DELIVERY ROOM:
Continuous Glucose Monitoring System (CGMS)
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Of pregnancies complicated by diabetes mellitus:

- 88%: Gestational diabetes
- 8%: pre-existing DM Type 2
- 4%: pre-existing DM Type 1

7% (200,000 cases per year) of all pregnancies are complicated by gestational diabetes.

The Australian Diabetes in Pregnancy Society Consensus statement recommends:
- A fasting glucose of 4.0–5.5 mmol/L
- A postprandial glucose of < 7.0 mmol/L after 1 h
- And < 8.0 mmol/L after 2 hours

The fasting blood glucose profiles: 71.9 – 78.3 (28 – 38 wks) mg/dl

Peek postprandial: 105.0 mg/dl

Mean value: 83.7 mg/dl

Time peak: 70 min +/- 13

Insulin therapy:
- the fasting blood glucose level > 105 mg/dl
- 2 h post-prandial values > 120 mg/dl

The euglycaemic is a target for fetal well-being
-- prevention of episodes of hypoglycemia
(ketoacidosis and anaerobic metabolism)

1- Parretti E. et al. First trimester maternal glucose levels from diurnal profiles in nondiabetic pregnancies. Diabetes Care 2001;24:1319
When does the **physiological peak** of post-prandial glucose occur?

---**Post-Pra.** Glucose Level > **Pre-Pra.**

( insulin treat adaptation )

---↑ Correlation of 1 hr glucose levels than 2 hrs..... 1,2

---Relation SMBG / Complication : unsatisfactory 3

( 4-6-8 glucose measurements/day not reflect the 24 h profile )

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SMBG : Self Monitoring Blood Glucose


2 Parretti E. et al.: Third-trimester maternal glucose levels from diurnal profiles in non-diabetic pregnancies. Diabetes Care 2001;24:1319-1323

Do non-diabetic and diabetic pregnant women have different post-prandial glucose profile?

82 +/- 18 min Glucose Peak in non–diabetic group
74 +/- 23 min Glucose Peak in diabetic group

not significant

60 min ???
90 min ???
120 min ?????

...... but ............ few studies are available about the pre- / post prandial glucose curves in patients with GDM and health pregnant women

What is the optimal time for post-prandial glucose measurement rated according to clinical outcome?

Significant Difference between the measurements

at 120 min and 135 min Post-Prandial

\( P < 0.05 \)

at 75 min and 105 min, by clinical outcome

\( P < 0.05 \)

at 60 min to 135 min, for mode of delivery

\( P < 0.05 \)

at 60 min to 135 min, for birth weight percentile

\( P < 0.05 \)

....no evidence for the recommended post-prandial cut-off values

60 min ???...... To short
120 min ????.??..... To long

Optimal Time : 45 – 120 min post-prandial

...but we would prefer a 60 min, because patients can calculate this more easily

can have more freedom to eat

Hyperglycemia:
in later stages of pregnancy is associated with an increased risk of macrosomia, birth weight

SMBG = an incomplete picture
= difficult to interpret
= difficult to extrapolate necessary information.
= the ideal timing to monitor hypo- or hyperglycemia remains a matter of debate

Acceptable regimen for blood glucose monitoring by SMBG is to measure:
-- before and 1 h after meals,
-- prior to going to sleep,
-- during the night (nocturnal hypoglycemia)
-- 8 values / 24 hrs

SMBG: Self Monitoring Blood Glucose
Hyperglycemia:

• In a period of 24 h, blood sugar in patients with diabetes fluctuates dramatically, and many of these occurrences are undocumented and unnoticed when using SMBG only 6 to 8 times per day.

• The maternal hyperglycemia causes a hyperplasia of pancreatic β-cells resulting in hyperinsulinemia fetal and hyperplasia of adipocytes.

But, .. The asymptomatic hypoglicemia? ( < 60 mg/dl, especially at night )
Hypoglicemia

Maternal hypoglycaemia is
--a common occurrence in pre-existing
diabetes in pregnancy,
--a potentially damaging
to mother and fetus,
( in the first trimester can be teratogenic)

-First Self-sampling\(^1\) for
blood sugar determination - 1962

1 Keen H et al. Self-sampling for blood sugar. Lancet 1962; 1: 1037-1040
Continuous Glucose Monitoring System (CGMS)

displays glucose levels every 1 min / 5 min/ 72 hrs
in non-pregnant and pregnant patients with diabetes

--day-to-day glucose variability
--complete view of a glucose profile
--glycaemic control during the first trimester
--measure the glucose content of interstitial fluid

--measure glucose levels during delivery
--allows the detection of otherwise unnoticed hypo- and hyperglycemic episodes

interstitial fluid glucose is similar to plasma glucose

Food and Drug Administration-approved devices:
--CGMS (Medtronic, Inc., Sylmar, CA)
--Guardian REAL-Time System (Medtronic MiniMed, Northridge, CA)
--SEVEN system (DexCom, San Diego, CA),
--FreeStyle Navigator (Abbott Diabetes Care, Alameda, CA)
Continuous Glucose Monitoring System (CGMS)

- reduce the range of glucose excursion in patients insulin treated
- reduce the costs of insulin therapy
- reducing maternal-fetal-neonatal complications
- identify the early episodes of maternal hyperglycemia and hypoglycemia

15 gravid women with type 1 diabetes:
strong accuracy of the CGMS in comparison to SMBG

Diabetes Technol Ther 2004; 6: 645-651

SMBG : Self Monitoring Blood Glucose
Continuous Glucose Monitoring System (CGMS)

47 Israeli women with GDM compared the glycemic profile by CGMS to SMBG of glucose after a 72-h period.
--23 women were treated with diet alone
--24 with diet and insulin.

CGMS for 72 h, a total of 763 +/- 62 glucose measurements / patient (versus 18–24 SMBG measurements /72-h /patient).

• In the insulin-treated group, CGMS revealed 132 +/- 31 min / day of hyperglycemia (glucose level >140mg=dL) that was undetected by SMBG.
  • 14 insulin-treated women were found to nocturnal hypoglycemia, undetected by SMBG.

• In the diet-treated group experienced 94 +/- 23 min/ day of undetected hyperglycemia.

• Through the information supplemented by CGMS, therapeutic regimens were adjusted for 36 of the 47 patients.

Chen R et al.: Continuous glucose monitoring for the evaluation and improved control of gestational diabetes mellitus
J Matern Fetal Neonatal Med 2003;14:256-260
Continuous Glucose Monitoring System (CGMS)

55 pregnant women – 37 with gestational diabetes (10 type 2 and 8 type 1)

62% showed undetected postprandial hyperglycaemia and overnight hypoglycaemia.

CGMS is a well-tolerated clinically useful tool in the management of gestational diabetes and pre-existing diabetes in pregnancy.

### Summary of Literature Review

<table>
<thead>
<tr>
<th>Authors (year)</th>
<th>Participants</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feldman et al. (2003)</td>
<td>Type 1, non-pregnant (n = 30)</td>
<td>97.6% of readings within clinically acceptable zones</td>
</tr>
<tr>
<td>Gross et al. (2000)</td>
<td>Non-pregnant patients (n = 135), 87% type 1</td>
<td>96.2% readings within clinically acceptable zones</td>
</tr>
<tr>
<td>Clarke et al. (2005)</td>
<td>Type 1 non-pregnant (n = 16)</td>
<td>Navigator more accurate than CGMS during hypoglycemia</td>
</tr>
<tr>
<td>Kerssen et al. (2004)</td>
<td>Type 1, pregnant (n = 15)</td>
<td>93.8% of readings within clinically acceptable zones</td>
</tr>
<tr>
<td>Chen et al. (2003)</td>
<td>GDM, pregnant (n = 57)</td>
<td>CGMS detected hyperglycemia and nocturnal hypoglycemia, otherwise undetected by SMBG. These findings were used to adjust therapeutic regimen in patients.</td>
</tr>
<tr>
<td>McLachlan et al. (2007)</td>
<td>GDM, pregnant (n = 37); type 2, pregnant (n = 10); type 1, pregnant (n = 8)</td>
<td>62% of CGMS traces detected hyperglycemia and nocturnal hypoglycemia and were used to alter therapeutic regimen. 77% patient satisfaction Therapeutic changes made based on CGMS information showed a reduction in hyperglycemia and nocturnal hypoglycemia.</td>
</tr>
<tr>
<td>Yogevey et al. (2003)</td>
<td>Type 1 pregnant (n = 6); GDM, pregnant (n = 2)</td>
<td>95.4% of reading within clinically acceptable zones Real-time access to CGM readings decreased time spent in hyperglycemia and nocturnal hypoglycemia, while increasing time in target glucose range when compared to patients using SMBG alone.</td>
</tr>
<tr>
<td>Garg et al. (2006)</td>
<td>Type 1, non-pregnant (n = 75); type 2, non-pregnant (n = 16)</td>
<td>CGM during pregnancy improves maternal HbA1c in the third trimester, decreases infant birth weight, and reduces risk of macrosomia. Real-time CGM during pregnancy improves maternal HbA1c and decreases infant birth weight. CGM detected higher number of GDM women in need of antihyperglycemic medication than SMBG alone.</td>
</tr>
<tr>
<td>Murphy et al. (2008)</td>
<td>Type 1, pregnant (n = 46); type 2, pregnant (n = 25)</td>
<td>Characterization of obese and normal weight, without diabetes glycemic profiles using CGM</td>
</tr>
</tbody>
</table>
Yogev (2004) used CGMS to monitor pregnant women without diabetes in order to create a normoglycemia profile for comparison to women with pregnancies complicated by diabetes.

57 obese and normal weight women without diabetes were monitored for 72 h with the CGMS.

Fasting blood glucose was 75 +/- 12mg/dL
mean blood glucose level was 110 +/- 16mg/dL
CGMS, postprandial glucose peaks was 70 +/- 13 min.

The obese women displayed
--higher postprandial glucose peak values,
--increased time interval for attainment of the glucose peak,
--lower mean blood glucose during the night.

Interestingly, no difference was found between obese and normal weight women regarding fasting and mean blood glucose.

The primary aim:
CGMS in mothers with DM in labour, and to review our current guidelines regarding maternal glycaemic control.

A second aim: to investigate the relationship between
The maternal glucose concentrations 2 h before delivery and
the postnatal glucose adaptation of the newborn

Participating women: 20 pregnant women insulin-treated DM
(17 with Type 1 DM, 1 Type 2 DM, 2 gestational DM)

• ≥ 37 wks
• insulin-treated
• planned vaginal delivery,
• CGMS monitoring during the last 2 h prior to delivery
• All were treated with an intensive multiple daily insulin regimen or insulin pump
• CGMS monitoring was initiated in the delivery room
• 5 mothers were excluded
• Accurate readings for at least 2 h prior to delivery in 15 women.

Definition of hypoglycaemia
The Swedish Paediatric Association (1997) defines hypoglycaemia as **capillary blood glucose < 2.2 mmol/l** for both preterm and term infants.

9/15 (60%) infants had blood glucose concentrations < 2.2 mmol/l, most often 2 h after birth; 5/15 (33%) infants needed glucose infusions even though we considered the diabetic women to have good glycaemic control.

CGMS recordings in the mother

Mean glucose concentration 0–120 min before delivery were significantly associated with the need for glucose infusion in the newborn infant.

The mothers of the infants who received glucose had a **significantly higher mean glucose concentration 2 h before delivery** than those of infants who did not require glucose [7.5 ± 2.2 mmol/l vs. 5.3 ± 1.5 mmol/l; \( P = 0.028 \)].
• Postnatal infant hypoglycaemia is probably induced at the time of labour.

• High maternal blood glucose concentrations will increase the risk of hypoglycaemia in the offspring 1,2

Glucagon levels play an important role in the enzymatic initiation and maintenance of neonatal glucose production from the liver 3, and postnatal hypoglycaemia in infants of diabetic mothers may also be caused by an insufficient glucagon response 4

The **CGMS method**: the best in detecting episodes of hyper- and hypoglycaemia and for the assessment of **day-to-day glucose variability** 5,6

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Conclusions

During delivery,
Patients with DG controlled by diet alone
- does not require administration insulin,
- require control of blood glucose at entry / discharge\textsuperscript{1,2}.

Patients with DG controlled by insulin therapy,
- you should monitor hourly blood glucose levels
- maintain range 80-110 mg / dL (4.4-6.1 mmol / L)\textsuperscript{1,2}.

BUT: \textbf{CGMS PROFILE} vs SMBG seems to be a well-tolerated clinical method for close monitoring of maternal glucose concentrations during delivery\textsuperscript{3}.

\textsuperscript{1} Turok DK, et al.: Management of gestational diabetes mellitus. Am Fam Physician 2003;Nov 1;68(9):1767-1772
\textsuperscript{2} Patrelli TS et al.: Management del diabete gestazionale Riv Ost Gin Prat Med Perinat 2007; 22 (2): 5-9
\textsuperscript{3} Stenninger E et al.: Continuous Subcutaneous Glucose Monitoring System in diabetic mothers during labour and postnatal glucose adaptation of their infants Diabet. Med. 2008;25: 450–454
NOTES
Medtronic Sensor Daily Overlay
Mar 13 - Mar 15, 2006
(3 days)

GLUCOSE - mg/dL

03/13/06 03/14/06 03/15/06
Post Meal High
Over Night Low

TIME OF DAY

Transmitter
Glucose Sensor

Current glucose is 128

CareLink USB

Computer with diabetes management software

Medtronic PDM P800

Diabetes Management System
Benvenuto/a, Giovanni Nardelli.

### Attività recente - Ultimi cinque trasferimenti

<table>
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<tr>
<th>Data</th>
<th>Dispositivo</th>
<th>Nº di serie</th>
</tr>
</thead>
</table>

### Operaione successiva

- ![Trasferisci dati dal dispositivo personale](#)
- ![Inserisci dati nel diario personale](#)
- ![Genera report](#)

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**Aggiungi dato sui chetoni**

Giorno del diario: 10 marzo 2010

Ora: 16:30

Valore dei chetoni nelle urine: Negativo

Commento: 

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[Annulla](#) [Aggiungi](#)
The FreeStyle Navigator system will be available in the second quarter of 2008.
Sensor Support Mount
Stays on your skin after Sensor is inserted. Holds the Sensor in place. Attaches the Sensor to the Transmitter.

Sensor
Measures your glucose level.

Adhesive Protective Liner
Adhesive that is affixed to your skin.

Contact Points
Connect the Sensor to the Transmitter.

Wireless Transmitter
Connects to the Sensor and sends glucose values to the Receiver once every minute.

Tabs and Guides
The tabs slide into the Support Mount and hold the Transmitter in place.
An arrow pointing right means your glucose is constant or steady. It’s not increasing or decreasing more than 1 mg/dL each minute.

A diagonal arrow pointing upward means your glucose is slowly rising 1 to 2 mg/dL each minute.

A single arrow pointing straight up means your glucose is rising 2 to 3 mg/dL each minute.

Double arrows pointing straight up means your glucose is rapidly rising more than 3 mg/dL each minute.

A diagonal arrow pointing downward means your glucose is slowly falling 1 to 2 mg/dL each minute.

A single arrow pointing straight down means your glucose is falling 2 to 3 mg/dL each minute.
Double arrows pointing straight down means your glucose is rapidly falling more than 3 mg/dL each minute.

Alerts and ALARM

HIGH
200 mg/dL

LOW
80 mg/dL

Low Glucose ALARM = 55 mg/dL
Thanks for your attention