TECNOLOGIE IN GRAVIDANZA

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Riunione Annuale Congiunta

SID-AMD

INTRODUZIONE

- Quali le tecnologie più usate e più studiate ad oggi in gravidanza?

- IL GLUCOMETRO
- Ancora oggi le linee guida suggeriscono di non farne a meno, anche se si utilizzano le tecnologie più avanzate, per confermare decisioni terapeutiche che spettano alla paziente
- Fondamentale nel diabete tipo 2 in gravidanza e nel GDM, dove le tecnologie fanno fatica ad affermarsi per mancanza di studi consistenti

Avanzando nelle tecnologie…

- MICROINFUSORI, PATCH PUMP, SMART-PEN, SENSORI…..si provano tutte….

- Il monitoraggio in continuo in gravidanza(CGM), è ad oggi la tecnologia che ha dato più soddisfazione in termini di risultati documentati.

Ma perché si provano tutte?

2. CURA DEL DIABETE PRIMA E DURANTE LA GRAVIDANZA

Preconcepimento

Tutte le donne in età fertile con diabete di tipo 1 o tipo 2, devono essere informate dell'importanza di raggiungere e mantenere un buon controllo metabolico nel periodo precedente il concepimento, dei rischi di una gravidanza non programmata, dei vantaggi di una gravidanza programmata e della necessità di pianificare il concepimento utilizzando metodi contraccettivi efficaci. *VI B*

È opportuno che ogni donna con diabete che intenda intraprendere una gravidanza sia sottoposta a screening ed eventuale trattamento delle complicanze della malattia (retinopatia, nefropatia, neuropatia, malattia cardiovascolare). *VI B*

Nella fase precedente il concepimento deve essere ricercata l'ottimizzazione del controllo glicemico. L'obiettivo terapeutico è definito da valori di HbA1c normali o il più possibile vicini alla norma (≤48 mmol/mol, ≤6,5%), in assenza o limitando al massimo le ipoglicemie. *III B*

In fase di programmazione di gravidanza, è indicata l'assunzione di un supplemento di acido folico alla dose di almeno 400 µg/die, con l'obiettivo di prevenire difetti del tubo neurale. *VI B*

Preconception Counseling

Recommendations

15.1 Starting at puberty and continuing in all people with diabetes and reproductive potential, preconception counseling should be incorporated into routine diabetes care. **A**

15.2 Family planning should be discussed, and effective contraception (with consideration of long-acting, reversible contraception) should be prescribed and used until an individual's treatment plan and A1C are optimized for pregnancy. **A**

15.3 Preconception counseling should address the importance of achieving glucose levels as close to normal as is safely possible, ideally A1C <6.5% (48 mmol/mol), to reduce the risk of congenital anomalies, preeclampsia, macrosomia, preterm birth, and other complications. **A**

Obiettivi metabolici in gravidanza

Obiettivi terapeutici:
concepimento : glicata≤6,5%
Glicata III° trim <6%
Glicemie intrapartum:
70-120 (140)

Standard italiani 2018

Glicemia

- Digiuno **≤90**
- 1 ora **≤130**
- 2 ore **≤120**

- **HbA1c < 6 %**

Standard ADA 2024

Glicemia

- Dig 70-95
- 1h110-140
- 2h100-120
- **HbA1c < 6 %**
- **<7% se ipo**

Current recommendations for hypoglycemia:
thresholds include blood glucose <70 mg/dL (<3.9 mmol/L) and sensor glucose <63 mg/dL (<3.5 mmol/L)

Obiettivi metabolici in gravidanza

- No trial robusti a supporto per entrambi i target raccomandati
- Standard 2018: si ispirano ai valori più bassi nella gravidanza fisiologica
- Standard ADA 2024: target scelti per uniformarsi ad ACOG
- I valori più alti del range per il GDM; i più bassi sono i valori fisiologici
- **ADA raccomanda i target più bassi se ottenuti in maniera sicura**
- Il monitoraggio postprandiale è correlato a migliori outcome glicemici e minor rischio di preeclampsia
- Le glicemie postprandiali correlano col peso alla nascita

- Padmanabhan S, Lee VW, Mclean M, et al. The association of falling insulin requirements with maternal biomarkers and placental dysfunction: a prospective study of women with preexisting diabetes in pregnancy. Diabetes Care 2017;40:1323–1330
- Jovanovic-Peterson L, Peterson CM, Reed GF, et al. Maternal postprandial glucose levels and infant birth weight: the Diabetes in Early Pregnancy Study. Am J Obstet Gynecol 1991;164: 103–111

Il ruolo del CGM

Standard Italiani 2018

- **Monitoraggio in continuo**, in aggiunta all'autocontrollo su sangue capillare, in donne con DM1 in gravidanza si è dimostrato in grado di migliorare il compenso glicemico materno e gli outcome neonatali (IIA)

Standard of care 2024

15.9 When used in addition to pre- and postprandial blood glucose monitoring, continuous glucose monitoring (CGM) can help to achieve the A1C goal in diabetes and pregnancy. **B**

15.10 CGM is recommended in pregnancies associated with type 1 diabetes. **A** When used in addition to blood glucose monitoring, achieving traditional pre- and postprandial goals, real-time CGM can reduce the risk for large-for-gestational age infants and neonatal hypoglycemia in pregnancy complicated by type 1 diabetes. **A**

15.11 CGM metrics may be used in addition to but should not be used as a substitute for blood glucose monitoring to achieve optimal pre- and postprandial glycemic goals. **E**

15.12 Commonly used estimated A1C and glucose management indicator calculations should not be used in pregnancy as estimates of A1C. **C**

Preexisting diabetes: glicemia puntuale o TIR?

- CGM Recommended in type 1
- In addition to pre e post prandial SMBG
- No estimated emoglobin o GMI ma HbA1c
- No menzione per il tipo 2 in gravidanza

- Tali raccomandazioni si basano su evidenze scientifiche

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

Il monitoraggio postprandiale è correlato a migliori outcome glicemici e minor rischio di preeclampsia
Le glicemie postprandiali correlano col peso alla nascita

Infants

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

- 1.68 million glucose measurements obtained from two previously published randomized controlled trials of CGM in pregnant women with diabetes.
- 117 women : type 1 diabetes (n = 89) and type 2 diabetes (n = 28) who used repeated CGM during pregnancy were recruited

RESULTS

A total of 54 of 117 (46%) women developed LGA. LGA was associated with lower mean glucose (7.0 vs. 7.1 mmol/L; $P < 0.01$) in trimester 1, with higher mean glucose in trimester 2 (7.0 vs. 6.7 mmol/L; $P < 0.001$) and trimester 3 (6.5 vs. 6.4 mmol/L; $P < 0.01$). FDA showed that glucose was significantly lower midmorning (0900–1100 h) and early evening (1900–2130 h) in trimester 1, significantly higher early morning (0330–0630 h) and throughout the afternoon (1130–1700 h) in trimester 2, and significantly higher during the evening (2030–2330 h) in trimester 3 in women whose infants were LGA.

CONCLUSIONS

FDA of CGM data identified specific times of day that maternal glucose excursions were associated with LGA. It highlights trimester-specific differences, allowing treatment to be targeted to gestational glucose patterns.

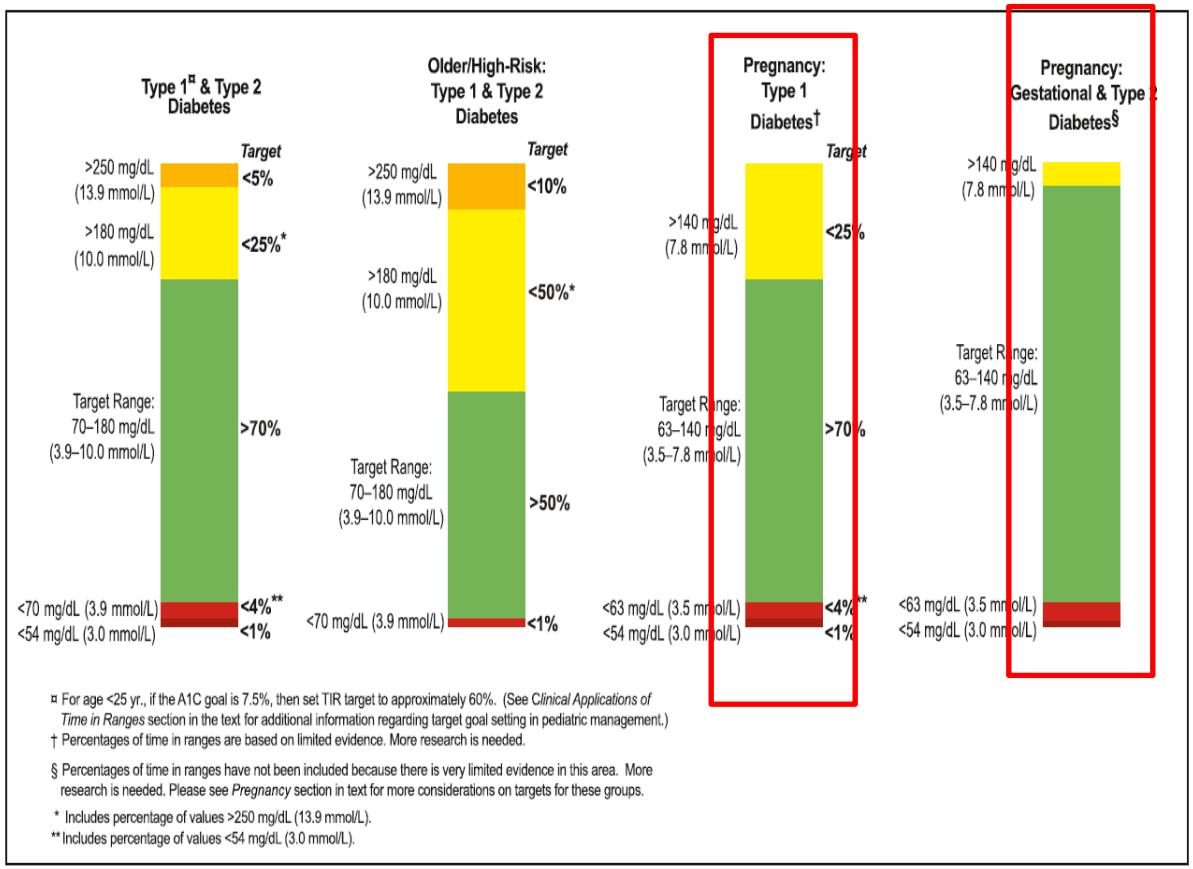
Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicentre international randomised controlled trial

*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**

- L'obiettivo: verificare se il monitoraggio glicemico in continuo (CGM) in modalità Real-time (Guardian Real Time Medtronic- Minimed Minilink Sensor Enlite) possa migliorare il compenso glicemico e gli outcome ostetrici e neonatali.
- studio clinico randomizzato e controllato, multicentrico,
- donne con diabete tipo 1 già in gravidanza o in programmazione
- 215 donne : CGM + autocontrollo o solo autocontrollo
- L'end-point primario: differenza di HbA1c
- End-point secondari: outcome materni e fetali.
- Risultati: lieve riduzione della glicata; aumento significativo del tempo speso in euglicemia (ps-TIR 63-140mg); riduzione significativa del tempo in iperglicemia; non riduzione del tempo in ipo o di ipo severe
- **Significativamente migliori gli outcome fetali**
- No diff tra CSII e MDI

Recommendations from the International Consensus on Time in Range

T. Battelino et al. Diabetes Care, Vol. 42, August 2019



¤ For age <25 yr., if the A1C goal is 7.5%, then set TIR target to approximately 60%. (See *Clinical Applications of Time in Ranges* section in the text for additional information regarding target goal setting in pediatric management.)

† Percentages of time in ranges are based on limited evidence. More research is needed.

§ Percentages of time in ranges have not been included because there is very limited evidence in this area. More research is needed. Please see *Pregnancy* section in text for more considerations on targets for these groups.

* Includes percentage of values >250 mg/dL (13.9 mmol/L).

** Includes percentage of values <54 mg/dL (3.0 mmol/L).

Il psTIR 63-140mg/dl

- La capacità predittiva dell'HbA1C nel determinare il rischio di outcome avversi è ben chiara. Management of Diabetes in Pregnancy: Standards of Medical Care in Diabetes-2022. Diabetes Care 2022;

- CONCEPTT study, Lancet, 2017
- Crescente evidenza di una diminuzione del rischio di LGA e outcome neonatali avversi associata ad un maggior psTIR tra le donne con DM1 che usano un CGM
- Murphy H, Diabetologia, 2019
- Kristensen K, Diabetologia 2019.

- Viene confermata la necessità di metriche dinamiche da affiancare agli obiettivi tradizionali nel predire complicanze neonatali

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]

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- A 5% lower TIR and 5% higher TAR during the second and third trimesters is associated with increased risk of large for gestational age infants, neonatal hypoglycaemia and neonatal intensive care unit admissions.
- For optimal neonatal outcomes, women and clinicians should aim for a ps-TIR of >70% (16 h, 48 min) and a ps-TAR of <25% (6 h)
- **As early as possible during pregnancy**.
- Not only towards the end of the third trim

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%
Trimester 3	60 ± 13	68 ± 13	>70%
TAR >7.8 mmol/l[c] (%)			
Trimester 1	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%

Diabetes Technology & Therapeutics
> Ahead of Print >
Original Article |

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

Valerie Gao, Janet K. Snell-Bergeon, Emily Malecha, Carly A. Johnson, and Sarit Polsky

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https://doi.org/10.1089/dia.2023.0548

- 160 donne con diabete tipo 1 analisi retrospettiva
- 109 CGM; 51 SMBG
- CGM group aveva più partecipanti con emoglobina glicata a target nei tre trimestri (p<0.01)
- Macrosomia > 4000gr (12.8% CGM vs. 29.4% SMBG, *P* = 0.01)
- Meno ricoveri TIN
- Non si riscontrano miglioramenti negli outcome materni (incremento ponderale, preeclampsia, ipertensione, % di parti cesarei) come del resto nel CONCEPTT e nel French Observational study
- **PsTIR >70% non raggiunto**

	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)	
CGM metrics in T1 (%)			
Average sensor readings, *n*	8898		
Mean sensor glucose, mg/dL	135.6 ± 2.6		
TBR <54 mg/dL	2.6 ± 0.2		
TBR <63 mg/dL	6.4 ± 0.4	N/A	N/A
TIR 63–140 mg/dL	55.8 ± 1.7		
TAR >140 mg/dL	38.9 ± 1.8		
TAR >180 mg/dL	20.6 ± 1.5		
CGM metrics in T2 (%)			
Average sensor readings, *n*	15,150		
Mean sensor glucose, mg/dL	134.8 ± 2.6		
TBR <54 mg/dL	2.4 ± 0.2		
TBR <63 mg/dL	5.6 ± 0.4[e]	N/A	N/A
TIR 63–140 mg/dL	56.5 ± 1.7		
TAR >140 mg/dL	39.0 ± 1.8		
TAR >180 mg/dL	19.1 ± 1.5		
CGM metrics in T3 (%)			
Average sensor readings, *n*	10,354		
Mean sensor glucose, mg/dL	133.1 ± 2.6		
TBR <54 mg/dL	1.7 ± 0.2[f,g]		
TBR <63 mg/dL	4.3 ± 0.4[f,g]	N/A	N/A
TIR 63–140 mg/dL	59.1 ± 1.7[e,g]		
TAR >140 mg/dL	37.8 ± 1.8		
TAR >180 mg/dL	16.8 ± 1.5[f,g]		

ORIGINAL ARTICLE

Performance of the Dexcom G7 Continuous Glucose Monitoring System in Pregnant Women with Diabetes

Sarit Polsky, MD, MPH,[1,*] Amy M. Valent, DO, MCR,[2,*] Elvira Isganaitis, MD, MPH,[3] Kristin Castorino, DO,[4] Grenye O'Malley, MD,[5] Stayce E. Beck, PhD, MPH,[6] Peggy Gao, MS,[6] Lori M. Laffel, MD, MPH,[3] Florence M. Brown, MD,[3,†] and Carol J. Levy, MD[5,†]

- data for accuracy analysis were obtained from 96 G7 sensors (Dexcom, Inc.) worn by 96 of 105 enrolled pregnant women with type 1 (n=59), type 2 (n=21), or gestational diabetes (n=25)
- Of the 1,739 pairs with CGM in the 70-180 mg/dL range, 83.2% were within 15% of comparator values.

CONCLUSIONS

The G7system is accurate and safe during pregnancies complicated by diabetes and does not require confirmatory fingerstick testing.

- Consensus error grid analysis showed 99.8% of pairs in the clinically acceptable A and B zones.

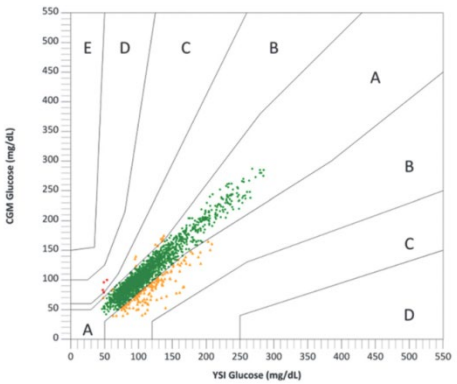

FIG. 1. Secondary endpoint: consensus (Parkes) error grid. Consensus error grid analysis of glucose values from the G7 CGM system versus YSI plasma glucose values (pooled data for 96 participants with 2102 YSI–CGM pairs). Green, yellow, and red dots are in Zones A, B, and C, respectively.

TABLE 3. ACCURACY BY COMPARATOR GLUCOSE RANGE

Comparator glucose range (mg/dL)	*Matched pairs* (n)	*%15/15 (%)*	*%20/20 (%)*	*%30/30 (%)*	*%40/40 (%)*	*Mean bias (mg/dL)*
<70	140	84.3	92.1	97.1	98.6	4.9
63–140	1659	84.2	92.3	97.7	99.0	−0.7
70–180	1799	84.2	92.2	97.5	98.8	−1.3
>180	163	94.5	96.9	99.4	100	−1.1
Overall	2102	85.0	92.5	97.6	98.9	−0.9

Nel GDM

SMBG o CGM?

Journal of Clinical Medicine

MDPI

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

- Pochi studi
- Piccoli campioni
- 1 studio RCT (n.106 SMBG vs CGM+SMBG) ha mostrato riduzione significativa di HbA1c in donne GDM insulino-trattate che usavano il CGM*
- * Wei, Q.; Sun, Z.; Yang, Y.; Yu, H.; Ding, H.; Wang, S. Effect of a CGMS and SMBG on Maternal and Neonatal Outcomes in Gestational Diabetes Mellitus: A Randomized Controlled Trial. Sci. Rep. 2016, 6, 19920.
- Studio prospettico osservazionale su 1302 GDM: relazione positiva tra le metriche derivate dal CGM durante la gravidanza e gli esiti della gravidanza (rischio di LGA)**
- ** Liang X et al. Continuous glucose monitoring-derived glycemic metrics and adverse pregnancy outcomes among women with gestational diabetes: a prospective cohort study. Lancet Reg Health West Pac. 2023 Jun 12;39:100823.

Nel diabete gestazionale SMBG o CGM?

frontiers | Frontiers in Endocrinology

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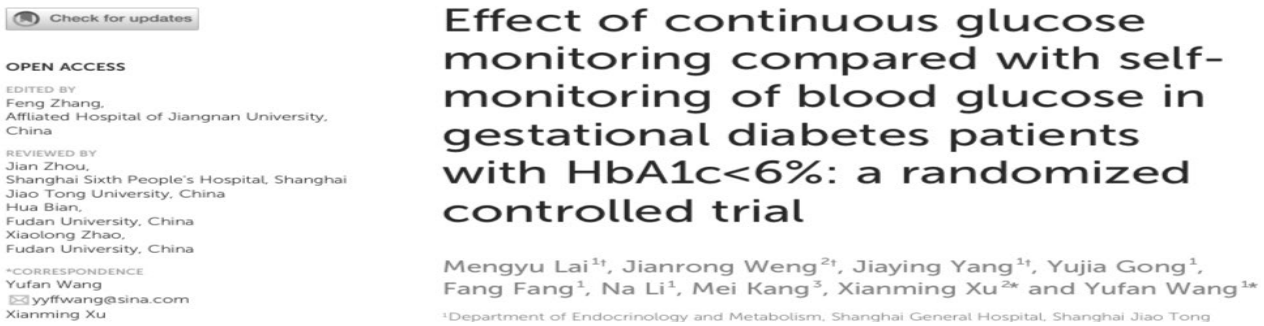

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Effect of continuous glucose monitoring compared with self-monitoring of blood glucose in gestational diabetes patients with HbA1c<6%: a randomized controlled trial

Mengyu Lai[1†], Jianrong Weng[2†], Jiaying Yang[1†], Yujia Gong[1], Fang Fang[1], Na Li[1], Mei Kang[3], Xianming Xu[2*] and Yufan Wang[1*]

[1]Department of Endocrinology and Metabolism, Shanghai General Hospital, Shanghai Jiao Tong

- CGM+SMBG (n.77) vs SMBG (n.77)
- No differenze in TIR e HbA1c
- The proportion with **GWG** within recommendations was higher in the CGM group (59.7% versus 40.3%, *p*=0.046)
- the newborn **birth weight** was lower (3123.79 ± 369.58 g versus 3291.56 ± 386.59 g, *p*=0.015). There were no significant differences in prenatal or obstetric outcomes
- CONCLUSIONS
- For GDM patients with HbA1c<6%, regular SMBG is a more economical blood glucose monitoring method and can achieve a similar performance in glycemic control as CGM, while CGM is beneficial for ideal GWG.

Il CGM per fare diagnosi di GDM

Diabetes Care
American Diabetes Association

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, and Anders L. Carlson

Le metriche ottenute mediante CGM sono risultate predittive di futuro DG
(AUROC 0,81 quando si utilizzava la percentuale di tempo con glucosio >140 mg/dl nel secondo trimestre; AUROC 0,74 se si consideravano i valori di glucosio >140 mg/dl 13ma e 14ma settimana)

Methods

- Observational, nonintervention study in expectant mothers without diabetes enrolled prior to 17 weeks.
- 768 participants were included in the analysis, of which 58 had GDM
- Wore blinded Dexcom G6 CGM throughout gestation
- Main outcome was diagnosis of GDM by OGTT and comparison of participants with GDM vs. without GDM at 24-34 weeks' gestation

Glucose Levels Across Maternity (GLAM) Study

Results

- Participants with GDM had higher mean glucose, more time >120 mg/dL, more time >140 mg/dL, and less time 63-140 mg/dL when compared to participants without GDM.
- Higher glycemic levels in participants with GDM were observed as early as gestational weeks 13-14 (Figure 1).
- CGM derived patterns in early pregnancy can identify individuals with GDM and may provide an opportunity for earlier intervention to mitigate risk

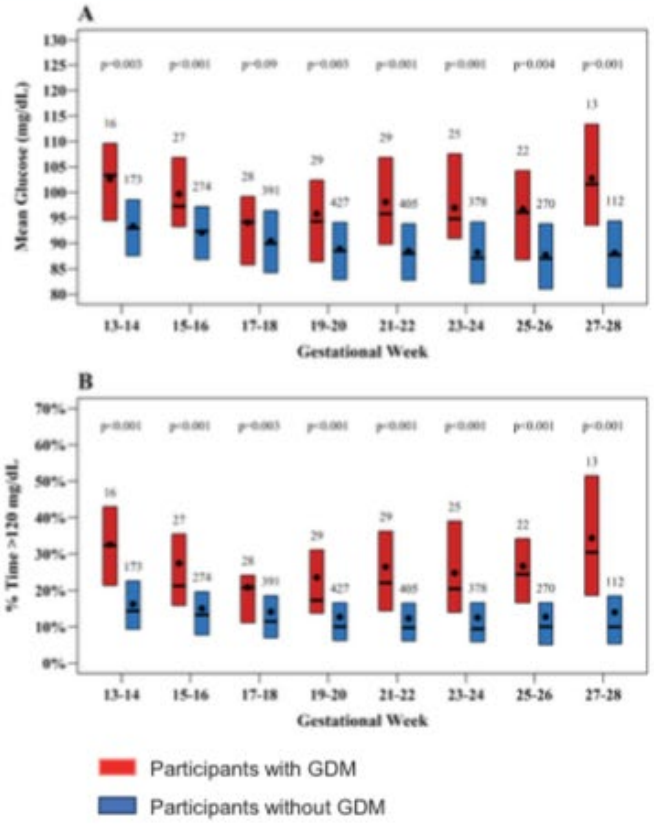


Figure 1 (Right). Boxplots of A) mean glucose and B) % time >120 mg/dL by GDM status and gestational week. Numbers above boxes represent number of participants. Dots in the middle of boxes represent means, lines in the middle of boxes represent medians. Top and bottom of boxes represent the 75th and 25th percentiles, respectively. P-values above each pair of boxes are testing the glycemic difference between participants with GDM vs. without GDM in each 2-week period.

Limiti

- basso numero di pazienti con DG e a una scarsa quantità di dati relativi alle settimane di gravidanza più precoci (<12 settimane.
- necessari ulteriori studi (in corso: MAGIC e GO MOMs) per:
- chiarire ulteriormente la relazione fra disglicemia materna e successiva diagnosi di DG,
- definire delle soglie diagnostiche con le metriche del CGM
- indagare la possibilità di prevedere outcome perinatali avversi tramite i dati ottenibili con il CGM
- valutare l'impatto clinico e il rapporto di costo/efficacia di un suo impiego precoce nelle pazienti a rischio.

Il CGM è utile durante il parto?

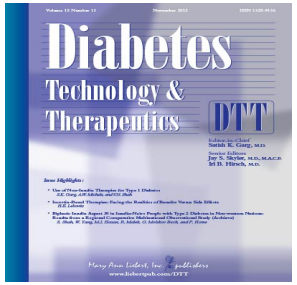
obiettivo principale: evitare l'iperglicemia materna, per evitare l'ipoglicemia, l'acidosi e l'ipossia fetale.

La glicemia desiderabile durante il travaglio ed al momento del parto dovrebbe essere compresa fra 70 e 125 mg/dl o anche un range glicemico meno stringente (90-140 m).

I rapidi cambiamenti della richiesta di glucosio e di insulina durante il travaglio e il parto rendono necessario un controllo frequente della glicemia, che deve essere effettuato ogni ora nel travaglio attivo, se i valori glicemici rimangono stabili

Per le donne in travaglio la frequente misurazione della glicemia mediante stick capillare può risultare stressante e può rappresentare un compito gravoso per il personale sanitario della sala travaglio/parto

resa R, et al. Experiences of continuous subcutaneous insulin infusion in pregnant women with type 1 diabetes during delivery from four Italian centers: a retrospective observational study. Diabetes Technol Ther 2013;15:328-34



n 65	Pre-HbA1c %	III° trim HbA1c	CBG T0' mg/dl	CBG T30' mg/dl	CBG T60' mg/dl
CSII n 47	6.7 ± 1.4	6.2 ± 1.7	111 ± 32	109±42	125± 51 mg/dl
CSII+ RTCGM n 18	6.3 ± 0.1	5.2± 0.4*	80 ± 14** mg/dl	79 ± 11 mg/dl **	98± 20 mg/dl

*p<0.001 **p<0.01

Target range: 70-140mg/dl

DIABETES TECHNOLOGY & THERAPEUTICS
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Mary Ann Liebert, Inc.
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DTT

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BRIEF REPORT

Adjustment of Maternal Variable Rate Insulin Infusions Using Real-Time Continuous Glucose Monitoring in Pregnant Women with Type 1 Diabetes

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- Pochi studi hanno valutato l'accuratezza di FGM e CGM in corso di travaglio e parto
- 'analisi retrospettiva di confronto fra CGM (Dexcom G6) e SCGM valutato point-of-care in donne con DM1
- buona accuratezza complessiva del CGM (Dexcom G6) durante il travaglio e il parto, con un ARD (Absolute Relative Difference – ARD) mediano del 6,1%
- accuratezza considerevolmente minore in caso di ipoglicemia (ARD mediana 44,3% per glicemia <70 mg/dl)
- Le scelte decisionali sulla velocità di infusione di glucosio/insulina in corso di travaglio e parto concordavano nel 75% dei casi con CGM (Dexcom G6) rispetto a SCGM
- Conclusioni
- MARD elevata in associazione al range ipoglicemico
- Dati in generale non sufficienti di correlazione tra pTIR intrapartum e ipo neonatale

non si può ancora supportare l'utilizzo esclusivo del CGM in ambito ospedaliero

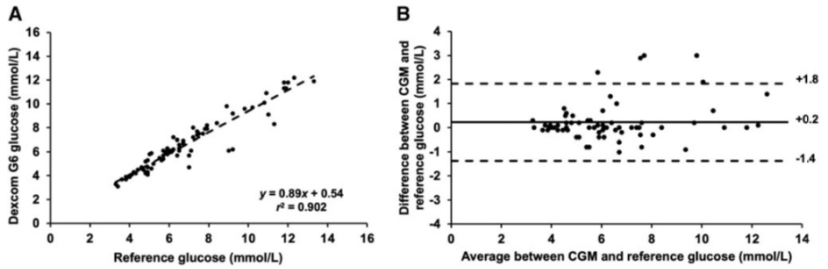

FIG. 1. Regression and Bland–Altman plots for CGM compared with reference glucose ($n = 228$). **(A)** For CGM compared with the reference POC blood glucose, the linear regression gradient of 0.89 and correlation coefficient $r^2 = 0.902$. **(B)** CGM compared with the reference glucose (mean bias +0.2 mmol/L, 95% limits of agreement −1.4, +1.8 mmol/L). CGM, continuous glucose monitoring; POC, point-of-care.

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Accuracy of intermittently scanned continuous glucose monitoring during caesarean delivery in pregnant women with insulin-treated diabetes

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- Prospettico osservazionale con dati real world mostrano una buona accuratezza del sistema FGM (FreeStyle Libre 1 e 2) durante il parto cesareo in donne con diabete insulino-trattato (DM1-12, DM2 -5 e GDM-2), con MARD del 9,28% rispetto al glucosio capillare, che migliorava all'8,82% escludendo i valori glicemici ≤70 mg/dl
- il 100% dei valori di glucosio interstiziale risultavano nelle zone A e B “clinicamente accettabili” della Clarke ErrorGrid
- La corrispondenza dei valori per guidare le scelte decisionali, secondo il protocollo infusionale glucosio/insulina utilizzato, concordavano globalmente nel 68% dei casi; la concordanza diveniva piena per valori compresi fra 70 e 110 mg/dL

- Conclusioni: piccolo campione ma monocentrico con stesso protocollo infusionale

Se gli studi confermeranno

- L'uso del CGM durante il travaglio e il parto può consentire di monitorare da vicino le donne, in modo più semplice rispetto al monitoraggio del glucosio capillare
- fornire più informazioni rispetto alla misurazione del glucosio capillare grazie alle frecce di tendenza e ai sistemi di allarme
- SMBG per decisioni terapeutiche

Quali CGM?

La maggior parte dei dispositivi rt-CGM è conforme per l'uso in gravidanza

(Dexcom G6, Dexcom G7; FreeStyle libre 1, 2 e 3; Guardian 3 e 4) forniscono letture accurate

Dexcom G7 e FreeStyle Libre 2 e 3 sono stati approvati dalla Food and Drug Administration (FDA) statunitense.

Questioni aperte

Symposium/Special Issue

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

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Sage

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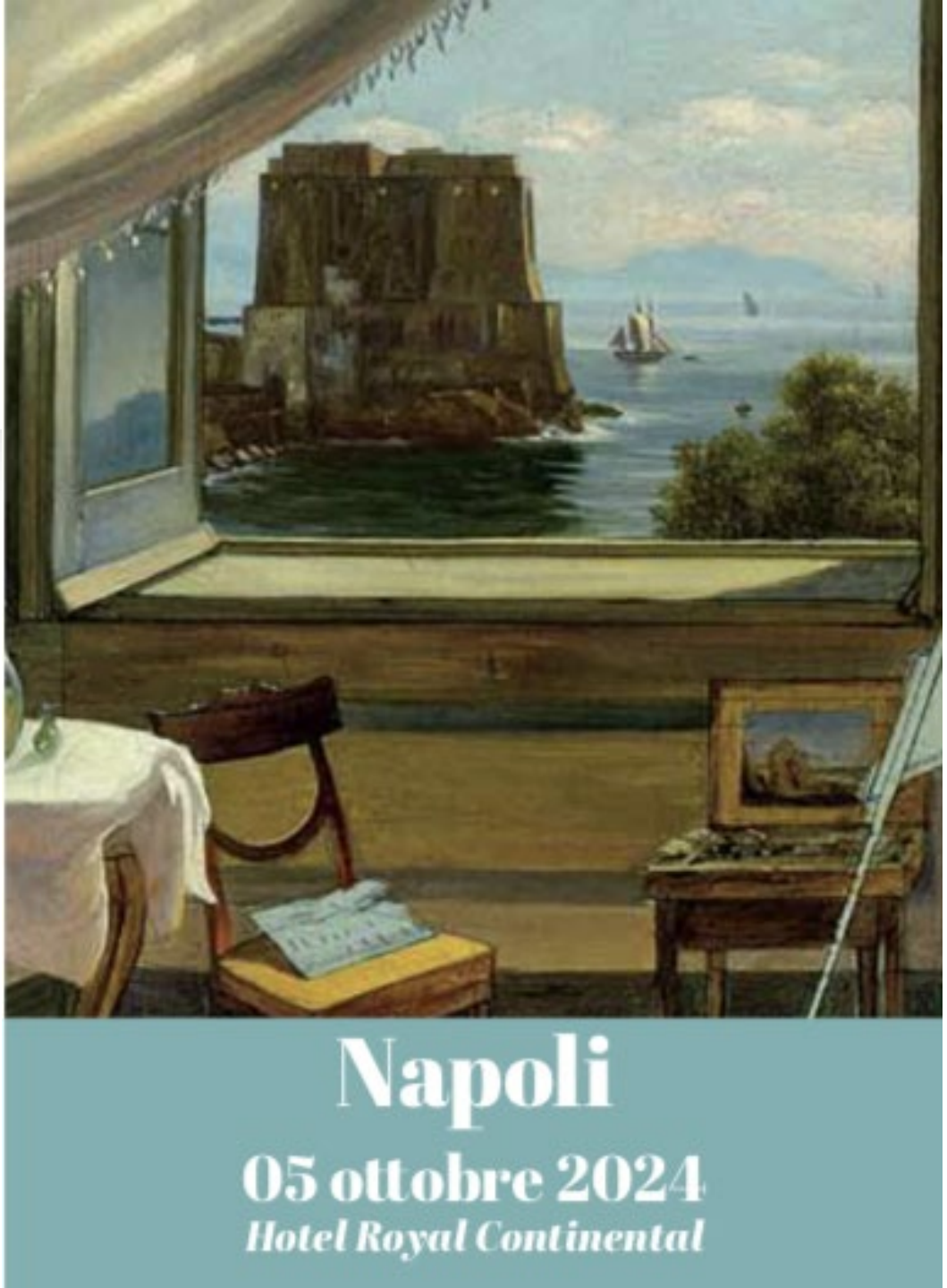
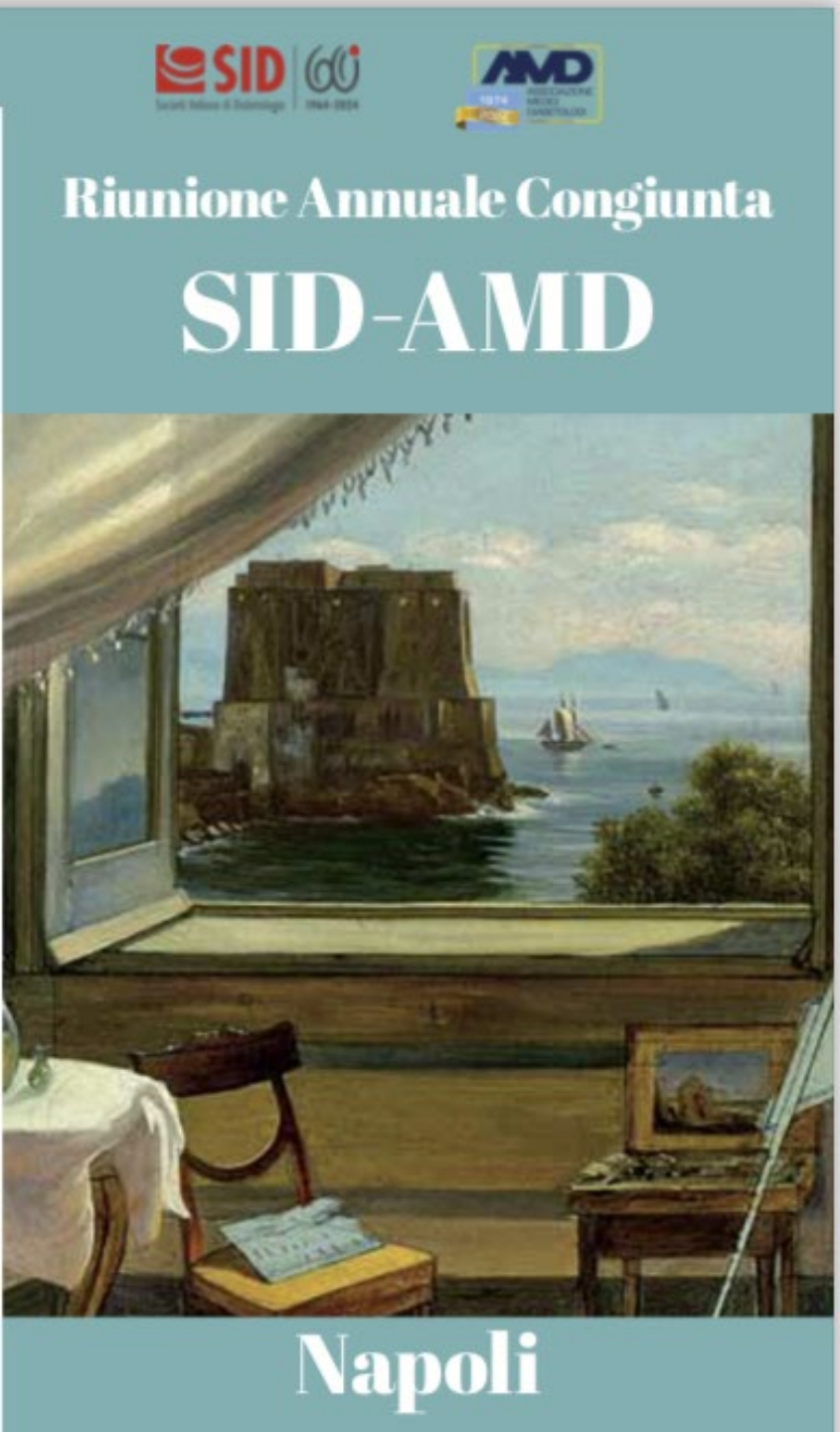
CGM reporting AGPs: All pregnancies associated with diabetes	• Should AGPs be available for pregnant individuals that are standardized to CGM metrics specific to pregnancy targets? If so, will manufacturers of CGM devices agree to provide pregnancy standardized reports? • Should GMI be included in reports? • Should reports separate daytime and nocturnal glucose patterns?
CGM metrics: All pregnancies associated with diabetes	• Could large studies definitively link CGM metrics to prediction of APOs? If so, are early or late CGM metrics more important? What CGM metrics are most associated with specific APOs? • Should glucose targets be the same for those with vascular disorders or hypertensive disorders at risk for SGA? • Should the CV target be the same or different from non-pregnant populations? • Is GMI a reasonable surrogate for HbA1C? If so, in which trimesters?
CGM use: GDM	• Is CGM use associated with improved maternal and/or neonatal health outcomes in GDM? • Should glucose targets be lower than in T1D? • Is CGM use associated with improved quality of life in GDM? • Should CGM be used in all individuals with GDM or just in those using insulin? • What are the cost implications of CGM use in GDM? Will obstetric providers have the training/resources to implement CGM in a high percentage of GDM pregnancies?
CGM use: T2D	• Is CGM use associated with improved maternal/neonatal health outcomes in pregnant individuals with T2D? • Should CGM targets be different than in T1D? • Is CGM use associated with improved quality of life in individuals with T2D? • What are the cost implications of CGM use in pregnant individuals with T2D?
CGM adoption: All pregnancies associated with diabetes	• What strategies would best increase uptake of CGM use among pregnant individuals with T1D? • What barriers among payers/ health insurance companies need to be addressed to adequately cover CGM supplies among pregnant individuals with GDM or T2D if proved efficacious?
Barriers to CGM use: All pregnancies associated with diabetes	• Are there differences in common barriers to CGM use (such as skin irritation and cost) between pregnant and non-pregnant individuals? • Are there unique barriers to CGM use among pregnant individuals?

Conclusioni

- Nel DM2 e nel GDM pochi dati e no raccomandazioni
- No dati sul miglioramento degli outcome
- No dati su Qol

- Il controllo della glicemia capillare rimane cost-effective
- La misurazione SMBG è sempre l'unica al momento per decisioni terapeutiche





Conclusioni

- Nel tipo 1 in gravidanza, il CGM in aggiunta al controllo puntuale della glicemia capillare è raccomandato perché anche modesti incrementi del TIR migliorano in maniera significativa gli outcome neonatali (LGA) e alcuni outcome materni
- Se le tecnologie avanzate, vedi HCL, riusciranno ad aiutare ad incrementare il psTIR > 70% in popolazioni più ampie, anche gli outcome materno-fetali in futuro miglioreranno su più vasta scala

Grazie per l’attenzione