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Rossano Calabro
Complesso Nausicaa - Itaca
c.da Zolfara, 1 - 87067, Rossano (CS)



Cosa c'è di nuovo su... **“Microinfusore in gravidanza”**

Antonino Di Benedetto

Dipartimento di Medicina Interna, Università di Messina

Coordinatore Gruppo di Studio AMD-SID “Diabete e Gravidanza”

Cosa c'è di nuovo su...

“Microinfusore in gravidanza”



The first pregnant woman with diabetes to use an insulin delivery pump to control blood glucose, pictured with her daughter at a few months of age.



***LAURA, 33 ANNI,
AFFETTA DA
DIABETE MELLITO TIPO 1,
DESIDERA
PROGRAMMARE UNA GRAVIDANZA***

ANAMNESI

- ✓ *Diabete mellito tipo 1 dall'età di 14 anni*
- ✓ *Schema insulinico basal-bolus*
- ✓ *Compensazione metabolica non ottimale: HbA1c quasi sempre > 8% (da alcuni anni)*
- ✓ *Frequenti ipoglicemie di grado lieve- moderato (1-2 mese)*
- ✓ *Regolare attività fisica (30-45 min di corsa, 1-2 volte la settimana)
Fuma (4-5 sigarette al giorno). Non beve alcolici*
- ✓ *Da diversi mesi ha ridotto la frequenza dell'autocontrollo glicemico.*
- ✓ *L'ultima visita presso il centro diabetologico di riferimento risale ad un anno addietro.*

ANAMNESI PATOLOGICA PROSSIMA

- ✓ *Negli ultimi 3 anni, 2 aborti nel primo trimestre di gestazione (gravidanze non programmate)*
- ✓ *Il ginecologo ci chiede una consulenza, per la programmazione della gravidanza*

✓ **ESAME OBIETTIVO**

- ✓ ***Peso 69 kg, altezza 170 cm, BMI 23.87 kg/m², circonferenza vita 77 cm, pressione arteriosa 110/65 mmHg.***

ESAMI DI LABORATORIO

- ✓ ***nella norma, eccetto: Hba1c 8,1%***

Diario glicemico:

- ✓ ***glicemia al risveglio: 150-180 mg/dl***
- ✓ ***glicemia post-prandiale: 180-230 mg/dl.***

Terapia insulinica:

- ✓ ***-analogo rapido: 6 UI colazione; 10 UI pranzo; 8 UI cena***
- ✓ ***-analogo lento: 14 UI a cena***

Quali sono le principali raccomandazioni per la programmazione della gravidanza ?

Reviews/Commentaries/Position Statements

CONSENSUS STATEMENT

Managing Preexisting Diabetes for Pregnancy

Summary of evidence and consensus recommendations for care

JOHN L. KITZMILLER, MD, MS¹
JENNIFER M. BLOCK, BS RN, CDE²
FLORENCE M. BROWN, MD³
PATRICK M. CATALANO, MD⁴
DEBORAH L. CONWAY, MD⁵
DONALD R. COUSTAN, MD⁶
ERICA P. GUNDERSON, RD, PHD⁷
WILLIAM H. HERMAN, MD, MPH⁸
LISA D. HOFFMAN, MSW, LCSW⁹
MARIBETH INTURRISI, RN MS CNS, CDE¹⁰

LOIS B. JOVANOVIC, MD¹¹
SIRI I. KJOS, MD¹²
ROBERT H. KNOPP, MD¹³
MARTIN N. MONTORO, MD¹⁴
EDWARD S. OGATA, MD¹⁵
PATHMAJA PARAMSOTHY, MD, MS¹⁶
DIANE M. READER, RD, CDE¹⁷
BARAK M. ROSENN, MD¹⁸
ALYCE M. THOMAS, RD¹⁹
M. SUE KIRKMAN, MD²⁰

This document presents consensus panel recommendations for the medical care of pregnant women with preexisting diabetes, including type 1 and type 2 diabetes. The intent is to help clinicians deal with the broad spectrum of problems that arise in management of diabetes before and during pregnancy, and to prepare diabetic women for treatment that may reduce complications in the

Management of Preexisting Diabetes and Pregnancy, authored by the consensus panel and published by the American Diabetes Association (ADA) in 2008 (1). A consensus statement on obstetrical and postpartum management will appear separately.

The recommendations are diagnostic and therapeutic actions that are known or believed to favorably affect maternal and

and codify the evidence that forms the basis for the recommendations (2). Unfortunately there is a paucity of randomized controlled trials (RCTs) of the different aspects of management of diabetes and pregnancy. Therefore our recommendations are often based on trials conducted in nonpregnant diabetic women or non-diabetic pregnant women, as well as on peer-reviewed experience before and during pregnancy in women with preexisting diabetes (3–4). We also reviewed and adapted existing diabetes and pregnancy guidelines (5–10) and guidelines on diabetes complications and comorbidities (2,3,11–14).

I. MANAGING PREEXISTING DIABETES FOR PREGNANCY

Quali sono le principali raccomandazioni per la programmazione della gravidanza ?

- Per le donne con diabete pre-gestazionale, la gestione del diabete in gravidanza deve iniziare dalla pre-concezione (B)
- Già dall'adolescenza, bisogna informare ed educare la donna e la famiglia sugli effetti del diabete in gravidanza e sull'importanza della contraccezione (B)

Il compenso glicemico nella programmazione della gravidanza

- *Informare la donna sull'importanza di un buon controllo glicemico (obiettivi glicemici e dell'HbA1c) (B)*
- *Raggiungere il compenso ottimale prima di intraprendere una gravidanza (B)*

Lo stretto compenso metabolico
è necessario in tutte le fasi della gravidanza

Conseguenze dell'iperglicemia

- **1° trimestre**
 - Aborti spontanei
 - Malformazioni
- **2°-3° trimestre**
 - Iperinsulinizzazione fetale
- **Ultime settimane di gestazione**
 - Morte del feto in utero
- **Travaglio e post-partum**
 - Ipoglicemia neonatale

Managing Preexisting Diabetes for Pregnancy

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LOIS B. JOVANOVIĆ, MD¹¹
SIRI I. KJOS, MD^{12, 13}
ROBERT H. KNOPP, MD¹³
MARTIN N. MONTORO, MD¹⁴
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PATHMAJA PARAMSOTHY, MD, MS¹⁶
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and codify the evidence that forms the basis for the recommendations (2). Unfortunately there is a paucity of randomized controlled trials (RCTs) of the different aspects of management of diabetes and pregnancy. Therefore our recommendations are often based on trials conducted in men or non-pregnant women; well as on observational data and during pregnancy in preexisting diabetes.

Throughout pregnancy, optimal glycemic goals are:

- ✓ premeal, bedtime, and overnight glucose **60 –99mg/dl**
- ✓ peak postprandial glucose **100 –129mg/dl**
- ✓ mean daily glucose **<110 mg/dl**
- ✓ **HbA1c <6.0 (B)**
- ✓ Higher glucose targets may be used in patients with hypoglycemia unawareness or the inability to cope with intensified management. (E)

Screening delle complicanze ed inquadramento clinico

Nella fase di programmazione della gravidanza

- ✓ Screening delle complicanze croniche del diabete e degli altri fattori di rischio cardiovascolare (A)
- ✓ Adeguamento della terapia farmacologica (alcuni farmaci di uso comune, come ACE inibitori, sartanici e statine non sono indicati in gravidanza) (A)

PRIMA VISITA PRESSO IL CENTRO DIABETOLOGICO

- ✓ Si ridiscute il programma alimentare
- ✓ Viene raccomandato di praticare regolarmente attività fisica e di sospendere l'abitudine al fumo
- ✓ Si apportano delle modifiche allo schema insulinico e si consiglia di intensificare l'automonitoraggio glicemico
- ✓ Si raccomanda il raggiungimento di un compenso metabolico più stretto, con livelli di HbA1c vicini ai valori normali (ADA,2008)
- ✓ Si avvia lo screening delle complicanze croniche

SCREENING COMPLICANZE

- ✓ **Fondo Oculare: Retinopatia Diabetica Non Proliferante di Grado Lieve**
- ✓ **Microalbuminuria: Negativa**
- ✓ **Gfr: 115 ml/min**
- ✓ **Non Segni/Sintomi di Neuropatia Diabetica**
- ✓ **Ecd Tsa ed Arti Inferiori: Nella Norma**
- ✓ **Valutazione Cardiologica: Nella Norma**

CONTROLLI SUCCESSIVI

- ✓ Laura è motivata, torna al centro ogni due settimane e successivamente con cadenza mensile.
- ✓ Viene intensificato l'autocontrollo glicemico e migliorata la titolazione dell'insulina
- ✓ Dopo tre mesi, il valore di Hba1c = 7,3%
- ✓ La paziente, però, insiste nel voler iniziare una gravidanza in tempi brevi



- È proponibile a Laura l'uso di un microinfusore?**
- Quali sono le evidenze scientifiche a supporto?**

QUALI SONO LE EVIDENZE SCIENTIFICHE SULL'UTILIZZO DEL MICROINFUSORE IN GRAVIDANZA ?

- Non vi sono indicazioni ufficiali da parte delle principali società scientifiche
- L'uso del microinfusore in gravidanza è ritenuto una possibile opzione

Continuous Subcutaneous Insulin Infusion ADA Position Statements *Diabetes Care* 2004; 27:S110, 2004

- An insulin pump may provide great lifestyle flexibility, particularly with regard to meal schedules and travel but may be too demanding for some individuals.
- **CSII can help improve metabolic control during pregnancy.**

Continuous subcutaneous insulin infusion versus multiple daily injections of insulin for pregnant women with diabetes (Review)

Farrar D, Tu

- There is a dearth of robust evidence to support the use of one particular form of insulin administration over another for pregnant women with diabetes

....

- Conclusions cannot be made from the data available and therefore a robust randomized trial is needed.



**THE COCHRANE
COLLABORATION®**

The Cochrane Library 2008, Issue 4

During pregnancy, women with insulin-treated diabetes should be offered continuous subcutaneous insulin infusion (CSII or insulin pump therapy) if adequate glycaemic control is not obtained by multiple daily injections of insulin without significant disabling hypoglycaemia

Issue date: March 2008 (reissued July 2008)

Diabetes in pregnancy

Management of diabetes and its complications from pre-conception to the postnatal period

REVIEWS

www.AJOG.org

OBSTETRICS

Continuous subcutaneous insulin infusion vs intensive conventional insulin therapy in pregnant diabetic women: a systematic review and metaanalysis of randomized, controlled trials

Asima Mukhopadhyay, MD; Tom Farrell, MD, MRCOG; Robert B. Fraser, MD, FRCOG; Bolarinde Ola, MRCOG, MD

TABLE 6

Odds ratio metaanalysis: CSII (experimental) vs MDI (control) on large for gestational age

Study (year)	CSII	MDI	OR (95% CI)
Coustan et al (1988)	1/11	0/11*	2.10 (0.02, 180.03)
Burkart et al (1988)	5/48	6/41	0.68 (0.15, 2.93)
Nosari et al (1993)	1/16	0/16*	2.07 (0.02, 172.24)
Carta et al (1993)	2/14	0/15*	4.83 (0.14, infinity)
Pooled†	9/89 (10.1%)	6/83 (7.2%)	1.04 (0.36, 3.01; <i>P</i> = 0.94)

* When 1 cell in a 2 × 2 table is 0, 0.5 is added.

† Random-effects OR (DerSimonian-Laird).

Insulin Pumps and Their Use in Pregnancy

Adrienne D. Wollitzer, B.A., Howard Zisser, M.D., and Lois Jovanovič, M.D.

Advantages of insulin pump use in pregnancy

1. Smoother basal insulin levels, which counteract the exaggerated changes of the Dawn Phenomenon
2. Ease of bolusing of meal-based insulin
3. Ability to quickly treat hypoglycemia by merely interrupting the insulin infusion or lower the basal rate

Disadvantages of insulin pump use in pregnancy

1. Higher prevalence of diabetic ketoacidosis if the infusion site is interrupted for longer than 4 h
2. Increased risk of skin site infection and need to add an antibiotic during pregnancy with subsequent increased risk of fungal infection

Insulin Pumps and Their Use in Pregnancy

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Conclusions

- Insulin pumps are **a safe and effective** way to maintain euglycemia during pregnancy.
- Although they do not necessarily lead to tighter glucose control, patients can achieve euglycemia with **fewer hypoglycemic episodes** at a comparable cost to MDI insulin regimens.
- Women who use pumps are more likely **to continue** insulin use and tight glucose control **after pregnancy**, which improves long-term morbidity and mortality to the mother as well as preventing early fetal malformation or spontaneous abortion in subsequent pregnancies.

Diabetes control and pregnancy outcomes in women with type 1 diabetes treated with continuous subcutaneous insulin infusion (CSII) or with multiinjections of rapid acting insulin analogues and insulin glargine (Glargine-MDI)

D. Bruttomesso^a, M. Bonomo^b, S. Costa^a, M. Dal Pos^a, G Di Cianni^c, F. Pellicano^d, E. Vitacolonna^e, AR Dodesini^f, L. Tonutti^g, A. Lapolla^h, A Di Benedettoⁱ, E. Torlone^l
for the IGCSIIIP (Italian Group for Continuous Subcutaneous Insulin Infusion in Pregnancy).

Variable	CSII	MDI-glargine	P
Number	100	44	
Age (years, M±SD)	32,0 ± 4,4	31,4 ± 5,2	NS
Diabetes duration (years)	16,5 ± 7,3	13,5 ± 7,9	0,03
BMI (kg/m ²)	23,52 ± 3,22	23,63 ± 4,71	NS
HbA1c (%) (mmol/mol)	7,20 ± 0,84 55,19±6,43	7,66 ± 1,68 60,21±13,20	NS
Insulin requirement (U/kg/die)	0,58 ± 0,18	0,66 ± 0,33	NS

Table 2 . Maternal and foetal outcomes of pregnant type 1 diabetic women treated with CSII or glargine-MDI . Values are absolute number (%) (SD. NS=Not significant.

Variable	CSII	MDI-glargine	P
Maternal outcomes			
HbA1c (%)			
1° trimester	6,6±0,7	7,2±1,3	0,0005*
2 trimester	6,1±0,6	6,7±1,1	0,0005*
End pregnancy	6,2±0,7	6,5±0,8	0,002*
Severe hypoglycemic episodes	3 (3,2)	2 (4,65)	NS
Ketoacidotic episodes	1 (1,1)	2 (4,7)	NS
Pregnancy-induced hypertension	14 (15,1)	3 (7)	NS
Preeclampsia	9 (9,7)	1 (2,3)	NS
Progression/new cases of retinopathy	9 (9,7)	2 (4,6)	NS
Progression/new cases of nephropathy	4 (4,3)	0	NS

Variable	CSII	MDI-glargine	P
Abortion	7 (7)	2 (4,6)	NS
Preterm delivery (< 37 wk)	30 (32,3)	14 (34,2)	NS
Cesarean delivery rate	72 (77,4)	30 (73,2)	NS
Gestational age at delivery (wk)	36,7 ± 2,0	36,6 ± 2,3	NS
Birth weight (g)	3390,9 ± 662,5	3243,2 ± 698,9	NS
LGA	46 (46)	20 (45,5)	NS
Ponderal Index > 2,85 (g/cm ³)	33 (33)	12 (27,3)	NS
Macrosomia	13 (13,98)	6 (14,63)	NS
APGAR score 1- min	8,5 ± 1,3	8,4 ± 1,7	NS
APGAR score 5-min	9,5 ± 1,4	9,6 ± 0,8	NS
Shoulder distocy	1 (1,1)	2 (4,9)	NS
Hypoglycemia	21 (22,8)	8 (19,5)	NS
Hyperbilirubinemia	16 (17,4)	11 (26,8)	NS
Intensive care need	18 (19,6)	9 (21,4)	NS
Respiratory distress syndrome	9 (9,9)	4 (9,8)	NS

Variable	CSII	MDI-glargine	P
Shoulder distocy	1 (1,1)	2 (4,9)	NS
Hypoglycemia	21 (22,8)	8 (19,5)	NS
Hyperbilirubinemia	16 (17,4)	11 (26,8)	NS
Intensive care need	18 (19,6)	9 (21,4)	NS
Respiratory distress syndrome	9 (9,9)	4 (9,8)	NS
Nulliparity rate	66 (66)	24 (54,6)	NS
Prepregnancy Hypertension	8 (8)	3 (6,8)	NS
Prepregnancy Retinopathy	37 (37)	11 (25)	NS
Prepregnancy Nefropahy	10 (10)	2 (4,6)	NS
Planned pregnancy	87 (87)	18 (41)	0,023

Emerging Treatments and Technologies

ORIGINAL ARTICLE

Closed-Loop Insulin Delivery During Pregnancy Complicated by Type 1 Diabetes

HELEN R. MURPHY, MD¹
DANIELA ELLERI, MD^{1,2}
JANET M. ALLEN, RN¹
JULIE HARRIS, RN¹
DAVID SIMMONS, MD³
GERRY RAYMAN, MD⁴

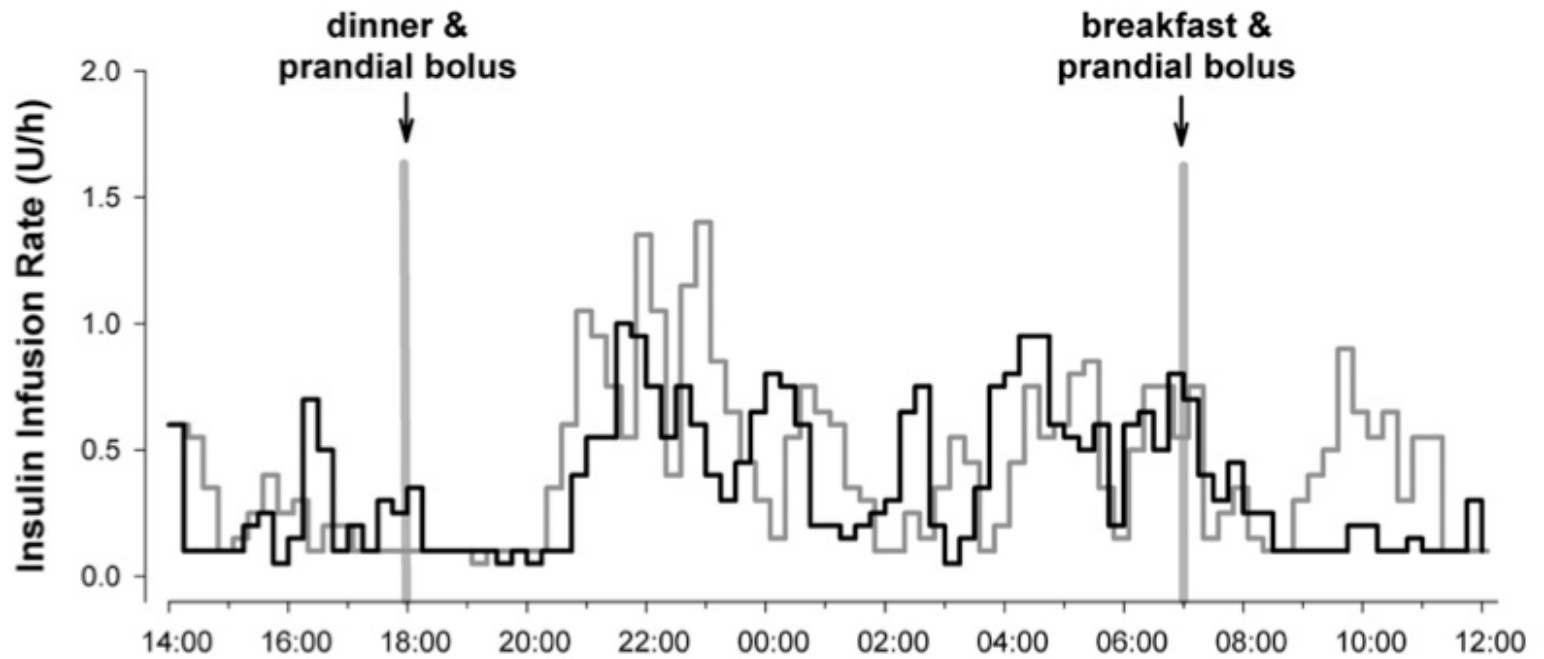
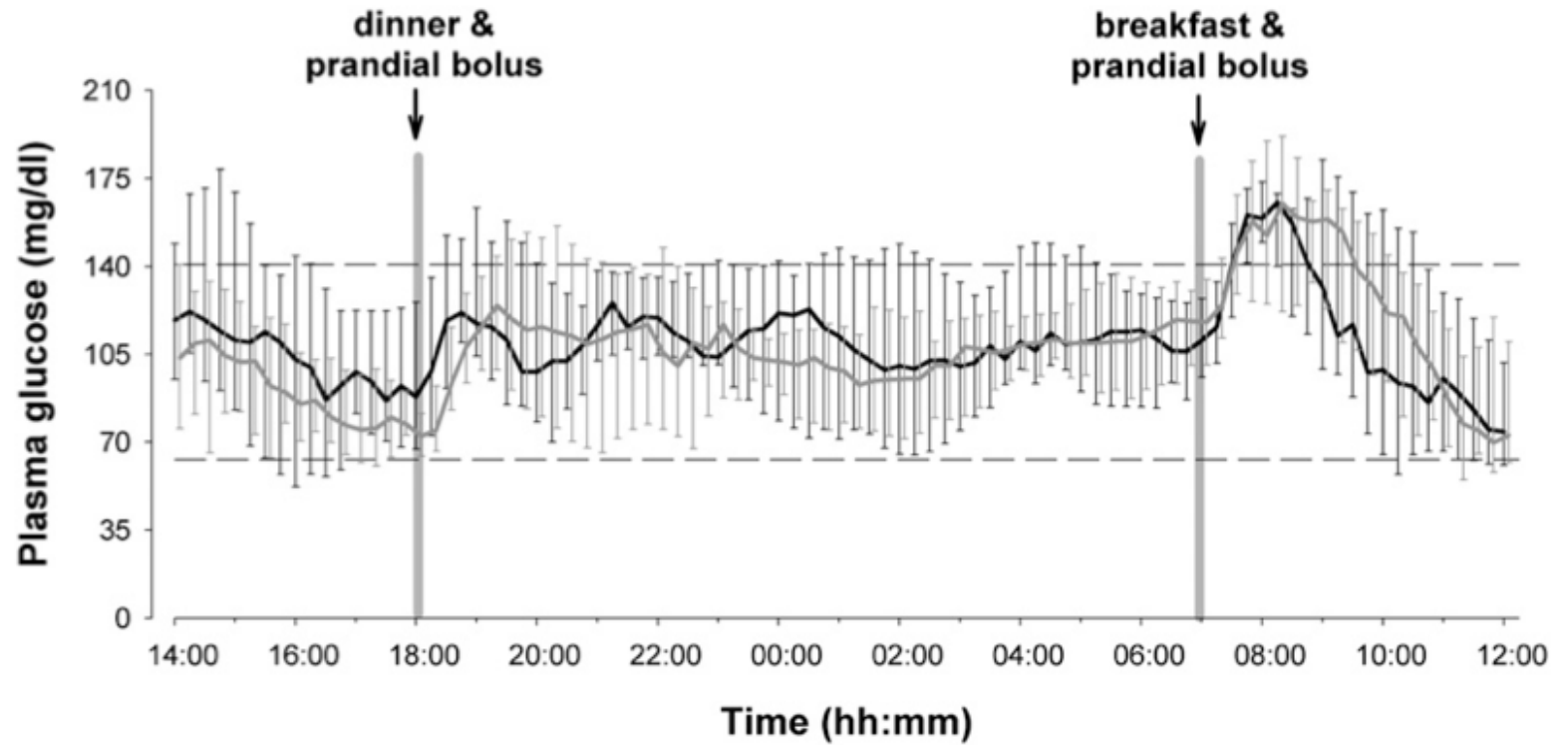
ROSEMARY TEMPLE, FRCP⁵
DAVID B. DUNGER, MD²
AHMAD HAIDAR, MSCA¹
MARIANNA NODALE, MSC¹
MALGORZATA E. WILINSKA, PHD^{1,2}
ROMAN HOVORKA, PHD^{1,2}

(congenital malformation, stillbirth, neonatal death) and of perinatal morbidity (preterm delivery, macrosomia, neonatal care admission) (3,4).

Strict glycemic control targets are more readily achievable by pregnant women with type 2 diabetes, with recent studies demonstrating improvements both in adverse pregnancy outcome and in perinatal morbidity (5). In contrast,

OBJECTIVE—This study evaluated closed-loop insulin delivery with a model predictive control (MPC) algorithm during early (12–16 weeks) and late gestation (28–32 weeks) in pregnant women with type 1 diabetes.

CONCLUSIONS—MPC algorithm performance was maintained throughout pregnancy, suggesting that overnight closed-loop insulin delivery could be used safely during pregnancy. More work is needed to achieve optimal postprandial glucose control.



Nuovo sito Web del Gruppo di Studio AMD-SID “Diabete e Gravidanza”

www.diabetegravidanza.it

GRAZIE

