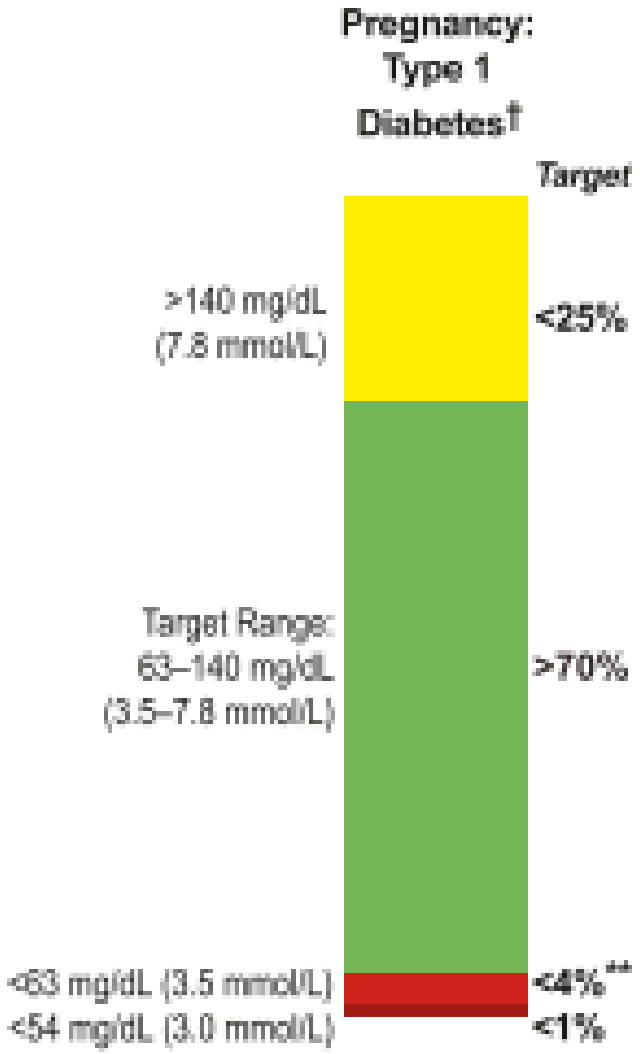
	CGM	Control	p value
Neonatal outcomes			
Number assessed	105	106	..
Pregnancy loss <20 weeks	5 (5%)	4 (4%)	1·0
Stillbirth	0	1	..
Termination	0	1	..
Congenital anomaly†	2	3	..
Preterm births			
Number assessed	100	102	..
Preterm <37 weeks	38 (38%)	43 (42%)	0·57
Early preterm <34 weeks	5 (5%)	11 (11%)	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
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

Values are mean (SD) and median (IQR) as appropriate. CGM=continuous glucose monitoring. NICU=neonatal intensive care unit. *Entry weight was self-reported or recorded pre-pregnancy weight, or both. The weight from 16 to 34 weeks was measured. †Congenital anomalies were aortic stenosis and hypospadias grade 1 (CGM group) and hypoplastic right heart syndrome (termination of pregnancy), aberrant right subclavian artery, and bilateral hydronephrosis (control group). ‡Gestational age at delivery was calculated only for the 100 pregnancies in the CGM group and the 101 pregnancies in the control group that were ongoing after 24 weeks' gestation. §Based on gestation-related optimal weight customised growth charts. ¶Composite outcome comprises pregnancy loss (miscarriage, stillbirth, and neonatal death); birth injury; neonatal hypoglycaemia; hyperbilirubinaemia; respiratory distress; and high-level neonatal care for more than 24 h.

Diabetes Care Volume 42, August 2019

Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range

Diabetes Care 2019;42:1593–1603 | https://doi.org/10.2337/dci19-0028



Diabetologia (2019) 62:1123–1128
https://doi.org/10.1007/s00125-019-4904-3

COMMENTARY

Continuous glucose monitoring targets in type 1 diabetes pregnancy: every 5% time in range matters

Helen R. Murphy[1]

Table 1 Patterns of glycaemia among pregnant CGM users with type 1 diabetes

Glucose measures	Kristensen et al, 2019 [1] iCGM or rt-CGM *N*=186[a]	Feig et al 2017 [2] rt-CGM *N*=108[a]	CGM target
Laboratory HbA_{1c}, mmol/mol (%)			
Trimester 1	52 ± 10.5 (6.9 ± 1.0)	51 ± 7·3 (6·8 ± 0·7)	
Trimester 2	45 ± 7.9 (6.3 ± 0.7)	44 ± 6.5 (6.2 ± 0.5)	
Trimester 3	46 ± 7.6 (6.3 ± 0.7)	46 ± 6.7 (6·3 ± 0·6)	
CGM mean glucose, mmol/l			
Trimester 1	7.8 ± 1.4	7·3 ± 1·2	
Trimester 2	7.4 ± 1.2	7.6 ± 1.2	
Trimester 3	7.1 ± 1.1	6·7 ± 0·9	
TIR 3.5–7.8 mmol/l[b] (%)			
Trimester 1	50 ± 14	52 ± 13	>70%
Trimester 2	55 ± 14	53 ± 15	>70%
	60 ± 13	68 ± 13	>70%
TAR [c] (%)			
	43 ± 15	39 (28–49)	<25%
Trimester 2	38 ± 15	43 (29–54)	<25%
Trimester 3	34 ± 15	27 (19–37)	<25%
TBR <3.5 mmol/l[d] (%)			
Trimester 1	7 ± 5	8 (4–14)	<4%
Trimester 2	7 ± 5	3 (1–6)	<4%
Trimester 3	6 ± 5	3 (1–6)	<4%
Glycaemic variability (% CV)[e]			
Trimester 1	40 ± 7	42 (38–47)	≤36%
Trimester 2	38 ± 6	35 (31–39)	≤36%
Trimester 3	36 ± 6	32 (28–37)	≤36%

Kristensen et al found that a 5–7% lower TIR during the second and third trimesters was associated with increased risk of LGA and neonatal outcomes, including macrosomia, shoulder dystocia, neonatal hypoglycaemia or NICU admissions of >24 h duration

In CONCEPTT, we also found that rt-CGM users (compared with self-monitoring) achieved a 5–7% higher TIR in the second and third trimesters, and this was associated with a halving in the odds ratio for LGA, neonatal hypoglycaemia and NICU admissions of >24 h duration

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COMMENTARY

Continuous glucose monitoring targets in type 1 diabetes pregnancy: every 5% time in range matters

Helen R. Murphy[1]

This ambitious target of >70% TIR is currently only reached in the final 3–4 weeks of type 1 diabetes pregnancy, which is too late for optimal neonatal outcomes. In CONCEPTT, only 10% of women achieved a TIR of >70% during the first and second trimesters, rising to 30% at 34 weeks. Almost twice as many achieved target HbA_{1c} levels. For optimal obstetric and neonatal outcomes, women and clinicians should aim to reach a TIR of >70% (16 h, 48 min) and a TAR of <25% (6 h), from as early as possible during pregnancy. Women who cannot achieve the TIR target of >70% in the second and early third trimester should be encouraged that a 5% increase in TIR is associated with clinically relevant improvements in neonatal health.

Technoleg Iechyd Cymru
Health Technology Wales

HEALTH TECHNOLOGY WALES (HTW) GUIDANCE 012 (September 2019)

Continuous glucose monitoring in pregnant women with type 1 diabetes

HTW Guidance: The case for adopting continuous glucose monitoring in pregnant women with type 1 diabetes is supported by the evidence.

The use of continuous glucose monitoring during pregnancy improves glycaemic control and reduces the incidence of pre-eclampsia in the mother as compared to self-monitoring of blood glucose. Continuous glucose monitoring reduces neonatal hypoglycaemia and the need and duration of neonatal intensive care stay.

Cost modelling estimates that the use of continuous glucose monitoring in type 1 diabetic mothers will lead to cost savings of £1,029 per pregnancy as compared to self-monitoring of blood glucose, with the cost savings largely driven by a reduction in neonatal intensive care requirements.

Impiego di rtCGM in Pazienti con Diabete Tipo 1 Adulti (dispositivi ad ago sottocutaneo e dispositivi impiantabili sottocute)

- Per ipoglicemia severa o inavvertita o problematica per la vita del paziente.

[N.B.: per ipoglicemia problematica si intende: ≥2 episodi di ipoglicemia severa negli ultimi 12 mesi o 1 episodio di ipoglicemia severa negli ultimi 12 mesi associato a ipoglicemia inavvertita o a estrema labilità glicemica o a paura delle ipoglicemie ricorrenti tale da impattare negativamente sulla gestione della vita quotidiana (cfr. Choudhary P 2015)]

Cfr. Bode 2009; Battelino 2011; Battelino 2012; New JP 2015; van Beers CA 2016; Heinemann L 2018

- Per emoglobina glicata persistentemente superiore al target desiderabile per il paziente, nonostante terapia insulinica intensiva e ottimizzata.

Cfr. Deiss D 2006; Tamborlane WV 2008; O'Connell MA 2009; Riveline 2012; Battelino 2012; Beck 2009a; Beck 2009b; Pickup 2011; Yeh 2012

- In donne con diabete tipo 1 in gravidanza, per migliorare il compenso metabolico e gli outcome neonatali ***(solo dispositivi ad ago sottocutaneo).***

Cfr. Murphy HR 2008; Secher AL 2013; Yu F 2014; Feig DS 2017

- Può essere utile in pazienti con condizioni lavorative o stili di vita in cui un controllo molto frequente è consigliabile ma non praticabile (ad es., minatori, subacquei, lavoratori dell'edilizia, ecc.).

DOCUMENTO DEL GRUPPO DI STUDIO INTERSOCIETARIO AMD - SID - SIEDP "TECNOLOGIA E DIABETE"

https://www.siditalia.it/clinica/linee-guida-altri/send/83-linee-guida-e-documenti-di-altri/4727-2019-documento-del-gruppo-intersocietario-amd-sid-siedp

National Institute for Health and Care Excellence

Final

Diabetes in pregnancy: management from preconception to the postnatal period

[A] Continuous glucose monitoring

NICE guideline NG3

Methods, evidence and recommendations

December 2020

CGM: efficacia in programmazione di gravidanza

National Institute for Health and Care Excellence

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Diabetes in pregnancy: management from preconception to the postnatal period

[A] Continuous glucose monitoring

NICE guideline NG3

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December 2020

F.1 Preconception period (women who are planning to become pregnant)

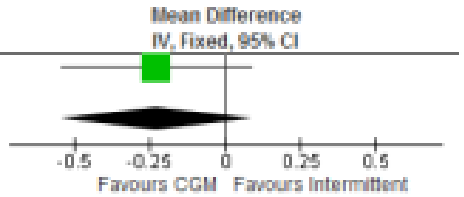
Continuous glucose monitoring vs. Intermittent capillary blood glucose monitoring

Maternal outcomes at ≤ 6 months

HbA1c (%)

Study or Subgroup	CGM Mean	CGM SD	CGM Total	Intermittent Mean	Intermittent SD	Intermittent Total	Weight	Mean Difference IV, Fixed, 95% CI
Feig 2017 (1)	7.12	0.64	42	7.35	0.87	46	100.0%	-0.23 [-0.55, 0.09]
Total (95% CI)			42			46	100.0%	-0.23 [-0.55, 0.09]

Heterogeneity: Not applicable
Test for overall effect: Z = 1.42 (P = 0.16)

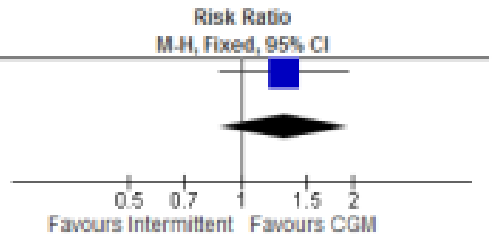


Footnotes
(1) 24 weeks

Achieved HbA1c target

Study or Subgroup	CGM Events	CGM Total	Intermittent Events	Intermittent Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Feig 2017 (1)	25	42	21	46	100.0%	1.30 [0.87, 1.95]
Total (95% CI)		42		46	100.0%	1.30 [0.87, 1.95]
Total events	25		21			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.29 (P = 0.20)



Footnotes
(1) 24 weeks. Target HbA1c levels no higher than 7.0% (53 mmol/ mol)

CGM: efficacia in corso di gravidanza

National Institute for Health and Care Excellence

Final

Diabetes in pregnancy: management from preconception to the postnatal period

[A] Continuous glucose monitoring

NICE guideline NG3

Methods, evidence and recommendations

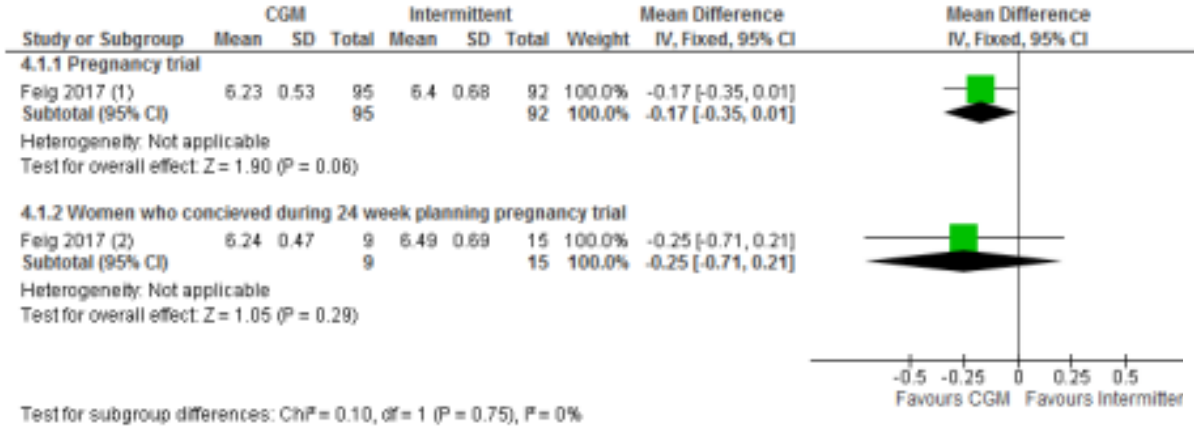
December 2020

F.2 During pregnancy

Continuous glucose monitoring vs. intermittent capillary blood glucose monitoring

Maternal outcomes at ≤ 6 months

HbA1c (%)



Test for subgroup differences: Chi² = 0.10, df = 1 (P = 0.75), I² = 0%

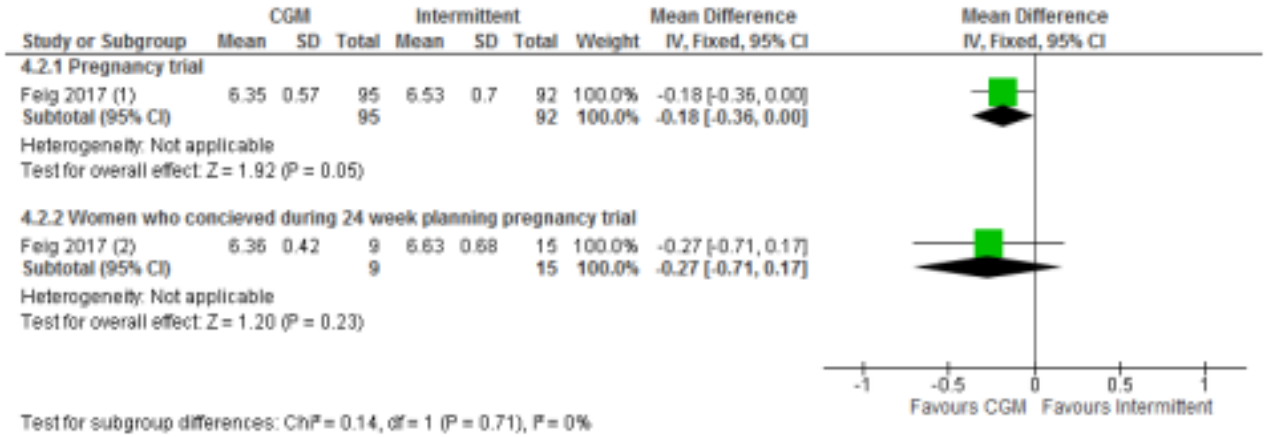
Footnotes

(1) At 24 weeks gestation

(2) At 24 weeks gestation

Maternal outcomes at > 6 months

HbA1c (%)



Test for subgroup differences: Chi² = 0.14, df = 1 (P = 0.71), I² = 0%

Footnotes

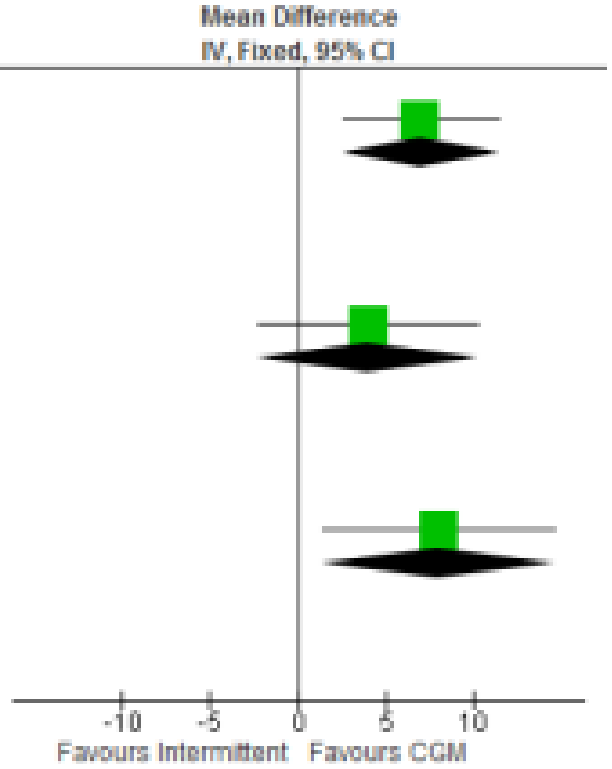
(1) At 34 weeks' gestation

(2) At 34 weeks' gestation

CGM: efficacia in corso di gravidanza

Time spent in target glucose range (%)

Study or Subgroup	CGM Mean	CGM SD	CGM Total	Intermittent Mean	Intermittent SD	Intermittent Total	Weight	Mean Difference IV, Fixed, 95% CI
4.4.1 Whole population								
Feig 2017 (1)	68	13	77	61	15	77	100.0%	7.00 [2.57, 11.43]
Subtotal (95% CI)			77			77	100.0%	7.00 [2.57, 11.43]
Heterogeneity: Not applicable								
Test for overall effect: Z = 3.09 (P = 0.002)								
4.4.2 Insulin pump users								
Feig 2017 (2)	66	13	35	62	14	37	100.0%	4.00 [-2.24, 10.24]
Subtotal (95% CI)			35			37	100.0%	4.00 [-2.24, 10.24]
Heterogeneity: Not applicable								
Test for overall effect: Z = 1.26 (P = 0.21)								
4.4.3 Multiple daily injection users								
Feig 2017 (3)	69	13	42	61	17	40	100.0%	8.00 [1.43, 14.57]
Subtotal (95% CI)			42			40	100.0%	8.00 [1.43, 14.57]
Heterogeneity: Not applicable								
Test for overall effect: Z = 2.39 (P = 0.02)								



Test for subgroup differences: Chi² = 0.87, df = 2 (P = 0.65), I² = 0%

Footnotes

(1) Glucose target range of 3.5-7.8 mmol/L

(2) Glucose target range of 3.5-7.8 mmol/L

(3) Glucose target range of 3.5-7.8 mmol/L

National Institute for Health and Care Excellence

Final

Diabetes in pregnancy: management from preconception to the postnatal period

[A] Continuous glucose monitoring

NICE guideline NG3

Methods, evidence and recommendations

December 2020

Continuous Glucose Monitoring in Pregnancy: Importance of Analyzing Temporal Profiles to Understand Clinical Outcomes

*Eleanor M. Scott,[1] Denice S. Feig,[2] Helen R. Murphy,[3] and Graham R. Law,[4] on behalf of the CONCEPTT Collaborative Group**

Diabetes Care 2020;43:1178–1184 | https://doi.org/10.2337/dc19-2527

Table 2—Standard summary metrics of CGM data across pregnancy comparing RT-CGM group to SMB MDI (*B*), and LGA to non-LGA (*C*)

	Baseline		24 weeks	
A: RT-CGM group to SMBG control group	CGM	SMBG	CGM	SMBG
Number	100	100	89	90
Glucose, mmol/L	7.3 ± 1.2	7.6 ± 1.1	7.6 ± 1.2	7.8 ± 1.3
0001–0600 h glucose, mmol/L	6.7 ± 1.5	7.1 ± 1.4	**7.2 ± 1.4**	**7.0 ± 1.4**
0601–0000 h glucose, mmol/L	7.5 ± 1.3	7.8 ± 1.2	**7.7 ± 1.3**	**8.1 ± 1.4**
Percentage of time 3.5–7.8 mmol/L	51.7 ± 13.0	51.5 ± 13.7	53.0 ± 15.5	49.8 ± 15.0
Percentage of time below 3.5 mmol/L	**10.0 ± 7.7**	**7.8 ± 6.4**	4.8 ± 4.8	5.5 ± 5.7
Percentage of time above 7.8 mmol/L	38.4 ± 14.9	40.6 ± 13.8	42.3 ± 17.6	44.7 ± 16.0
Individual SD	3.1 ± 0.8	3.2 ± 0.8	2.7 ± 0.6	2.9 ± 0.7
Individual CV, %	42.2 ± 8.7	42.4 ± 8.1	35.6 ± 5.9	36.9 ± 7.2

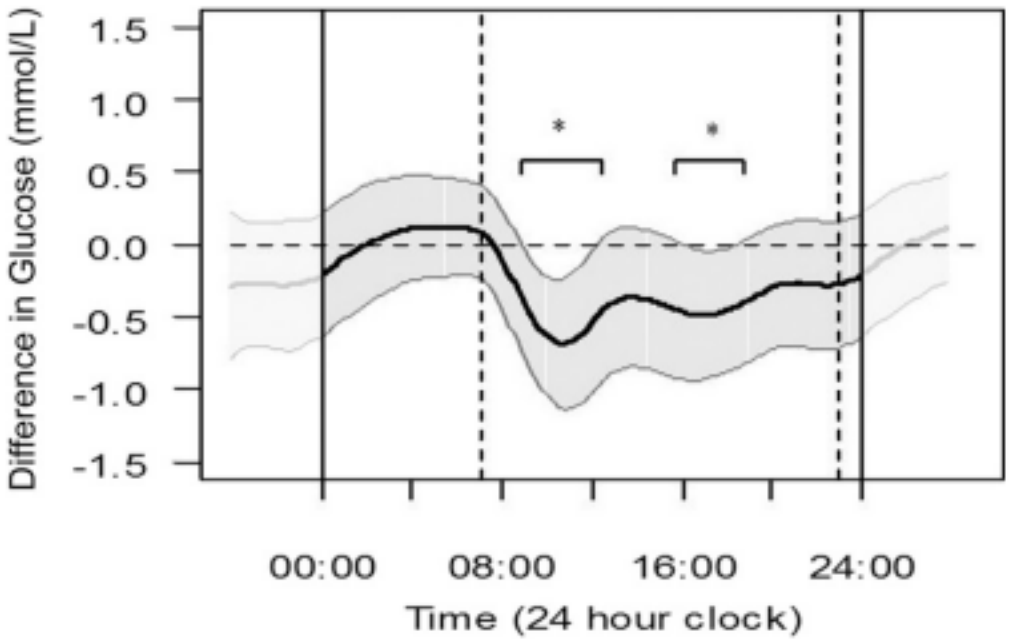


Figure 1—Differences in mean temporal glucose levels across the 24-h day, assessed by FDA (at 24 and 34 weeks' gestation combined) between those women who were randomized to RT-CGM (represented by the dark wavy line) compared with those using SMBG (represented by the horizontal zero dotted line) with 95% pointwise CIs (gray section). Where both of the CIs sit to the same side of 0.0, there is a significant difference. Dashed vertical lines represent daytime at 0700 h and 2300 h. *Significant differences using 95% CIs.

Continuous Glucose Monitoring in Pregnancy: Importance of Analyzing Temporal Profiles to Understand Clinical Outcomes

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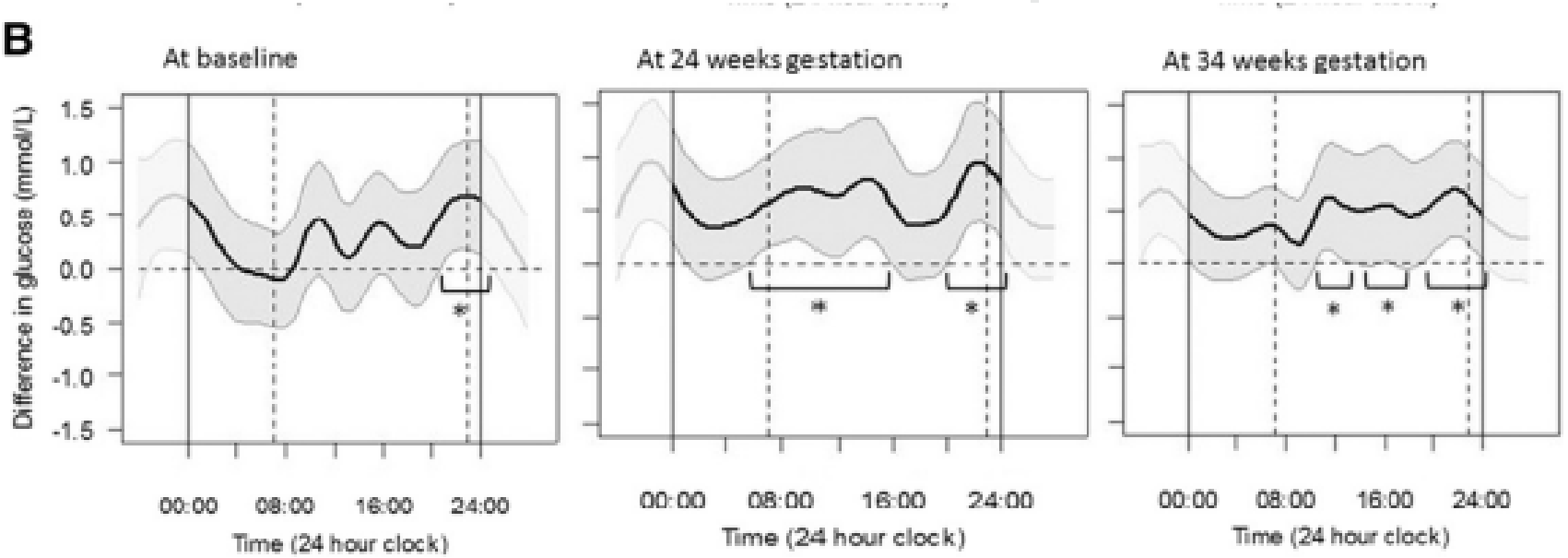
Table 2—Standard summary metrics of CGM data across pregnancy comparing RT-CGM group to SMBG control group (*A*), pump to MDI (*B*), and LGA to non-LGA (*C*)

	Baseline		24 weeks		34 weeks	
C: LGA to non-LGA	LGA	Non-LGA	LGA	Non-LGA	LGA	Non-LGA
Number	122	78	111	68	96	57
Glucose, mmol/L	7.6 ±					
0001–0600 h glucose, mmol/L	7.0 ±					
0601–0000 h glucose, mmol/L	7.8 ±					
Percentage of time 3.5–7.8 mmol/L	**49.6 ±**					
Percentage of time below 3.5 mmol/L	9.2 ±					
Percentage of time above 7.8 mmol/L	**41.2 ±**					
Individual SD	3.3 ±					
Individual CV, %	43.3 ±					



DIABETES TECHNOLOGY & THERAPEUTICS
Volume 23, Supplement 1, 2021
Mary Ann Liebert, Inc.
DOI: 10.1089/dia.2020.0667

DTT

DEXCOM 2021: RTCGM & COST IMPLICATIONS

Benefits of Real-Time Continuous Glucose Monitoring in Pregnancy

Jennifer M. Yamamoto, MD[1,2] and Helen R. Murphy, MD[3–5]

A systematic review combining data from CONCEPTT with that of the type 1 diabetes arm of the GlucoMOMS trial also showed evidence for a reduction in preeclampsia. This is important because preeclampsia and its consequences of growth restriction and preterm births are associated with substantial mother and infant morbidity and mortality globally

(…) a higher CGM TIR in the second and third trimesters was associated with a decreased risk of large-for gestational-age and a decreased risk of their composite neonatal outcome (shoulder dystocia, macrosomia, neonatal hypoglycemia, and neonatal intensive care admission)

(..) increasing TIR by 5% is associated with clinically meaningful improvements in outcomes

TABLE 1. FACTORS ASSOCIATED WITH TARGET GLYCEMIA (HEMOGLOBIN A1C LESS THAN 6.5% [48 MMOL/MOL]) IN EARLY PREGNANCY

Type 1 diabetes pregnancy

Category	*Odds ratio (95% CI)*
Maternal age category[a]	
Age 15–24 years	0.32 (0.25–0.40)
Age 35–44 years	1.30 (1.11–1.52)
Age >45 years	2.14 (0.65–7.13)
Maternal deprivation quintile[b]	
Deprivation N/A	0.70 (0.51–0.96)
Quintile 5	0.44 (0.35–0.55)
Quintile 4	0.48 (0.39–0.60)
Quintile 3	0.65 (0.53–0.80)
Quintile 2	0.67 (0.54–0.82)
Diabetes duration	
Diabetes duration N/A[c]	0.76 (0.38–1.51)
Duration <1 year	1.69 (1.11–2.57)
Duration 5–9 years	0.54 (0.43–0.67)
Duration 10–14 years	0.40 (0.32–0.50)
Duration >15 years	0.43 (0.36–0.52)
BMI (kg/m^2)	
BMI <18.5[d]	1.27 (0.71–2.29)
BMI 25–29.9	0.75 (0.64–0.87)
BMI 30–34.9	0.63 (0.51–0.77)
BMI 35–39.9	0.55 (0.39–0.78)
BMI >40	0.53 (0.31–0.90)

Continuous Glucose Monitoring Metrics and Birth Weight: Informing Management of Type 1 Diabetes Throughout Pregnancy

Diabetes Care 2022;45:1724–1734 | https://doi.org/10.2337/dc22-0078

Eleanor M. Scott,[1] Helen R. Murphy,[2] Karl H. Kristensen,[3] Denice S. Feig,[4] Karin Kjölhede,[5] Linda Englund-Ögge,[5] Kerstin E. Berntorp,[6] and Graham R. Law[7]

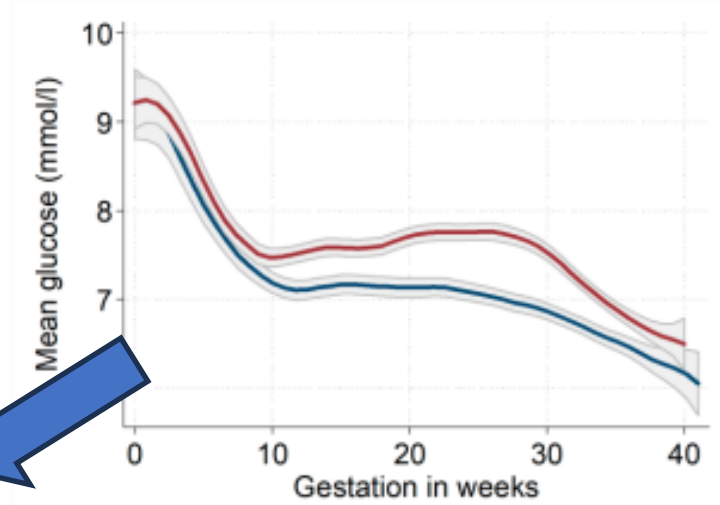
we show a sustained difference of 0.5 mmol/L (9 mg/dL) in mean CGM glucose concentration across the 24-h day, every week, from 10 weeks of gestation onward in women who had an LGA infant

Our data show that achieving tight CGM glucose targets from early pregnancy (10–12 weeks of gestation) is associated with normal birth weight outcomes.

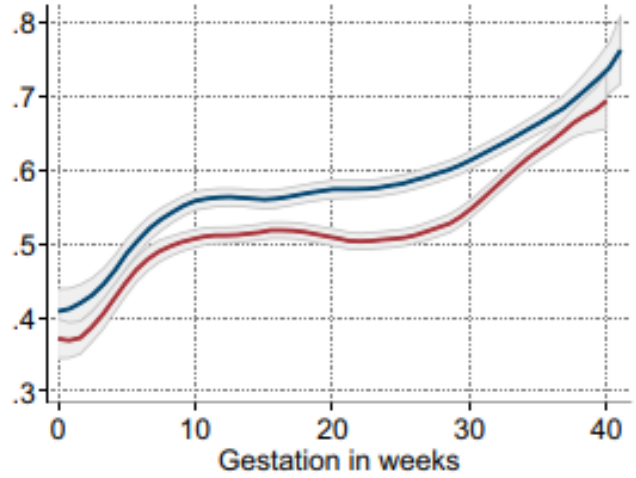
RESEARCH DESIGN AND METHODS

An analysis of >10.5 million CGM glucose measures from 386 pregnant women with type 1 diabetes from two international multicenter studies was performed. CGM glucose metrics and 24-h glucose profiles were calculated for each gestational week, and the relationship to normal (10–90th percentile) and large (>90th percentile) for gestational age (LGA) birth weight infants was determined.

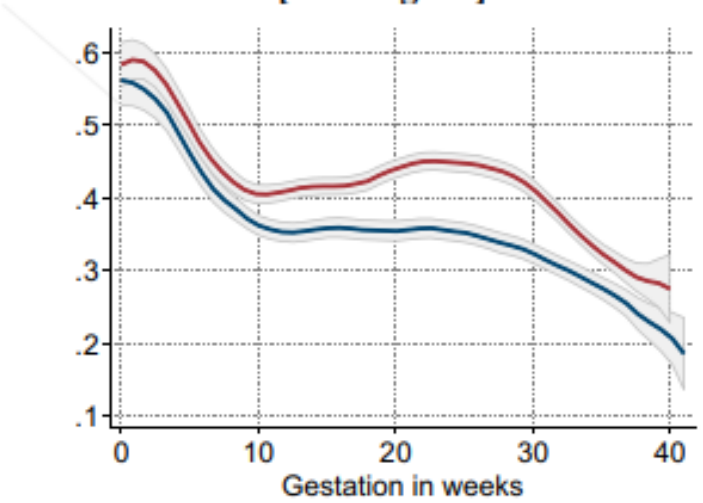
A Mean glucose (mmol/l)



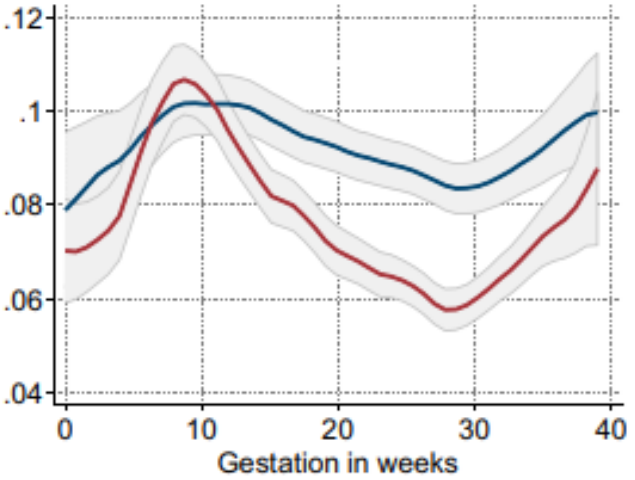
B Percentage time in range (TIR) 3.5-7.8mmol/L [63-140mg/dL]



C Percentage time above range (TAR) >7.8 mmol/L [>140mg/dL]



D Percentage time below range (TBR) <3.5 mmol/L [<63mg/dL]



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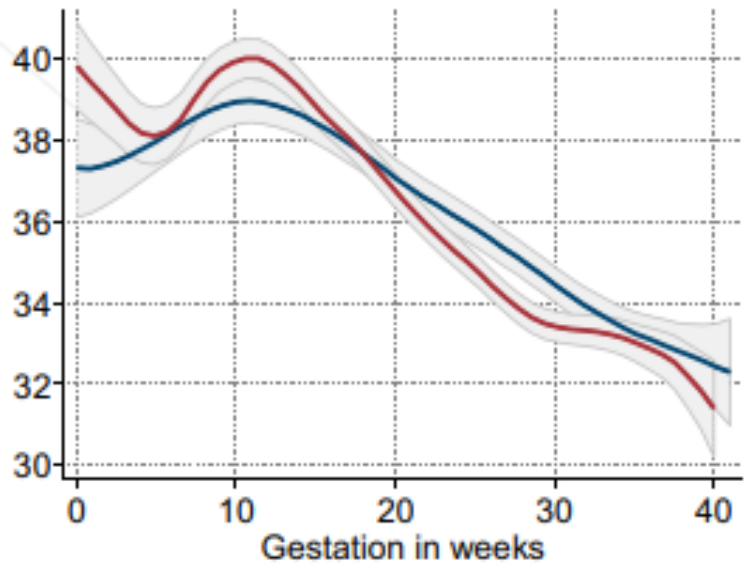
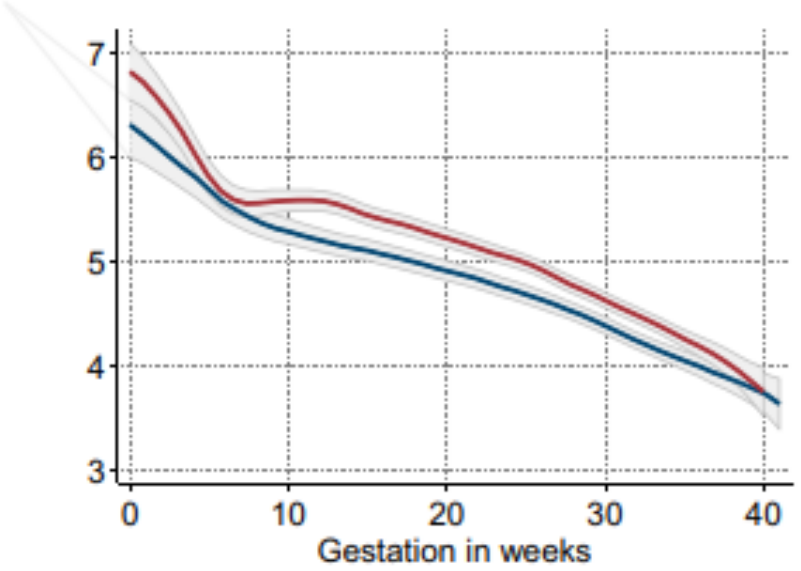
Diabetes Care 2022;45:1724–1734 | https://doi.org/10.2337/dc22-0078

E Coefficient of variation (%)



F MAGE (mmol/L)



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- Our current analysis suggests that aiming for a CGM **TIR of 55 to 60% by 10 weeks** of gestation may be sufficient for normal fetal growth, aiming to achieve 70% thereafter
- Achieving a mean glucose of 7.0 mmol/L (126 mg/dL) and spending **no more than 35% TAR** by 10 weeks were associated with normal fetal growth
- Additional dietary attention, psychoeducational support, and technologic interventions, such as closed-loop insulin delivery, may be required for women who do not achieve their pregnancy CGM glucose targets by 10 weeks

Symposium/Special Issue

Continuous Glucose Monitoring Metrics for Pregnancies Complicated by Diabetes: Critical Appraisal of Current Evidence

Journal of Diabetes Science and Technology
1–16

DOI: 10.1177/19322968241239341
journals.sagepub.com/home/dst
Sage

Emily D. Szmuilowicz, MD, MS[1], Linda Barbour, MD, MSPH, FACP[2], Florence M. Brown, MD[3], Celeste Durnwald, MD[4], Denice S. Feig, MD, MSc, FRCPC[5], Grenye O'Malley, MD[6], Sarit Polsky, MD, MPH[2], and Grazia Aleppo, MD[1]

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✓ **Un aumento del TIR del 4-7% porta ad una riduzione del 50% di LGA e ricovero in NICU**

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- ✓ **La media glicemica derivante dal CGM nel secondo e terzo trimestre si associa a LGA e potrebbe essere considerato il marker migliore**

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- ✓ **Il GMI correla meglio della HbA1c con il TIR nel I trimestre**

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- ✓ **Non sono dimostrate associazioni tra TBR ed eventi avversi neonatali e/o materni**

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- ✓ Non sono dimostrate associazioni tra TBR ed eventi avversi neonatali e/o materni
- ✓ **Al fine di aumentare il TIR si consiglia di anticipare il bolo 15 min prima del pasto ad inizio gravidanza e di circa 30-40 min prima del pasto a termine di gravidanza**

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- ✓ Al fine di aumentare il TIR si consiglia di anticipare il bolo 15 min prima del pasto ad inizio gravidanza e di circa 30-40 min a termine di gravidanza
- ✓ **Sarebbe opportuno che tutti i sistemi di scarico dati permettessero di modificare i target di AGP con quelli specifici per la gravidanza**

ORIGINAL ARTICLE

Clinical Effectiveness of Continuous Glucose Monitoring in Pregnancies Affected by Type 1 Diabetes

DIABETES TECHNOLOGY & THERAPEUTICS
Volume 26, Number 8, 2024

DOI: 10.1089/dia.2023.0548

Valerie Gao, MD,[1] Janet K. Snell-Bergeon, PhD,[2] Emily Malecha, BA,[2]
Carly A. Johnson, BS,[2] and Sarit Polsky, MD, MPH[2]

Table 2. Glycemic Control (Table view)

	CGM (n = 109)[a]	*SMBG (n = 51)*[b]	*P*
Average HbA1c across pregnancy (%)	6.5 ± 0.8	7.1 ± 1.0	<0.001
HbA1c in T1 (%)	6.6 ± 0.9	7.4 ± 1.2	<0.001
HbA1c in T2 (%)	6.0 ± 0.7	6.5 ± 0.8	<0.001
HbA1c in T3 (%)	6.2 ± 0.7	6.7 ± 0.9	0.001
HbA1c postpartum (%)	7.0 ± 1.2	7.8 ± 1.7	0.003
Met HbA1c goal T1 (≤6.5%)[c]	53 (48.6)	11 (22.0)	<0.001[d]
Met HbA1c goal T2 (≤6%)[c]	61 (56.0)	10 (20.0)	
Met HbA1c goal T3 (≤6%)[c]	49 (46.7)	9 (18.4)	
Never met HbA1c goal in any trimester	37 (33.9)	36 (70.6)	

studio retrospettivo su 160 donne
DM1 che abbiano usato CGM
almeno > 60 % del II e III trimestre

Clinical Effectiveness of Continuous Glucose Monitoring in Pregnancies Affected by Type 1 Diabetes

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Table 3. Maternal and Neonatal Outcomes (Table view)

Outcomes	*CGM (n = 109)*[a]	*SMBG (n = 51)*[b]	*P*
Maternal outcomes			
Gestational weight gain, kg, mean ± SD	15.6 ± 7.4	15.0 ± 6.0	0.64
Gestational hypertension, *n* (%)	24 (22.0)	7 (13.7)	0.21
Preeclampsia, *n* (%)	35 (32.1)	9 (17.7)	0.0499
Cesarean section, *n* (%)	75 (68.8)	33 (64.7)	0.61
Duration of hospital stay, days, mean ± SD	4.9 ± 2.1	5.5 ± 4.8	0.45
Neonatal outcomes			
Female sex, *n* (%)	48 (44.0)	21 (41.2)	0.73
Gestational age at delivery, weeks, mean ± SD	36.8 ± 2.1	36.9 ± 1.4	0.89
Preterm delivery, *n* (%)	35 (32.1)	19 (37.3)	0.52
Birth weight, g, mean ± SD	3382 ± 665	3598 ± 760	0.07
Birth weight centile (%)	74.2 ± 29.4	80.6 ± 28.3	0.19
Macrosomia >4000 g, *n* (%)	14 (12.8)	15 (29.4)	0.01
Macrosomia >4500 g, *n* (%)	3 (2.8)	8 (15.7)	0.004
Gestational size for age[c]			0.14
Small-for-gestational age	4 (3.7)	3 (5.9)	
Appropriate-for-gestational age	54 (49.5)	17 (33.3)	
Large-for-gestational age	51 (46.8)	31 (60.8)	
Duration of hospital stay, days, mean ± SD	9.2 ± 14.0	7.5 ± 8.2	0.46
NICU admission, *n* (%)	45 (52.9)	28 (68.3)	0.10
Duration of NICU stay, days, median [IQR][d]	5.5 [3.3–14.0]	5.0 [3.0–15.0]	0.64

Clinical Effectiveness of Continuous Glucose Monitoring in Pregnancies Affected by Type 1 Diabetes

Valerie Gao, MD,[1] Janet K. Snell-Bergeon, PhD,[2] Emily Malecha, BA,[2]
Carly A. Johnson, BS,[2] and Sarit Polsky, MD, MPH[2]

DIABETES TECHNOLOGY & THERAPEUTICS
Volume 26, Number 8, 2024

DOI: 10.1089/dia.2023.0548

Table 3. Maternal and Neonatal Outcomes (Table view)

Outcomes	*CGM (n = 109)*[a]	*SMBG (n = 51)*[b]	*P*
Maternal outcomes			
Gestational weight gain, kg, mean ± SD	15.6 ± 7.4	15.0 ± 6.0	0.64
Gestational hypertension, *n* (%)	24 (22.0)	7 (13.7)	0.21
Preeclampsia, *n* (%)	35 (32.1)	9 (17.7)	0.0499
Cesarean section, *n* (%)	75 (68.8)	33 (64.7)	0.61
Duration of hospital stay, days, mean ± SD	4.9 ± 2.1	5.5 ± 4.8	0.45
Neonatal outcomes			
Female sex, *n* (%)	48 (44.0)	21 (41.2)	0.73
Gestational age at delivery, weeks, mean ± SD	36.8 ± 2.1	36.9 ± 1.4	0.89
Preterm delivery, *n* (%)	35 (32.1)	19 (37.3)	0.52
Birth weight, g, mean ± SD	3382 ± 665	3598 ± 760	0.07
Birth weight centile (%)	74.2 ± 29.4	80.6 ± 28.3	0.19
Macrosomia >4000 g, *n* (%)	14 (12.8)	15 (29.4)	0.01
Macrosomia >4500 g, *n* (%)	3 (2.8)	8 (15.7)	0.004
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NICU admission, *n* (%)	45 (52.9)	28 (68.3)	0.10
Duration of NICU stay, days, median [IQR][d]	5.5 [3.3–14.0]	5.0 [3.0–15.0]	0.64

DIABETES TECHNOLOGY & THERAPEUTICS
Volume 23, Supplement 1, 2021
Mary Ann Liebert, Inc.
DOI: 10.1089/dia.2020.0667

DTT

DEXCOM 2021: RTCGM & COST IMPLICATIONS

Benefits of Real-Time Continuous Glucose Monitoring in Pregnancy

Jennifer M. Yamamoto, MD[1,2] and Helen R. Murphy, MD[3–5]

I dati riguardanti l'uso del CGM nel DM2 sono ancora limitati

Spesso derivano da studi che includono donne DM1 e DM2 , ma con una percentuale di DM2 generalmente intorno al 25-30%

Gli studi utilizzavano CGM di vecchia generazione (retrospettivi), in alcuni CGM ma non in continuo…

Alcuni studi hanno evidenziato una maggior richiesta di insulina nel gruppo CGM rispetto a quelle con monitoraggio tradizionale

TABLE 1. FACTORS ASSOCIATED WITH TARGET GLYCEMIA (HEMOGLOBIN A1C LESS THAN 6.5% [48 MMOL/MOL]) IN EARLY PREGNANCY

Type 2 diabetes pregnancy

Category	*Odds ratio (95% CI)*
Ethnicity[e]	
Ethnicity N/A	0.99 (0.79–1.24)
Unknown	1.79 (1.16–2.76)
Mixed	1.10 (0.76–1.58)
Asian	0.72 (0.64–0.82)
Black	0.72 (0.59–0.88)
Other	0.86 (0.61–1.20)
Deprivation N/A	0.99 (0.73–1.34)
Quintile 5	0.73 (0.57–0.93)
Quintile 4	0.84 (0.65–1.07)
Quintile 3	1.01 (0.78–1.30)
Quintile 2	1.09 (0.82–1.45)
Diabetes duration N/A	0.79 (0.59–1.06)
Duration <1 year	0.86 (0.72–1.02)
Duration 5–9 years	0.60 (0.52–0.68)
Duration 10–14 years	0.48 (0.39–0.60)
Duration >15 years	0.41 (0.27–0.61)
BMI <18.5	0.86 (0.36–2.10)
BMI 25–29.9	0.80 (0.66–0.97)
BMI 30–34.9	0.65 (0.54–0.79)
BMI 35–39.9	0.55 (0.45–0.68)
BMI >40	0.52 (0.42–0.64)

Voormolen DN, DeVries JH, Sanson RME, et al.: Continuous glucose monitoring during diabetic pregnancy (GlucoMOMS): a multicentre randomized controlled trial. Diabetes Obes Metab 2018

Murphy HR, Rayman G, Lewis K, et al.: Effectiveness of continuous glucose monitoring in pregnant women with diabetes: randomised clinical trial. BMJ 2008;337:a1680

Secher AL, Ringholm L, Andersen HU, et al.: The effect of real-time continuous glucose monitoring in pregnant women with diabetes: a randomized controlled trial. Diabetes Care 2013;36:1877–1883

Clinical Care/Education/Nutrition/Psychosocial Research
ORIGINAL ARTICLE

Changes in the Glycemic Profiles of Women With Type 1 and Type 2 Diabetes During Pregnancy

HELEN R. MURPHY, FRACP[1]
GERRY RAYMAN, MD[1]
KATHERINE DUFFIELD, RGN[2]
KAREN S. LEWIS, RGN[1]
SUSAN KELLY, RGN, RM[1]
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DUNCAN FOWLER, MD[1]
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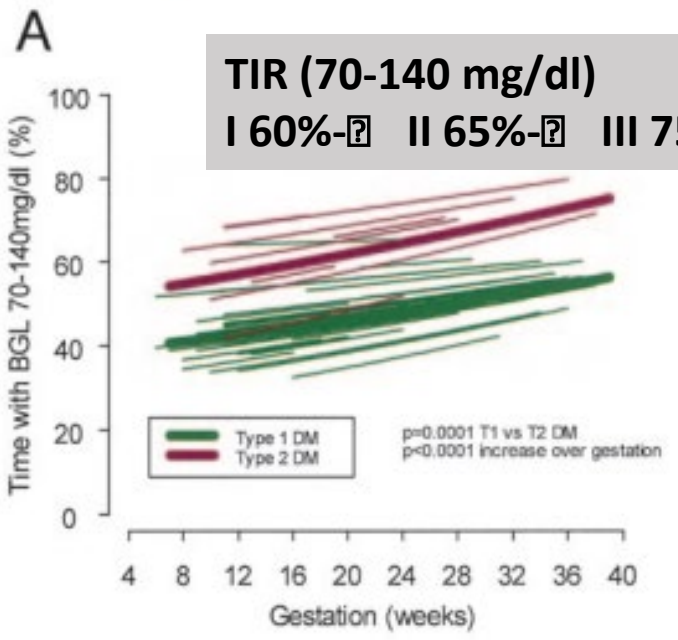
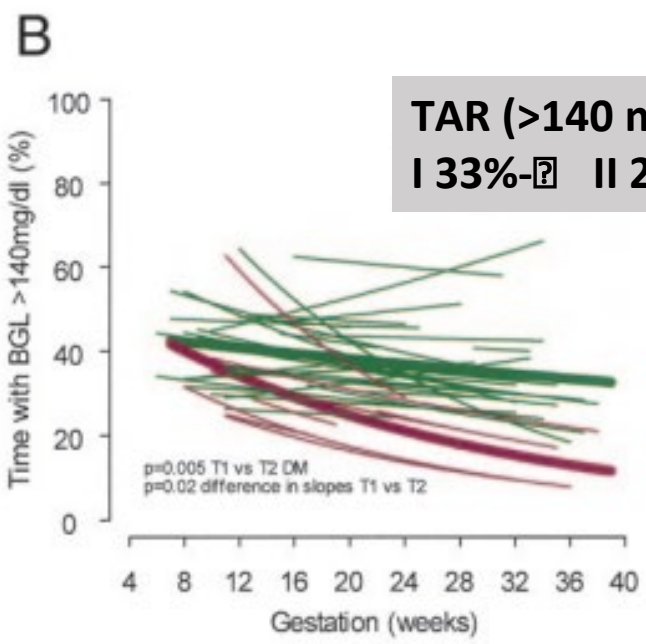
Glycemic profiles during pregnancy



TIR (70-140 mg/dl)
I 60%-□ II 65%-□ III 75%



TAR (>140 mg/dl)
I 33%-□ II 20%-□ III 12%

Observational Study > Diabetes Technol Ther. 2023 Dec;25(12):836-844.
doi: 10.1089/dia.2023.0300. Epub 2023 Oct 30.

Continuous Glucose Monitoring Metrics in High-Risk Pregnant Women with Type 2 Diabetes

Anna McLean [1 2], Elizabeth Barr [1], Georgina Tabuai [2], Helen R Murphy [3], Louise Maple-Brown [1 4]

Objective: To describe glucose metrics in a high-risk population of women with type 2 diabetes (T2DM) in pregnancy and to explore the associations with neonatal outcomes. ***Research Design and Methods:*** Prospective observational study of 57 women. Continuous glucose monitoring (CGM) trajectories were determined from metrics collected in early and late gestation using the first and last two (mean 16 and 35) weeks of Freestyle Libre data. Logistic regression was used to examine associations of CGM metrics with neonatal hypoglycemia (glucose <2.6 mmol/L requiring intravenous dextrose) and large for gestational age (LGA) (>90th percentile for gestational age and sex). Pregnancy-specific target glucose range was 3.5-7.8 mmol/L (63-140 mg/dL). ***Results:*** Forty-one women used CGM for 15 weeks (mean age 33 years, 73% Aboriginal or Torres Strait Islander, 32% living remotely). There was limited change in average metrics from early to late pregnancy. For the subgroup with sensor use >50% (n = 29), mean time in range (TIR) increased by 9%, time above range reduced by 12%, average glucose reduced by 1 mmol/L, and time below range increased by 3%. Neonatal hypoglycemia was associated with most CGM metrics, HbA1c and CGM targets, particularly those from late pregnancy. LGA was associated with hyperglycemic metrics from early pregnancy. Each 1% increase TIR was associated with a 4%-5% reduction in risk of neonatal complications. ***Conclusion:*** In this high-risk group of women with T2DM, CGM metrics only improved during pregnancy in those with greater sensor use and were associated with LGA in early pregnancy and neonatal hypoglycemia throughout. Culturally appropriate health care strategies are critical for successful use of CGM technology.

Journal of *Clinical Medicine*

MDPI

Da 435 articoli, 14 sono stati inclusi in questa review

L'uso del CGM è stato utilizzato da un minimo di 48-72h ad un massimo di 14 gg

Systematic Review

Efficacy of Continuous Glucose Monitoring on Glycaemic Control in Pregnant Women with Gestational Diabetes Mellitus—A Systematic Review

Agata Majewska *, Paweł Jan Stanirowski, Mirosław Wielgoś and Dorota Bomba-Opoń

J. Clin. Med. **2022**, *11*, 2932

This systematic review supports the thesis that CGM is superior to SMBG in the management of dysglycaemia in GDM. Our findings suggest that CGM better detects hyper- and hypolgycaemic events and is a more appropriate predictor of qualification for insulin therapy. Therefore, these results provide justification for the idea that CGM plays an important role in glycaemia management in GDM. CGM improves the detection of fasting and postprandial hyperglycaemia. Additionally, it better assesses nocturnal hypoglycemia episodes. Improved identification of dysglycaemia allows for better patient compliance as well as decreases the rate of unnecessary interventions, including qualification for insulin therapy and further improper dose adjustment.

On the other hand, the results for neonatal outcomes, including LGA incidence in both methods of measurement, were inconclusive. There is limited evidence that CGM improves any of the analysed neonatal outcomes. Furthermore, it will be essential to elucidate the role of CGM in changing patient health behaviour patterns.

To conclude, more prospective studies focusing on maternal and neonatal outcomes in GDM-complicated pregnancies monitored by CGM need to be conducted to support the existing evidence and to solve the inconclusive findings.

ORIGINAL ARTICLE | MAY 03 2024

Continuous Glucose Monitoring Profiles in Pregnancies With and Without Gestational Diabetes Mellitus

Celeste Durnwald; Roy W. Beck; Zoey Li; Elizabeth Norton; Richard M. Bergenstal; Mary Johnson; Sean Dunnigan; Matthew Banfield; Katie Krumwiede; Judy Sibayan; Peter Calhoun; Anders L. Carlson

OBJECTIVE

To determine whether continuous glucose monitoring (CGM)-derived glycemic patterns can characterize pregnancies with gestational diabetes mellitus (GDM) as diagnosed by standard oral glucose tolerance test at 24–28 weeks' gestation compared with those without GDM.

RESEARCH DESIGN AND METHODS

The analysis includes 768 individuals enrolled from two sites prior to 17 weeks' gestation between June 2020 and December 2021 in a prospective observational study. Participants wore blinded Dexcom G6 CGMs throughout gestation. Main outcome of interest was a diagnosis of GDM by oral glucose tolerance test (OGTT). Glycemic levels in participants with GDM versus without GDM were characterized using CGM-measured glycemic metrics.

RESULTS

Participants with GDM (n = 58 [8%]) had higher mean glucose (109 ± 13 vs. 100 ± 8 mg/dL [6.0 ± 0.7 vs. 5.6 ± 0.4 mmol/L], P < 0.001), greater glucose SD (23 ± 4 vs. 19 ± 3 mg/dL [1.3 ± 0.2 vs. 1.1 ± 0.2 mmol/L], P < 0.001), less time in range 63–120 mg/dL (3.5–6.7 mmol/L) (70% ± 17% vs. 84% ± 8%, P < 0.001), greater percent time >120 mg/dL (>6.7 mmol/L) (median 23% vs. 12%, P < 0.001), and greater percent time >140 mg/dL (>7.8 mmol/L) (median 7.4% vs. 2.7%, P < 0.001) than those without GDM throughout gestation prior to OGTT. Median percent time >120 mg/dL (>6.7 mmol/L) and time >140 mg/dL (>7.8 mmol/L) were higher as early as 13–14 weeks of gestation (32% vs. 14%, P < 0.001, and 5.2% vs. 2.0%, P < 0.001, respectively) and persisted during the entire study period prior to OGTT.

ORIGINAL ARTICLE | MAY 03 2024

Continuous Glucose Monitoring Profiles in Pregnancies With and Without Gestational Diabetes Mellitus

Celeste Durnwald; Roy W. Beck; Zoey Li; Elizabeth Norton; Richard M. Bergenstal; Mary Johnson; Sean Dunnigan; Matthew Banfield; Katie Krumwiede; Judy Sibayan; Peter Calhoun; Anders L. Carlson

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RESEARCH DESIGN AND METHODS

The analysis includes 768 individuals enrolled from two sites prior to 17 [illegible] June 2020 and December 2021 in a prospective observational [illegible] Dexcom G6 CGMs throughout gestation. Main [illegible] glucose tolerance test (OGTT). [illegible] characterized using [illegible]

CONCLUSIONS

Prior to OGTT at 24–34 weeks' gestation, pregnant individuals who develop GDM have higher CGM-measured glucose levels and more hyperglycemia compared with those who do not develop GDM.

[illegible] (n = 58 [8%]) had higher mean glucose (109 ± 13 vs. 100 ± 8 mg/dL [6.0 ± 0.7 [illegible] ± 0.4 mmol/L], P < 0.001), greater glucose SD (23 ± 4 vs. 19 ± 3 mg/dL [1.3 ± 0.2 vs. 1.1 ± 0.2 mmol/L], P < 0.001), less time in range 63–120 mg/dL (3.5–6.7 mmol/L) (70% ± 17% vs. 84% ± 8%, P < 0.001), greater percent time >120 mg/dL (>6.7 mmol/L) (median 23% vs. 12%, P < 0.001), and greater percent time >140 mg/dL (>7.8 mmol/L) (median 7.4% vs. 2.7%, P < 0.001) than those without GDM throughout gestation prior to OGTT. Median percent time >120 mg/dL (>6.7 mmol/L) and time >140 mg/dL (>7.8 mmol/L) were higher as early as 13–14 weeks of gestation (32% vs. 14%, P < 0.001, and 5.2% vs. 2.0%, P < 0.001, respectively) and persisted during the entire study period prior to OGTT.

BMJ Open Diabetes Research & Care

Glucose levels measured with continuous glucose monitoring in uncomplicated pregnancies

Anders L Carlson,[1] Roy W Beck,[2] Zoey Li ,[2] Elizabeth Norton,[3] Richard M Bergenstal,[1] Mary Johnson,[1] Sean Dunnigan,[1] Matthew Banfield,[1] Katie J Krumwiede,[1] Judy R Sibayan,[2] Peter Calhoun,[2] Celeste Durnwald[3]

For this paper, the cohort was limited to participants with an uncomplicated pregnancy, which was defined as a pregnancy without large for gestational age, hypertensive disorders, or GDM based on OGTT. Participants included in the analysis were required to have an HbA1c <5.7% (<39 mmol/mol) at screening, a completed OGTT, an APO assessment at delivery, and at least 14 days of CGM data during their gestational period with at least 10 days of CGM data in the second trimester.

Table 2 Glycemic profiles of uncomplicated pregnancies, overall and by trimester

	Entire gestational period	1st trimester	2nd trimester	3rd trimester
Number of participants	413	118	413	355
Days of CGM readings, median (IQR)	123 (86–147)	18 (14–25)	69 (50–80)	53 (36–64)
Mean glucose—mg/dL (mmol/L), mean±SD	98±7 (5.4±0.4)	103±7 (5.7±0.4)	98±7 (5.4±0.4)	98±8 (5.4±0.4)
<90 mg/dL (<5.0 mmol/L), n (%)	42 (10)	2 (2)	53 (13)	57 (16)
90–<95 mg/dL (5.0–<5.3 mmol/L), n (%)	89 (22)	10 (8)	83 (20)	74 (21)
95–<100 mg/dL (5.3–<5.6 mmol/L), n (%)	121 (29)	31 (26)	114 (28)	85 (24)
100–<105 mg/dL (5.6–<5.8 mmol/L), n (%)	93 (23)	33 (28)	92 (22)	82 (23)
105–<110 mg/dL (5.8–<6.1 mmol/L), n (%)	44 (11)	26 (22)	45 (11)	31 (9)
110–<120 mg/dL (6.1–<6.7 mmol/L), n (%)	24 (6)	16 (14)	26 (6)	22 (6)

BMJ Open Diabetes Research & Care

Glucose levels measured with continuous glucose monitoring in uncomplicated pregnancies

Anders L Carlson,[1] Roy W Beck,[2] Zoey Li ,[2] Elizabeth Norton,[3] Richard M Bergenstal,[1] Mary Johnson,[1] Sean Dunnigan,[1] Matthew Banfield Katie J Krumwiede,[1] Judy R Sibayan,[2] Peter Calhoun,[2] Celeste Durnwald[3]

Table 2 Glycemic profiles of uncomplicated pregnancies, overall and by trimester

	Entire gestational period	1st trimester	2nd trimester	3rd trimester
Glucose SD—mg/dL (mmol/L), mean±SD	19±3 (1.1±0.2)	18±3 (1.0±0.2)	18±3 (1.0±0.2)	19±3 (1.1±0.2)
Glucose coefficient of variation (%), mean±SD	19%±3%	18%±2%	19%±3%	20%±3%
% time 63–120 mg/dL (3.5–6.7 mmol/L), mean±SD	85%±7%	83%±8%	85%±7%	84%±8%
Median (quartiles)	86% (82–89%)	84% (79–89%)	87% (83–90%)	85% (80–90%)
95–<99%, n (%)	2 (<1)	2 (2)	5 (1)	6 (2)
90–<95%, n (%)	78 (19)	25 (21)	101 (24)	73 (21)
85–<90%, n (%)	159 (38)	23 (19)	148 (36)	109 (31)
80–<85%, n (%)	94 (23)	35 (30)	92 (22)	76 (21)
70–<80%, n (%)	62 (15)	24 (20)	53 (13)	71 (20)
50–<70%, n (%)	18 (4)	9 (8)	14 (3)	19 (5)
<50%, n (%)	0 (0)	0 (0)	0 (0)	1 (<1)
% time 63–140 mg/dL (3.5–7.8 mmol/L), mean±SD	94%±3%	95%±3%	95%±3%	94%±4%
Median (quartiles)	95% (93–96%)	95% (93–97%)	95% (94–97%)	95% (92–96%)
% time <70 mg/dL (<3.9 mmol/L), median (quartiles)	4.2% (2.1–6.9%)	1.8% (1.0–3.6%)	3.5% (1.8–6.6%)	4.7% (2.1–8.7%)
Area over the curve 70 mg/dL (3.9 mmol/L), median (quartiles)	0.4 (0.2–0.7)	0.2 (0.1–0.3)	0.3 (0.2–0.6)	0.4 (0.2–0.8)
% time <63 mg/dL (<3.5 mmol/L), median (quartiles)	1.8% (0.9–3.2%)	0.8% (0.4–1.6%)	1.5% (0.8–3.0%)	2.0% (0.8–3.9%)

BMJ Open Diabetes Research & Care

Glucose levels measured with continuous glucose monitoring in uncomplicated pregnancies

Anders L Carlson,[1] Roy W Beck
Richard M Bergenstal,[1] Mary Jo
Katie J Krumwiede,[1] Judy R Sib

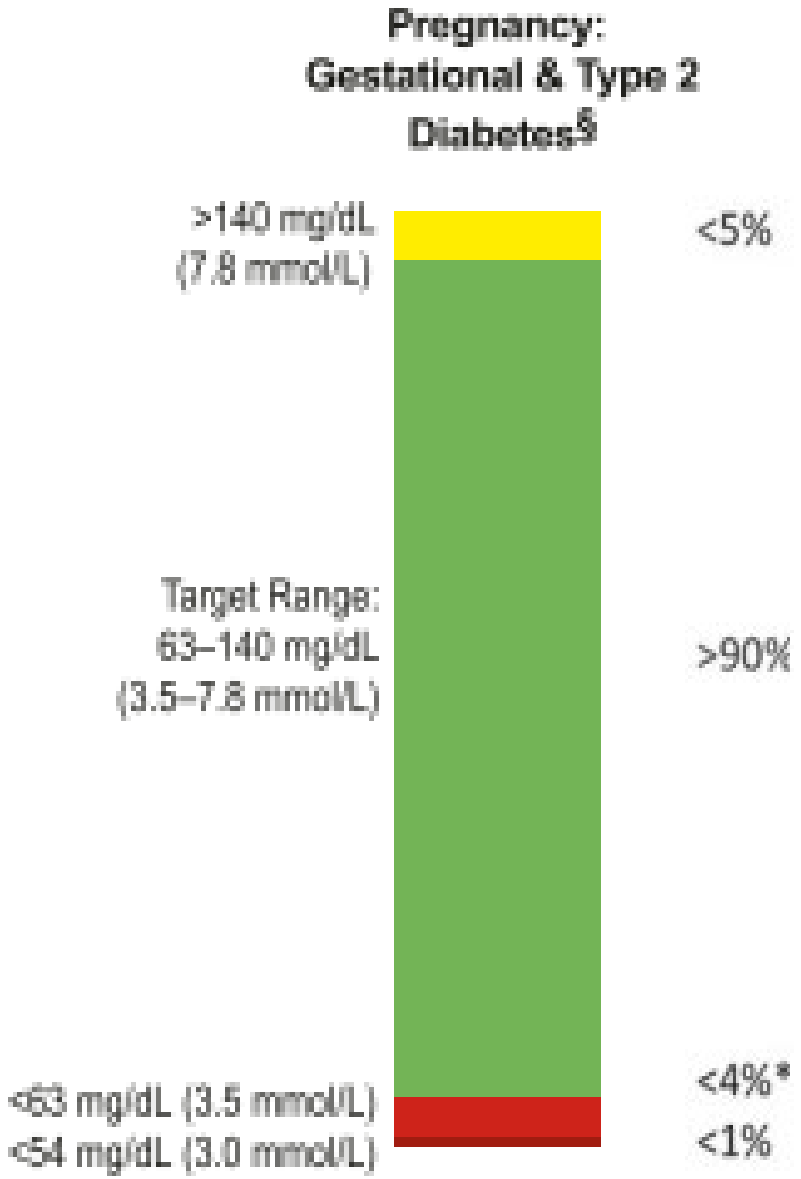
Table 3 Post-prandial profiles of uncomplicated pregnancies, overall and by trimester

	Entire gestational period	2nd trimester	3rd trimester
Number of participants	157	150	76
Number of meals	3747	2543	1183
Fasting glucose*—mg/dL (mmol/L), mean±SD	88±14 (4.9±0.8)	88±14 (4.9±0.8)	87±14 (4.8±0.8)
Baseline glucose prior to meal†—mg/dL (mmol/L), mean±SD	91±18 (5.1±1.0)	91±18 (5.1±1.0)	90±18 (5.0±1.0)
Post-prandial glucose level—mg/dL (mmol/L), mean±SD			
30 min after meal time	103±22 (5.7±1.2)	104±21 (5.8±1.2)	101±22 (5.6±1.2)
1 hour after meal time	108±23 (6.0±1.3)	107±23 (5.9±1.3)	109±23 (6.1±1.3)
2 hours after meal time	102±21 (5.7±1.2)	102±21 (5.7±1.2)	102±21 (5.7±1.2)
3 hours after meal time	97±20 (5.4±1.1)	97±19 (5.4±1.1)	97±20 (5.4±1.1)
Post-prandial peak glucose—mg/dL (mmol/L), mean±SD	126±22 (7.0±1.2)	126±22 (7.0±1.2)	125±22 (6.9±1.2)
Glucose meal excursion‡—mg/dL (mmol/L), mean±SD	36±22 (2.0±1.2)	36±21 (2.0±1.2)	35±22 (1.9±1.2)
Time to peak glucose—min, median (IQR)	62 (40–124)	60 (39–123)	67 (42–125)
Rate of glucose rise§—mg/dL/min (mmol/L/min), median (IQR)	0.5 (0.2–0.9) (0.03 (0.01–0.05))	0.5 (0.2–1.0) (0.03 (0.01–0.06))	0.5 (0.2,–0.9) (0.03 (0.01–0.05))

Diabetes Care Volume 42, August 2019

Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range

Diabetes Care 2019;42:1593–1603 | https://doi.org/10.2337/dci19-0028



Received: 26 May 2022 | Revised: 19 August 2022 | Accepted: 28 August 2022

DOI: 10.1002/edm2.369

Endocrinology, Diabetes & Metabolism Open Access WILEY

REVIEW ARTICLE

A systematic review: Cost-effectiveness of continuous glucose monitoring compared to self-monitoring of blood glucose in type 1 diabetes

Yuxin Jiao[1] | Rose Lin[1] | Xinyang Hua[2] | Leonid Churilov[3] | Michele J. Gaca[4] | Steven James[5] | Philip M. Clarke[6] | David O'Neal[7] | Elif I. Ekinci[8,9]

This systematic review suggests that CGM appears to be a cost-effective tool for individuals with type 1 diabetes. Cost-effectiveness is driven by reducing short- and long-term complications. Use in patients with suboptimal management or at risk of severe hypoglycaemia is most cost-effective.

Abstract

Continuous glucose monitoring (CGM) is rapidly becoming a vital tool in the management of type 1 diabetes. Its use has been shown to improve glycaemic management and reduce the risk of hypoglycaemic events. The cost of CGM remains a barrier to its widespread application. We aimed to identify and synthesize evidence about the cost-effectiveness of utilizing CGM in patients with type 1 diabetes. Studies were identified from MEDLINE, Embase and Cochrane Library from January 2010 to February 2022. Those that assessed the cost-effectiveness of CGM compared to self-monitored blood glucose (SMBG) in patients with type 1 diabetes and reported lifetime incremental cost-effectiveness ratio (ICER) were included. Studies on criti- re excluded. Nineteen studies were identified. Most ubcutaneous insulin infusion and SMBG to a sensor- timated ICER range was [$18,734–$99,941] and the Y) gain range was [0.76–2.99]. Use in patients with ater hypoglycaemic risk revealed more homogenous d studies assessed CGM in the context of multiple daily injections (MDI) ($n = 4$), MDI and SMBG versus SAP ($n = 2$) and three studies included hybrid closed-loop systems. Most studies ($n = 17$) concluded that CGM is a cost-effective tool. This systematic review suggests that CGM appears to be a cost-effective tool for individuals with type 1 diabetes. Cost-effectiveness is driven by reducing short- and long-term complications. Use in patients with suboptimal management or at risk of severe hypoglycaemia is most cost-effective.


Grazie per la Vostra
attenzione