Roma, 8-11 novembre 2018

HANDS ON 3:
TECNOLOGIE PER IL DIABETE

ITALIAN CHAPTER

MONITORAGGIO GLICEMICO IN CONTINUO:

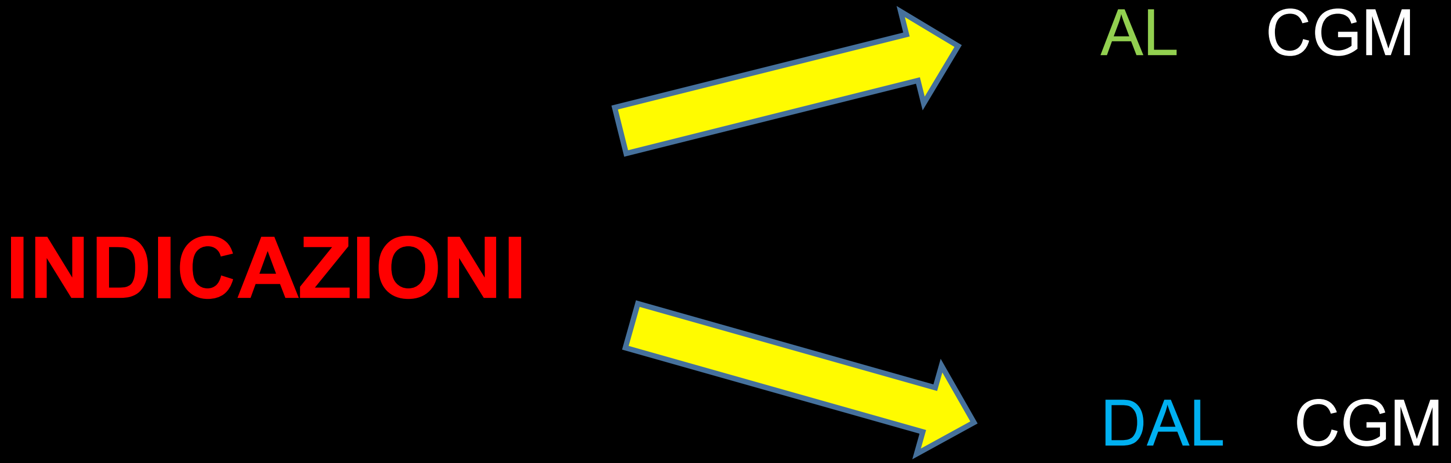
LE INDICAZIONI

dott.ssa Maria Isabella Ramunni
U.T. di Endocrinologia e Malattie Metaboliche
P.T.A. ‘Jaia’ di Conversano
DSS12- ASL BA

giovedì 8 novembre 2018

Conflitti di interesse

Ai sensi dell’art. 3.3 sul conflitto di interessi, pag 17 del Regolamento Applicativo Stato-Regioni del 5/11/2009, dichiaro che negli ultimi 2 anni ho avuto rapporti diretti di finanziamento con i seguenti soggetti portatori di interessi commerciali in campo sanitario: nessuno



INDICAZIONI

AL CGM

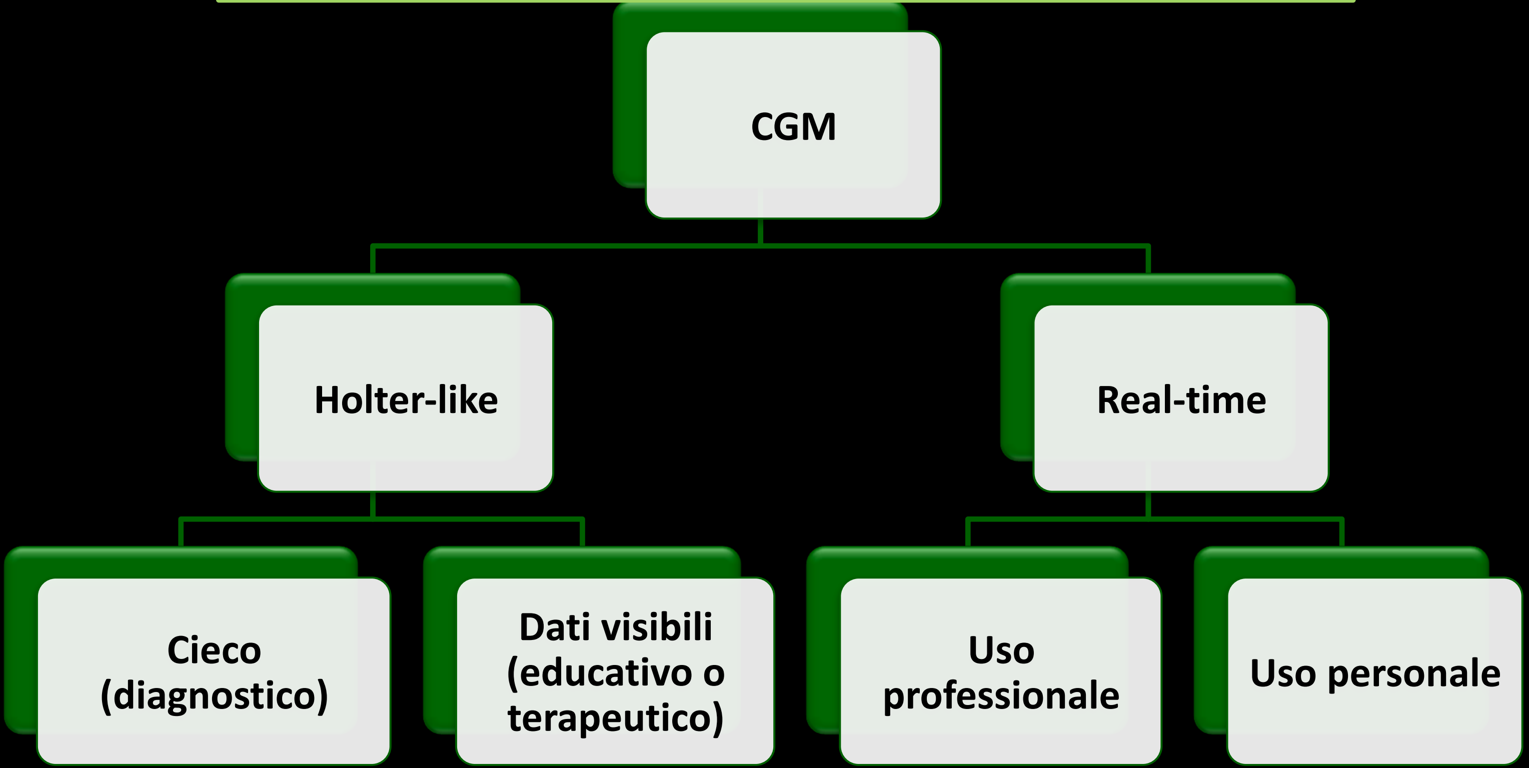
DAL CGM

AL **CGM**

INDICAZIONI

DAL CGM

UTILIZZI DEL CGM



- CGM
  - Holter-like
    - Cieco (diagnostico)
    - Dati visibili (educativo o terapeutico)
  - Real-time
    - Uso professionale
    - Uso personale

HANDS ON 3: TECNOLOGIE PER IL DIABETE

- *Come e quando impiegare il monitoraggio glicemico continuo (CGM) ?*

  Il CGM deve essere considerato nei pazienti con DM1 e DM2 in terapia insulinica Basal – bolus per migliorare i livelli di HbA1 c e ridurre le ipoglicemie

  Linee guida AACE per il trattamento integrato del diabete 2015-2017

- *RACCOMANDAZIONI AACE-CHAPTER ITALIA*

  Esistono fortissime evidenze a favore del CGM nel DM1, sia in MDI basal-bolus che con CSII

STANDARD ITALIANI DI CURA SID – AMD 2018

Quando il monitoraggio della glicemia interstiziale (CGM e FGM)?

- **Nei pazienti con DM1 con insufficiente controllo glicemico persistente nel tempo e/o con ipoglicemie gravi o inavvertite nonostante l'ottimizzazione della terapia insulinica è raccomandato il RT- CGM**

- **L'uso di RT –CGM è consigliato durante la gravidanza nelle donne con DM1**

- **L' impiego di RT –CGM può essere utile in pazienti in cui, per condizioni lavorative o stili di vita in cui un controllo molto frequente è consigliabile, ma non praticabile (ad es.: minatori, subacquei, lavoratori dell'edilizia, ecc)**

STANDARD ITALIANI DI CURA SID – AMD 2018

Quando il monitoraggio della glicemia interstiziale (CGM e FGM)?(2)

- **L'uso del RT-CGM intermittente o continuativo può essere utile in persone con diabete tipo 2 in compenso non ottimale come strumento di ottimizzazione della gestione**
- **L'uso retrospettivo o diagnostico (Holter-like) del CGM può essere utile nei pazienti con sospette alterazioni glucidiche non diabetiche (sindromi ipoglicemiche, glicogenosi, fibrosi cistica) o sospetta gastroparesi diabetica. Può essere utilizzato anche in pazienti tipo 1, per valutare l'andamento del profilo glicemico e adattare opportunamente la terapia insulinica, o in pazienti con diabete tipo 2 fragili e/o instabili**
- **Nei pazienti con DM1 in buon controllo glicemico senza ipoglicemie inavvertite è raccomandato l'uso di FGM**

STANDARD ITALIANI DI CURA SID – AMD 2018

Quando invece NO ? (CGM e FGM)?

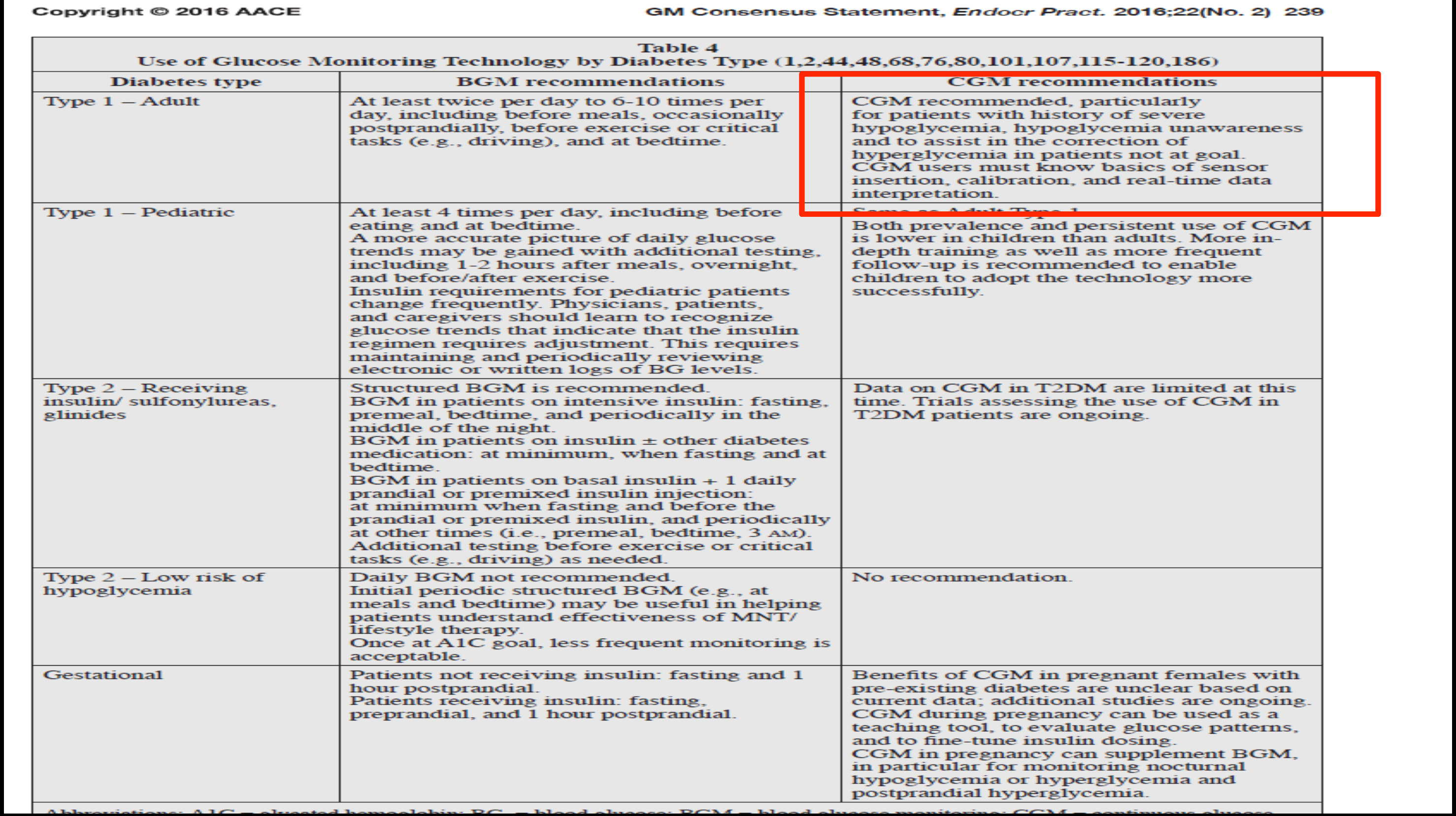
- *Si raccomanda di **non** utilizzare i sistemi di monitoraggio in continuo del glucosio interstiziale in caso di mancanza di motivazione e di compliance alla terapia ed all' utilizzo adeguato del sensore, paura/mancanza di fiducia per sistemi tecnologici, patologie psichiatriche gravi, non compensate, in atto, o inabilità /incapacità ad usare lo strumento*

- *Nei 6-12 mesi successivi alla prima prescrizione di un sistema di monitoraggio continuo del glucosio interstiziale (CGM o FGM), è necessario verificare il corretto utilizzo dello strumento ed il raggiungimento degli obiettivi prefissati. Nel caso che tale verifica dia esiti negativi, è necessario valutare l'opportunità di **sospendere** l'uso del sistema CGM o FGM*

HANDS ON 3
TECNOLOGIE PER IL DIABETE

Roma, 8-11 novembre 2018

ITALIAN CHAPTER



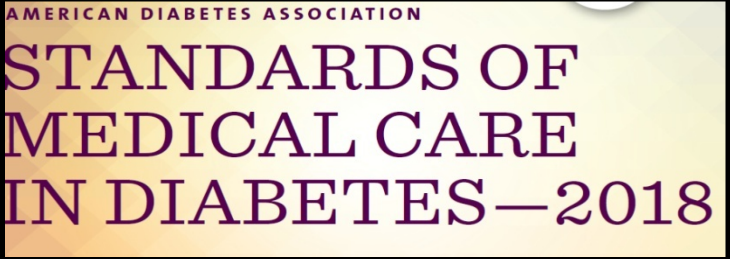
Copyright © 2016 AACE

Table 4
Use of Glucose Monitoring Technology by Diabetes Type (1,2,44,48,68,76,80,101,107,115-120,186)

Diabetes type	BGM recommendations	CGM recommendations
Type 1 – Adult	At least twice per day to 6-10 times per day, including before meals, occasionally postprandially, before exercise or critical tasks (e.g., driving), and at bedtime.	CGM recommended, particularly for patients with history of severe hypoglycemia, hypoglycemia unawareness and to assist in the correction of hyperglycemia in patients not at goal. CGM users must know basics of sensor insertion, calibration, and real-time data interpretation.
Type 1 – Pediatric	At least 4 times per day, including before eating and at bedtime. A more accurate picture of daily glucose trends may be gained with additional testing, including 1-2 hours after meals, overnight, and before/after exercise. Insulin requirements for pediatric patients change frequently. Physicians, patients, and caregivers should learn to recognize glucose trends that indicate that the insulin regimen requires adjustment. This requires maintaining and periodically reviewing electronic or written logs of BG levels.	Same as Adult Type 1. Both prevalence and persistent use of CGM is lower in children than adults. More in-depth training as well as more frequent follow-up is recommended to enable children to adopt the technology more successfully.
Type 2 – Receiving insulin/ sulfonylureas, glinides	Structured BGM is recommended. BGM in patients on intensive insulin: fasting, premeal, bedtime, and periodically in the middle of the night. BGM in patients on insulin ± other diabetes medication: at minimum, when fasting and at bedtime. BGM in patients on basal insulin + 1 daily prandial or premixed insulin injection: at minimum when fasting and before the prandial or premixed insulin, and periodically at other times (i.e., premeal, bedtime, 3 AM). Additional testing before exercise or critical tasks (e.g., driving) as needed.	Data on CGM in T2DM are limited at this time. Trials assessing the use of CGM in T2DM patients are ongoing.
Type 2 – Low risk of hypoglycemia	Daily BGM not recommended. Initial periodic structured BGM (e.g., at meals and bedtime) may be useful in helping patients understand effectiveness of MNT/ lifestyle therapy. Once at A1C goal, less frequent monitoring is acceptable.	No recommendation.
Gestational	Patients not receiving insulin: fasting and 1 hour postprandial. Patients receiving insulin: fasting, preprandial, and 1 hour postprandial.	Benefits of CGM in pregnant females with pre-existing diabetes are unclear based on current data; additional studies are ongoing. CGM during pregnancy can be used as a teaching tool, to evaluate glucose patterns, and to fine-tune insulin dosing. CGM in pregnancy can supplement BGM, in particular for monitoring nocturnal hypoglycemia or hyperglycemia and postprandial hyperglycemia.

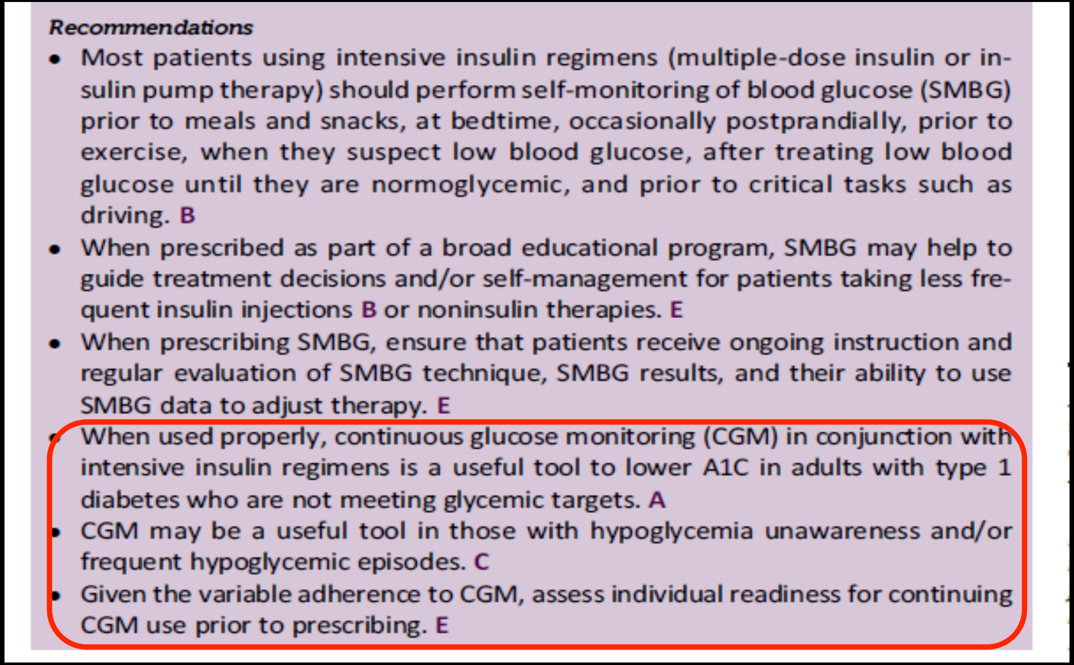
Abbreviations: A1C = glycated hemoglobin; BG = blood glucose; BGM = blood glucose monitoring; CGM = continuous glucose

HANDS ON 3
TECNOLOGIE PER IL DIABETE



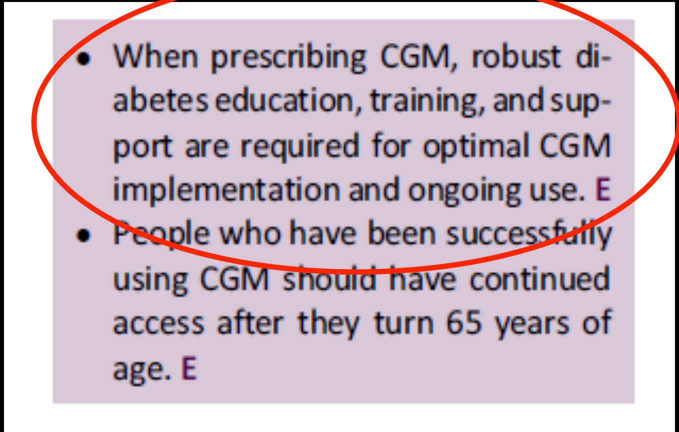
AMERICAN DIABETES ASSOCIATION

STANDARDS OF MEDICAL CARE IN DIABETES—2018



Recommendations

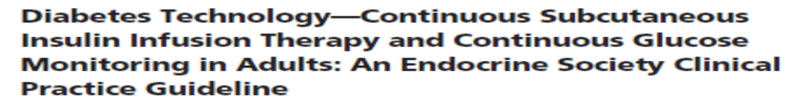
- Most patients using intensive insulin regimens (multiple-dose insulin or insulin pump therapy) should perform self-monitoring of blood glucose (SMBG) prior to meals and snacks, at bedtime, occasionally postprandially, prior to exercise, when they suspect low blood glucose, after treating low blood glucose until they are normoglycemic, and prior to critical tasks such as driving. B
- When prescribed as part of a broad educational program, SMBG may help to guide treatment decisions and/or self-management for patients taking less frequent insulin injections B or noninsulin therapies. E
- When prescribing SMBG, ensure that patients receive ongoing instruction and regular evaluation of SMBG technique, SMBG results, and their ability to use SMBG data to adjust therapy. E
- When used properly, continuous glucose monitoring (CGM) in conjunction with intensive insulin regimens is a useful tool to lower A1C in adults with type 1 diabetes who are not meeting glycemic targets. A
- CGM may be a useful tool in those with hypoglycemia unawareness and/or frequent hypoglycemic episodes. C
- Given the variable adherence to CGM, assess individual readiness for continuing CGM use prior to prescribing. E



- When prescribing CGM, robust diabetes education, training, and support are required for optimal CGM implementation and ongoing use. E
- People who have been successfully using CGM should have continued access after they turn 65 years of age. E

HANDS ON 3:
TECNOLOGIE PER IL DIABETE

Ancora per i pazienti ……



Diabetes Technology—Continuous Subcutaneous Insulin Infusion Therapy and Continuous Glucose Monitoring in Adults: An Endocrine Society Clinical Practice Guideline

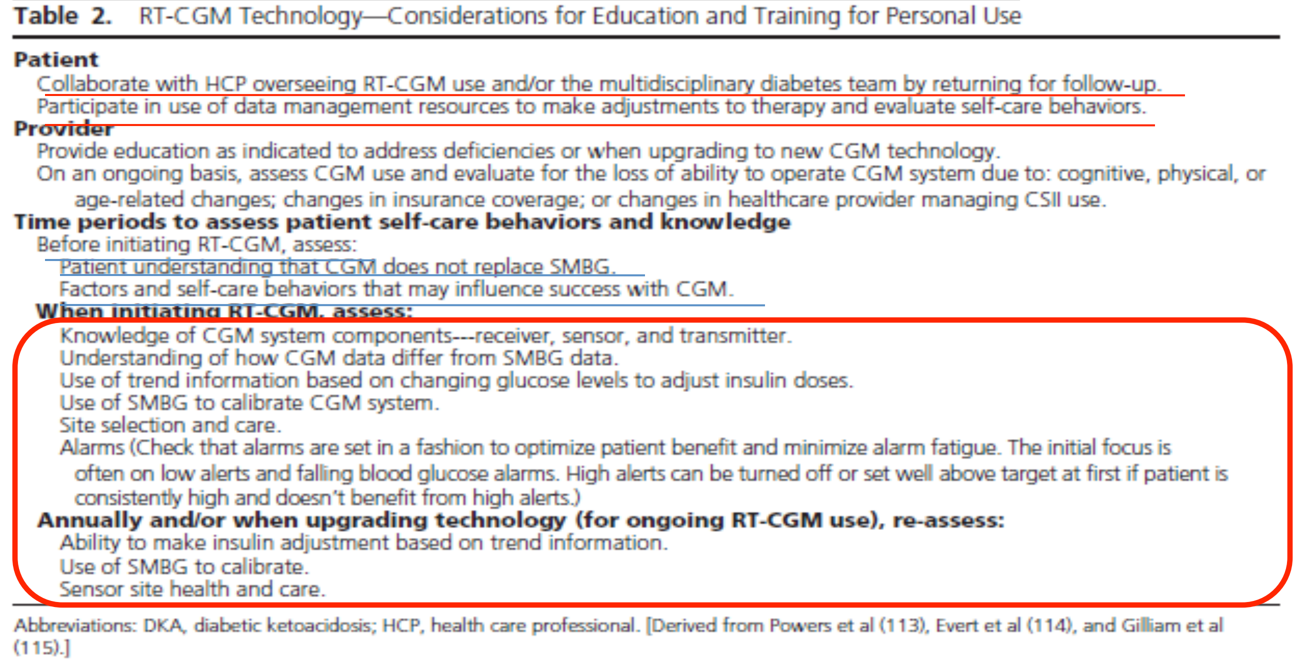


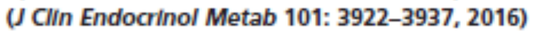
Table 2. RT-CGM Technology—Considerations for Education and Training for Personal Use

Patient
- Collaborate with HCP overseeing RT-CGM use and/or the multidisciplinary diabetes team by returning for follow-up.
- Participate in use of data management resources to make adjustments to therapy and evaluate self-care behaviors.

Provider
- Provide education as indicated to address deficiencies or when upgrading to new CGM technology.
- On an ongoing basis, assess CGM use and evaluate for the loss of ability to operate CGM system due to: cognitive, physical, or age-related changes; changes in insurance coverage; or changes in healthcare provider managing CSII use.

Time periods to assess patient self-care behaviors and knowledge
- Before initiating RT-CGM, assess:
  - Patient understanding that CGM does not replace SMBG.
  - Factors and self-care behaviors that may influence success with CGM.
- **When initiating RT-CGM, assess:**
  - Knowledge of CGM system components---receiver, sensor, and transmitter.
  - Understanding of how CGM data differ from SMBG data.
  - Use of trend information based on changing glucose levels to adjust insulin doses.
  - Use of SMBG to calibrate CGM system.
  - Site selection and care.
  - Alarms (Check that alarms are set in a fashion to optimize patient benefit and minimize alarm fatigue. The initial focus is often on low alerts and falling blood glucose alarms. High alerts can be turned off or set well above target at first if patient is consistently high and doesn't benefit from high alerts.)
- **Annually and/or when upgrading technology (for ongoing RT-CGM use), re-assess:**
  - Ability to make insulin adjustment based on trend information.
  - Use of SMBG to calibrate.
  - Sensor site health and care.

Abbreviations: DKA, diabetic ketoacidosis; HCP, health care professional. [Derived from Powers et al (113), Evert et al (114), and Gilliam et al (115).]



(*J Clin Endocrinol Metab* 101: 3922–3937, 2016)

INDICAZIONI

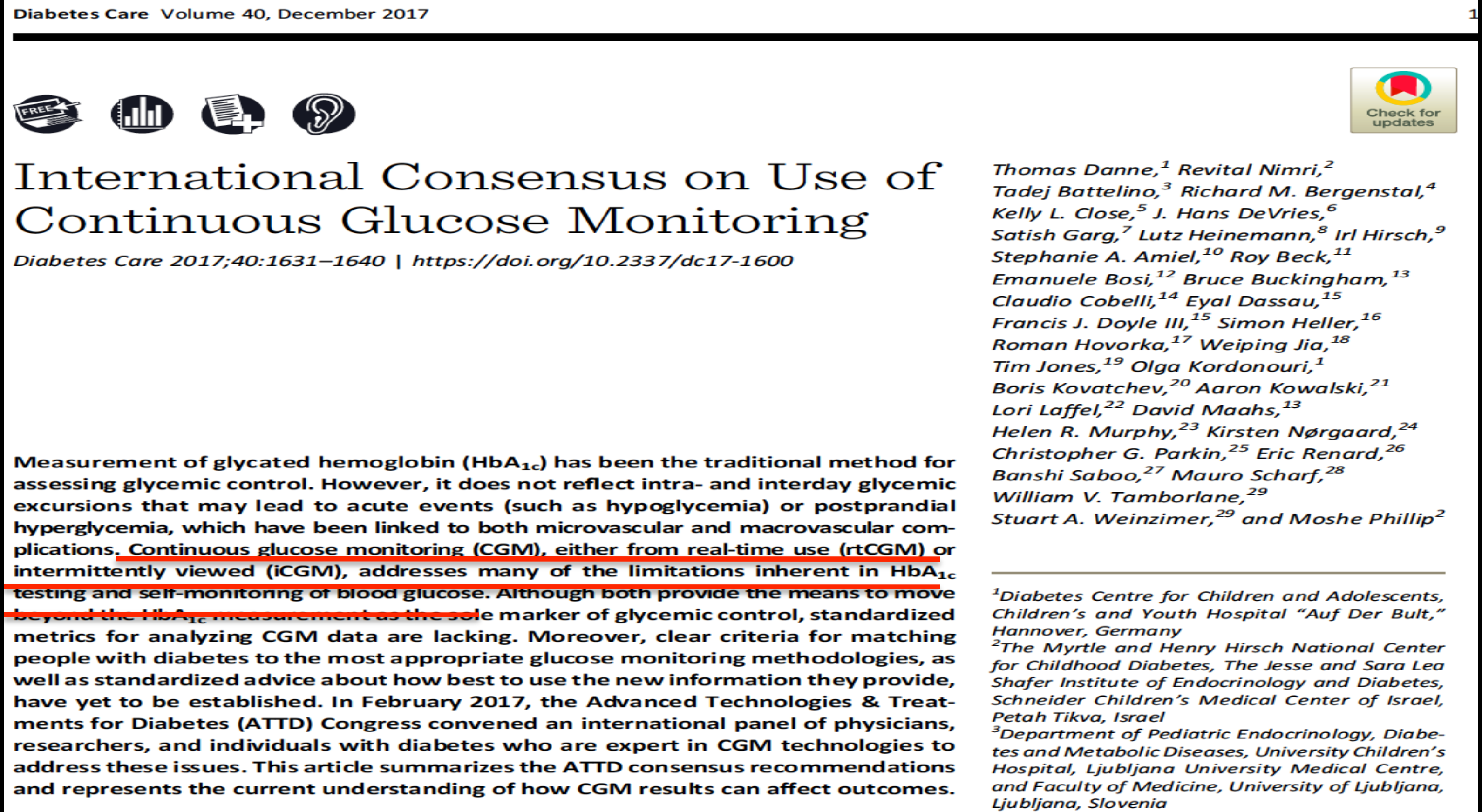
AL CGM

DAL CGM

Roma, 8-11 novembre 2018

HANDS ON 3:
TECNOLOGIE PER IL DIABETE

ITALIAN CHAPTER



Diabetes Care Volume 40, December 2017

International Consensus on Use of Continuous Glucose Monitoring

Diabetes Care 2017;40:1631–1640 | https://doi.org/10.2337/dc17-1600

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Measurement of glycated hemoglobin (HbA$_{1c}$) has been the traditional method for assessing glycemic control. However, it does not reflect intra- and interday glycemic excursions that may lead to acute events (such as hypoglycemia) or postprandial hyperglycemia, which have been linked to both microvascular and macrovascular complications. Continuous glucose monitoring (CGM), either from real-time use (rtCGM) or intermittently viewed (iCGM), addresses many of the limitations inherent in HbA$_{1c}$ testing and self-monitoring of blood glucose. Although both provide the means to move beyond the HbA$_{1c}$ measurement as the sole marker of glycemic control, standardized metrics for analyzing CGM data are lacking. Moreover, clear criteria for matching people with diabetes to the most appropriate glucose monitoring methodologies, as well as standardized advice about how best to use the new information they provide, have yet to be established. In February 2017, the Advanced Technologies & Treatments for Diabetes (ATTD) Congress convened an international panel of physicians, researchers, and individuals with diabetes who are expert in CGM technologies to address these issues. This article summarizes the ATTD consensus recommendations and represents the current understanding of how CGM results can affect outcomes.

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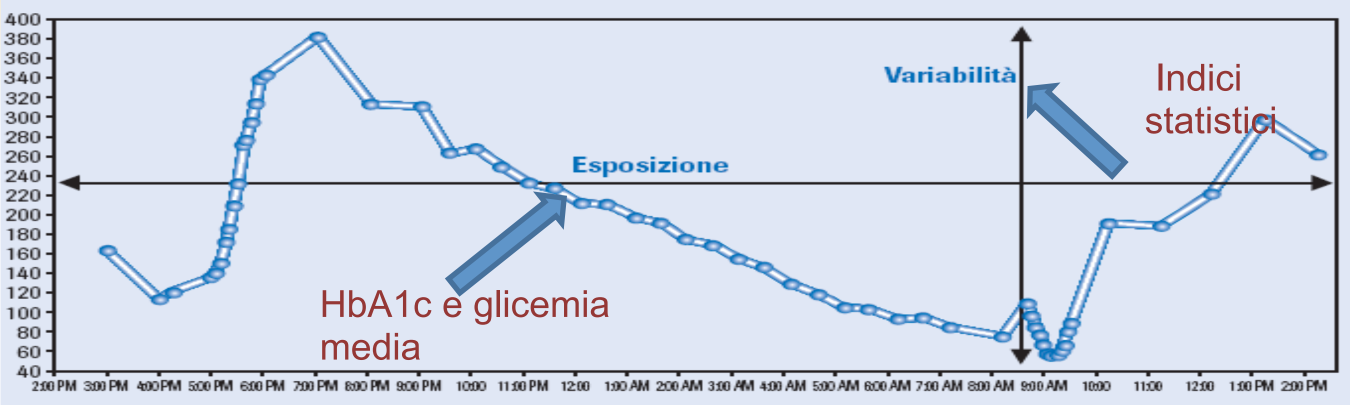
Una nuova visione del controllo glicemico

E' necessario controllare contemporaneamente
l'esposizione e la variabilità glicemica



La variabilità glicemica rappresenta la frequenza e l'ampiezza della fluttuazione attorno alla media dei valori glicemici di un paziente.

L'esposizione rappresenta la media delle glicemie di un determinato periodo di tempo.

JAMA®
The Journal of the American Medical Association

VARIABILITA' GLICEMICA

- **Rappresenta la frequenza e l'ampiezza delle oscillazioni della media della glicemia**
- **Correla con le complicanze acute (ipoglicemia) - ma anche croniche - e la qualità della vita**
- **È associata ad incremento dello stress ossidativo**

Le Monier, JAMA, 2006

VARIABILITA’ GLICEMICA: Come si misura? (1)

- **SD**, deviazione standard: dispersione del dato intorno alla media glicemica;
- **MAGE** (mean amplitude of glycaemic excursions): media delle escursioni glicemiche giornaliere che eccedono la deviazione standard misurata nelle 24 ore)
- **CONGA** (n) (continuous overall net glycemic action): SD delle differenze registrate tra l ‘osservazione corrente e l’osservazione nelle ore precedenti

Da : A. Ceriello et al, Variabilità glicemica : indicatore emergente nel trattamento del DM;
Il Giornale di AMD, 2013; 16: 245-248

VARIABILITA' GLICEMICA: COME SI MISURA (2)?

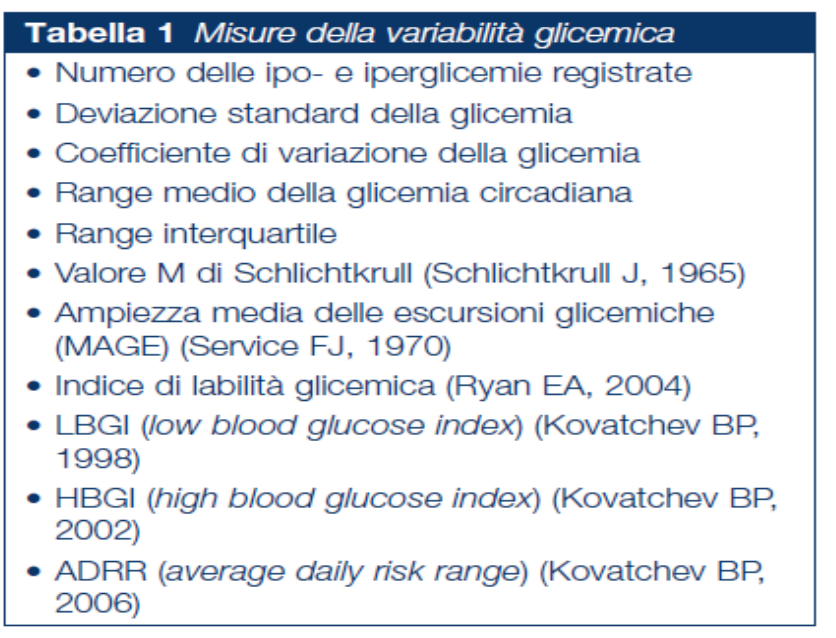


Tabella 1 *Misure della variabilità glicemica*

- Numero delle ipo- e iperglicemie registrate
- Deviazione standard della glicemia
- Coefficiente di variazione della glicemia
- Range medio della glicemia circadiana
- Range interquartile
- Valore M di Schlichtkrull (Schlichtkrull J, 1965)
- Ampiezza media delle escursioni glicemiche (MAGE) (Service FJ, 1970)
- Indice di labilità glicemica (Ryan EA, 2004)
- LBGI (*low blood glucose index*) (Kovatchev BP, 1998)
- HBGI (*high blood glucose index*) (Kovatchev BP, 2002)
- ADRR (*average daily risk range*) (Kovatchev BP, 2006)

Tratto da: De Micheli, D'Ugo, Ceriello: L'importanza del controllo della variabilità glicemica nella prevenzione delle complicanze del DM, GIDM, 2007, 27, 227-239

HANDS ON 3
TECNOLOGIE PER IL DIABETE

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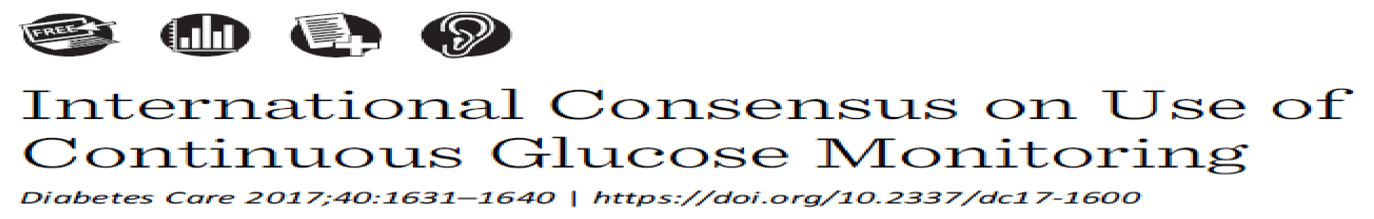
- … SD, il coefficiente di variazione (CV) ed il MAGE sono ampiamente usati per quantificare la variabilità glicemica. Il CV (che è la DS divisa per la media) ha il vantaggio di essere una misurazione relativa alla media, che lo rende più descrittivo per le escursioni ipoglicemiche rispetto alla SD da sola …

- Livelli stabili di glucosio sono definiti per un CV < 36 % e livelli instabili di glucosio sono definiti per un CV > 36 %



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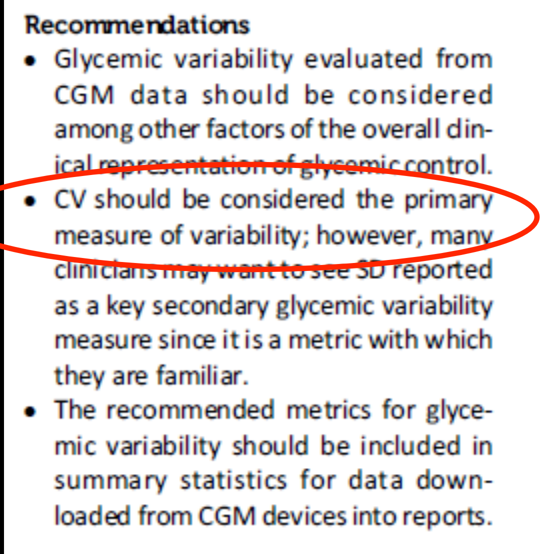

Recommendations

- Glycemic variability evaluated from CGM data should be considered among other factors of the overall clinical representation of glycemic control.
- CV should be considered the primary measure of variability; however, many clinicians may want to see SD reported as a key secondary glycemic variability measure since it is a metric with which they are familiar.
- The recommended metrics for glycemic variability should be included in summary statistics for data downloaded from CGM devices into reports.

Roma, 8-11 novembre 2018

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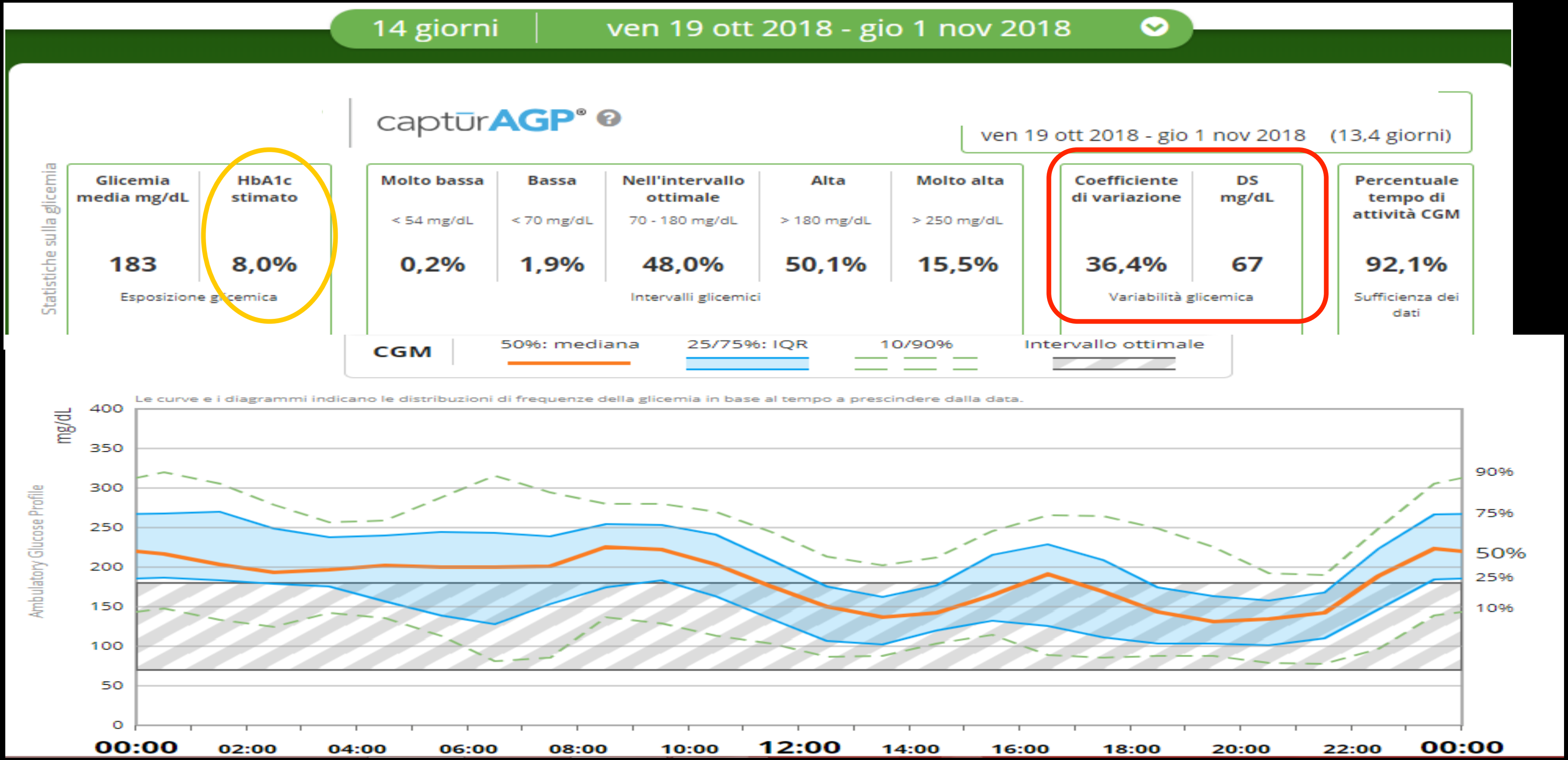

14 giorni | ven 19 ott 2018 - gio 1 nov 2018

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ven 19 ott 2018 - gio 1 nov 2018 (13,4 giorni)

Statistiche sulla glicemia

Glicemia media mg/dL	HbA1c stimato	Molto bassa < 54 mg/dL	Bassa < 70 mg/dL	Nell'intervallo ottimale 70 - 180 mg/dL	Alta > 180 mg/dL	Molto alta > 250 mg/dL	Coefficiente di variazione	DS mg/dL	Percentuale tempo di attività CGM
183	8,0%	0,2%	1,9%	48,0%	50,1%	15,5%	36,4%	67	92,1%
Esposizione glicemica		Intervalli glicemici					Variabilità glicemica		Sufficienza dei dati

CGM | 50%: mediana | 25/75%: IQR | 10/90% | Intervallo ottimale

Le curve e i diagrammi indicano le distribuzioni di frequenze della glicemia in base al tempo a prescindere dalla data.

mg/dL
Ambulatory Glucose Profile
400
350
300
250
200
150
100
50
0
90%
75%
50%
25%
10%
00:00
02:00
04:00
06:00
08:00
10:00
12:00
14:00
16:00
18:00
20:00
22:00
00:00

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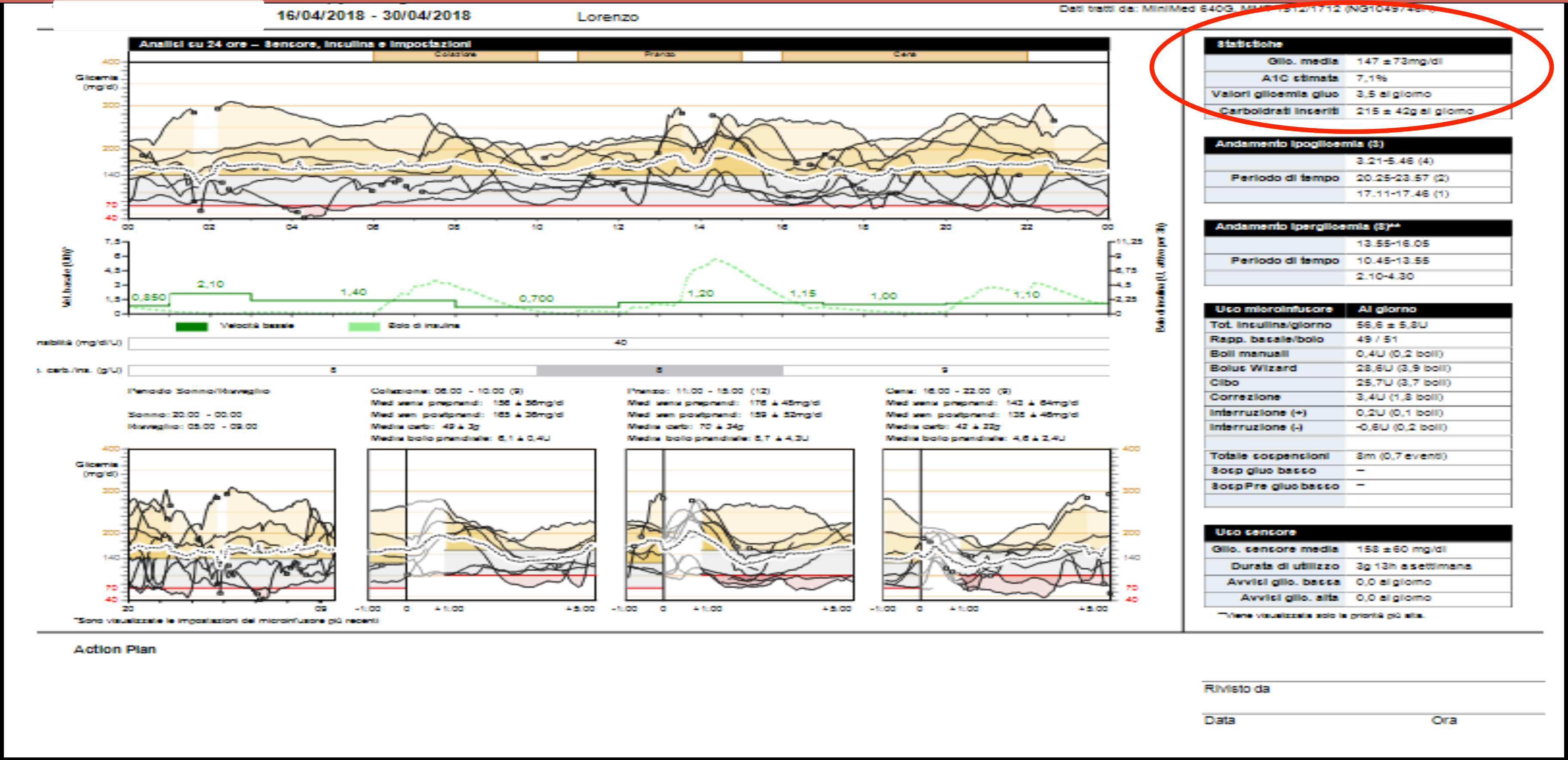


16/04/2018 - 30/04/2018 Lorenzo

Dati tratti da: MiniMed 640G, MMT-1512/1712 (NG1049748H)

Analisi su 24 ore – Sensore, Insulina e Impostazioni

Colazione
Pranzo
Cena
Glicemia (mg/dl)
400
300
200
140
70
40
00
02
04
06
08
10
12
14
16
18
20
22
00
Vel. basale (U/h)
7,5
6
4,5
3
1,5
0
0,850
2,10
1,40
0,700
1,20
1,15
1,00
1,10
11,25
9
6,75
4,5
2,25
0
Bolo di insulina (U, attivo per 3h)
Velocità basale
Bolo di insulina

Sensibilità (mg/dl/U) 40

Rapp. carb./ins. (g/U) 8 | 8 | 9

Periodo Sonno/Risveglio

Sonno: 20.00 - 00.00
Risveglio: 05.00 - 09.00

Colazione: 06.00 - 10.00 (9)
Med sens preprand: 156 ± 58mg/dl
Med sen postprand: 165 ± 38mg/dl
Media carb: 49 ± 3g
Media bolo prandiale: 6,1 ± 0,4U

Pranzo: 11:00 - 15.00 (12)
Med sens preprand: 176 ± 45mg/dl
Med sen postprand: 159 ± 52mg/dl
Media carb: 70 ± 34g
Media bolo prandiale: 5,7 ± 4,3U

Cena: 16.00 - 22.00 (9)
Med sens preprand: 142 ± 64mg/dl
Med sen postprand: 135 ± 46mg/dl
Media carb: 42 ± 22g
Media bolo prandiale: 4,6 ± 2,4U

Glicemia (mg/dl)
400
300
200
140
70
40
20
09
-1:00
0
+1:00
+5:00

*Sono visualizzate le impostazioni del microinfusore più recenti

Statistiche	
Gllc. media	147 ± 73mg/dl
A1C stimata	7,1%
Valori glicemia gluc	3,5 al giorno
Carboidrati inseriti	215 ± 42g al giorno

Andamento ipoglicemia (8)	
	3.21-5.46 (4)
Periodo di tempo	20.25-23.57 (2)
	17.11-17.46 (1)

Andamento iperglicemia (8)**	
	13.55-16.05
Periodo di tempo	10.45-13.55
	2.10-4.30

Uso microinfusore	Al giorno
Tot. insulina/giorno	56,6 ± 5,8U
Rapp. basale/bolo	49 / 51
Boli manuali	0,4U (0,2 boli)
Bolus Wizard	28,6U (3,9 boli)
Cibo	25,7U (3,7 boli)
Correzione	3,4U (1,8 boli)
Interruzione (+)	0,2U (0,1 boli)
Interruzione (-)	-0,6U (0,2 boli)
Totale sospensioni	8m (0,7 eventi)
Sosp gluc basso	–
SospPre gluc basso	–

Uso sensore	
Gllc. sensore media	158 ± 60 mg/dl
Durata di utilizzo	3g 13h a settimana
Avvisi gllc. bassa	0,0 al giorno
Avvisi gllc. alta	0,0 al giorno

**Viene visualizzata solo la priorità più alta.

Action Plan

Rivisto da

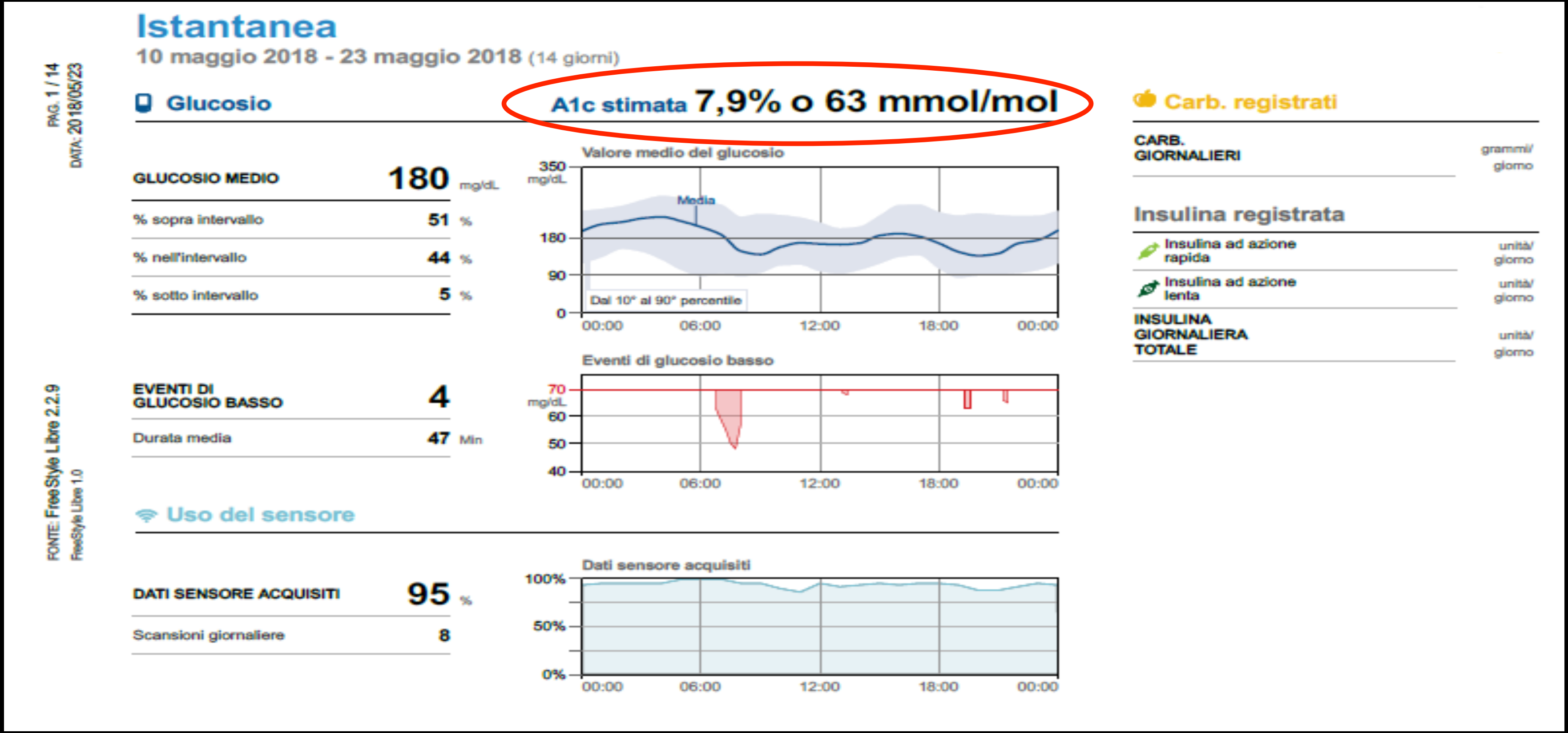
Data

Ora

HANDS ON 3: TECNOLOGIE PER IL DIABETE

Roma, 8-11 novembre 2018

ITALIAN CHAPTER


Valore medio del glucosio
350
mg/dL
Media
180
90
0
Dal 10° al 90° percentile
00:00
06:00
12:00
18:00
00:00
Eventi di glucosio basso
70
mg/dL
60
50
40
00:00
06:00
12:00
18:00
00:00
Dati sensore acquisiti
100%
50%
0%
00:00
06:00
12:00
18:00
00:00

Istantanea

10 maggio 2018 - 23 maggio 2018 (14 giorni)

PAG. 1 / 14
DATA: 2018/05/23

Glucosio

A1c stimata 7,9% o 63 mmol/mol

GLUCOSIO MEDIO	180	mg/dL
% sopra intervallo	51	%
% nell'intervallo	44	%
% sotto intervallo	5	%

EVENTI DI GLUCOSIO BASSO	4	
Durata media	47	Min

Uso del sensore

DATI SENSORE ACQUISITI	95	%
Scansioni giornaliere	8	

Carb. registrati

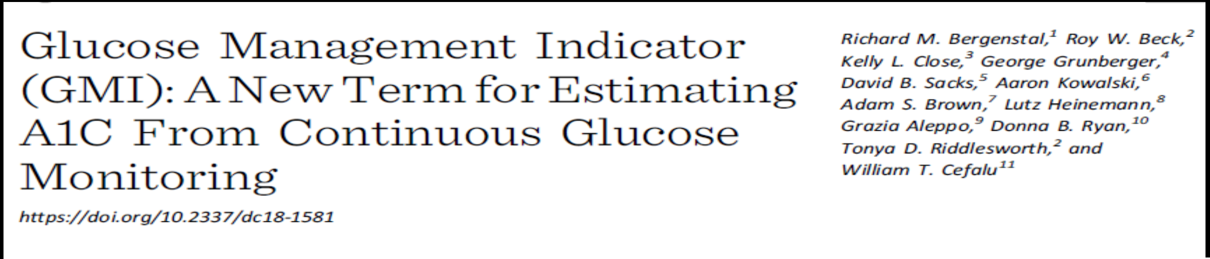
CARB. GIORNALIERI	grammi/giorno

Insulina registrata

Insulina ad azione rapida	unità/giorno
Insulina ad azione lenta	unità/giorno
INSULINA GIORNALIERA TOTALE	unità/giorno

FONTE: FreeStyle Libre 2.2.9
FreeStyle Libre 1.0

HANDS ON 3:
TECNOLOGIE PER IL DIABETE



Glucose Management Indicator (GMI): A New Term for Estimating A1C From Continuous Glucose Monitoring

https://doi.org/10.2337/dc18-1581

Richard M. Bergenstal,[1] Roy W. Beck,[2]
Kelly L. Close,[3] George Grunberger,[4]
David B. Sacks,[5] Aaron Kowalski,[6]
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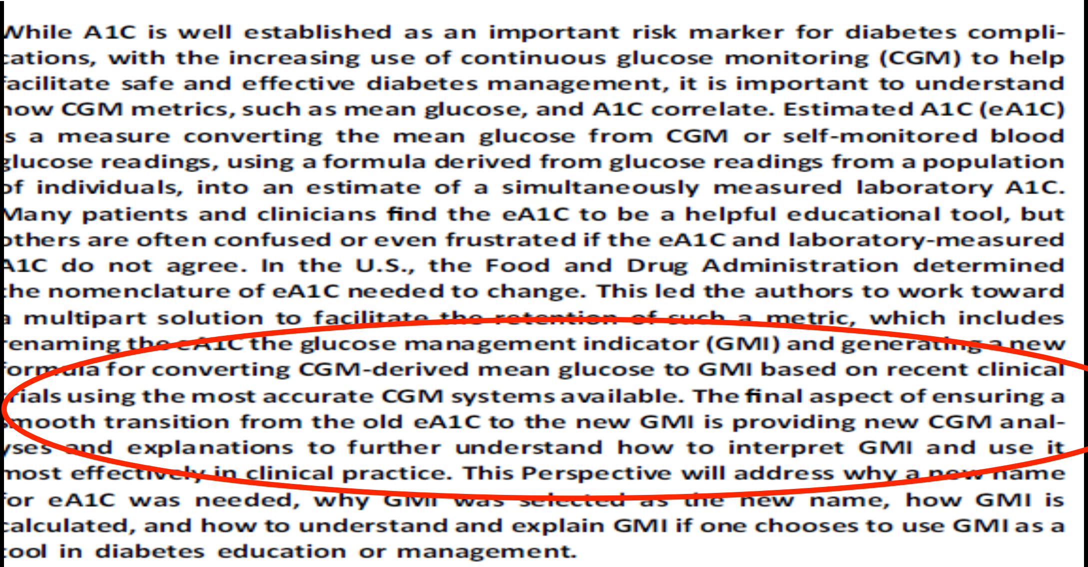
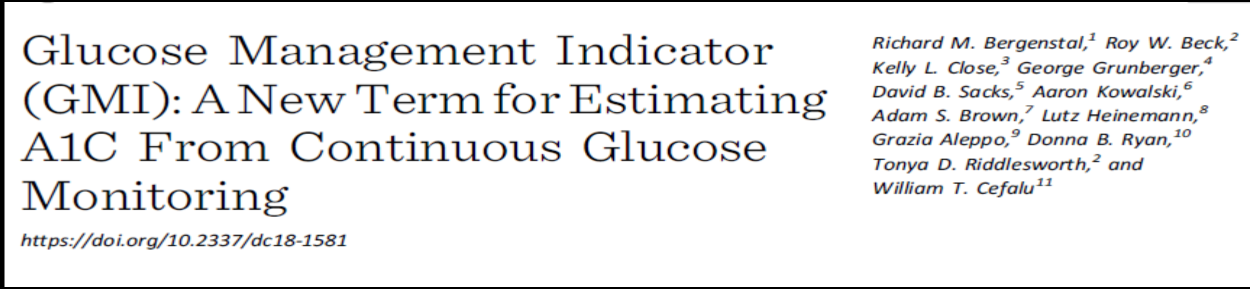
William T. Cefalu[11]



While A1C is well established as an important risk marker for diabetes complications, with the increasing use of continuous glucose monitoring (CGM) to help facilitate safe and effective diabetes management, it is important to understand how CGM metrics, such as mean glucose, and A1C correlate. Estimated A1C (eA1C) s a measure converting the mean glucose from CGM or self-monitored blood glucose readings, using a formula derived from glucose readings from a population of individuals, into an estimate of a simultaneously measured laboratory A1C. Many patients and clinicians find the eA1C to be a helpful educational tool, but others are often confused or even frustrated if the eA1C and laboratory-measured A1C do not agree. In the U.S., the Food and Drug Administration determined the nomenclature of eA1C needed to change. This led the authors to work toward a multipart solution to facilitate the retention of such a metric, which includes renaming the eA1C the glucose management indicator (GMI) and generating a new formula for converting CGM-derived mean glucose to GMI based on recent clinical rials using the most accurate CGM systems available. The final aspect of ensuring a smooth transition from the old eA1C to the new GMI is providing new CGM analyses and explanations to further understand how to interpret GMI and use it most effectively in clinical practice. This Perspective will address why a new name for eA1C was needed, why GMI was selected as the new name, how GMI is calculated, and how to understand and explain GMI if one chooses to use GMI as a tool in diabetes education or management.

HANDS ON 3:
TECNOLOGIE PER IL DIABETE



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Il CGM fornisce informazioni aggiuntive che consentono la personalizzazione della terapia: fra questi la eHbA1c che è una misura che converte la glicemia media in un valore stimato di HbA1c

Il termine eHbA1c ha generato, a volte, frustrazione e confusione

È stato coniato il termine “Glucose Management Indicator (GMI)”: questo, insieme ad altri parametri derivati dal CGM, fornisce informazioni per una gestione sempre più personalizzata della malattia diabetica. Nel futuro occorreranno ulteriori studi per poter correlare questo e gli altri dati glucometrici, ricavati dal CGM, con lo sviluppo delle complicanze croniche del DM

GRAZIE PER L' ATTENZIONE !

siams
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