Donatella Lo Presti
Centro di Riferimento Regionale di Diabetologia Pediatrica
A.O.U. Policlinico di Catania
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La tecnologia in età pediatrica

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

- Menarini
- Movi
- Lilly

La dott.ssa Lo Presti dichiara altresì il proprio impegno ad astenersi, nell'ambito dell'evento, dal nominare, in qualsivoglia modo o forma, aziende farmaceutiche e/o denominazione commerciale e di non fare pubblicità di qualsiasi tipo relativamente a specifici prodotti di interesse sanitario (farmaci, strumenti, dispositivi medico-chirurgici, ecc.).

L'impegno del team pediatrico nell'educazione all'autogestione

- Gestione della DKA all'esordio
- Accoglienza dell'intera famiglia fornendo un supporto emotivo che sostenga l'integrazione sociale (**psicologo nel team**)
- Progettazione di eventi educativi per pazienti e genitori
- Divulgazione scolastica
- Gestione delle patologie intercorrenti
- Monitoraggio auxologico
- Educazione alimentare integrata col metodo del «carbo-counting» (**dietista nel team**)
- Schemi di terapia insulinica personalizzati che «mimino» la fisiologia della secrezione pancreatica grazie alle nuove insuline

- **Utilizzo nuove tecnologie (closed loop)**

OBIETTIVO: EUGLICEMIA!

…dal Coping

To cope with = far fronte a…

…all'Empowerment

Empowerment = potenziamento

"… i mari senza onde non fanno esperti i marinai …"

Proverbio africano

Compenso glicemico: *bene e…PRESTO!*

The Beneficial Effects of Earlier Versus Later Implementation of Intensive Therapy in Type 1 Diabetes

*John M. Lachin,[1] Ionut Bebu,[1] and David M. Nathan,[2] for the DCCT/EDIC Research Group**

Diabetes Care 2021;44:2225–2230 | https://doi.org/10.2337/dc21-1331

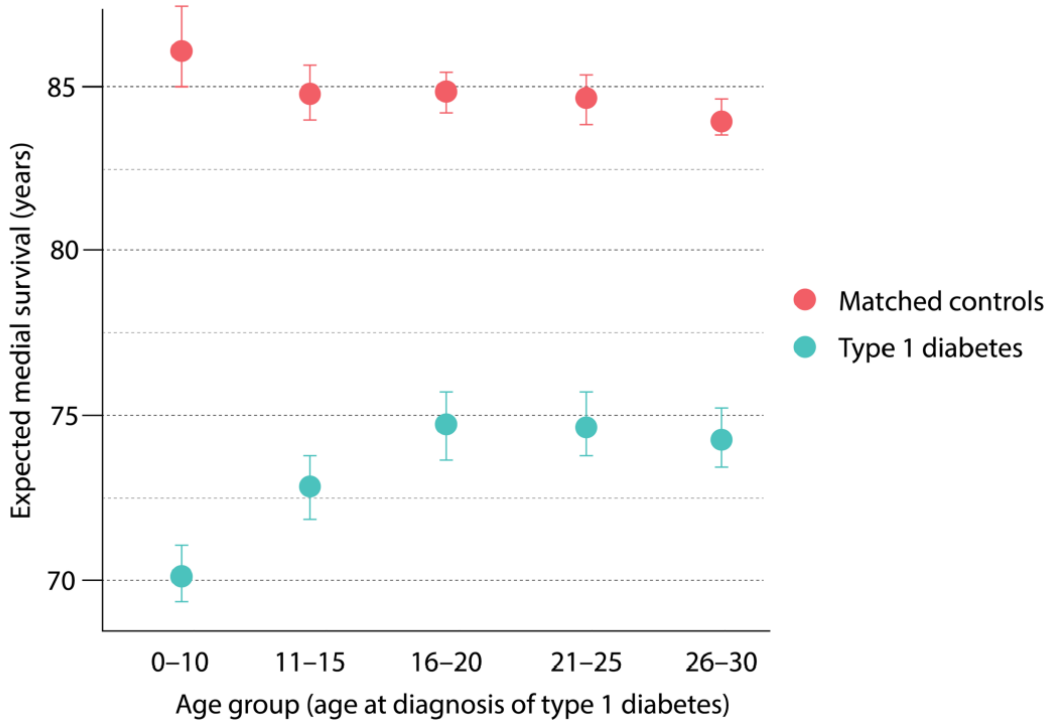
RESULTS

A hypothetical patient treated earlier with 10 years of intensive therapy and a mean HbA_{1c} of 7% (53 mmol/mol) followed by 10 years with a mean of 9% (75 mmol/mol) would have a 33% reduction in the risk of CVD and a 52% reduction in reduced eGFR compared with a patient with a mean HbA_{1c} of 9% (75 mmol/mol) over the first 10 years followed by later intensive therapy over 10 years with an HbA_{1c} of 7% (53 mmol/mol). Despite both patients having the same average glycemic exposure over the 20 years, the patient with the lower HbA_{1c} over the first 10 years had a lower risk of progression of complications over the 20 years than the patient who had the higher value initially.

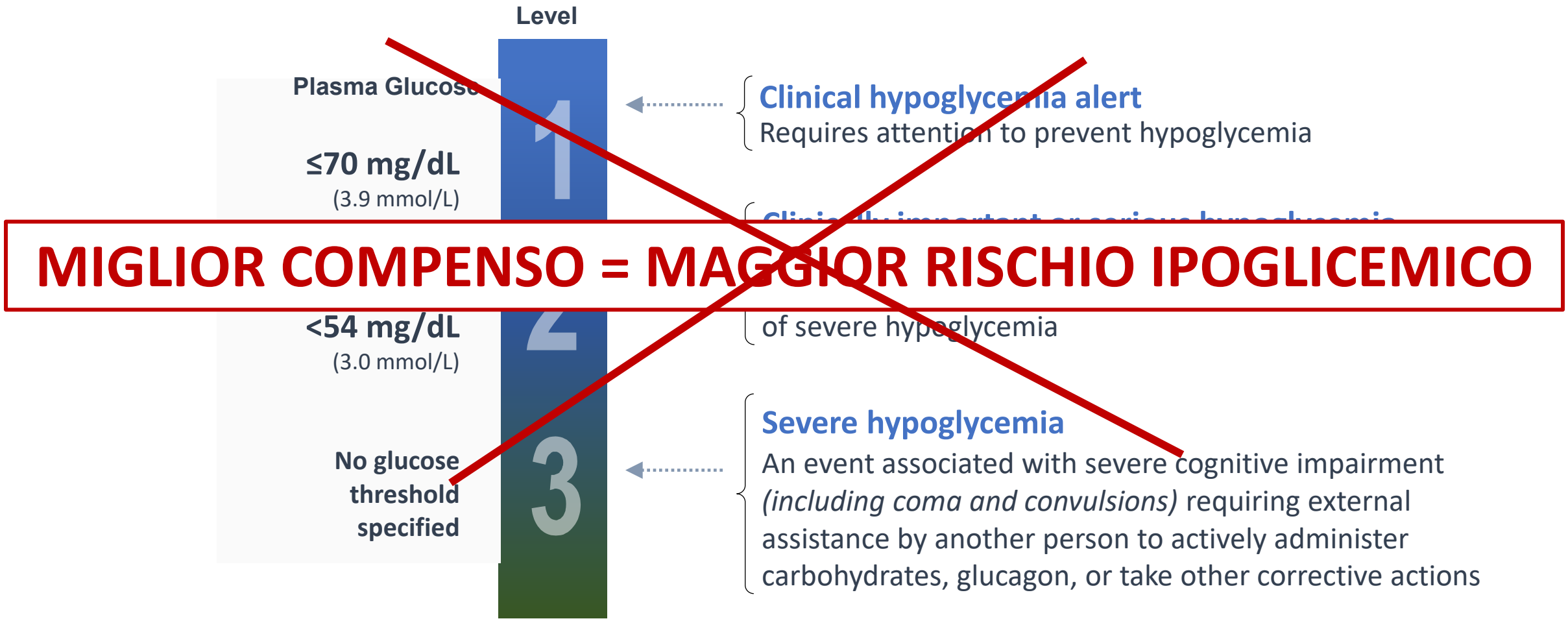
Lancet. 2018 August 11; 392(10146): 477–486. doi:10.1016/S0140-6736(18)31506-X.

Excess mortality and cardiovascular disease in type 1 diabetes in relation to age at onset: a nationwide study of 27,195 young adults with diabetes

Araz Rawshani[1,*], Professor Naveed Sattar[2,*], Stefan Franzén[3], Aidin Rawshani[4], Professor Andrew T Hattersley, Ann-Marie Svensson[3], Professor Björn Eliasson[5], Professor Soffia Gudbjörnsdottir[2,3]



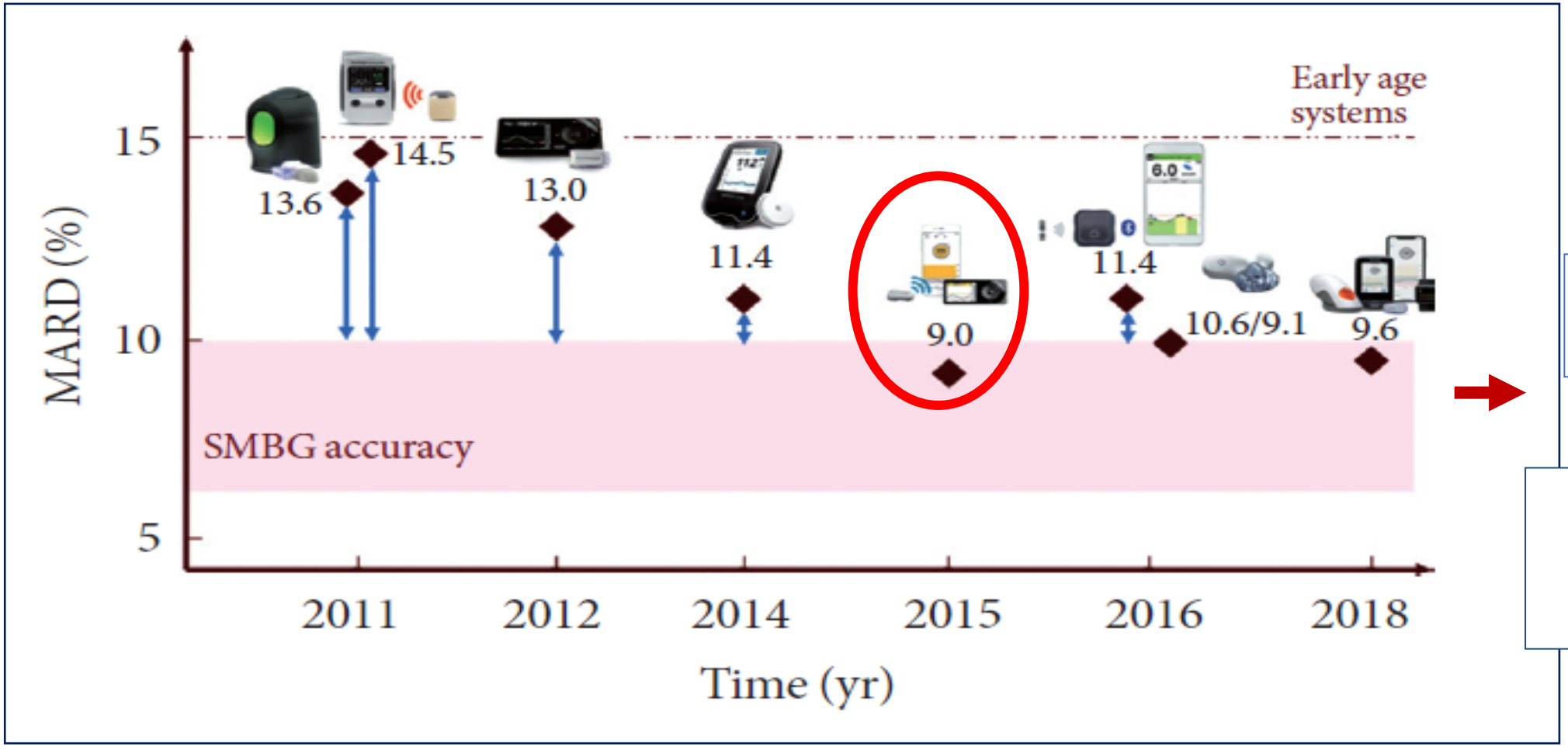
Gli sforzi profusi fino a una decina di anni fa nel tentative di migliorare il compenso glicemico SOFFRIVANO del LIMITE del rischio ipoglicemico



MIGLIOR COMPENSO = MAGGIOR RISCHIO IPOGLICEMICO

La svolta epocale del monitoraggio in continuo della glicemia

MARD < 10 rende il dato paragonabile al rilievo da sangue capillare e lo strumento idoneo per l'uso *"non aggiuntivo"*



I sistemi PLGS

Diabetes Care Volume 41, October 2018 2155

Predictive Low-Glucose Suspend Reduces Hypoglycemia in Adults, Adolescents, and Children With Type 1 Diabetes in an At-Home Randomized Crossover Study: Results of the PROLOG Trial

Gregory P. Forlenza,[1] Zoey Li,[2] Bruce A. Buckingham,[3] Jordan E. Pinsker,[4] Eda Cengiz,[5] R. Paul Wadwa,[1] Laya Ekhlaspour,[3] Mei Mei Church,[4] Stuart A. Weinzimer,[5] Emily Jast,[1] Tatiana Marcal,[3] Camille Andre,[4] Lori Carria,[5] Vance Swanson,[6] John W. Lum,[2] Craig Kollman,[2] William Woodall,[2] and Roy W. Beck[2]

Diabetes Care 2018;41:2155–2161 | https://doi.org/10.2337/dc18-0771

RCT crossover: PLGS vs. SAP

- 31% riduzione TBR in PLGS
- Nessuna variazione media glicemica
- Modesta ma significativa variazione TIR (2%=30'/die)
- Una ipo severa in SAP

OBJECTIVE

This study evaluated a new insulin delivery system designed to reduce insulin delivery when trends in continuous glucose monitoring (CGM) glucose concentrations predict future hypoglycemia.

RESEARCH DESIGN AND METHODS

Individuals with type 1 diabetes (n = 103, age 6–72 years, mean HbA_{1c} 7.3% [56 mmol/mol]) participated in a 6-week randomized crossover trial to evaluate the efficacy and safety of a Tandem Diabetes Care t:slim X2 pump with Basal-IQ integrated with a Dexcom G5 sensor and a predictive low-glucose suspend algorithm (PLGS) compared with sensor-augmented pump (SAP) therapy. The primary outcome was CGM-measured time <70 mg/dL.

RESULTS

Both study periods were completed by 99% of participants; median CGM usage exceeded 90% in both arms. Median time <70 mg/dL was reduced from 3.6% at baseline to 2.6% during the 3-week period in the PLGS arm compared with 3.2% in the SAP arm (difference [PLGS − SAP] = −0.8%, 95% CI −1.1 to −0.5, $P < 0.001$). The corresponding mean values were 4.4%, 3.1%, and 4.5%, respectively, representing a 31% reduction in the time <70 mg/dL with PLGS. There was no increase in mean glucose concentration (159 vs. 159 mg/dL, P = 0.40) or percentage of time spent >180 mg/dL (32% vs. 33%, P = 0.12). One severe hypoglycemic event occurred in the SAP arm and none in the PLGS arm. Mean pump suspension time was 104 min/day.

CONCLUSIONS

The Tandem Diabetes Care Basal-IQ PLGS system significantly reduced hypoglycemia without rebound hyperglycemia, indicating that the system can benefit adults and youth with type 1 diabetes in improving glycemic control.

REVIEW ARTICLES | JULY 09 2021

The Impact of Hypo- and Hyperglycemia on Cognition and Brain Development in Young Children with Type 1 Diabetes

Subject Area: Endocrinology , Women's and Children's Health

Michal Nevo-Shenker; Shlomit Shalitin

Horm Res Paediatr (2021) 94 (3-4): 115–123.

Brain Health in Children with Type 1 Diabetes: Risk and Protective Factors

Sarah S. Jaser[1], **Lori C. Jordan**[1,2,3]

[1]Department of Pediatrics, Vanderbilt University Medical Center, 2525 West End Ave., Suite 1200, Nashville, TN 37203, USA

[2]Department of Neurology, Vanderbilt University Medical Center, Nashville, TN, USA

[3]Department of Radiology and Radiological Science, Vanderbilt University Medical Center, Nashville, TN, USA

Abstract

Purpose of Review—To synthesize findings from studies of neurocognitive complications in children with type 1 diabetes (T1D) and highlight potential risk and protective factors.

Recent Findings—Emerging evidence suggests that hyperglycemia and time in range may be more important for brain development than episodes of hypoglycemia. Further, diabetic ketoacidosis (DKA) at the time of T1D diagnosis appears to be a particular risk factor for neurocognitive complications, particularly deficits in executive function skills and memory, with differences in cerebral white matter microstructure seen via advanced magnetic resonance imaging methods, and lower scores on measures of attention and memory observed among children who were diagnosed in DKA. Other factors that may influence neurocognitive development include child sleep, caregiver distress, and diabetes device use, presumably due to improved glycemic control.

Impact of Type 1 Diabetes in the Developing Brain in Children: A Longitudinal Study

Diabetes Care 2021;44:983–992 | https://doi.org/10.2337/dc20-2125

OBJECTIVE

To assess whether previously observed brain and cognitive differences between children with type 1 diabetes and control subjects without diabetes persist, worsen, or improve as children grow into puberty and whether differences are associated with hyperglycemia.

RESEARCH DESIGN AND METHODS

One hundred forty-four children with type 1 diabetes and 72 age-matched control subjects without diabetes (mean ± SD age at baseline 7.0 ± 1.7 years, 46% female) had unsedated MRI and cognitive testing up to four times over 6.4 ± 0.4 (range 5.3–7.8) years; HbA_{1c} and continuous glucose monitoring were done quarterly. FreeSurfer-derived brain volumes and cognitive metrics assessed longitudinally were compared between groups using mixed-effects models at 6, 8, 10, and 12 years. Correlations with glycemia were performed.

RESULTS

Total brain, gray, and white matter volumes and full-scale and verbal intelligence quotients (IQs) were lower in the diabetes group at 6, 8, 10, and 12 years, with estimated group differences in full-scale IQ of −4.15, −3.81, −3.46, and −3.11, respectively ($P < 0.05$), and total brain volume differences of −15,410, −21,159, −25,548, and −28,577 mm^3 at 6, 8, 10, and 12 years, respectively ($P < 0.05$). Differences at baseline persisted or increased over time, and brain volumes and cognitive scores negatively correlated with a life-long HbA_{1c} index and higher sensor glucose in diabetes.

CONCLUSIONS

Detectable changes in brain volumes and cognitive scores persist over time in children with early-onset type 1 diabetes followed longitudinally; these differences are associated with metrics of hyperglycemia. Whether these changes can be reversed with scrupulous diabetes control requires further study. These longitudinal data support the hypothesis that the brain is a target of diabetes complications in young children.

Early onset T1D impacts brain development

Diabetes Research in Children Network (DirecNet)

- 144 children with T1D
- 72 matched healthy control
- Age at baseline 4-9 years
- Follow up 6,4 0,4 years
- MRI and cognitive tests

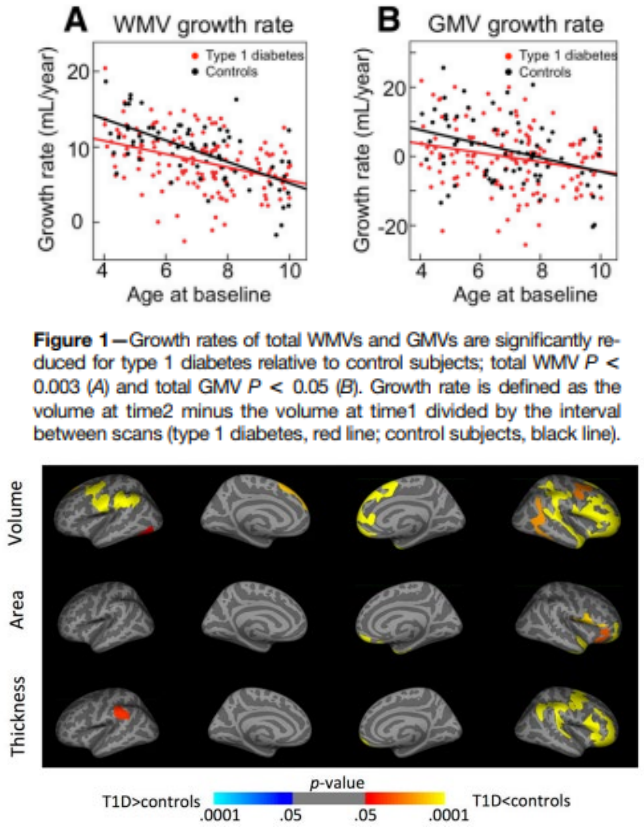


Figure 1—Growth rates of total WMVs and GMVs are significantly reduced for type 1 diabetes relative to control subjects; total WMV $P < 0.003$ (*A*) and total GMV $P < 0.05$ (*B*). Growth rate is defined as the volume at time2 minus the volume at time1 divided by the interval between scans (type 1 diabetes, red line; control subjects, black line).

Reduced grey and white matter growth in youth with early onset T1 Diabetes

Negative correlation between A1c AUC>6% and % TAR and cognitive scores

Mazaika P. et al, Diabetes 2016

DIABETES TECHNOLOGY & THERAPEUTICS
Volume 21, Number 1, 2019
Mary Ann Liebert, Inc.
DOI: 10.1089/dia.2018.0264

ORIGINAL ARTICLE

Safety Evaluation of the MiniMed 670G System in Children 7–13 Years of Age with Type 1 Diabetes

Gregory P. Forlenza, MD,[1] Orit Pinhas-Hamiel, MD,[2] David R. Liljenquist, MD,[3] Dorothy I. Shulman, MD,[4] Timothy S. Bailey, MD,[5] Bruce W. Bode, MD,[6] Michael A. Wood, MD,[7] Bruce A. Buckingham, MD,[8] Kevin B. Kaiserman, MD,[9] John Shin, M[illegible] Suiying Huang, MSc,[10] Scott W. Lee, MD,[10] and Francine R. Kaufma[illegible]

Abstract

Objective: To evaluate the safety of in-home use of the MiniMed™ 670G[illegible] nology in children with type 1 diabetes (T1D).

Methods: Participants ($N = 105$, ages 7–13 years, mean age 10.8 ± 1.8 years) [illegible] in the United States and one in Israel) and completed a 2-week baseline run-i[illegible] by a 3-month study phase with Auto Mode enabled. Sensor glucose (SG[illegible] percentage of SG values across glucose ranges, and SG variability, during [illegible] compared. Participants underwent frequent sample testing with i-STAT® ven[illegible] a hotel period (6 days/5 nights) to evaluate the system's continuous glucose[illegible]

Results: Auto Mode was used a median of 81% of the time. From baseline to[illegible] by 6.9 ± 17.2 mg/dL ($P < 0.001$), HbA_{1c} decreased from 7.9% ± 0.8% to 7.5%[illegible] time in target glucose range (70–180 mg/dL) increased from 56.2% ± 11.4%[illegible] the SG coefficient of variation decreased from 39.6% ± 5.4% to 38.5% ± 3.8%[illegible] values within target glucose range was 68.2% ± 9.1% and that of i-STAT ref[illegible] The percentage of values within 20%/20 of the i-STAT reference was 85.2%[illegible] hypoglycemia or diabetic ketoacidosis during the study phase.

Conclusion: In-home use of MiniMed 670G system Auto Mode for 3 month[illegible] MiniMed 670G system use by adolescents and adults with T1D, was safe a[illegible] levels and increased time in target glucose range, compared with baseline.

TABLE 2. GLYCATED HEMOGLOBIN, SENSOR GLUCOSE, GLYCEMIC CONTROL, VARIABILITY, INSULIN DELIVERED, AND BODY WEIGHT DURING THE RUN-IN AND STUDY PHASE

	Run-in phase	*Study phase*	P
HbA_{1c}, %	7.9 ± 0.8 (7.9, 7.2–8.4)	7.5 ± 0.6 (7.5, 7.1–7.8)	<0.001
SG, mg/dL	169 ± 22 (168, 155–184)	162 ± 12 (162, 154–169)	<0.001†
Percentage of sensor glucose values across ranges, mg/dL			
≤50	0.8 ± 1.2 (0.5, 0.1–1.1)	0.5 ± 0.5 (0.4, 0.2–0.8)	0.0012†
≤54	1.3 ± 1.5 (0.8, 0.3–2.0)	0.8 ± 0.7 (0.7, 0.3–1.1)	<0.001†
≤60	2.2 ± 2.3 (1.4, 0.7–3.3)	1.4 ± 1.0 (1.2, 0.7–1.9)	<0.001†
≤70	4.7 ± 3.8 (3.5, 1.8–7.2)	3.0 ± 1.6 (2.9, 1.8–3.8)	<0.001†
>70–140	35.0 ± 10.5 (33.5, 27.8–43.7)	42.6 ± 6.3 (42.5, 38.6–46.0)	<0.001
>70–180	56.2 ± 11.4 (55.9, 50.2–63.4)	65.0 ± 7.7 (64.6, 60.3–70.4)	<0.001
>180	39.1 ± 12.8 (38.4, 31.4–47.7)	32.0 ± 7.7 (32.4, 26.5–36.8)	<0.001
>250	13.3 ± 7.7 (11.5, 7.5–18.3)	10.3 ± 5.1 (9.8, 6.4–12.9)	<0.001†
>300	4.7 ± 3.8 (3.7, 1.8–7.0)	3.7 ± 2.7 (3.1, 1.7–4.9)	0.0037†
Within-day SD of SG, mg/dL	57.7 ± 8.3 (58.4, 52.2–65.0)	54.7 ± 7.5 (55.0, 49.7–59.1)	<0.001
Within-day CV of SG, %	34.8 ± 4.3 (34.4, 32.0–37.8)	33.7 ± 3.1 (33.7, 31.4–35.8)	0.0023
TDD, U/(kg·d)*	0.8 ± 0.2 (0.8, 0.7–0.9)	0.9 ± 0.2 (0.8, 0.7–0.9)	0.0037†
Basal insulin as % of TDD*	44.5 ± 7.4 (45.3, 39.1–49.9)	44.0 ± 7.3 (44.7, 40.3–47.8)	0.7281†
Weight, kg*	42.8 ± 13.0 (40.1, 32.4–51.6)	44.9 ± 13.4 (42.3, 33.8–53.3)	<0.001†

The run-in phase duration was 2 weeks and the study phase duration was 3 months. All values are shown as mean ± SD (median, interquartile range).

*One participant's height and weight were not captured at enrollment.

†Wilcoxon signed-rank test.

CV, coefficient of variation; HbA_{1c}, glycated hemoglobin; SG, sensor glucose; TDD, total daily dose of insulin, includes basal + microbolus.

I sistemi HCL

Incremento significativo del TIR
ma ancora non si persegue l'obiettivo prefisso (TIR > 70%!)
Si comincia a «guadagnare» sul TAR!

Limiti di sicurezza del primo HCL…

- Strumento dotato di «autoapprendimento» che adeguava ogni giorno a mezzanotte la basale sulla base dei sei giorni precedenti.
- Il sistema lavorava con **incrementi fino a 2,5 volte la basale media** ma ciò spesso **NON era sufficiente a correggere iperglicemie**
- Impossibile modulare il **target di 120 !**
- Nel passaggio in manuale la PLGS non si riavviava in automatico!
- **Frequenti uscite dalla modalità automatica** per:

1. erogare boli di correzione (corboidrati fantasma)
2. «eccesso di basale massima»
3. «eccesso di basale minima»

Tratto da «ISPAD Clinical Practice Consensus Guidelines 2022: diabetes technology insulin delivery»

AID system	Study design duration	Comparison group	Population	Baseline	Difference from baseline
Medtronic 780G	RCT – crossover 4 weeks	AHCL - PLGS	60 23,5 years	TIR 59 ± 10,4±	**TIR + 14,4 %**
Tandem Control IQ	RCT – parallel group 16 weeks	AHCL / SAP	101 11,3 ± 2 years	A1c 7,6 1 % TIR 53 17%	**A1c – 0,4% TIR + 11%**
CamAPs	RCT – crossover 16 weeks	HCL / SAP	74 5,6 ± 1,6 years	A1c 7,3 ± 0,7 % TIR 61,2 ± 10,1 %	**A1c - 0,4 % TIR + 8,7 %**
Omnipod 5	Single arm 3 months	MDI SAP HCL	80 4,7 ± 1 years	A1c 7,4 ± 1% TIR 57,2 ± 15,3%	**A1c - 0,55% TIR + 10,9%**
Omnipod 5	Single arm 3 months	MDI SAP HCL	112 10,3 ± 2,2 yy	A1c 7,67 ± 0,95 TIR 52,5 ± 15,6	**A1c - 0,71% TIR + 15,6%**
DBLG1	Crossover study 4 weeks	HCL / SAP	17 8,2 ± 1,6 years	A1c 7,2 ± 0,5 % TIR 58,7 ± 1,5%	**A1c n/a TIR + 7,5%**

UTILIZZO DEI SISTEMI AHCL IN ETA' EVOLUTIVA

1. Per tutti?
2. Fin dall'esordio?
3. Algoritmo indifferente?

ISPAD Clinical Practice Consensus Guidelines 2022: Diabetes Technology, Insulin Delivery

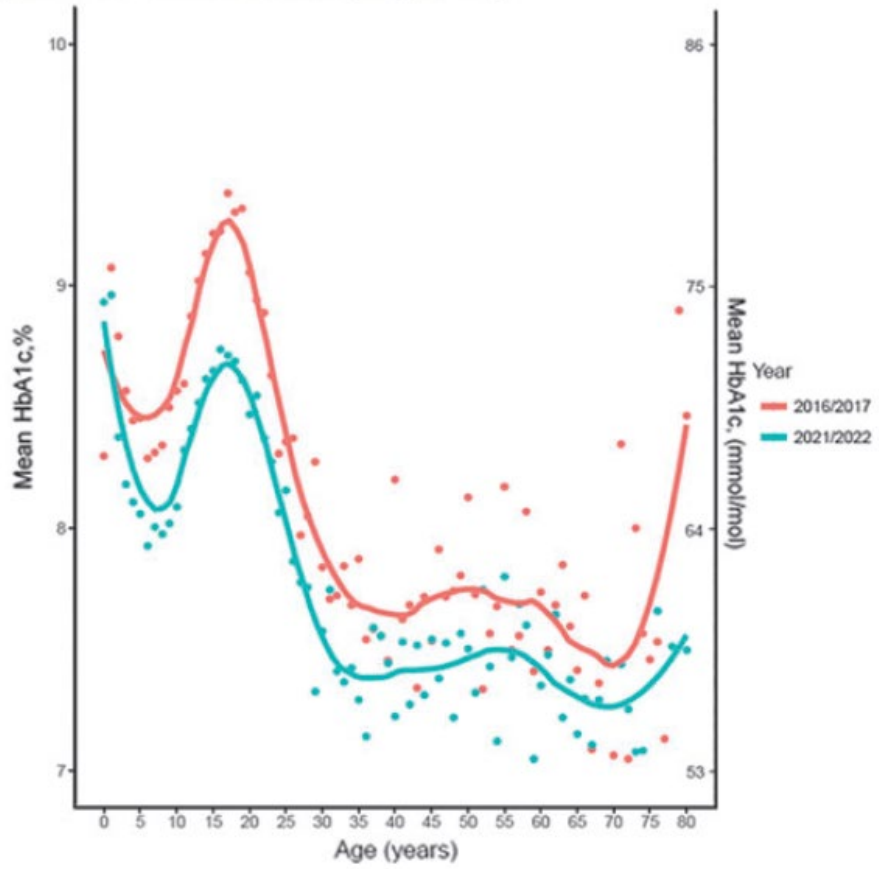
Jennifer L. Sherr, Melissa Schoelwer, Tiago Jeronimo Dos Santos, Leenatha Reddy, Torben Biester, **Alfonso Galderisi**, Jacobus van Dyk, Marisa E. Hilliard, Cari Berget, Linda A., Di Meglio

Youth should be offered the most advanced insulin delivery technology that is available, appropriate and affordable for them (B)

- Continous Subcutaneous Insulin Infusion (CSII pump therapy) is reccomended and appropriate for youth with diabetes regardeless of age **(A)**
- AID systems are strongly reccomended for youth with diabetes **(A)**
- AID systems improve Time in Range by minimizing hypoglycemia and hyperglycemia **(A)**

A Trends in HbA1c by Age

(2016/2017 versus 2021/2022; all patients)

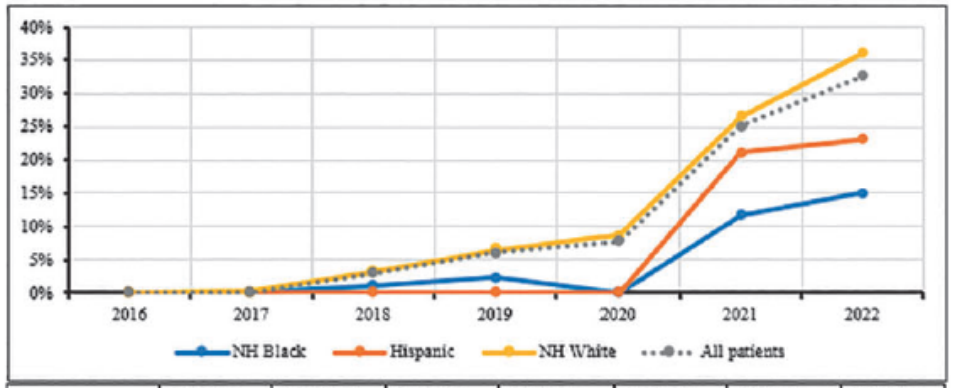


	2016 & 2017	2021 & 2022
N	27584	33070
Mean HbA1c (SD)	8.7 (1.9)	8.4 (2.1)
% with HbA1c <7% [N (%)]	5416 (20)	8557 (26)
% with HBA1c >9% [N (%)]	11811 (43)	10169 (31)
p-value		p-value <0.01

Longitudinal Trends in Glycemic Outcomes and Technology Use for Over 48,000 People with Type 1 Diabetes (2016–2022) from the T1D Exchange Quality Improvement Collaborative

DIABETES TECHNOLOGY & THERAPEUTICS
Volume 25, Number 11, 2023

C Trends in HCLS Use



	2016 (%)	2017 (%)	2018 (%)	2019 (%)	2020 (%)	2021 (%)	2022 (%)
NH White	0	0	3	6	9	27	36
Hispanic	0	0	0	0	0	21	23
NH Black	0	0	1	2	0	12	15
All patients	0	0	3	6	8	25	33

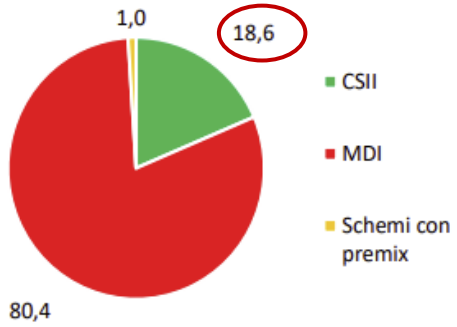
Note: Percentages are calculated based on a subset of the population for whom HCLS data was available.

FIG. 2. Trends in device use by race/ethnicity 2016–2022. This figure depicts trends in device use by race/ethnicity from 2016 to 2022, displayed by year and device type (CGM, **A**); insulin pump (**B**); and (HCLS, **C**). CGM, continuous glucose monitor; HCLS, hybrid-closed loop system.

In età evolutiva si incrementa velocemente l'utilizzo della tecnologia

Annali AMD 2022

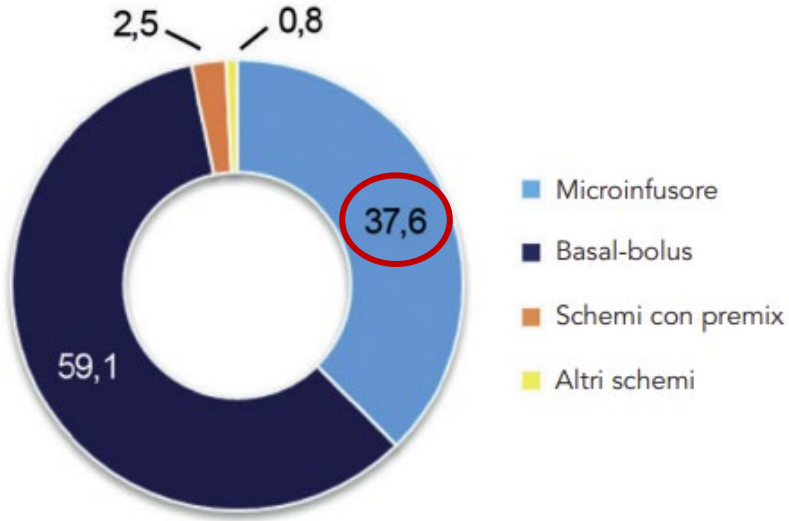
Distribuzione dei pazienti per gruppo di trattamento ipoglicemizzante (%)



ISPED CARD
Italian Society of Pediatric Endocrinology Diabetology
Continuous ClinicAl monitoRing of Diabetes

Associazione Italiana ISPED CARD

Schema insulinico (%)



…fin dall'esordio?

- Parallel multi-center
- 1:1 randomisation
- Age 10-16,9 (N=97)
- Within 21 days from diagnosis

Primary end-point: stimulated C-peptide AUC of the 12 month

Boughton CK et al. N Engl J Med 2022

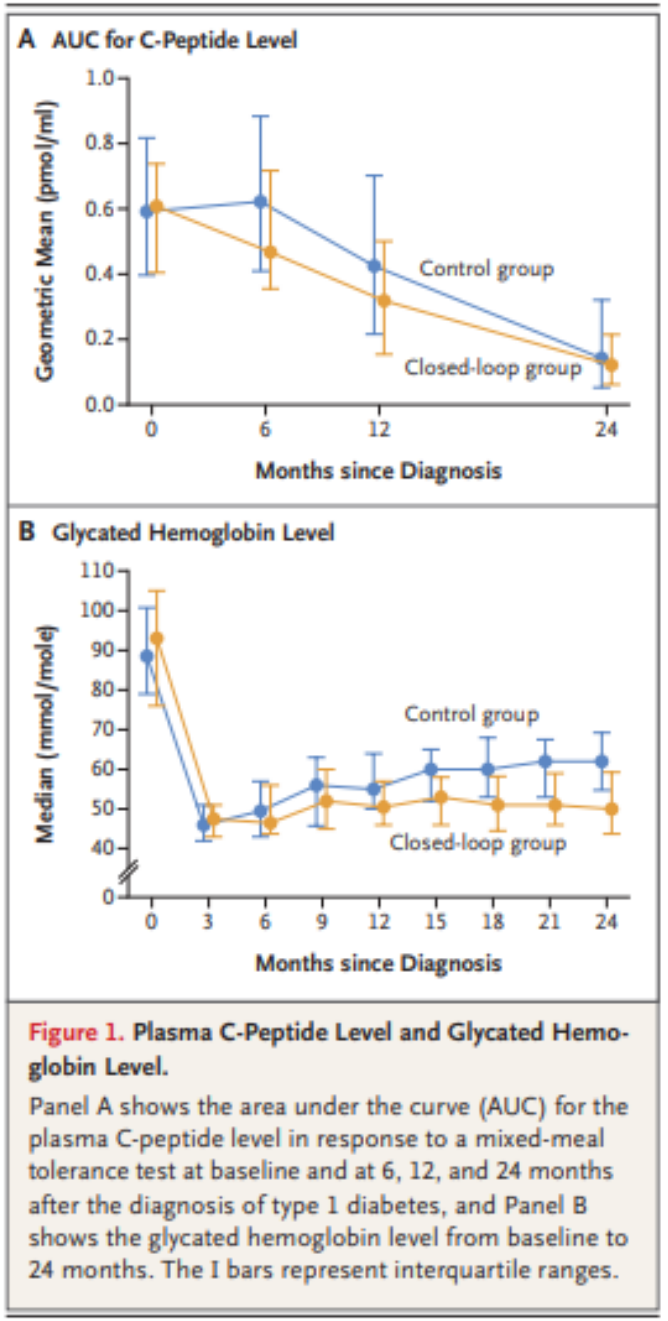
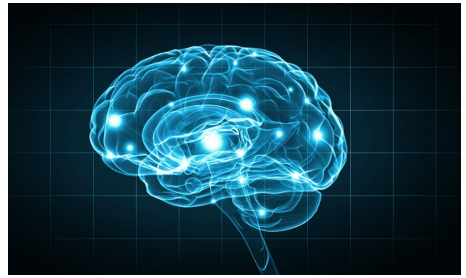


Figure 1. **Plasma C-Peptide Level and Glycated Hemoglobin Level.**

Panel A shows the area under the curve (AUC) for the plasma C-peptide level in response to a mixed-meal tolerance test at baseline and at 6, 12, and 24 months after the diagnosis of type 1 diabetes, and Panel B shows the glycated hemoglobin level from baseline to 24 months. The I bars represent interquartile ranges.

Closed loop e test neurocognitivi



	STANDARD CARE		CLOSED LOOP	
	baseline	6 months	baseline	6 months
% TIR	43	44	40	58
% > 250 mg/dl	26	26	39	14
% TBR	3,7	3,3	3,3	3,9

	Standard care	Closed loop
	Delta 0-6	Delta 0-6
% reasoning Index	+ 2.05	+6.1
Verbal comprehension Index	+ 0.29	+1.48
Full scale IQ	+1.95	+4.05

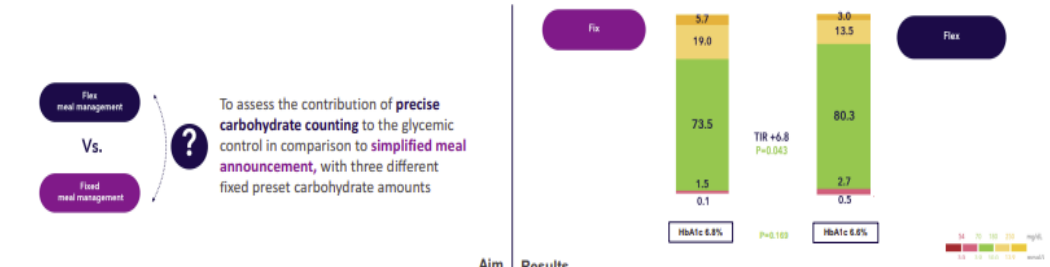
Reiss et al, Nat Comm. 2022

*I sistemi AHCL **si mostrano più sicuri fin dall'esordio** per l'efficace protezione dall'ipoglicemia (veloci variazioni della sensibilità insulinica nelle nuove diagnosi!) e perché colmano la naturale inesperienza nell'autogestione in generale e nel calcolo dei carboidrati in particolare…..*

Simplified Meal Announcement Versus Precise Carbohydrate Counting in Adolescents With Type 1 Diabetes Using the MiniMed 780G Advanced Hybrid Closed Loop System: A Randomized Controlled Trial Comparing Glucose Control

Goran Petrovski, Judith Campbell, Maheen Pasha, Emma Day, Khalid Hussain, Amel Khalifa, and Tim van den Heuvel

Diabetes Care 2023;46(3):544–550 | https://doi.org/10.2337/dc22-1692



Per gli inesperti si può lavorare confezionando «pasti fissi» personalizzati

E i più piccoli possono assumere la merenda a scuola senza dover per forza praticare il bolo

Carbohydrate Tolerance Threshold for Unannounced Snacks in Children and Adolescents With Type 1 Diabetes Using an Advanced Hybrid Closed-Loop System

Gianluca Tornese,[1] Claudia Carletti,[1] Manuela Giangreco,[1] Daniela Nisticò,[2] Elena Faleschini,[1] and Egidio Barbi[1,2]

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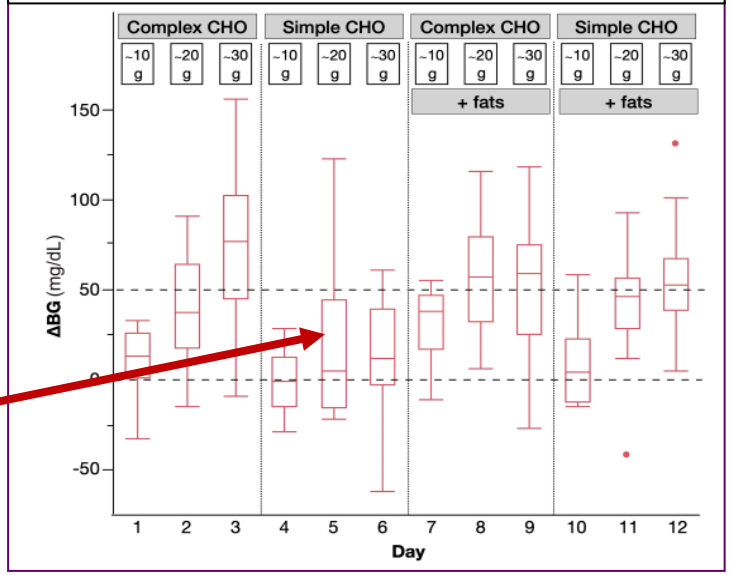


Algoritmo APGo

- **Con caratteristiche PID e MPC**
- Controllo sia da PDM che con app «easy Patch»
- Autoapprendimento
- Target 100 – 110 – 120
- Tre livelli di attività:

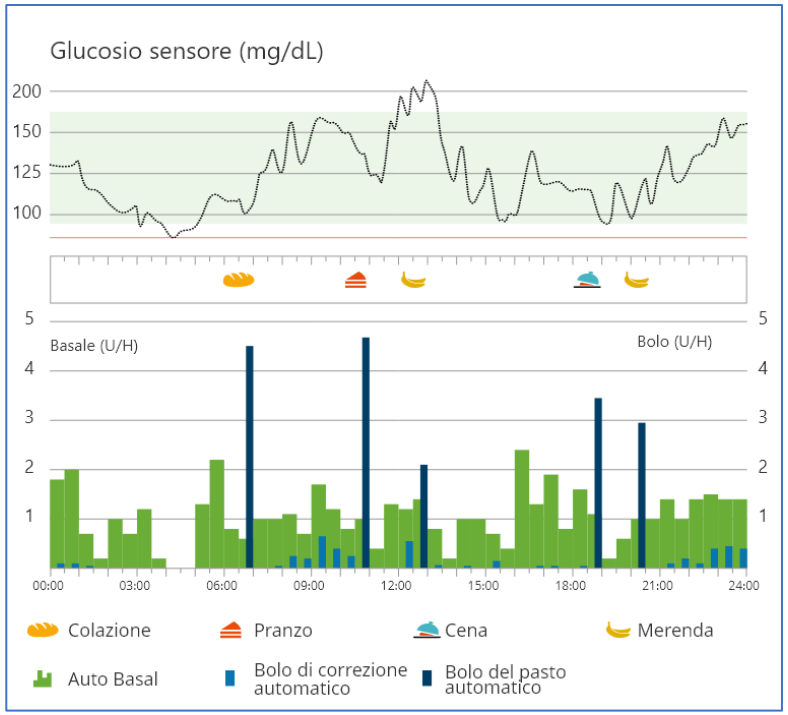
1. PLGS
2. AUTOMODE
3. **AUTOMEAL (TDD >10U/W >20Kg)**

AUTOMEAL: consente di non dover contare i carboidrati del pasto.

Non è necessario annunciare pasti < 5 g. di CHO

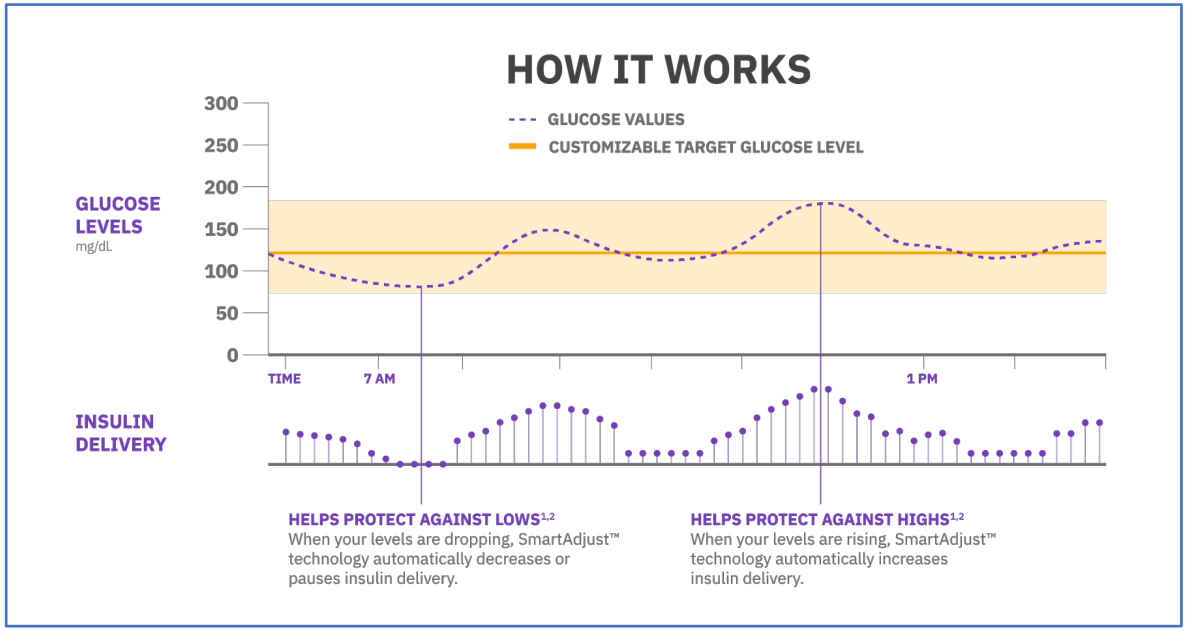
Un sistema di icone indicherà gli altri pasti sui quali il sistema calibra il bolo in base «all'apprendimento» effettuato (somministra metà del bolo presunto subito e il resto a correzione del rialzo glicemico)

Pasti < a 20 g. di CHO sono pasti spuntino



Tecnologia SmartAdjust

- In modalità automatica la basale si adatta ogni 5 minuti per riportare la glicemia al Target impostato (variabile fra 110 e 150) e tenendo conto della previsione glicemica a 60 minuti
- **Il Target è personalizzabile in 8 differenti segmenti orari**
- La velocità basale adattiva si aggiorna ad ogni cambio POD in base alla TDI dei POD precedenti
- **Lo Smartbolus considera il «trend» glicemico**
- Scarico dati in automatico su piattaforma Glooko (cod. proconnect)
- **Integrabile con Dexcom G6 e Libre 2 PLUS**
- Impermeabile, comunica anche in acqua



UTILIZZO DEI SISTEMI AHCL IN ETA' EVOLUTIVA

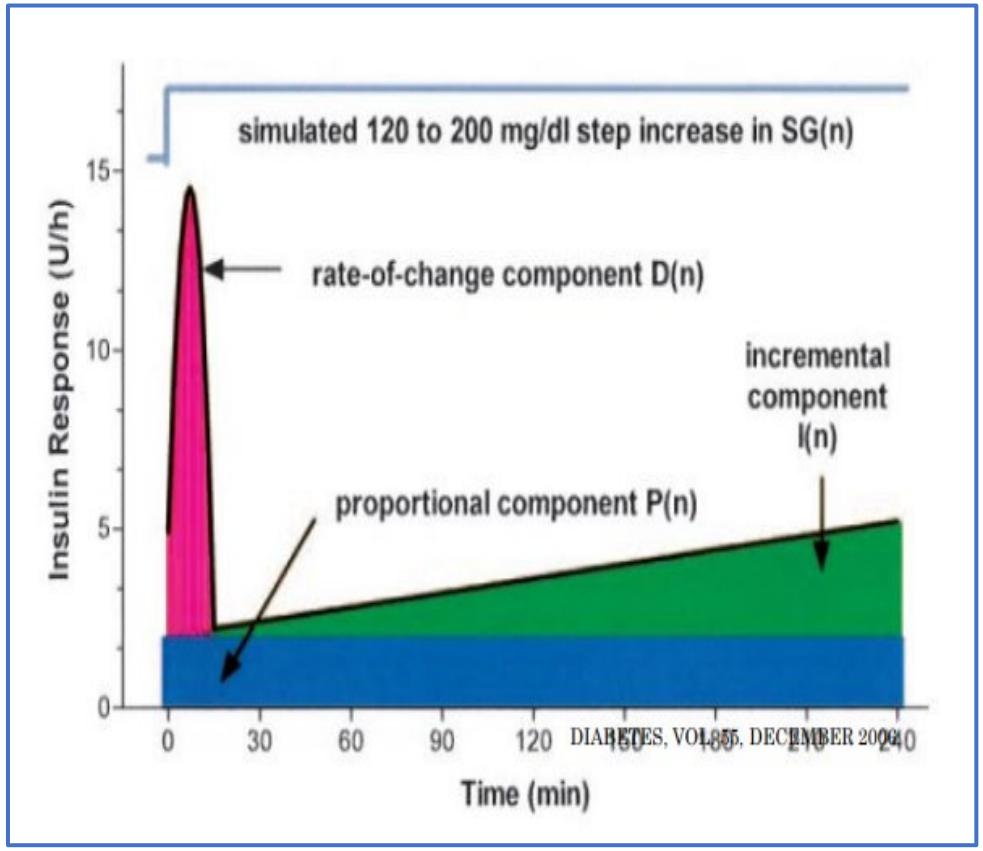
1. Per tutti!
2. Fin dall'esordio!
3. Algoritmo indifferente?

Algoritmo PID: "*reattivo*"

- **Proporzionale**: considera la differenza fra input in entrata e valore di riferimento (target glicemico)
- **Integrale**: tiene conto del tempo per cui dura l' «errore» rispetto al target (area sotto la curva)
- **Derivativo**: considera la velocità della variazione

AUTOAPPRENDIMENTO

FUZZY LOGIC: si basa su un «set» di regole derivanti dalle modalità di ragionamento e dalle decisioni prese dal clinico



Sistema più "fisiologico"?...
Il pancreas «pensa» come un PID?...

MPC: Model Predictive Control

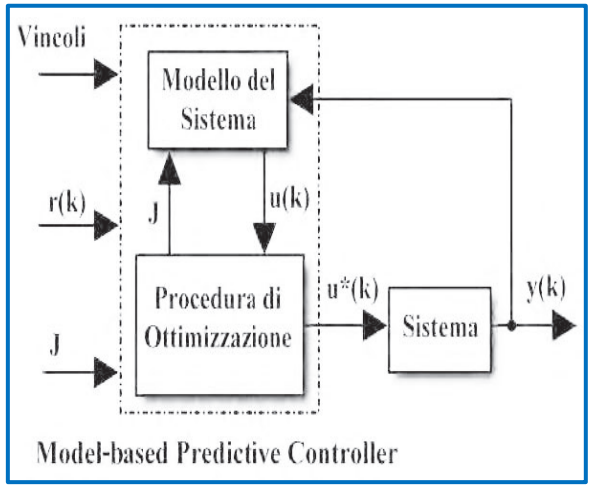
In tali algoritmi l'erogazione basale si adegua in modo tale che la differenza fra glicemia predetta e target glicemico sia minimo in un arco temporale compreso fra 15 e 60 minuti.

Gli adeguamenti a carico della velocità di erogazione basale sono molto in genere più importanti rispetto al PID ed esistono funzioni di incremento e decremento basale per periodi definiti dal paziente

Esistono diversi algoritmi predittivi con caratteristiche

Differenti!

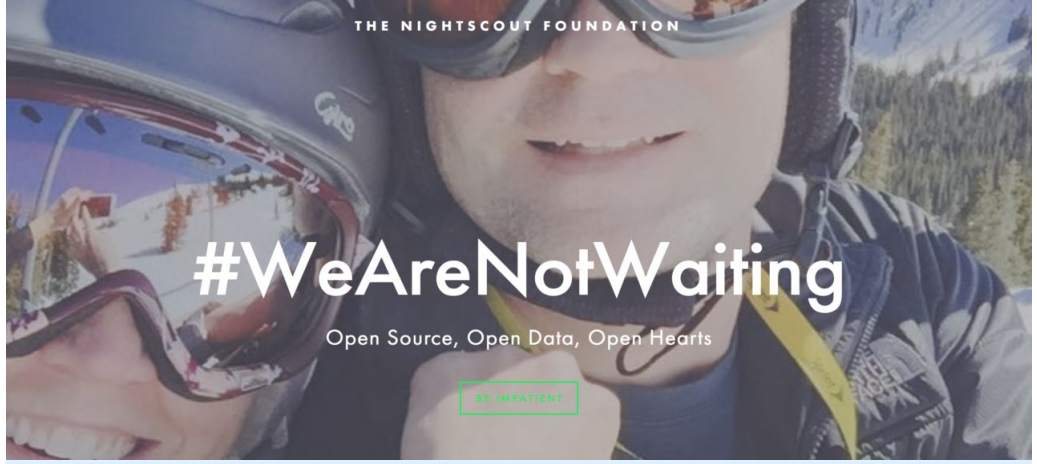
Esistono sistemi misti PID/MPC

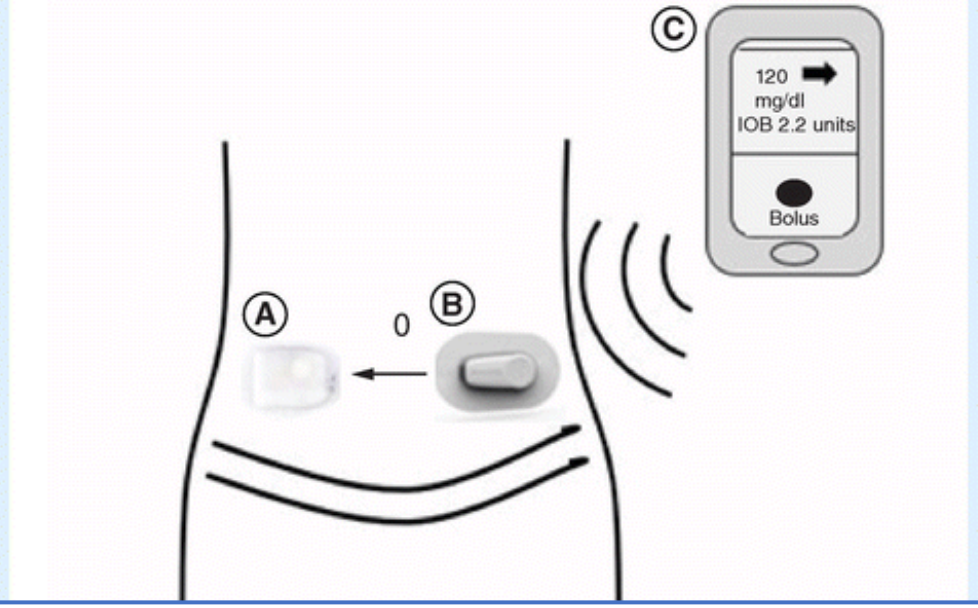


Vari sistemi MPC:

Chi ha target fisso e chi no
Alcuni possono modulare il target per segmenti orari
Chi ha FSI modulabile e chi autodeterminato dall'algoritmo
Chi ha IOB fissa e chi modulabile
Chi fa autoapprendimento in basale e chi anche al pasto
Chi somministra boli di correzione automatica e chi no
Chi li somministra ogni ora e chi ogni 5 o 10 minuti
Chi lavora con boli ai pasti che tengono conto del trend glicemico
Chi incrementa la basale fino a 4 volte l'ultima erogata e chi fino al 50% della totale
Chi ha un certo grado di interoperabilità

Tandem Control IQ	Omnipod 5	Diabeloop	CamAPS FX
Tandem (USA)	Insulet (USA)	Diabeloop (France)	Cambridge AP (UK)
			
>6 year and >25 kg (>10 U insulin per day)	>6 year	>18 year (>8 U insulin per day)	From 1 year and >10 kg (from 5 U insulin per day)
Yes (reimbursment Dexcom G6 is very restricted in Belgium)	No (FDA-label, CE-label pending)	Yes (reimbursment Dexcom G6 is very restricted in Belgium)	No (yes in UK, Netherlands)
Dexcom G6 (future: Dexcom G7, Libre)	Dexcom G6 (future: Dexcom G7, Libre)	Dexcom G6 (future: Eversense, Percusense)	Dexcom G6
Tandem t:slim X2 (future: Mobi, Mobi:tubeless, t:slim X3)	Omnipod	Roche Insight (future: Roche Solo, Kaleido, Dana-i, Panda, Medsafe WITH)	Dana-RS, Dana-i, YpsoPump
Glooko+Clarity (EU), t:connect (US)	Glooko	Glooko	Glooko
t:connect app with phone bolus (only US)	Omnipod 5 app (only android)	In development	CamAPS FX app
112,5-160 mg/dl (fixed range)	110, 120, 130, 140 of 150 mg/dl (adjustable per time block)	Adjustable between 100-130 mg/dl	**80-200 mg/dl** (adjustable per time block)
Sleep mode (target 112,5-120 mg/dl without autocorrection boluses) - Sport mode (target 140-160 mg/dl with autocorrection boluses)	HypoProtect (target 150 mg/dl and restricted insulin delivery, can be scheduled 1-24h)	Zen mode (= temporary increase of target, less insulin on board and less agressive algorithm)	Ease-off mode (target 126 mg/dl can be scheduled for 0-24h) - Boost mode (insulin +35% until target => more agressive algorithm can be scheduled for 0-13h)
Basal insulin rate, TDI, weight, IC ratio, insulin sensitivity	Basal insulin rate, TDI, average amount of carbs for a typical meal	Weight, TDI (total daily insulin dose), and average amount of carbsat a typical meal	TDI and weight
Autocorrection boluses every hour. Algorithm looks at predicted glycemia => not learning. Prolonged bolus is possible.	Algorithm on the POD, control with PDM or phone (only android, future: iOS), bolus calculator also takes the glucose trend into account	Autocorrectiebolussen om de 5 minutes. Algoritme on handset => need to keep this nearby. Learning algorithm. Privacy mode possible.	Autocorrection boluses every 10 minutes. Algorithm in an app (only android) => need to keep mobile phone nearby. Only one approved in **pregnancy** or with **Fiasp**. Learning algorithm.
Basal insulin rate, TDI, IC ratio, insulin sensitivity for correction boluses (Active insulin time is fixed: 5 hours)	IC ratio, insulin sensitivity for corrections, active insulin time	Hypoglycemia limit; agressivity of the algorithm at hyperglycemia, normoglycemia and at meals	IC ratio, amount of carbs per meal size (small, medium, big, very big meal)





- Open Aps
- Android Aps
- Loop (dal 2020 Tidepool loop ne ha acquisito i diritti commercializzando una versione non approvata in Europa)

2013

…e poi ci sono i sistemi DoItYourself

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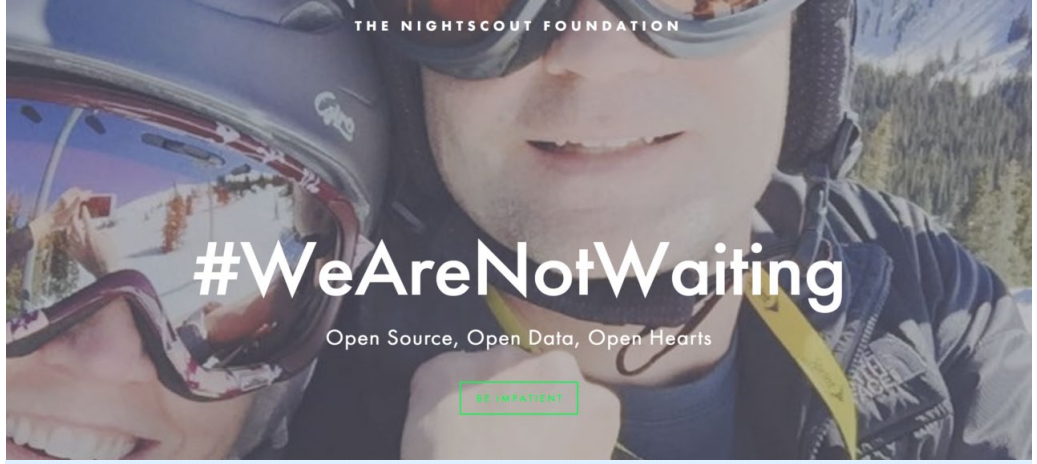
User and Healthcare Professional Perspectives on Do-It-Yourself Artificial Pancreas Systems: A Need for Guidelines

Jaclyn A. Shepard, PsyD[1], Marc Breton, PhD[2], Revital Nimri, MD[3], Joseph T. F. Roberts, PhD[4], Timothy Street, MEng, BEng[5], David Klonoff, MD, FACP, FRCPE, Fellow AIMBE[6], and Katharine Barnard-Kelly, PhD[7,8]

AID commerciali	AID open-source
Training da parte del curante e supporto da parte dell'industria	Interoperabilità ampia Supporto da parte della community
Servizio clienti	Costo di acquisto e gestione inferiori
Meno variabili/più semplici	Più variabili da considerare
Copertura di garanzia	Smart watch e opzioni bolo da remoto
Approvato da Enti regolatori	Full-closed…



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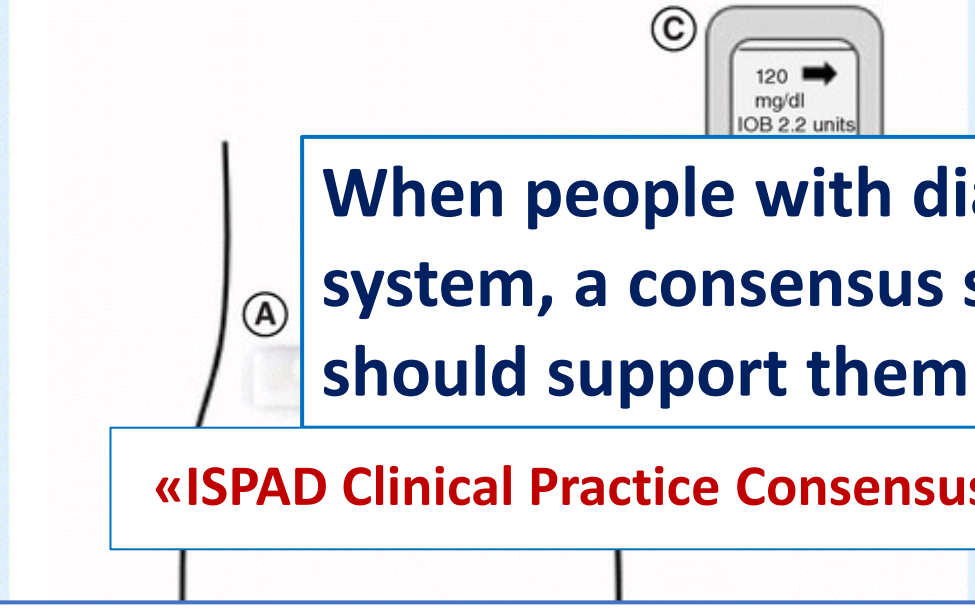

When people with diabetes choose to use an open source system, a consensus statement suggests that providers should support them1

«ISPAD Clinical Practice Consensus Guidelines 2022: diabetes technology insulin delivery»

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- Android Aps
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Servizio clienti	Costo di acquisto e gestione inferiori
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Quali aspetti considerare, in età evolutiva, nella scelta del sistema?

- *PID?*
- *MPC?*
- *DBLG1?*
- *CamAPS?*
- *SmartAdjust?*
- *APGo*
- *……open APS?*

Considerare:

- Limiti imposti dall'età ma soprattutto dalla TDD
- Necessità di periodo in manuale da parte dell'algoritmo
- Variabilità glicemica (età prescolare)
- Competenze nel *counting* del ragazzo/a o dei caregivers
- Tipologia di monitoraggio glicemico in uso
- Autonomia nell'adeguamento basale
- Autonomia nel calcolo di FSI

negli adolescenti:

- Frequenza di boli omessi
- Eventuali disturbi alimentari anche border
- Attività sportiva e sua tipologia (sport acquatici)
- Gravidanza?

E' DI FONDAMENTALE IMPORTANZA RISPETTARE LE PREFERENZE DEL PAZIENTE!

Messaggi conclusivi

- L'età evolutiva è un mondo molto variegato con bisogni speciali e peculiari delle varie fasce di età. Unico aspetto comune la **necessità di un controllo glicemico ottimale fin dall'esordio** allo scopo di prevenire le complicanze croniche di malattia e garantire invariata durata di vita
- L'uso dei sistemi AHCL migliora il compenso glicemico e la qualità di vita in **TUTTE** le fasce di età, si impone pertanto come terapia di scelta anche **fin dall'esordio**
- Il ruolo del paziente è centrale nella scelta del device e l'interoperabilità aiuterà la personalizzazione della cura con maggior benessere delle persone con diabete
- **Motivi che possono indurci a mantenere un soggetto con DM1 in MDI sono: importante allergia alla colla dei device o un suo cosciente rifiuto!**
- Esiste un concetto di **personalizzazione** anche **dei diversi algoritmi** ed è questa oggi la competenza aggiuntiva che si chiede al diabetologo
- Delegare la cura ad un algoritmo non comporta una deresponsabilizzazione dell'utilizzatore o un venir meno del **ruolo educativo del medico**
- Ad oggi il fattore limitante per il raggiungimento della NORMOGLICEMIA rimane la modalità di erogazione nel sottocutaneo dell'insulina.

gli «oltre» della diabetologia….

Materials and methods – results:

PID vs MPC population sample