

# Post-partum: transizione metabolica e gestione della complessità

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Diapositiva preparata da CRISTINA BIANCHI e ceduta alla Società Italiana di Diabetologia.  
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SISTEMI  
AID

## Dichiarazione Conflitto d'Interessi

La sottoscritta Dott.ssa Cristina Bianchi

DICHIARA

di aver ricevuto negli ultimi due anni compensi o finanziamenti dalle seguenti Aziende Farmaceutiche e/o Diagnostiche:

- Novonordisk

- Lilly

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Cristina Bianchi, MD PhD



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# Post-partum



- The postpartum period, also known as the puerperium, is the phase immediately following childbirth and lasts approximately 6-8 weeks, during which the mother's body returns to its pre-pregnancy state.
- It's a delicate time of great change, not only for the mother's body, but also for the new family structure that is created with the baby's arrival.
- Coping well during the postpartum period is important to help new mothers cope with their new life. Women must learn to care not only for themselves, but also for their offspring.

# Post-partum in type 1 diabetes



- Women with type 1 diabetes mellitus face extra challenges also soon after childbirth because they have a double role: caring for the baby and managing their diabetes.
- After giving birth, the need for insulin is drastically reduced (up to 50%), making it necessary to quickly adjust the therapy.
- Breastfeeding, while important for the offspring, may represent an added challenge for the mother with type 1 diabetes in managing the disease.

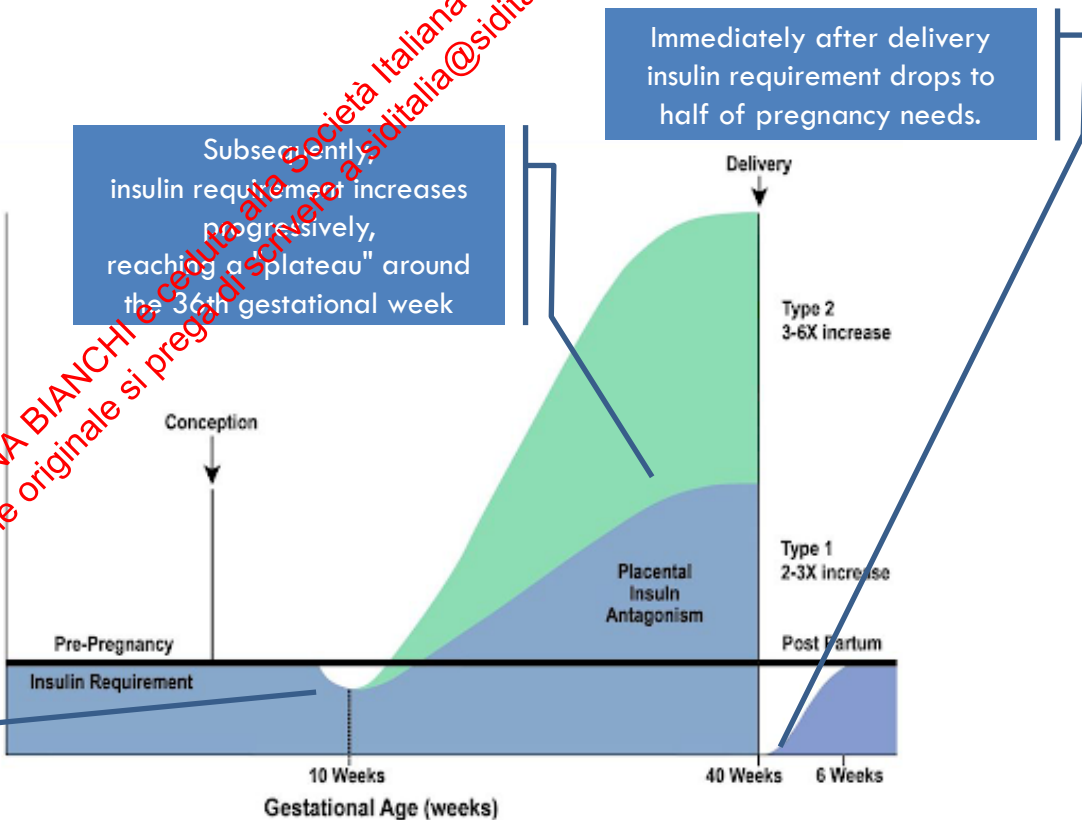
# Insulin therapy in pregestational diabetes during pregnancy

The daily insulin requirement in pregnancy varies considerably over the course of gestation

| 1st quarter | 2ts quarter | 3ts quarter |
|-------------|-------------|-------------|
| 0.7 U/Kg    | 0.8 U/Kg    | 0.9 U/Kg    |



Insulin requirement decreases in the first weeks of gestation (10-20%)



# Management immediately after birth until discharge from hospital

Insulin requirements drop immediately after birth and women are at **increased risk of hypoglycaemia** in the first hours-to-days after birth.

Several factors may contribute to hypoglycaemia including:

- ✓ Continued action of pregnancy insulin doses (due to large insulin doses in late pregnancy)
- ✓ Continuing to use pregnancy insulin doses/pump settings, which may be due to not changing the settings or not believing that the much lower recommended doses are enough
- ✓ Continuing to aim for tight glycaemic targets of pregnancy
- ✓ Reduced hypo awareness
- ✓ Nausea and vomiting
- ✓ Breastfeeding

# AID use in post-partum



Pregnant women with diabetes report feeling vulnerable when the ability to control their own blood glucose levels is taken away from them during hospital admission for delivery and post-partum care, and is instead 'in the hands' of less experienced antenatal and delivery ward staff.

It is important to improve the knowledge of healthcare providers and women with diabetes to ensure greater consistency in blood glucose management during the perinatal period, supporting women who are able to self-manage using insulin pumps and advanced diabetes technologies.

The automated nature of AID systems and their ability to adapt to glucose levels in real time could make them useful tools not only during pregnancy, labor and delivery, but also in the immediate postpartum period.



# Challenges for AID systems in the post-partum



The major challenges for AIDs in the postpartum period are:

- rapid adaptability to changes in insulin sensitivity (insulin requirement)
- limit the tendency to hypoglycemia
- adapt to glycemic changes during breastfeeding.



# AID in women with type 1 diabetes during early post-partum



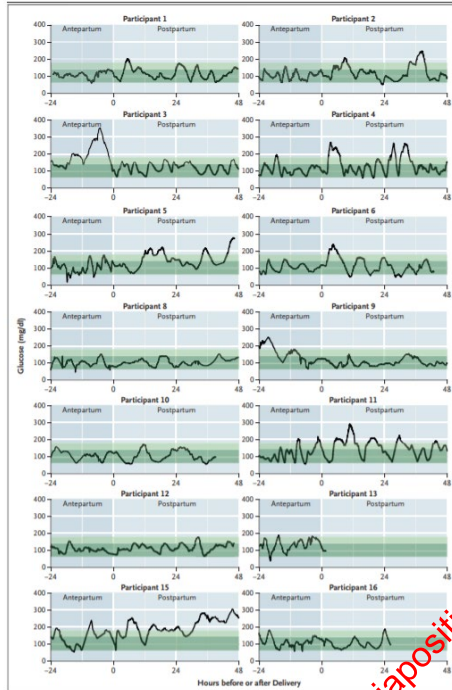
Continuation phase  
of an open-label, multicentre,  
randomized, crossover trial



14 pregnant women  
with type 1 diabetes



AID - CamAPS FX  
until delivery



- In the 24 hours before delivery, women had glucose 110 mg/dL [104-128], with glucose levels in TIR (63-140) 86.8%
- In the **first 48 hours after delivery**, women had a median **glucose 117 mg/dL** [104-131], with **TIR (70-180) 73.7%**
- **No episodes of maternal hypoglycemia**
- The median total daily insulin dose was **53.6%** [48.6-73.6] **of the predelivery dose on day 1 post-partum**, and **53.5%** [46.9-59.9%] **on day 2 post-partum**, with substantial variation among the participants

# AID in women with type 1 diabetes during early post-partum



Continuation phase  
of 2 open-label, multicentre,  
randomized, crossover trial



27 pregnant women  
with type 1 diabetes



AID - CamAPS FX  
until delivery

|                                               | Vaginal<br>delivery<br>n = 4 | Emergency<br>cesarean<br>section n = 12 | Elective<br>cesarean<br>section n = 11 |
|-----------------------------------------------|------------------------------|-----------------------------------------|----------------------------------------|
| Mean glucose, mmol/L (SD)                     | 6.3 (0.2)                    | 7.0 (1.5)                               | 7.0 (1.6)                              |
| Mean glucose, mg/dL (SD)                      | 113 (3.6)                    | 126 (27)                                | 126 (29)                               |
| Median time-in-target*, % (IQR)               | 84.5 (78.7, 88.8)            | 84.4 (48.5, 93.7)                       | 76.5 (48.2, 93.0)                      |
| Median time below target, % (IQR)             | 0 (0, 3.4)                   | 0.8 (0, 2.0)                            | 0 (0, 2.2)                             |
| Median time above target, % (IQR)             | 15.7 (11.2, 22.0)            | 11.4 (6.3, 50.4)                        | 16.5 (7.1, 51.8)                       |
| Median sensor glucose SD, mmol/L (IQR)        | 1.7 (1.4, 2.0)               | 1.5 (1.2, 2.2)                          | 1.8 (1.1, 2.2)                         |
| Median sensor glucose SD, mg/dL (IQR)         | 31 (25, 36)                  | 27 (22, 40)                             | 32 (20, 40)                            |
| Median number of hypoglycemic events (IQR)    | 0 (0, 1.0)                   | 0 (0, 1.0)                              | 0 (0, 1.0)                             |
| Number of women with a hypoglycemic event (%) | 1 (25.0)                     | 3 (27.2)                                | 3 (27.2)                               |

\*The glucose target range during labor and delivery was 3.5–7.8 mmol/L (63–140 mg/dL).

- During labor and delivery: glucose  $124 \pm 25$  mg/dL, pTIR 82% (IQR 49.3-93.0).
- In the **first 48 hours after delivery**: glucose  $130 \pm 25$ , with TIR 83.3% (IQR 75.2-94.6).
- **No** episodes of severe **maternal hypoglycemia** during labor, delivery or the immediate post-partum period.

# AID during intrapartum and early postpartum period

## - The CRISTAL Study -



Open-label, multicentre,  
randomized,  
controlled study



Since Jan. 2021  
Up to Sept. 2022



95 pregnant women (8 -11 weeks)  
with type 1 diabetes  
(HbA1c >10% → mean 6.5%)

AID – Smart Guard

Standard care  
(MDI/pump/SAP + CGM)

95 pregnant participants with T1D

1:1

46 in AHCL group  
(intervention)

49 in SoC group  
(control)

43 gave birth

46 gave birth

Secondary observational analysis on  
differences in glycemic control and safety  
outcomes intrapartum and early postpartum

27 (62.8%) used  
AHCL

Intrapartum

45 (97.8%) used  
SoC

37 (86.0%) used  
AHCL

Early  
postpartum

34 (73.9%) used  
SoC

Intrapartum

63 45 mg/dL  
3.5 5.8 mmol/L

27 AHCL†

27.0%  
±17.4

P=0.054

71.5%  
±17.7

P=0.030

1.1%  
±2.4

P=0.146

43 SoC†

35.3%  
±17.5

63.1%  
±17.0

1.5%  
±2.3

Early postpartum

70 180 mg/dL  
3.9 10.0 mmol/L

37 AHCL†

8.0%  
±6.2

P=0.809

86.8%  
±6.7

P=0.124

5.2%  
±3.3

P=0.084

34 SoC

8.6%  
±8.5

83.8%  
±8.1

7.6%  
±6.3

# AID during intrapartum and early postpartum period

## - The CRISTAL Study -



Open-label, multicentre,  
randomized,  
controlled study



Since Jan. 2021  
Up to Sept. 2022

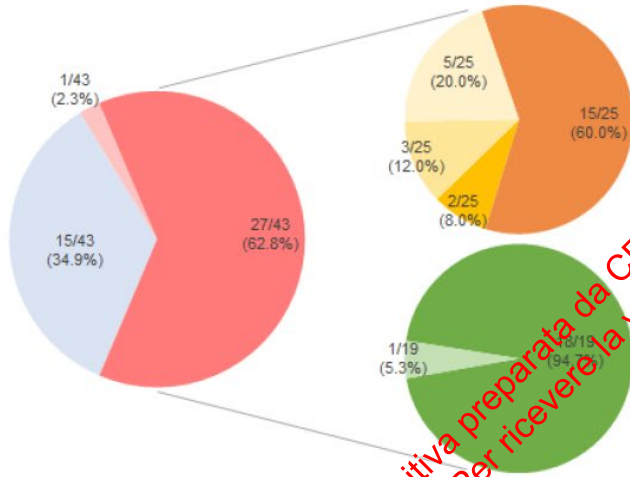


95 pregnant women (8 -11 weeks)  
with type 1 diabetes  
(HbA1c >10% → mean 6.5%)

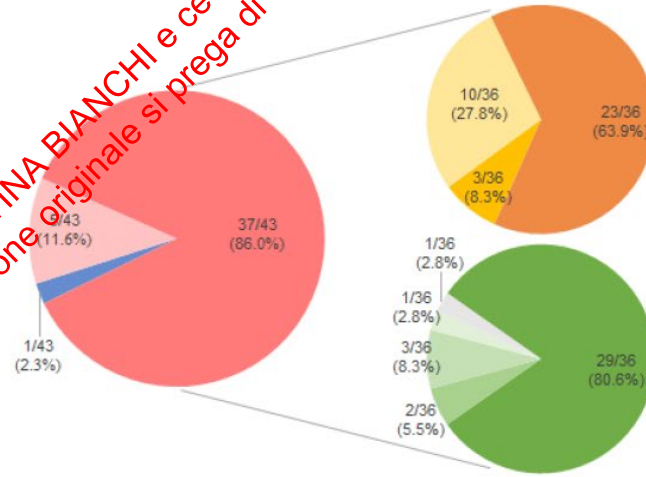
AID – Smart Guard

Standard care  
(MDI/pump/SAP + CGM)

### INTRAPARTUM



### EARLY POSTPARTUM



### Insulin delivery method

Insulin infusion ■ MDI  
Insulin pump: ■ CSII ■ SAP ■ AHCL

### Glucose target

■ 5.5 mmol/L ■ 6.1 mmol/L  
■ 6.7 mmol/L ■ Temporary 8.3 mmol/L

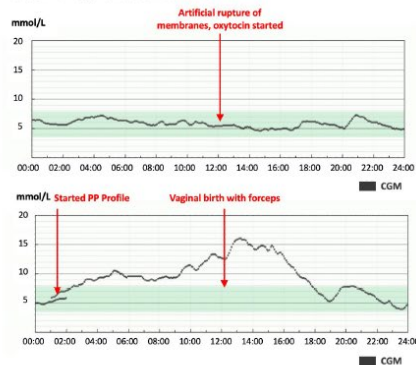
### Active insulin time

■ 2 h ■ 2 h 30 ■ 3 h  
■ 3 h 30 ■ 4 h

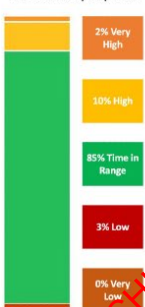
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# Real-world use of Control-IQ™ technology after delivery and AGP during the first postpartum week

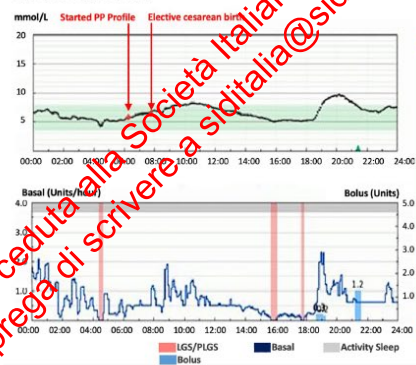
Case #1: Days of labour and birth



AGP 1<sup>st</sup> week postpartum



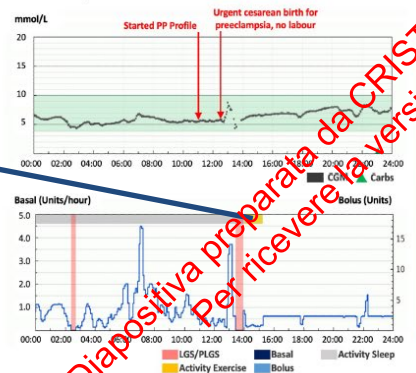
Case #2: Days of birth



AGP 1<sup>st</sup> week postpartum



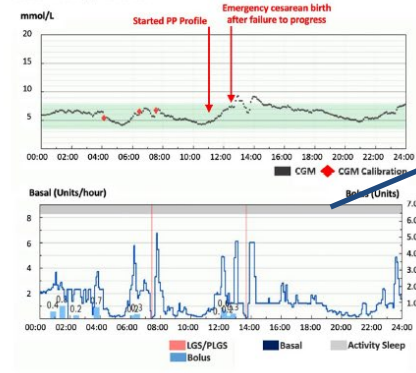
Case #3: Day of birth



AGP 1<sup>st</sup> week postpartum



Case #4: Days of birth



AGP 1<sup>st</sup> week postpartum



Exercise Activity was active with a target range of 140–160 mg/dL

Sleep Activity was active during the day, with target range of 112.5–121 mg/dL

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# Recommendations/checklist for optimizing Control-IQ use during labor, birth and postpartum

- a. Program a Postpartum Profile with:
  - (i) 2/3 pre-pregnancy basal rates (or 80% end of end of pregnancy basal rate)
  - (ii) 20% weaker correction factors than pre-pregnancy
  - (iii) 10%–20% weaker insulin to carb ratios than pre-pregnancy
- b. Switch to postpartum profile just before caesarean birth or at the start of pushing
- c. Run Sleep Activity during labour and birth
- d. Consider Control-IQ Technology with no Activity enabled if running too low
- e. If frequent hypoglycaemia with breastfeeding, consider switching to Control-IQ technology with no Activity enabled or Exercise Activity



# Post-partum Diabetes Management: AID settings

## - AMD-SID statement -

|                            | CamAPS FX                                                               | Smart Guard                                                             | Control I-Q                                                                            |
|----------------------------|-------------------------------------------------------------------------|-------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| <b>Glucose target</b>      | >108 mg/dl                                                              | 100 or 120 mg/dl                                                        | -                                                                                      |
| <b>Active Insulin Time</b> | Adapt as needed                                                         | 2 h                                                                     | -                                                                                      |
| <b>CHO/Insulin</b>         | Bring back to values close to those pre-pregnancy                       | Bring back to values close to those pre-pregnancy                       | Bring back to values close to those pre-pregnancy                                      |
| <b>Insulin sensitivity</b> | -                                                                       | -                                                                       | Adapt as needed                                                                        |
| <b>Body weight</b>         | Update                                                                  | -                                                                       | Update                                                                                 |
| <b>Basal rate</b>          | 50% of the basal rate at the end of pregnancy<br>(only for manual mode) | 50% of the basal rate at the end of pregnancy<br>(only for manual mode) | 2/3 of the pre-pregnancy basal rate (or 50% of the basal rate at the end of pregnancy) |
| <b>Hypoglycemic trend</b>  | Ease-off mode<br>(reduce basal rate and stop <120 mg/dl)                | Temporary target 150 mg/dl                                              | Exercise mode                                                                          |



# Post-partum AID settings: international consensus statement

|                                                                                                                                       | Suggested settings intrapartum                                                                                                                                                                                                                        | Suggested settings postpartum                                                                                                                                                                                                                                                                                                                                                                                                                         |
|---------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>CamAPS FX</b>                                                                                                                      |                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| RCT data available intrapartum and up to 6 months postpartum <sup>161</sup>                                                           | Increase glucose target to 5.5–6.0 mmol/L (99–108 mg/dL); insulin-to-carbohydrate ratios of between 1:12g and 1:15g                                                                                                                                   | Glucose target of 6.0 mmol/L (108 mg/dL) and use of called time-off as required; mean postpartum glucose target was 6.0 mmol/L (108 mg/dL) in the AIDA <sup>162</sup> postpartum study; insulin-to-carbohydrate ratios of between 1:12g (non-breastfeeding) and 1:15g (breastfeeding)                                                                                                                                                                 |
| <b>Diabeloop</b>                                                                                                                      |                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| No data available                                                                                                                     | No recommendation due to absence of evidence                                                                                                                                                                                                          | Adapt glucose targets between 5.5 mmol/L and 7.2 mmol/L (99–130 mg/dL); adapt aggressiveness in hyperglycaemia, normoglycaemia and at meals, as needed                                                                                                                                                                                                                                                                                                |
| <b>iLet</b>                                                                                                                           |                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| No data available                                                                                                                     | No recommendation due to absence of evidence                                                                                                                                                                                                          | Adapt glucose targets between 6.1 mmol/L and 7.2 mmol/L (110–130 mg/dL) as needed                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Medtronic MiniMed 670/770G</b>                                                                                                     |                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| No RCT data available intrapartum on automatic mode; RCT data available 3–7 days onwards until 6 months postpartum <sup>163,167</sup> | No recommendation due to absence of evidence                                                                                                                                                                                                          | Glucose target of 6.7 mmol/L (120 mg/dL, non-customisable); active insulin time of 2–3 h                                                                                                                                                                                                                                                                                                                                                              |
| <b>Medtronic MiniMed 780G</b>                                                                                                         |                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| RCT data available intrapartum and early postpartum <sup>164</sup>                                                                    | Glucose target can most frequently remain at 5.5 mmol/L (99 mg/dL); increase as needed to a glucose target of 6.1 mmol/L or 6.7 mmol/L (110 mmol/L or 120 mg/dL); active insulin time of 2 h; increase insulin-to-carbohydrate ratios by at least 50% | Glucose target can most frequently remain at 5.5 mmol/L (99 mg/dL); increase as needed to a glucose target of 6.1 mmol/L or 6.7 mmol/L (110 mmol/L or 120 mg/dL); 150 mg/dL is rarely needed; active insulin time of 2 h; increase insulin-to-carbohydrate ratios by at least 50% (and an average increase by 80% is needed when breastfeeding)                                                                                                       |
| <b>Omnipod 5 (SmartAdjust)</b>                                                                                                        |                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| No data available                                                                                                                     | No recommendation due to absence of evidence                                                                                                                                                                                                          | Adapt glucose targets between 6.1 mmol/L and 8.3 mmol/L (110–150 mg/dL); might benefit from resetting the pump to prepregnancy settings or spending some time in manual mode before resuming automation                                                                                                                                                                                                                                               |
| <b>Tandem t:slim X2 or Tandem Mobi with Control-IQ or Control-IQ+ technology</b>                                                      |                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Data available from a case series; <sup>17,169</sup> RCT ongoing <sup>170</sup>                                                       | Sleep activity range of 6.2–6.7 mmol/L (112–120 mg/dL) during labour and delivery                                                                                                                                                                     | Sleep activity function can often be continued if postpartum profile is activated;* if frequent hypoglycaemia or fear of postpartum hypoglycaemia then Control-IQ without an activity target range of 6.2–8.8 mmol/L (112–160 mg/dL) can be used with sleep activity overnight or, if needed, temporary use of the exercise activity range of 7.7–8.8 mmol/L (140–160 mg/dL) can be used                                                              |
| <b>Sequel Twist and open source systems (do-it-yourself APS—eg, LoopT and Android APS)</b>                                            |                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Little data available; case reports                                                                                                   | Stop two custom temporary overrides for delivery (50% and 75% of insulin needs, with a target of 5.5 mmol/L [99 mg/dL] enabled indefinitely) in advance, but do not activate until needed based on glucose, stage of labour, and mode of childbirth   | Change target to 6.1–7.5 mmol/L (110–135 mg/dL) postpartum; continue temporary overrides until postpartum settings* are activated; if Android APS experience is very limited, consider the following setting adjustments: stop dynamic insulin sensitivity factor, reduce the maximum units per hour and maximum total insulin on board by around 25–50% compared with the pregnancy values, and reduce the so-called maximum allowed bolus by 25–50% |



Nella struttura dove lavori, il personale di sala parto e del Reparto di Ostetricia/Ginecologia è adeguatamente informato/formato all'uso di tecnologie avanzate nelle donne con diabete mellito tipo 1?

- A. No
- B. No, ma stiamo valutando la creazione di un protocollo di gestione condiviso
- C. Sì, abbiamo un protocollo di gestione condiviso
- D. Sì, abbiamo un protocollo di gestione condiviso, ma non sempre viene seguito nelle donne con AID

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# Women's experiences with Control-IQ technology in peripartum



- Participants were satisfied with the experience on the AID and the autonomy that was given to them to make decisions on their own diabetes management.
- Participants expressed trust in Control-IQ technology to continue automated insulin adjustment while they focused on the events of their labour and birth experience.
- Some participants expressed concern that staff on the postpartum unit lacked familiarity towards diabetes technologies and hesitancy towards the autonomy of self-diabetes management.
- Some participants felt frustrated and judged by staff who performed fingerstick glucose monitoring on the postpartum unit, particularly when staff made comments like “that's high hey?” about minor glucose elevations.

# Management immediately after birth until discharge from hospital

We recommend postpartum insulin pump settings be agreed and documented in the woman's individual care plan at 34-36 weeks.

The postpartum basal rate can be programmed into the pump in advance as an additional basal profile; all other settings must be programmed after birth.

As soon as possible after birth (and certainly before the first bolus) the woman **MUST** change the pump settings to her postpartum settings.

It is commonly advised to omit the bolus insulin for the first light meal after birth.



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Rivaluti la terapia delle donne con diabete mellito tipo 1 dopo il parto?

- A. No
- B. Sì, dopo circa 4 settimane
- C. Sì, dopo circa 3 mesi
- D. Sì, al termine dell'allattamento

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Nelle donne con diabete mellito tipo 1, il controllo glicemico nei mesi successivi al parto:

- A. Solitamente migliora
- B. Resta tendenzialmente stabile
- C. Frequentemente peggiora
- D. Non so

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# Postpartum glycemic control in women with type 1 diabetes



Real world data



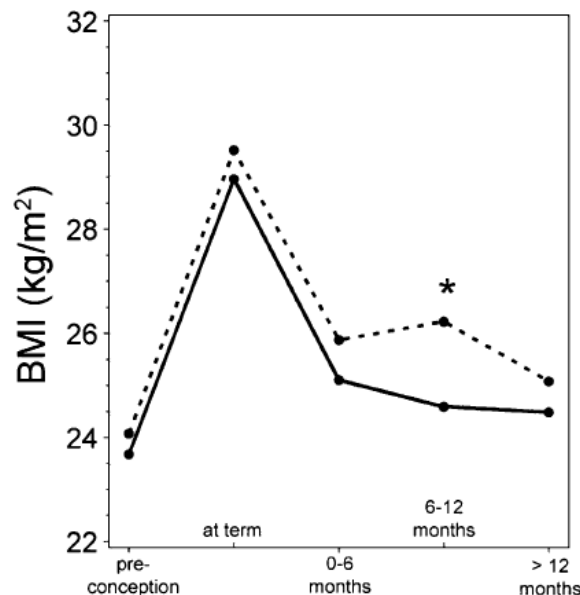
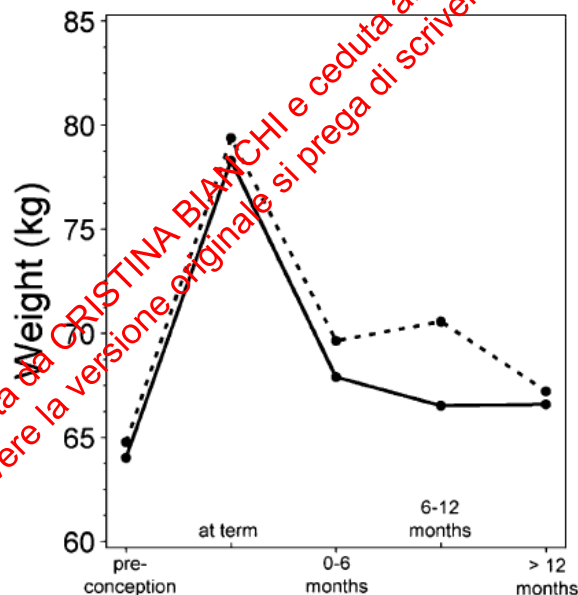
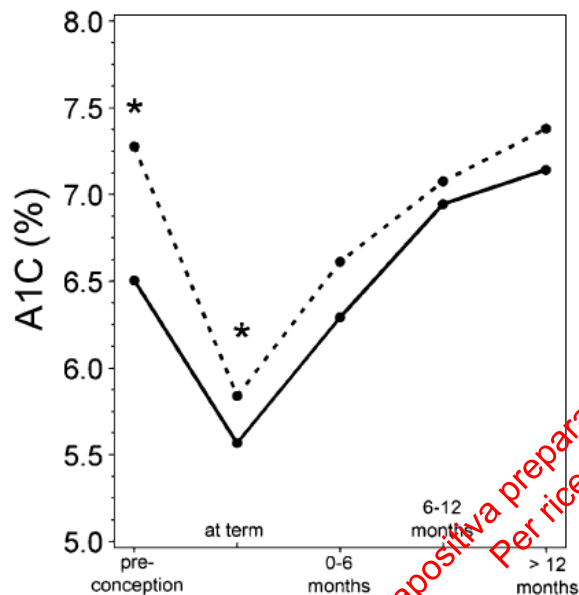
Since 1999  
Up to 2011



250 pregnant women  
with type 1 diabetes

Solid line → pregnancy planning

Dotted line → not planning



# Quality of life during post-partum in type 1 diabetes



Multicenter  
trial



245 pregnant  
women



176 with GDM

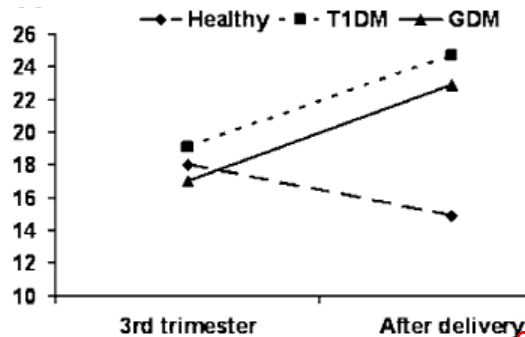
30 with type 1 diabetes

39 healthy controls

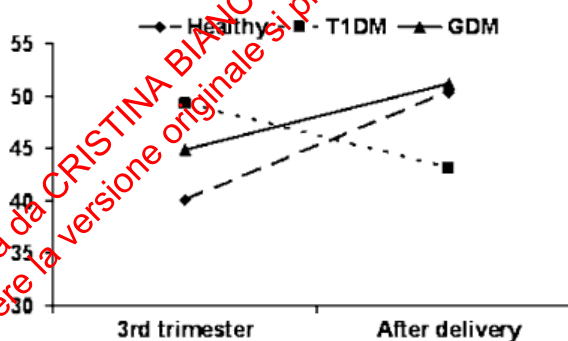
All SF-36 Health Survey and the Center for Epidemiological Studies-Depression (CES-D) Scale in third trimester of pregnancy and after delivery

## Health-related Quality of life (SF-36)

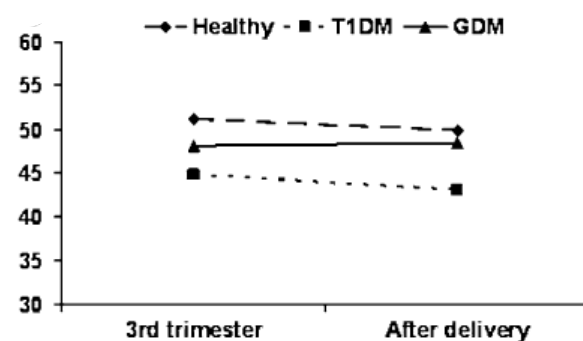
### Depression specific (CES-D)



### Physical component summary



### Mental component summary



Higher scores indicate a more favorable physical functioning and psychological well-being

# AID during the first 6 months postpartum

## - The AiDAPT Study -



Open-label, multicentre,  
randomized,  
controlled study



124 pregnant women (8 -11 weeks)  
with type 1 diabetes  
(HbA1c 6.5-10% → mean 7.7%)

AID - CamAPS FX → 25

Standard care → 24

(Mediator pump - 98% CGM)

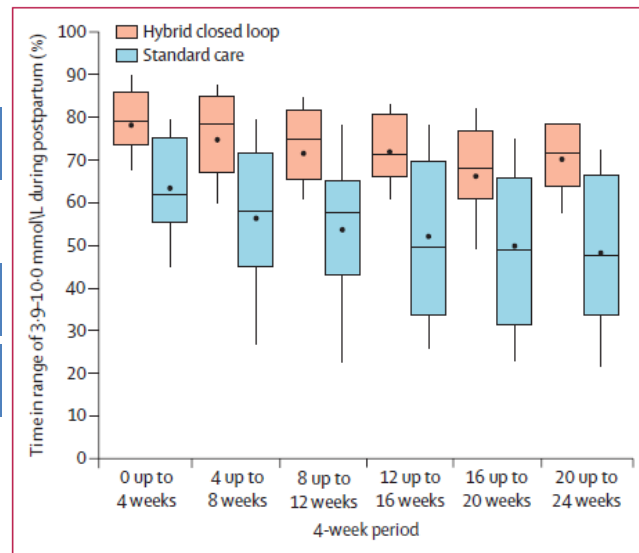
6 months  
postpartum  
extension

|                                                                  | Baseline*                 |                      | Postpartum†               |                      | Adjusted treatment difference‡ (95% CI) | p value for treatment effect‡ | p value for interaction‡ |
|------------------------------------------------------------------|---------------------------|----------------------|---------------------------|----------------------|-----------------------------------------|-------------------------------|--------------------------|
|                                                                  | Hybrid closed-loop (n=28) | Standard care (n=29) | Hybrid closed-loop (n=28) | Standard care (n=29) |                                         |                               |                          |
| CGM data, h                                                      | NA                        | NA                   | 3892 (622)                | 3636 (989)           | NA                                      | NA                            | NA                       |
| Number of participants§                                          |                           |                      |                           |                      |                                         |                               |                          |
| From 0 to 3 months                                               | 26/28                     | 27/29                | 26/28                     | 27/29                | ..                                      | ..                            | ..                       |
| 3 to 6 months                                                    | 25/28                     | 24/29                | 25/28                     | 24/29                | ..                                      | ..                            | ..                       |
| Percentage of time with glucose levels 3.9-10.0 mmol/L           | 73% (14%)                 | 70% (13%)            | 72% (12%)                 | 54% (17%)            | 15% (7 to 22)                           | 0.0037                        | ..                       |
| From 0 to 3 months                                               | 74% (14%)                 | 70% (13%)            | 75% (12%)                 | 57% (16%)            | 15% (7 to 23)                           | ..                            | ..                       |
| 3 to 6 months                                                    | 73% (13%)                 | 72% (13%)            | 70% (9%)                  | 50% (19%)            | 16% (7 to 24)                           | ..                            | ..                       |
| Percentage of time with glucose levels 3.9-7.8 mmol/L            | 50% (15%)                 | 47% (12%)            | 51% (11%)                 | 33% (13%)            | NA                                      | NA                            | NA                       |
| From 0 to 3 months                                               | 50% (15%)                 | 47% (12%)            | 54% (12%)                 | 35% (12%)            | NA                                      | NA                            | NA                       |
| 3 to 6 months                                                    | 51% (15%)                 | 48% (12%)            | 48% (10%)                 | 30% (15%)            | NA                                      | NA                            | NA                       |
| Percentage of time with glucose levels >10.0 mmol/L (SD)         | 22% (15%)                 | 22% (12%)            | 26% (12%)                 | 42% (18%)            | -14% (-23 to -6)                        | 0.0055                        | 0.78                     |
| From 0 to 3 months                                               | 22% (15%)                 | 22% (12%)            | 22% (13%)                 | 39% (17%)            | -16% (-23 to -9)                        | ..                            | ..                       |
| 3 to 6 months                                                    | 21% (15%)                 | 21% (12%)            | 28% (10%)                 | 47% (21%)            | -15% (-23 to -6)                        | ..                            | ..                       |
| Median percentage of time with glucose levels >13.9 mmol/L (IQR) | 3% (1 to 9)               | 3% (1 to 7)          | 7% (3 to 11)              | 15% (8 to 24)        | -9% (-16 to -2)                         | 0.029                         | 0.18                     |
| From 0 to 3 months                                               | 3% (1 to 9)               | 3% (1 to 7)          | 4% (2 to 10)              | 13% (6 to 22)        | -9% (-16 to -2)                         | ..                            | ..                       |
| 3 to 6 months                                                    | 2% (1 to 7)               | 2% (1 to 6)          | 8% (4 to 12)              | 28% (15 to 37)       | -12% (-20 to -3)                        | ..                            | ..                       |
| Median percentage of time with glucose levels <3.9 mmol/L (IQR)  | 5.0% (3.1 to 6.8)         | 4.6% (2.3 to 11.8)   | 2.4% (1.5 to 4.0)         | 2.6% (1.5 to 5.2)    | -0.7% (-2.0 to 0.5)                     | 0.49                          | 0.78                     |
| From 0 to 3 months                                               | 5.0% (3.1 to 6.8)         | 4.6% (2.3 to 11.8)   | 2.5% (1.4 to 4.3)         | 2.9% (2.0 to 5.0)    | -0.8% (-2.2 to 0.6)                     | ..                            | ..                       |
| 3 to 6 months                                                    | 4.9% (3.1 to 6.8)         | 4.0% (2.3 to 12.9)   | 2.3% (1.3 to 3.7)         | 2.2% (1.1 to 6.0)    | -0.6% (-2.0 to 0.7)                     | ..                            | ..                       |
| Median percentage of time with glucose levels <3.0 mmol/L (IQR)  | 1.2% (0.2 to 2.2)         | 0.7% (0.3 to 3.1)    | 0.3% (0.3 to 0.6)         | 0.6% (0.2 to 1.3)    | -0.2% (-0.6 to 0.1)                     | 0.33                          | 0.78                     |
| From 0 to 3 months                                               | 1.2% (0.2 to 2.2)         | 0.7% (0.3 to 3.1)    | 0.4% (0.3 to 0.7)         | 0.6% (0.2 to 1.2)    | -0.3% (-0.8 to 0.1)                     | ..                            | ..                       |
| 3 to 6 months                                                    | 1.0% (0.2 to 2.2)         | 0.6% (0.3 to 3.1)    | 0.4% (0.2 to 0.7)         | 0.5% (0.2 to 1.5)    | -0.2% (-0.6 to 0.1)                     | ..                            | ..                       |

+15% TIR

-1.4% TAR  
(180-250 mg/dl)

-9% TAR  
(>250 mg/dl)



# AID during postpartum period

## - The CLIMB Study -



Pilot, parallel-arm,  
open-label, randomized  
controlled trial



Since July 2020  
Up to Feb. 2023



18 women with type 1 diabetes  
randomized  
in first postpartum week

AID – Smart Guard  
SAP



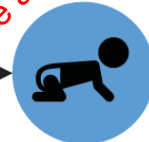
Pregnancy:  
Enrolled



Birth:  
Randomized



1-12 weeks postpartum:  
Randomized phase



12-24 weeks postpartum:  
Continuation phase



Conclusions



# Women's experiences with AHCL systems in post-partum

## - The CLIMB Study -



Pilot, parallel-arm,  
open-label, randomized  
controlled trial



Since July 2020  
Up to Feb. 2023



18 women with type 1 diabetes  
randomized  
at first postpartum week

↗ AID – Smart Guard  
↘ SAP

| Theme                                          | Subtheme                       | Illustrative quote                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|------------------------------------------------|--------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Preventing lows is great<br>but not everything | Great “when it works”          | “Yeah, it’s been really good. Actually, my blood sugar has been really good. And it’s given the peace of mind for just you know, knowing that it’s adjusting as needed for my background insulin, and it’s been, it’s definitely easier.” (Participant 08, 24 weeks postpartum)                                                                                                                                                                                                                                                                                                                                       |
|                                                | Specifically to prevent “lows” | “Well, the automode has really helped with overnight lows. So, it’s definitely nice when we’re already kind of getting up in the middle of the night to deal with [baby] and helping out there. And so not having to also deal with night lows. It’s been great.” (Partner 05, 24 weeks postpartum)<br>“When I was sick, and in the hospital for like 4 days, it was good to be in automode because I wasn’t eating because they were draining the infection. So, I was happy when I was in the hospital because it was very ... I was doing very well in automode.” (Participant 01, 12 weeks postpartum, auto mode) |





L'allattamento al seno può influenzare l'andamento glicemico?

Si

No

Non so



Diapositiva preparata da CRISTINA BIANCHI e ceduta alla Società Italiana di Diabetologia.  
Per ricevere la versione originale si prega di scrivere a [siditalia@siditalia.it](mailto:siditalia@siditalia.it)

# Diabetes management during breastfeeding period in mothers with type 1 diabetes



Multi-centre randomized controlled trial (MODIAB-Web study)



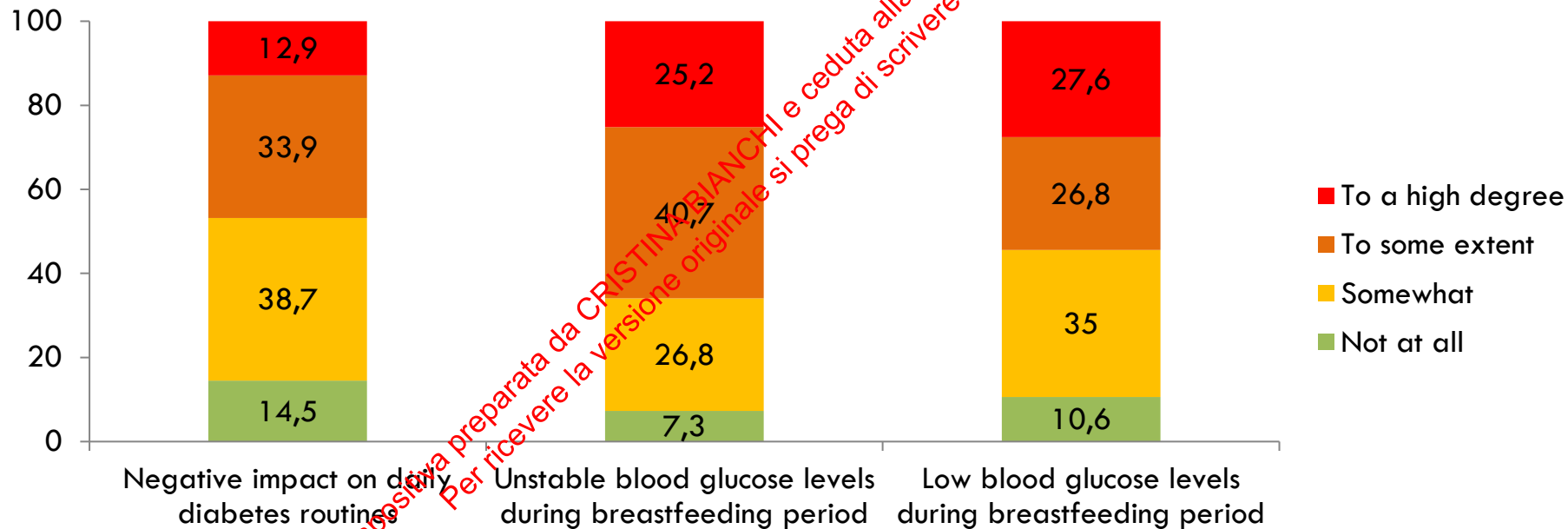
Since Nov. 2011  
Up to Dec. 2014



135 women  
with type 1 diabetes



self-reported  
questionnaires at 2  
months after childbirth





# AID during breastfeeding

## - The CLIMB Study -



Pilot, parallel-arm,  
open-label,  
randomized controlled trial

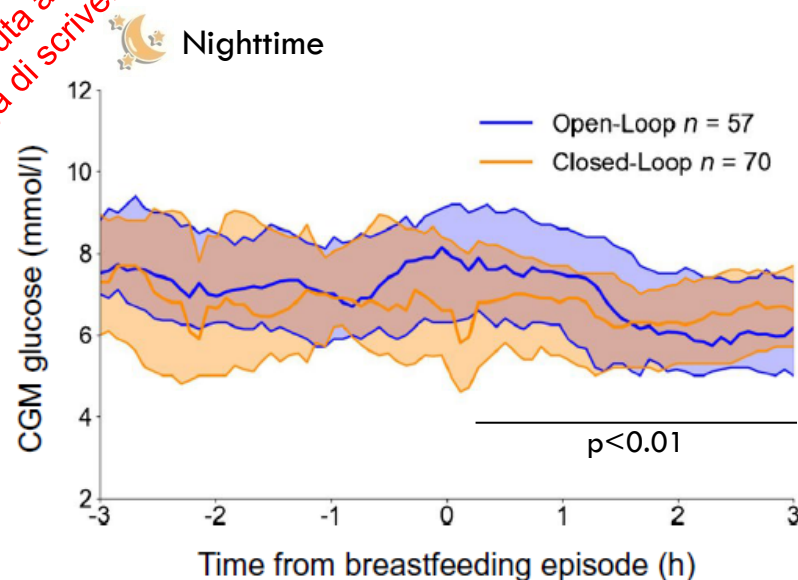
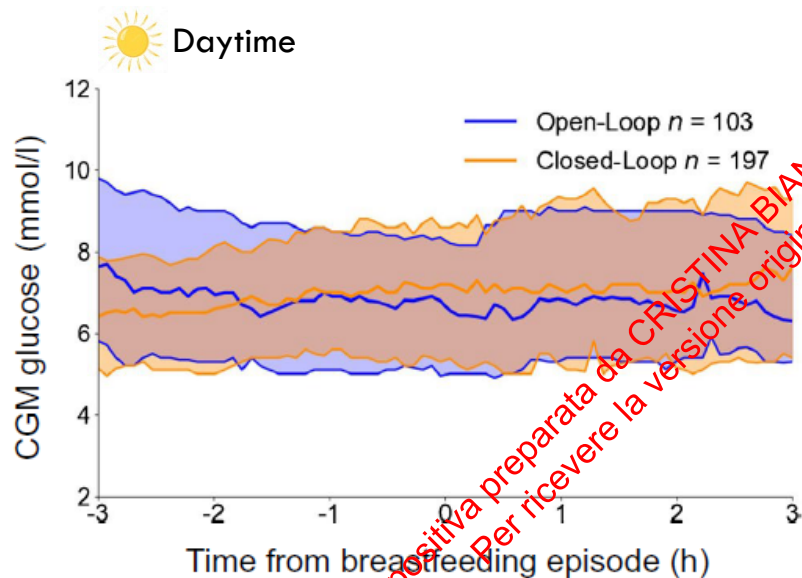


Since July 2020  
Up to Feb. 2023



18 women with type 1 diabetes  
randomized  
at first postpartum week

AID – Smart Guard  
SAP



# Conclusions: the aid of AID



- ✓ Advances in technology are transforming diabetes management also in pregnancy.
- ✓ The automated nature of closed loop and its ability to adapt to real-time glucose levels make it well suited for use during pregnancy, including labor, delivery, postpartum period and breastfeeding.
- ✓ Moreover, AID may reduce women's stress and the burden of managing diabetes also in the postpartum period, when the mother has to dedicate a lot of time to caring for her baby.



**Thanks  
for listening!**

Diapositiva preparata da CRISTINA BIANCHI e ceduta alla Societa Italiana di Diabetologia.  
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