

April 20th 2018



CONTINUOUS GLUCOSE MONITORING AND PREGNANCY

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Diabetes Care and Research in Europe:
The St Vincent Declaration
1989

"Achieve pregnancy outcome in the diabetic woman that *approximates* that of the non-diabetic woman"

GLYCEMIC GOALS FOR PREGNANT WOMEN WITH DIABETES





Similar to the targets recommended by the American College of Obstetricians and Gynecologists (14), the ADA-recommended targets for women with type 1 or type 2 diabetes (the same as for GDM; described below) are as follows:

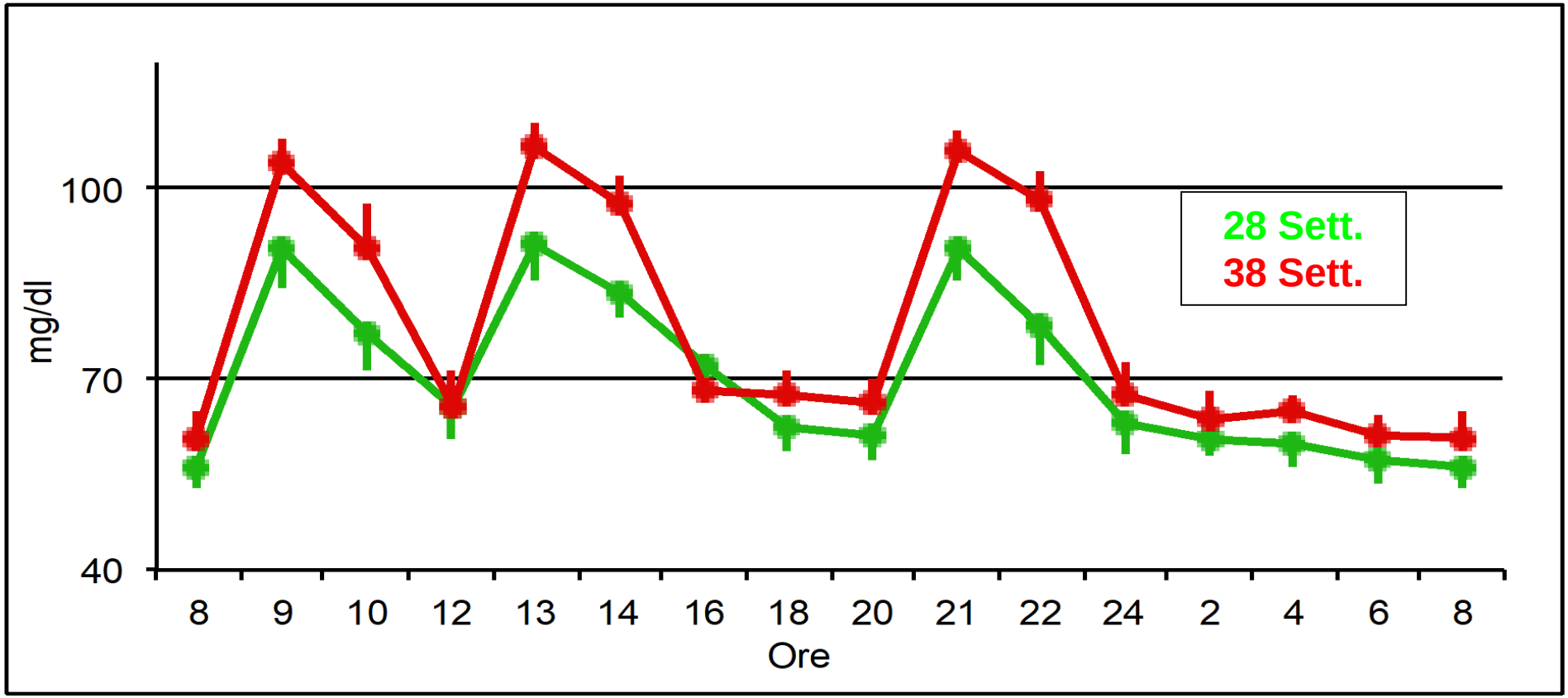
- Fasting ≤95 mg/dL (5.3 mmol/L) and either
- One-hour postprandial ≤140 mg/dL (7.8 mmol/L) or
- Two-hour postprandial ≤120 mg/dL (6.7 mmol/L)

American Diabetes Association, Standard of Medical Care in Diabetes, 2018

GLYCEMIC PROFILES DURING PREGNANCY

(women without diabetes)





Parretti E., Diabetes Care, 24:1319-23, 2001

GLUCOSE MONITORING DURING PREGNANCY



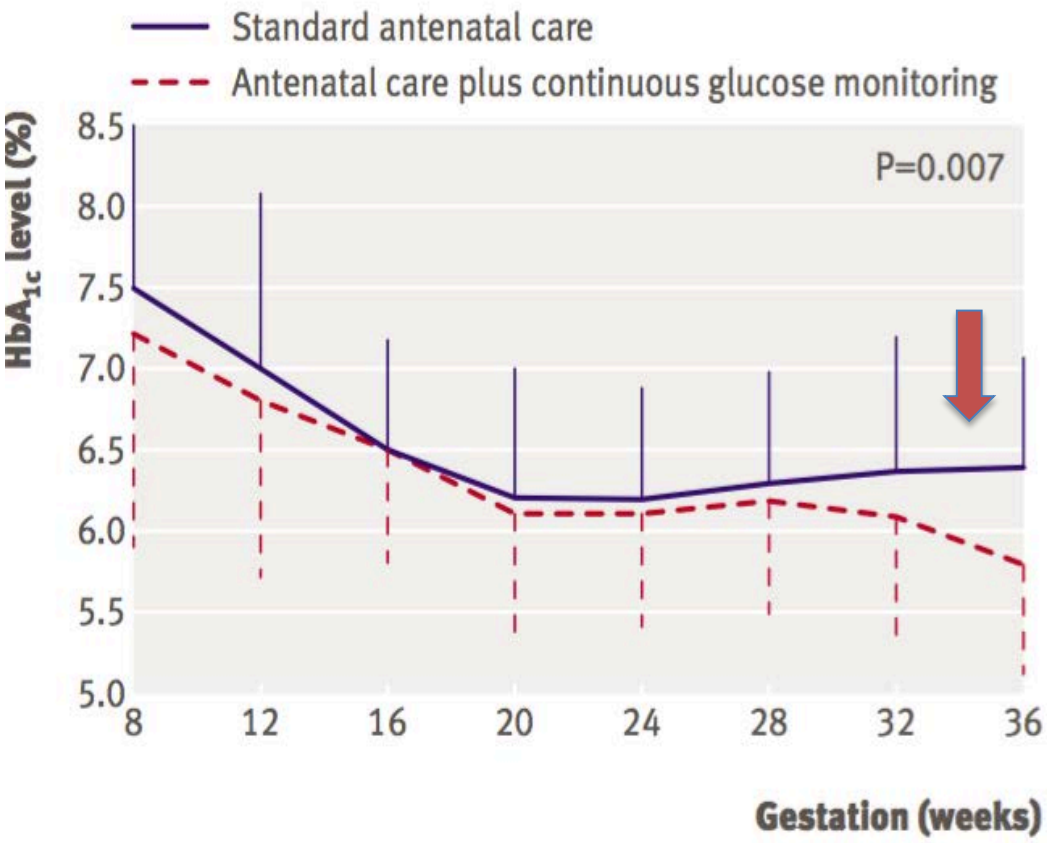
- Self Monitoring of Blood Glucose (SMBG)
- Retrospective (Blinded) Continuous Glucose Monitoring
- RT-CGM, Sensor Augmented Insulin Pump (SAP) Therapy
- The Smart Pumps (LGS, PLGS)
- Flash Glucose Monitoring (FGM)



2008 2013 2018

RETROSPECTIVE (BLINDED) CONTINUOUS GLUCOSE MONITORING

Effectiveness of continuous glucose monitoring in pregnant women with diabetes: randomised clinical trial



Intervention Continuous glucose monitoring was used as an educational tool to inform shared decision making and future therapeutic changes at intervals of 4-6 weeks during pregnancy. All other aspects of antenatal care were equal between the groups.

Main outcome measures The primary outcome was maternal glycaemic control during the second and third trimesters from measurements of HbA_{1c} levels every four weeks. Secondary outcomes were birth weight and risk of macrosomia using birthweight standard deviation scores and customised birthweight centiles. Statistical analyses were done on an intention to treat basis.

MACROSOMIA:
35% (intervention arm) **P=0.05**
60% (control arm)

Murphy et al, BMJ 2008

2008 2013 2018

REAL-TIME (INTERMITTENT) CONTINUOUS GLUCOSE MONITORING

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

	Real-time CGM	Control subjects	*P* value
N (% with type 1 diabetes)	79 (80)	75 (80)	
Live births	76 (96%)	73 (97%)	
Miscarriage	3 (4%)	2 (3%)	1.00
Males	34 (45%)	31(42%)	0.78
Weight gain in pregnancy (kg)	14.4 (−0.4 to 32.5)	13.9 (−2.0 to 31.0)	0.92
Preeclampsia	7 (9%)	6 (8%)	0.83
Caesarean section	28 (37%)	33 (45%)	0.30
Gestational age at birth (days)	263 (206–280)	264 (231–277)	0.14
Preterm delivery	16 (21%)	12 (16%)	0.47
Birth weight (g)	3,510 (1,070–4,356)	3,436 (2,045–4,424)	0.80
Birth weight z-score	1.07 (−2.32 to 3.78)	0.66 (−1.13 to 3.45)	0.20
Large-for-gestational-age infant	34 (45%)	25 (34%)	0.19
2-h plasma glucose (mmol/L)	2.8 (0.5–5.5)[a]	2.8 (1.1–6.7)	0.22
Neonatal hypoglycemia	25 (36%)[a]	29 (40%)	0.62
Severe neonatal hypoglycemia	9 (13%)[a]	10 (14%)	0.88
Preterm delivery and/or severe neonatal hypoglycemia	20 (29%)[a]	16 (22%)	0.36

INTERVENTION:
6 DAYS RT-CGM
(8°, 12°, 21°, 27°, 33°)

COMPARABLE GLUCOSE CONTROL

COMPARABLE OUTCOMES

Secher AL et al, Diabetes Care 2013

2008 2013 2018

Continuous Glucose Monitoring in Pregnancy: We Have the Technology but Not All the Answers



CGM before and during pregnancy. It is not the devices per se but how patients, their spouses/significant others, and health professionals interact with CGM that will likely determine outcomes. At this point in time we have the technology, but we don't have all the answers.

HELEN R. MURPHY, MBBCHBAO, FRACP, MD

DIABETES CARE, VOLUME 36, JULY 2013

FOUR YEARS LATER …





Cochrane Library

Cochrane Database of Systematic Review





glucose during pregnancy for
es (Review)

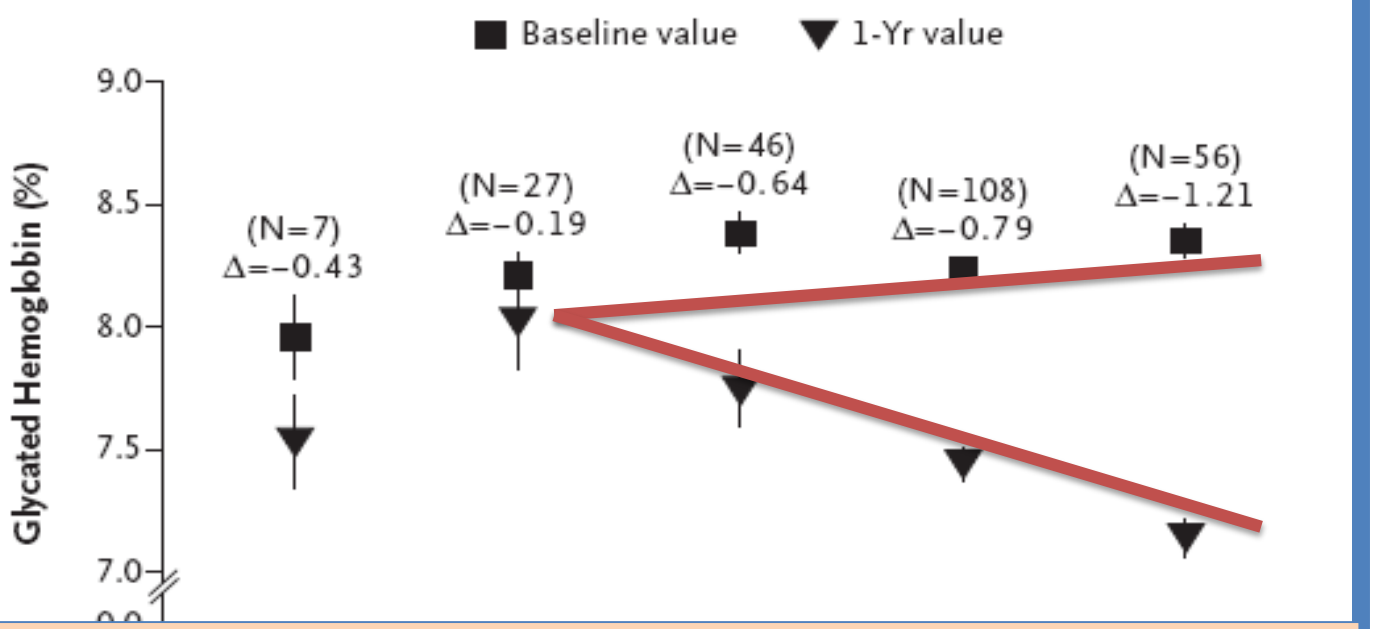
abase Syst Rev. 2017 Jun 11;6

This review found no evidence that any glucose monitoring technique is superior to any other technique among pregnant women with pre-existing type 1 or type 2 diabetes. The evidence base for the effectiveness of monitoring techniques is weak and additional evidence from large well-designed randomised trials is required to inform choices of glucose monitoring techniques.

The NEW ENGLAND JOURNAL of MEDICINE

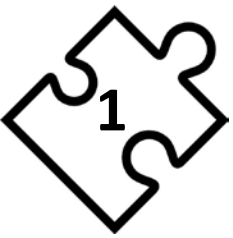
ESTABLISHED IN 1812 JULY 22, 2010 VOL. 363 NO. 4

Effectiveness of Sensor-Augmented Insulin-Pump Therapy in Type 1 Diabetes



Many studies during pregnancy, even with RT-CGM, have an average sensor use < 15 - 20% of the total time

New England Journal of Medicine, 2010



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

(>6 days per week)

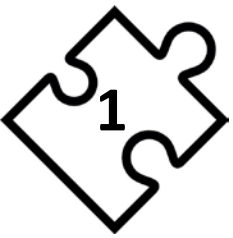
Denice S Feig, Lois E Donovan, Rosa Corcoy, Kellie E Murphy, Stephanie A Amiel, Katharine F Hunt, Elizabeth Asztalos, Jon F R Barrett, J Johanna Sanchez, Alberto de Leiva, Moshe Hod, Lois Jovanovic, Erin Keely, Ruth McManus, Eileen K Hutton, Claire L Meek, Zoe A Stewart, Tim Wysocki, Robert O'Brien,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

Primary Objective: determine if **RT-CGM** can improve glycemic control in women with T1D who are pregnant or planning pregnancy

Results: 325 women (215 pregnant – 110 planning)

- Real-Time + SMBG vs. SMBG
- Lower HbA1c in pregnant women using CGM (mean difference –0.19%; p=0.02)
- CGM users spent more time in target (68% vs 61%; P=0.003) and less time hyperglycaemic (27% vs 32%; P=0.0279)
- Perinatal outcomes: lower incidence of: large for gestational age, neonatal intensive care admissions lasting more than 24h, neonatal hypoglycaemia. Shorter length of hospital stay

Lancet. 2017, published online September 15, 2017



2008 2013 2018

DIABETES, OBESITY AND METABOLISM
A JOURNAL OF PHARMACOLOGY AND THERAPEUTICS

ORIGINAL ARTICLE

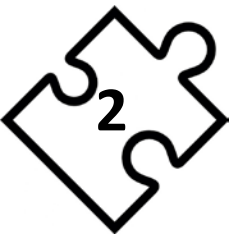
Continuous Glucose Monitoring during Diabetic Pregnancy (GlucoMOMS); a multicentre randomised controlled trial

Daphne N. Voormolen PhD, J. Hans DeVries, ... See all authors ›

First published: 30 March 2018
https://doi.org/10.1111/dom.13310

The incidence of macrosomia was 31.0% in the CGM group and 28.4% in the standard treatment group (RR 1.06, 95%CI 0.83- 1.37). HbA1c levels were similar between treatment groups

In diabetic pregnancy, intermittent retrospective CGM use did not reduce the risk of macrosomia. CGM use provides detailed information about glycaemic fluctuations but as a treatment strategy does not translate into improved pregnancy outcome



2008 2013 2018

Current Diabetes Reports (2018) 18: 4
https://doi.org/10.1007/s11892-018-0973-9

DIABETES AND PREGNANCY (M-F HIVERT AND CE POWE, SECTION EDITORS)

Emerging Technologies for the Management of Type 1 Diabetes in Pregnancy

Jennifer M. Yamamoto[1] · Helen R. Murphy[2,3,4]

Published online: 30 January 2018
© The Author(s) 2018. This article is an open access publication

Using CGM to Gain Insight into Glucose Pathophysiology

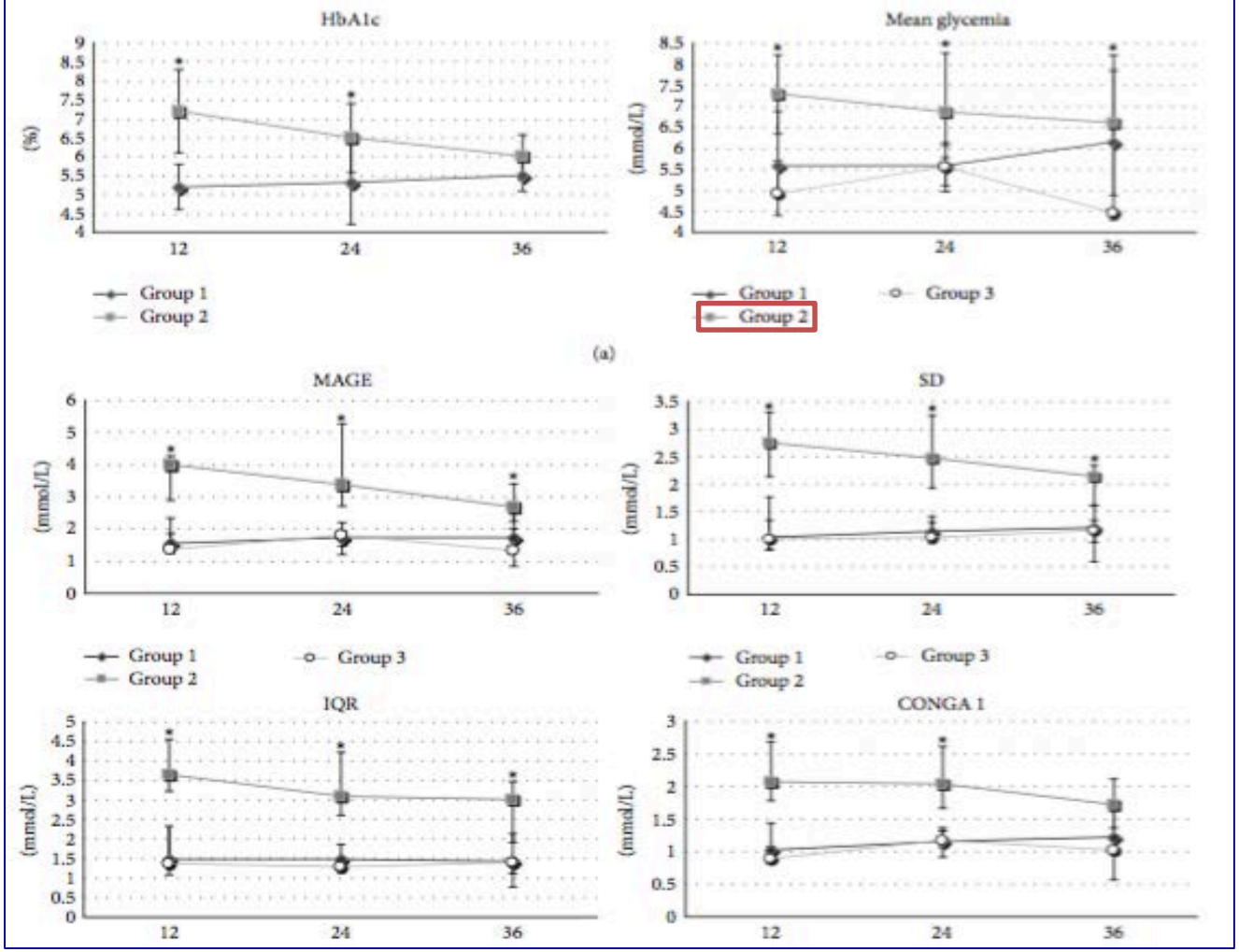
The detailed information provided by CGM is improving our understanding of various aspects of glucose control and in some cases deepening our understanding of the complex relationship between glucose and pregnancy outcomes

2

Clinical Study

Glucose Fluctuations during Gestation: An Additional Tool for Monitoring Pregnancy Complicated by Diabetes

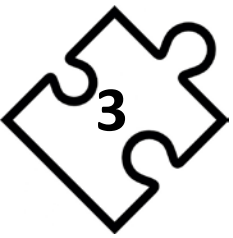
M. G. Dalfrà,[1] N. C. Chilelli,[1] G. Di Cianni,[2] G. Mello,[3] C. Lencioni,[2] S. Biagioni,[3] M. Scalese,[4] G. Sartore,[1] and A. Lapolla[1]



WOMEN WITH TYPE 1 DIABETES SHOWED A HIGHER GLYCEMIC VARIABILITY

2-FOLD HIGHER RISK OF HYPERGLYCEMIC SPIKES

HbA1c VALUES DID NOT CORRELATE WITH GLYCEMIC VARIABILITY INDICATORS IN TYPE 1 DIABETES PREGNANCIES



GETTING CLOSER TO THE "CLOSED LOOP":

THE SMART PUMPS

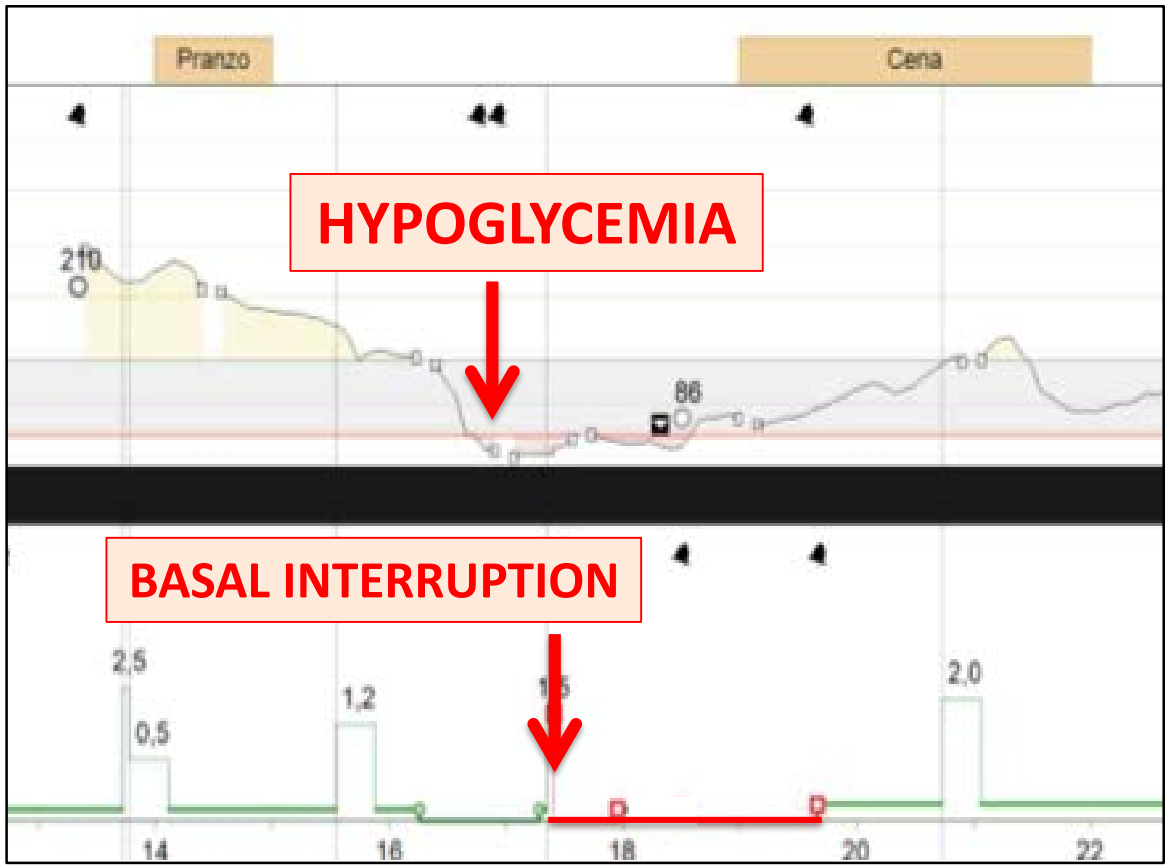
LOW GLUCOSE SUSPEND (LGS)

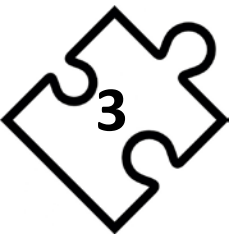
PREDICTIVE LOW GLUCOSE SUSPEND (PLGS)

3

HOW DOES IT WORK…

LGS





HOW DOES IT WORK…

PLGS

Frequency of Morning Ketosis After Overnight Insulin Suspension Using an Automated Nocturnal Predictive Low Glucose Suspend System

*Roy W. Beck,[1] Dan Raghinaru,[1] R. Paul Wadwa,[2] H. Peter Chase,[2] David M. Maahs,[2] and Bruce A. Buckingham,[3] for the In Home Closed Loop Study Group**

Diabetes Care 2014;37:1224–1229 | DOI: 10.2337/dc13-2775

THE RISK OF DEVELOPMENT OF KETOSIS AND DKA USING THESE SYSTEMS TO SUSPEND INSULIN DELIVERY

IS NOT INCREASED

4

GLUCOSE MONITORING DURING PREGNANCY



- Self Monitoring of Blood Glucose (SMBG)
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- Flash Glucose Monitoring (FGM)

4

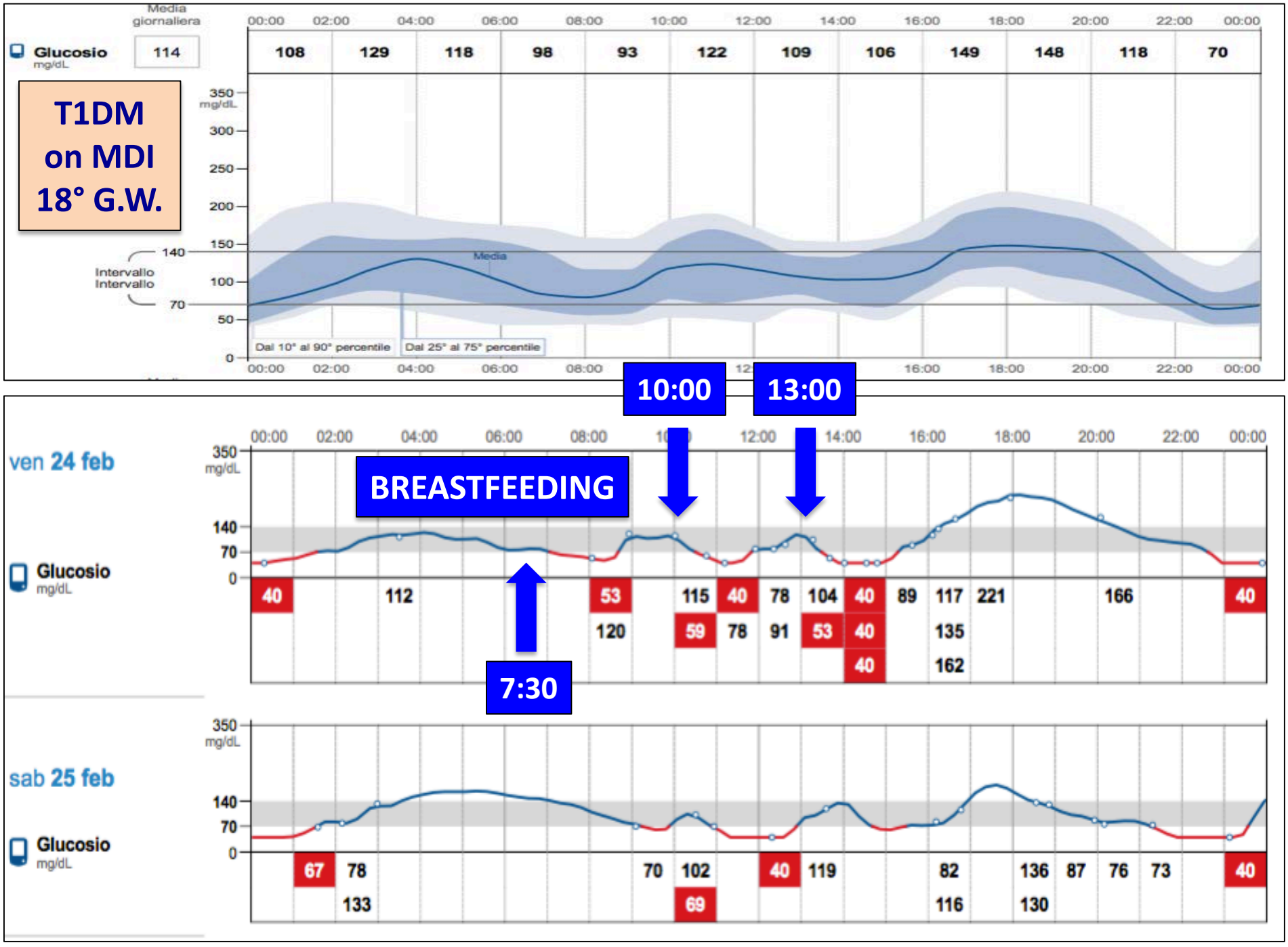
T1DM
on MDI
17° G.W.

- PLANNED PREGNANCY (HbA1c 6.4%)
- SECOND PREGNANCY
- BREASTFEEDING OF THE FIRST BABY



Self Monitoring of Blood Glucose

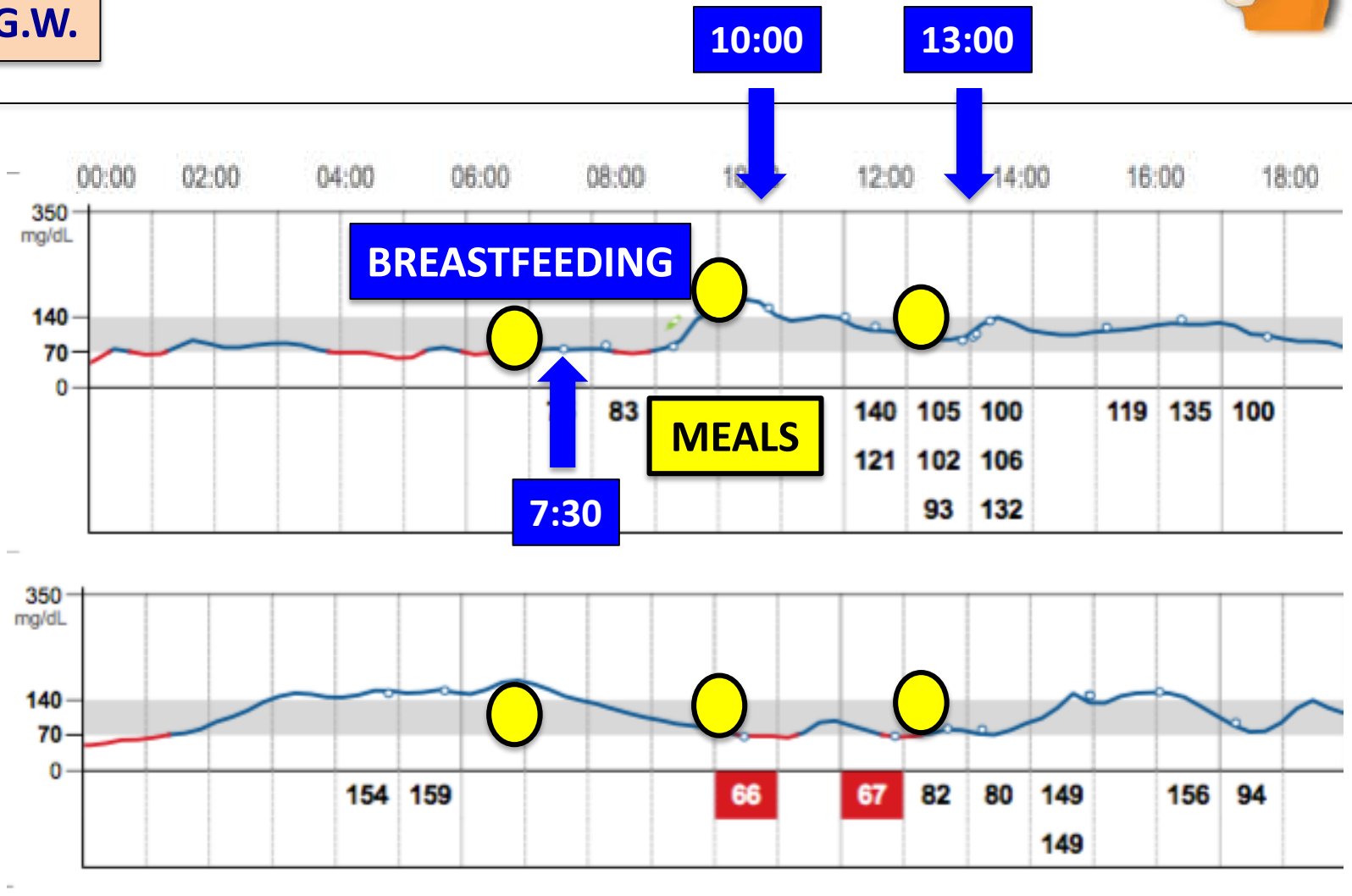
	BB	AB	BL	AL	BD	AD
16/02/2017	112	48	67	59	79	118
17/02/2017	87	132	65	134		
18/02/2017	64	70	49	132	89	98
19/02/2017	70	54	80		76	133
20/02/2017	88	111	43	140		
21/02/2017	81	146			68	109
22/02/2017	51	137	115		71	122


T1DM
on MDI
18° G.W.
Media giornaliera
Glucosio
mg/dL
114
108 129 118 98 93 122 109 106 149 148 118 70
Intervallo
Intervallo
Media
Dal 10° al 90° percentile
Dal 25° al 75° percentile
10:00
13:00
BREASTFEEDING
7:30
ven 24 feb
sab 25 feb

T1DM
on MDI
21° G.W.

THREE WEEKS LATER





2008 2013 2018

FGM DURING PREGNANCY

ATTD 2017 E-POSTER VIEWING ABSTRACTS

205

ACCURACY EVALUATION OF FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM WHEN USED BY PREGNANT WOMEN WITH DIABETES

E. Scott[1], *A. Kautzky-Willer*[2]

[1]*St James's University Hospital, Department of Diabetes and Endocrinology, Leeds, United Kingdom*
[2]*Medical University of Vienna, Department of Internal Medicine III Division of Endocrinology and Metabolism, Vienna, Austria*

DIABETES TECHNOLOGY & THERAPEUTICS
Volume 20, Number 3, 2018
Mary Ann Liebert, Inc.
DOI: 10.1089/dia.2017.0386

DTT

ORIGINAL ARTICLE

Accuracy, User Acceptability, and Safety Evaluation for the FreeStyle Libre Flash Glucose Monitoring System When Used by Pregnant Women with Diabetes

Eleanor M. Scott, BM BS, MD, FRCP[1] Rudy W. Bilous, MD, FRCP[2] and Alexandra Kautzky-Willer, Professor, MD[3]

Evidences on FGM Efficacy during pregnancy?

Kishimoto *et al. Journal of Diabetes & Metabolic Disorders* (2017) 16:44
DOI 10.1186/s40200-017-0327-1

Journal of Diabetes & Metabolic Disorders

CASE REPORT Open Access

Successful glycemic control using a flash glucose monitoring system for a pregnant woman with diabetes: a case report

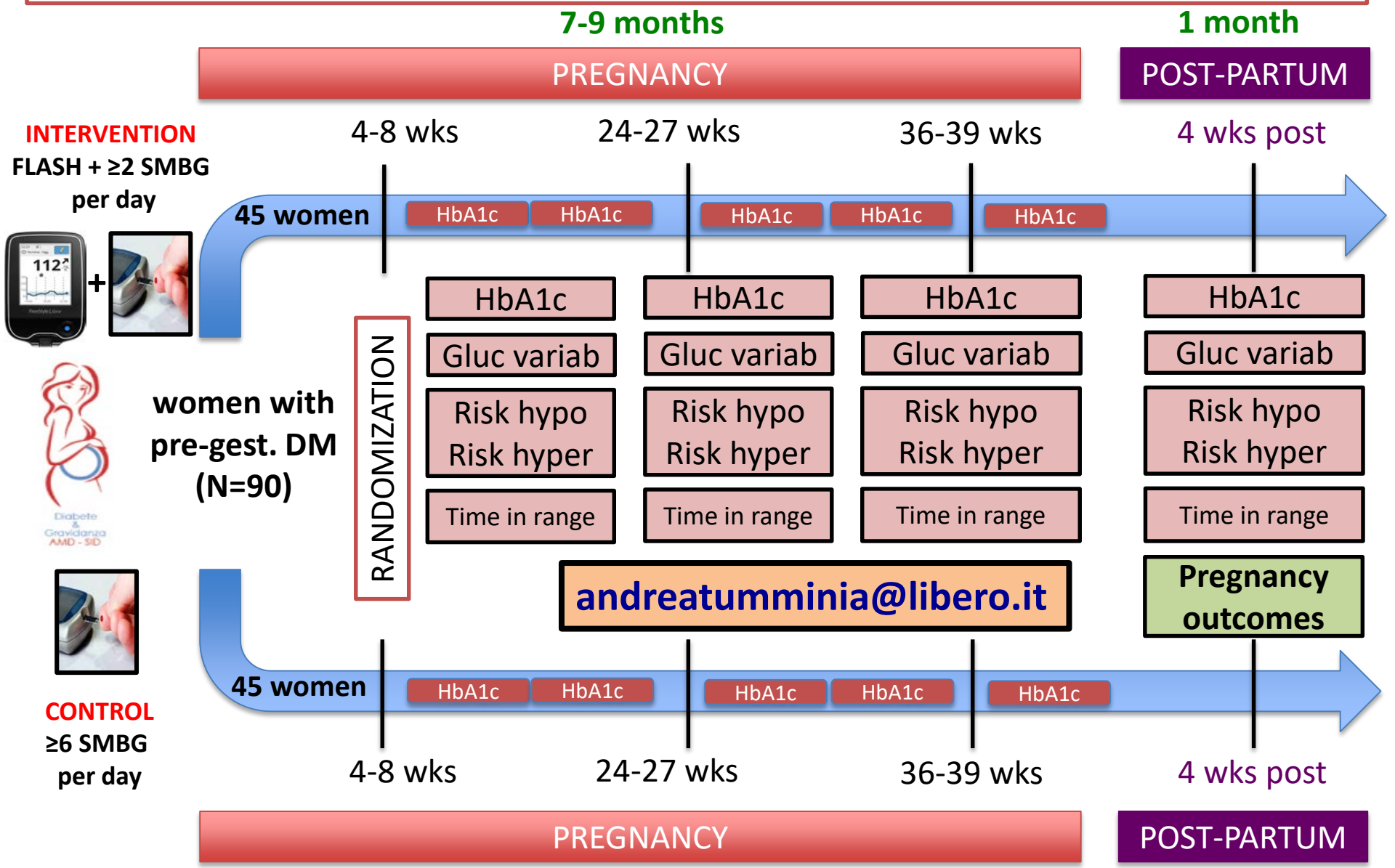
Miyako Kishimoto[1,2*], Saori Tamada[3] and Yoko Oshiba[1,3]

Experience with FreeStyle Libre Flash glucose monitoring system in management of refractory dumping syndrome in pregnancy shortly after bariatric surgery

Peter Novodvorsky, Emma Walkinshaw, [...], and Alia Munir

Efficacy of Flash Glucose Monitoring in pregnant women with poorly controlled diabetes: a randomized controlled trial

(GRUPPO DI STUDIO SID-AMD DIABETE E GRAVIDANZA)





1

% of Time

(intermittent vs. continuous)



2

Pathophysiology insight



3

Smart functions LGS, PLGS

4

CONTINUOUS EDUCATION

2008 2013 2018

Continuous Glucose Monitoring in Pregnancy: We Have the Technology but Not All the Answers

CGM before and during pregnancy. It is not the devices per se but how patients, their spouses/significant others, and health professionals interact with CGM that will likely determine outcomes. At this point in time we have the technology, but we don't have all the answers.

HELEN R. MURPHY, MBBCHBAO, FRACP, MD

DIABETES CARE, VOLUME 36, JULY 2013



THANKS FOR YOUR ATTENTION

