



UMG
dubium sapientiae initium

UNIVERSITA' DEGLI STUDI "MAGNA GRÆCIA"
CATANZARO

'Automonitoraggio glicemico dal SMBG al CGM e oltre'

Concetta Irace

Dipartimento di Scienze della Salute

Università degli Studi Magna Graecia di Catanzaro

DIABETE DI TIPO 1 COME E' CAMBIATO IL TRATTAMENTO INSULINICO?

SID - BARI 16-17 OTTOBRE 2020



Diapositiva preparata da CONCETTA IRACE e ceduta alla Società Italiana di Diabetologia.
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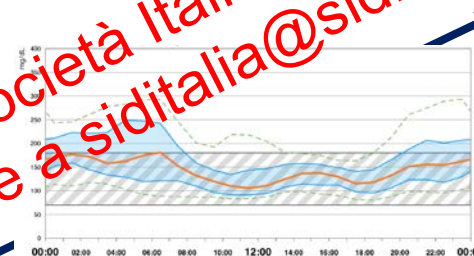
L'evoluzione del monitoraggio glicemico, dalla misurazione spot al dato continuo

Raccolta e presentazione delle glicemie



	Pre-Breakfast	Post-Breakfast	Pre-Lunch	Post-Lunch	Pre-Supper	Post-Supper	Bedtime
Tuesday	X	X	X	X	X	X	X
Tuesday	X	X	X	X	X	X	X
Wednesday	X	X	X	X	X	X	X
Thursday	X	X	X	X	X	X	X
Friday	X	X	X	X	X	X	X
Saturday	X	X	X	X	X	X	X
Sunday	X	X	X	X	X	X	X

Structured SMBG



Anni

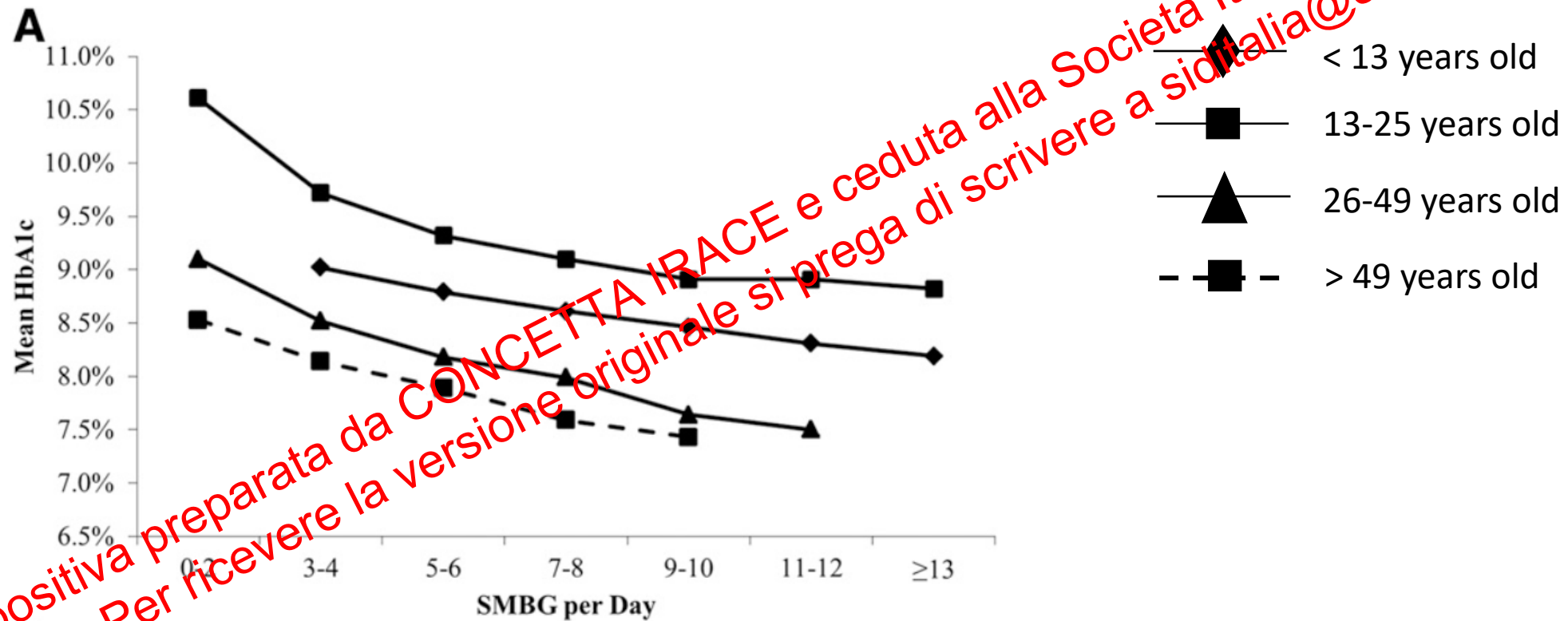
Automonitoraggio SMBG della glicemia capillare

- **Indispensabile** per i pazienti con diabete **tipo 1**, e parte integrante della terapia [A]
- Per raggiungere gli obiettivi glicemici postprandiali e quindi ottenere un buon controllo glicemico globale è **utile** anche la misurazione della glicemia postprandiale [B]

- I pazienti che utilizzano **schemi terapeutici intensivi** dovrebbero effettuare autocontrollo domiciliare [B]

- ✓ prima dei pasti o spuntini
- ✓ prima di andare a letto
- ✓ occasionalmente dopo i pasti
- ✓ prima di ogni attività fisica
- ✓ quando vi sia il sospetto di una ipoglicemia
- ✓ dopo aver trattato una ipoglicemia
- ✓ prima di ogni attività critica come guidare

Evidence of a Strong Association Between Frequency of Self-Monitoring of Blood Glucose and Hemoglobin A1c Levels in T1D Exchange Clinic Registry Participants



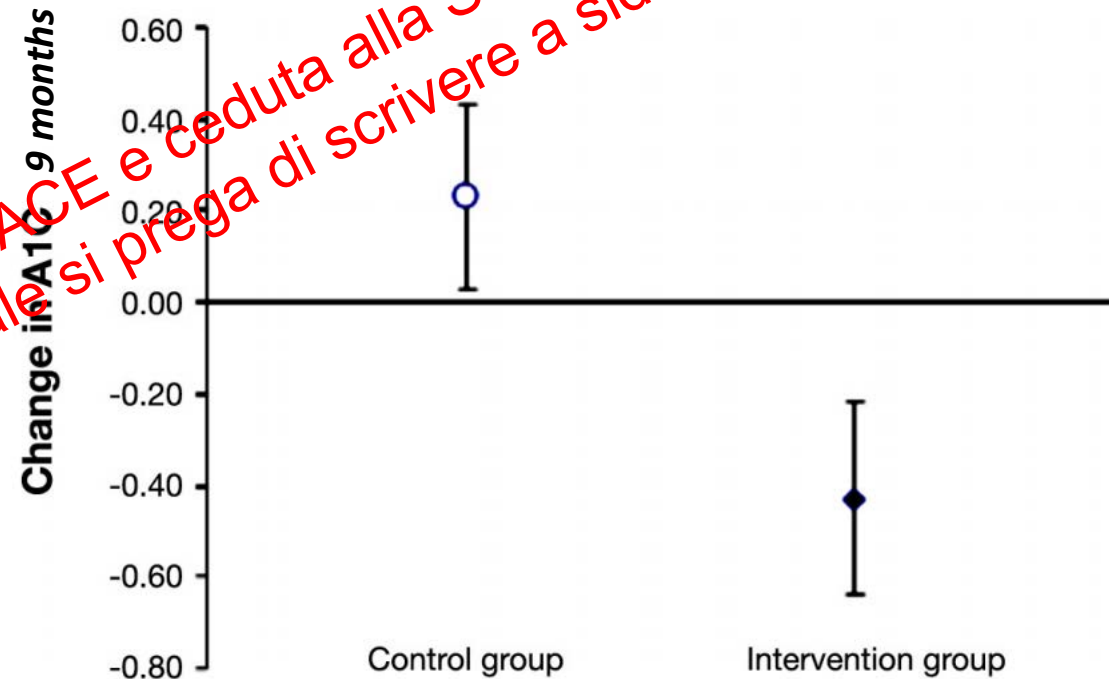
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Self-Monitoring of Blood Glucose in Type 1 Diabetes Patients with Insufficient Metabolic Control: Focused Self-Monitoring of Blood Glucose Intervention Can Lower Glycated Hemoglobin A1C

Table 1.
Baseline Clinical Characteristics of the Control and Intervention Groups^a

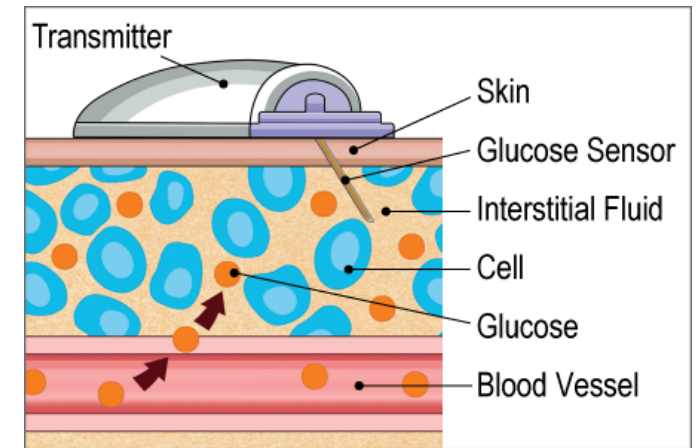
	Control	Intervention
Age (years)	38 ± 9	39 ± 12
Diabetes duration (years)	19 ± 12	20 ± 11
Body mass index (kg/m ²)	26 ± 5	25 ± 3
Women (%)	52.4	57.4
Retinopathy (%)	42	43.5
Nephropathy (%)	20	19
Neuropathy (%)	15	13
Daily smokers (%)	15.4	16
CSII users (%)	22.5	20.4
Mean A1C at inclusion (%)	8.61 ± 0.09	8.65 ± 0.10

^a Data are means ± SD unless otherwise indicated



Continuous glucose monitoring

- Misurano in continuo il glucosio interstiziale (1-5 min);
- La rilevazione del glucosio interstiziale ha un ritardo variabile da 0-12 min rispetto al valore della glicemia;
- Sono costituiti da tre elementi:
 - ✓ sensore transcutaneo o sottocutaneo;
 - ✓ trasmettitore;
 - ✓ ricevitore o MMA (mobile medical App);
- Il sensore ha una durata da 6 giorni a 6 mesi.



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Definition of types of Continuous Glucose Monitoring

Real-time CGM (rtCGM)	CGM system that measures glucose levels continuously and provide the user automated alarms and alerts at specific glucose levels and/or for changing glucose levels.
Intermittent scanned CGM (isCGM)	CGM systems that measure glucose levels continuously but only display glucose values when swiped by a reader or smart phone that reveals the glucose levels.
Blinded (professional) CGM	CGM devices that measure glucose levels that are not displayed to the patients in real time. These devices are in general initiated in a clinic using a reader that is owned by the clinic. They are removed after a period of time (10-14 days) and analyzed by the patient and provider to assess glycemic patterns and trends.

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Calibri (Corpo)

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Testo a capo

Unisci e centra

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Formattazione condizionale

Formatta come tabella

Stili cella

Inserisci

Elimina

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	A	B	C	D	E	F	G	H	I	J	K	L
	Data e ora (AAAA-MM-GGThh:mm:ss)	Valore glicemico	Data e ora (AAAA-MM-GGThh:mm:ss)	Valore glicemico	Data e ora (AAAA-MM-GGThh:mm:ss)	Valore glicemico	Data e ora (AAAA-MM-GGThh:mm:ss)	Valore glicemico	Data e ora (AAAA-MM-GGThh:mm:ss)	Valore glicemico		
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3	2020-10-01T00:11:33	146	2020-10-01T03:06:31	139	2020-10-01T06:01:30	103	2020-10-01T08:56:31	81	2020-10-01T11:51:31	76		
4	2020-10-01T00:16:32	147	2020-10-01T03:11:31	134	2020-10-01T06:06:30	101	2020-10-01T09:01:32	85	2020-10-01T11:56:30	72		
5	2020-10-01T00:21:32	144	2020-10-01T03:16:30	131	2020-10-01T06:11:32	100	2020-10-01T09:06:31	87	2020-10-01T12:01:32	68		
6	2020-10-01T00:26:32	141	2020-10-01T03:21:32	130	2020-10-01T06:16:30	100	2020-10-01T09:11:31	88	2020-10-01T12:06:31	76		
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35	2020-10-01T02:51:30	139	2020-10-01T05:46:31	105	2020-10-01T08:41:31	91	2020-10-01T11:36:31	74	2020-10-01T16:51:31	133		

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Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range

<https://doi.org/10.2337/dci19-0028>

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Limiti della Emoglobina Glicata

- Fornisce indicazioni sul compenso glicemico degli ultimi 2-3 mesi
- Il valore potrebbe non essere attendibile in caso di:
 - ✓ Emoglobinopatie
 - ✓ Anemia
 - ✓ Insufficienza renale cronica
 - ✓ Differente velocità di glicazione

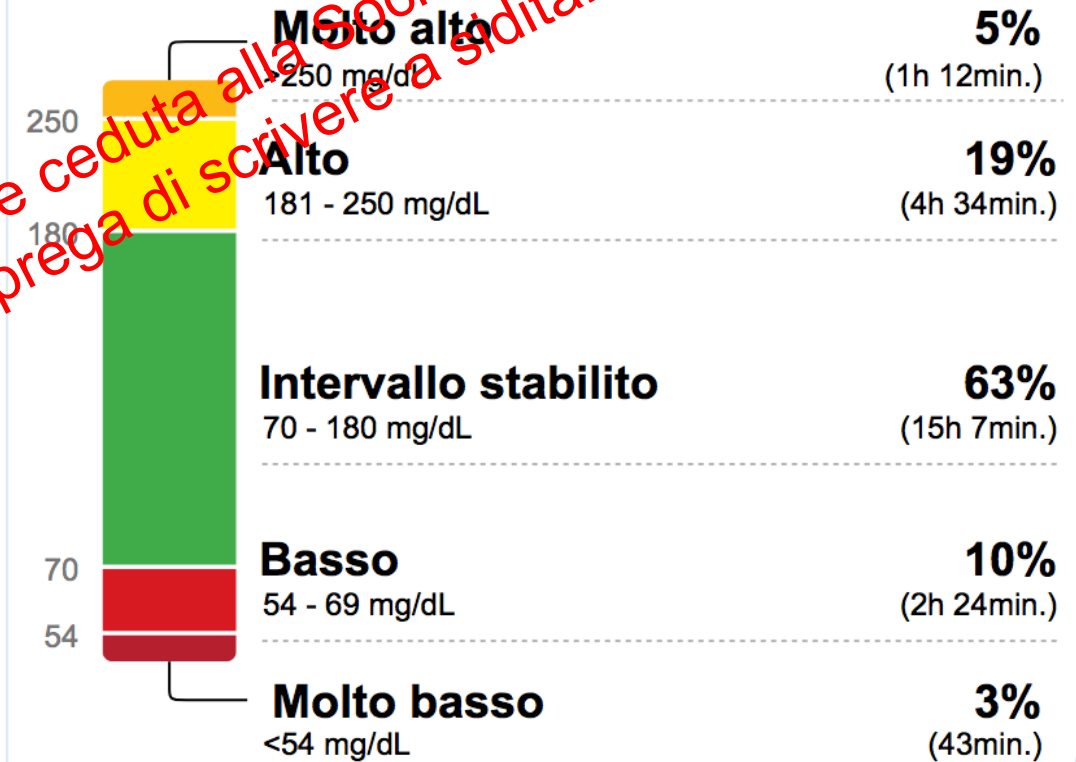
- Nessuna informazione su
 - ✓ Variabilità glicemica intra- ed inter-giornaliera
 - ✓ Iperglicemia post-prandiale
 - ✓ Carico Ipoglicemico
 - ✓ Beneficio del cambio terapeutico nel breve termine

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Continuous Glucose Monitoring

PARAMETRI GLUCOMETRICI STATICI

- TIR (70-180 mg/dL)
- TBR (< 70 mg/dL)
- TAR (> 250 mg/dL)
- Variabilità glicemica
- GMI (Glucose Management Indicator)
- Glicemia media



DIABETES TECHNOLOGY & THERAPEUTICS
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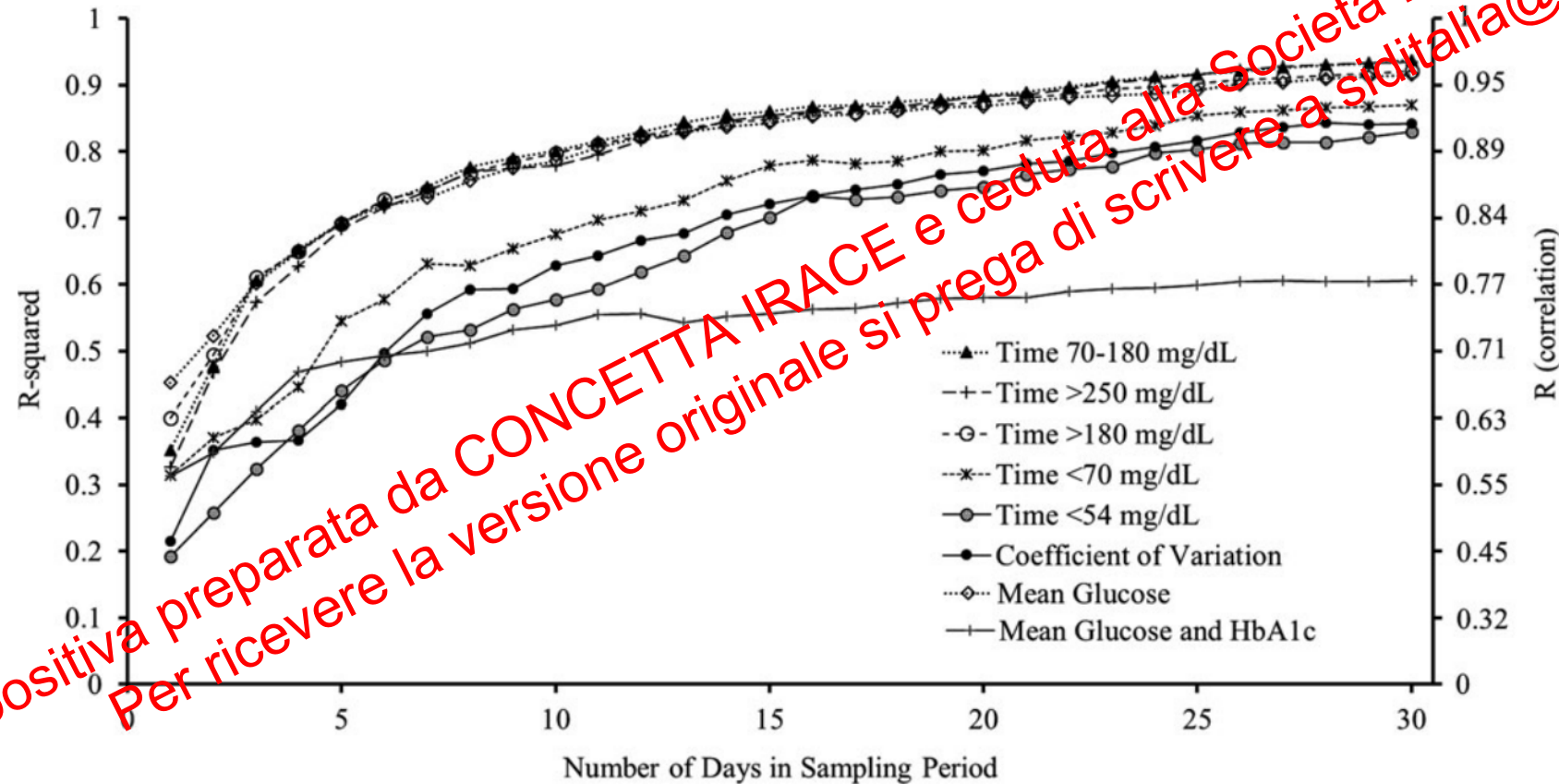
BRIEF REPORT

Optimal Sampling Duration for Continuous Glucose Monitoring to Determine Long-Term Glycemic Control

Tonya D. Riddlesworth, PhD,¹ Roy W. Beck, MD, PhD,¹ Robin L. Gal, MSPH,¹ Crystal G. Connor, MS,¹ Richard M. Bergenstal, MD,² Sooji Lee, MS,³ and Steven M. Willi, MD³

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Correlation (R^2 and R) for CGM glucose metrics with the full 3-month values



Continuous Glucose Monitoring

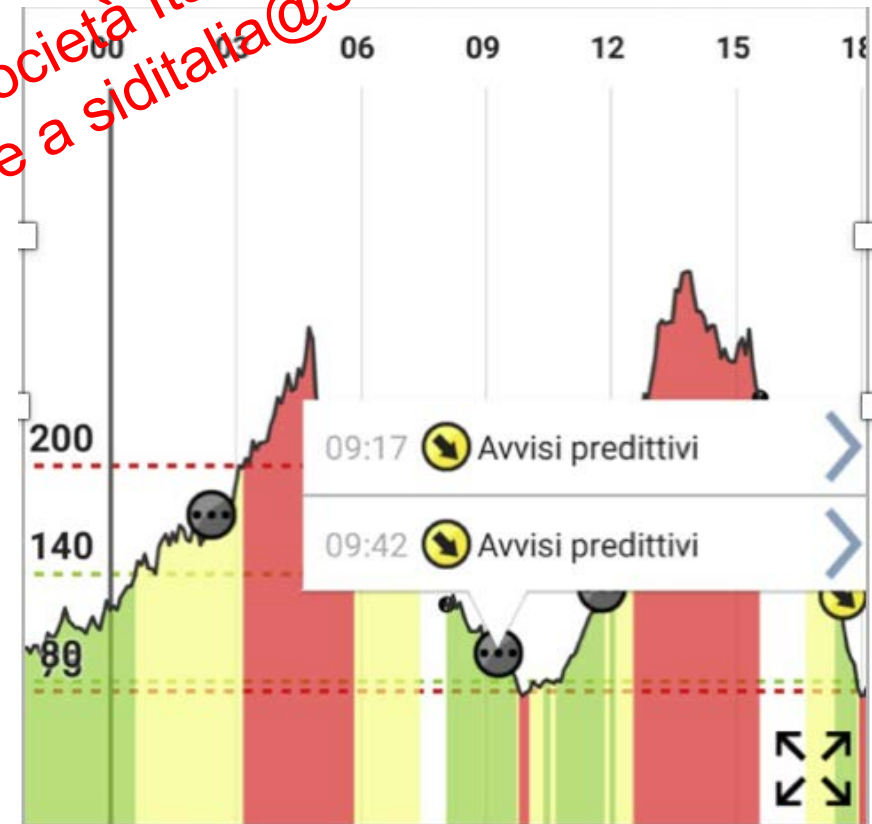
PARAMETRI GLUCOMETRICI DINAMICI

- Allarmi predittivi
- Frecce di tendenza [ROC]
- Allarmi per velocità di variazione del glucosio



Allarmi predittivi (CGM)

- Avvertono 10, 20, o 30 min prima del raggiungimento del valore basso/alto stabilito dal medico diabetologo;
- L'allarme predittivo è indipendente dal valore di partenza;
- Sistemi ibridi pompa-sensore utilizzano questo sistema per interrompere o aumentare l'infusione basale di insulina.



Frecce di Tendenza

- La tendenza si genera in base all'andamento che la glicemia ha avuto negli ultimi 15-20 minuti e cioè se è stata stabile, se sta aumentando o se sta diminuendo;
- Essa predice ciò che accadrà nei successivi 30 min se non ci sono nuove variazioni;
- Ciascun sistema ha un sua definizione di tendenza



	isCGM	rtCGM	rtCGM	rtCGM	rtCGM sottocutaneo
↑↑↑	NA	NA	>3 mg/dl 0.2 mmol/l per minute	NA	NA
↑↑	NA	>3 mg/dl >0.2 mmol/l per minute	2-3 mg/dl 0.1-0.2 mmol/l per minute	>2 mg/dl >0.1 mmol/l per minute	NA
↑	>2 mg/dl >0.1 mmol/l per minute	2-3 mg/dl 0.1-0.2 mmol/l per minute	1-2 mg/dl 0.05-0.1 mmol/l per minute	1-2 mg/dl 0.05-0.1 mmol/l per minute	>2 mg/dl >0.1 mmol/l per minute
↗	1-2 mg/dl 0.05-0.1 mmol/l per minute	1-2 mg/dl 0.05-0.1 mmol/l per minute	NA	NA	1-2 mg/dl 0.05-0.1 mmol/l per minute
→	<1 mg/dl <0.05 mmol/l per minute	<1 mg/dl <0.05 mmol/l per minute	NA	NA	0-1 mg/dl 0-0.05 mmol/l per minute
↘	1-2 mg/dl 0.05-0.1 mmol/l per minute	1-2 mg/dl 0.05-0.1 mmol/l per minute	NA	NA	1-2 mg/dl 0.05-0.1 mmol/l per minute
↓	2-3 mg/dl >0.1 mmol/l per minute	2-3 mg/dl 0.1-0.2 mmol/l per minute	1-2 mg/dl 0.05-0.1 mmol/l per minute	1-2 mg/dl 0.05-0.1 mmol/l per minute	>2 mg/dl >0.1 mmol/l per minute
↓↓	NA	>3 mg/dl >0.2 mmol/l per minute	2-3 mg/dl 0.1-0.2 mmol/l per minute	>2 mg/dl >0.1 mmol/l per minute	NA
↓↓↓	NA	NA	>3 mg/dl >0.2 mmol/l per minute	NA	NA

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Utilizzo delle frecce di Tendenza

Table 4. Scorecard for Type 1 Diabetes.

Scorecard Type 1 diabetes			Glucose level												Ketone positive ^b		
			<70 mg/dL ^a <3.9 mmol/L	70-180 mg/dL 3.9-10 mmol/L				180-250 mg/dL 10-13.9 mmol/L				>250 mg/dL >13.9 mmol/L					
Change			CU	Correction factor mg/dL mmol/L				Correction factor mg/dL mmol/L				Correction factor mg/dL mmol/L					
				<25 <1.4	25-<50 1.4-<2.8	50-<75 2.8-<4.2	>75 >4.2	<25 <1.4	25-<50 1.4-<2.8	50-<75 2.8-<4.2	>75 >4.2	<25 <1.4	25-<50 1.4-<2.8	50-<75 2.8-<4.2	>75 >4.2		
				Insulin units				Insulin units				Insulin units					
	↑↑	↑↑↑	CU	+3.5	+2.5	+1.5	+1	+4.5	+3.5	+2.5	+1.5	+1	+5	+4	+3	+2	Max corr ^b
↑	↑	↑↑		+2.5	+2	+1	+0.5	+3.5	+2.5	+1.5	+1	+4	+3	+2	+1.5	+1	Max corr ^b
↗	↗	↑		+1.5	+1	+0.5	+0.5	+2.5	+1.5	+1	+0.5	+3	+2	+1.5	+1	+1	Max corr ^b
→	→		1 fast-acting CUs	+0	+0	+0	+0	+0	+0	+0	+0	+0	+0	+0	+0	+0	Max corr ^b
↘	↘	↓	2 fast-acting CUs	-2.5	-1.5	-1	-0.5	-2	-1	-0.5	-0.5	-2.5	-1	-0.5	-0	-0	Max corr ^b
↓	↓	↓↓	2 fast-acting CUs	-3.5	-2.5	-1.5	-1	-3	-2	-1	-1	-3.5	-2	-1	-0.5	-0.5	Max corr ^b
	↓↓	↓↓↓	2 fast-acting CUs	-4.5	-3.5	-2.5	-1.5	-4	-3	-1.5	-1	-4	-2.5	-1	-0.5	-0.5	Max corr ^b

Status Oct 2019. A further correction is recommended no earlier than 2 hours after the last insulin dose. These values are intended as a guide only and need to be adjusted to the insulin sensitivity and individual values of the patient.

^aWith a baseline glucose value <50 mg/dL (<2.8 mmol/L), three fast-acting carbohydrate units are recommended.

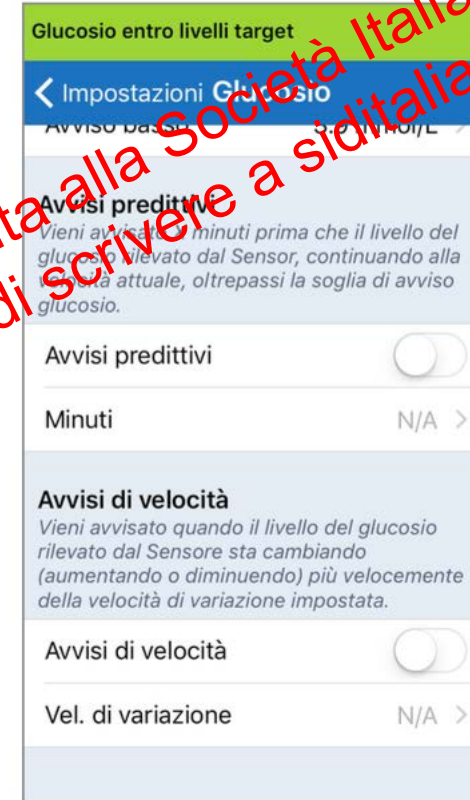
^bIf ketones are positive, the individually suggested maximal correction should be applied independent of the trend arrow information.

Utilizzo delle frecce di Tendenza

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Allarmi per velocità di variazione del glucosio

- Gli avvisi sulla velocità di variazione informano l'utente quando i livelli del glucosio stanno variando (diminuendo o aumentando) secondo una velocità impostata che può variare da 1,5 a 5 mg/dL/min.



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The clinical relevance of CGM

1.a relationship between TIR and A1C
2. ...to fundamentally change clinical care with use of the new metrics, it would be important to demonstrate that the metrics relate to and predict clinical outcomes.

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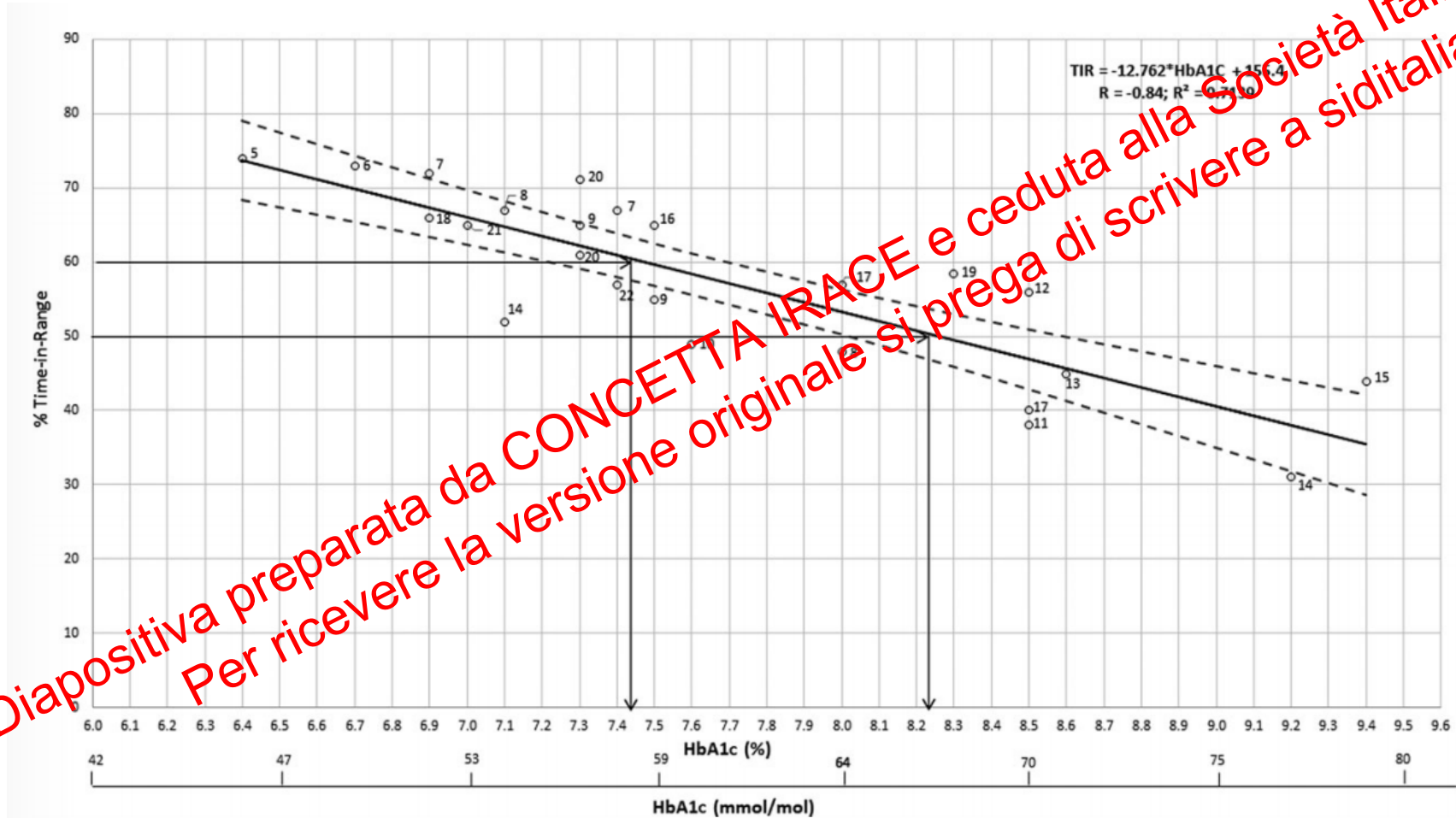
ORIGINAL ARTICLE

The Relationship of Hemoglobin A1c to Time-in-Range in Patients with Diabetes

Robert A. Vigersky, MD and Chantal McMahon, PhD

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The relationship between HbA1c and %TIR. The solid line is the best fit and the dotted lines represent the 95% confidence interval.



Hemoglobin A1c in % and mmol/mol at each decile of time-in-range per equation in the figure

<i>Time-in-range</i>	<i>HbA1c (%)</i>	<i>HbA1c (mmol/mol)</i>
0%	12.1	109
10%	11.4	101
20%	10.6	92
30%	9.8	84
40%	9.0	75
50%	8.3	67
60%	7.5	59
70%	6.7	50
80%	5.9	42
90%	5.1	32
100%	4.3	23

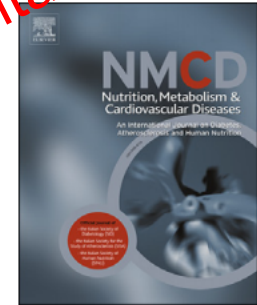
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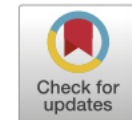
Nutrition, Metabolism & Cardiovascular Diseases

journal homepage: www.elsevier.com/locate/nmcd



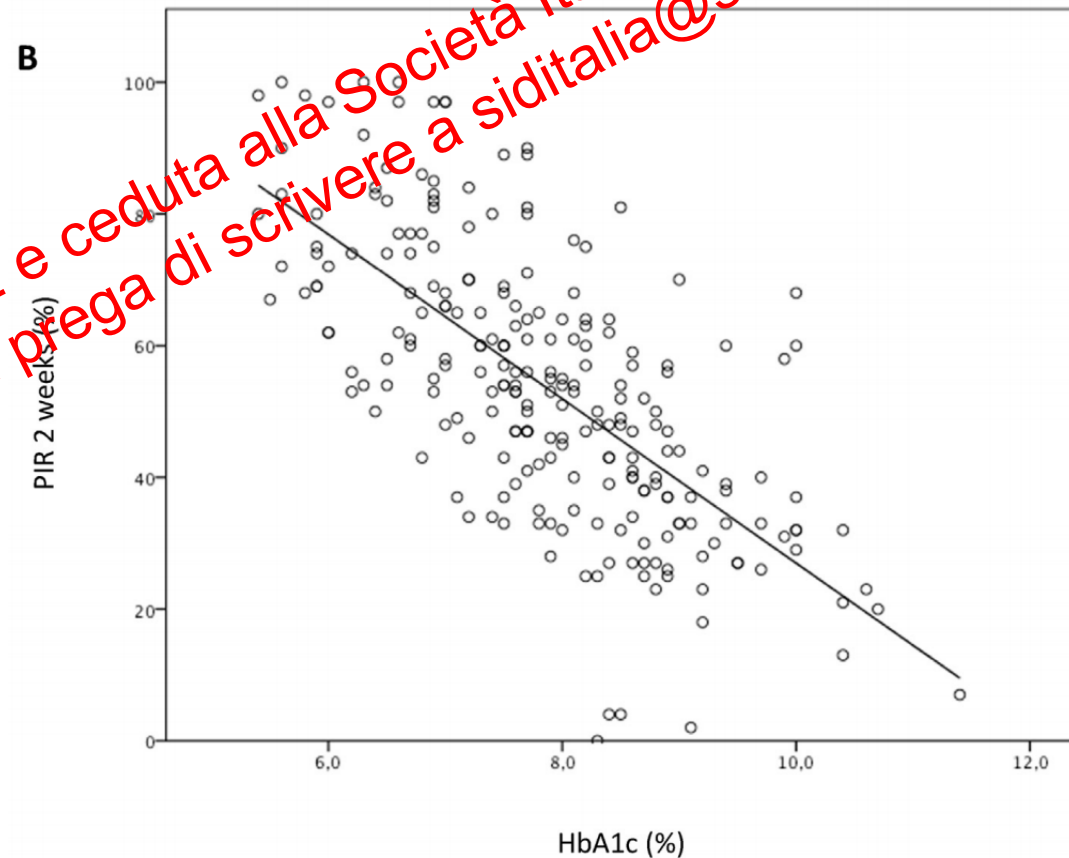
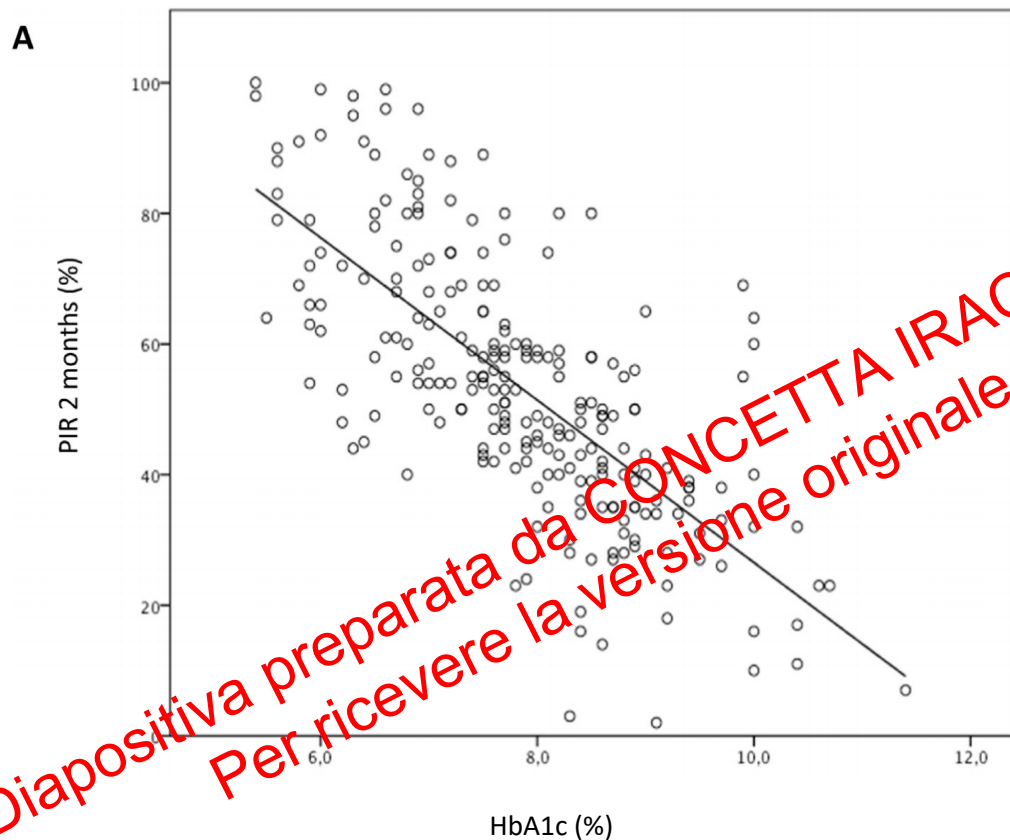
Time spent in target range assessed by self-monitoring blood glucose associates with glycated hemoglobin in insulin treated patients with diabetes

Antonio Cutruzzola^{a,1}, Concetta Irace^{b,1}, Martina Parise^b, Raffaella Fiorentino^c,
Pier Francesco Pio Tripodi^d, Serena Ungaro^d, Valerie Babinsky^e, Agostino Gnasso^{a,*}



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Relationship between HbA1c-DCCT and PIR measured over 2 months [A], and 2 weeks [B]



T1D, 2 months and 2 weeks (both) $R -0.71$, $R^2 0.50$, $p < 0.0001$;
T2D, 2 months $R -0.79$, $R^2 0.62$, $p < 0.0001$; 2 weeks $R -0.71$, $R^2 0.50$, $p < 0.0001$.

Calculated HbA1c in % and mmol/mol at each decile of point spent in range (PIR)

PIR	2-month time range		2-week time range	
	HbA1c %	HbA1c mmol/mol	HbA1c %	HbA1c mmol/mol
0%	10.0	86	9.9	85
10%	9.6	81	9.5	80
20%	9.2	77	9.1	76
30%	8.8	73	8.7	72
40%	8.4	68	8.3	67
50%	8.0	64	7.9	63
60%	7.6	60	7.5	58
70%	7.2	55	7.1	54
80%	6.8	51	6.7	50
90%	6.4	46	6.3	45
100%	6.0	42	5.9	41

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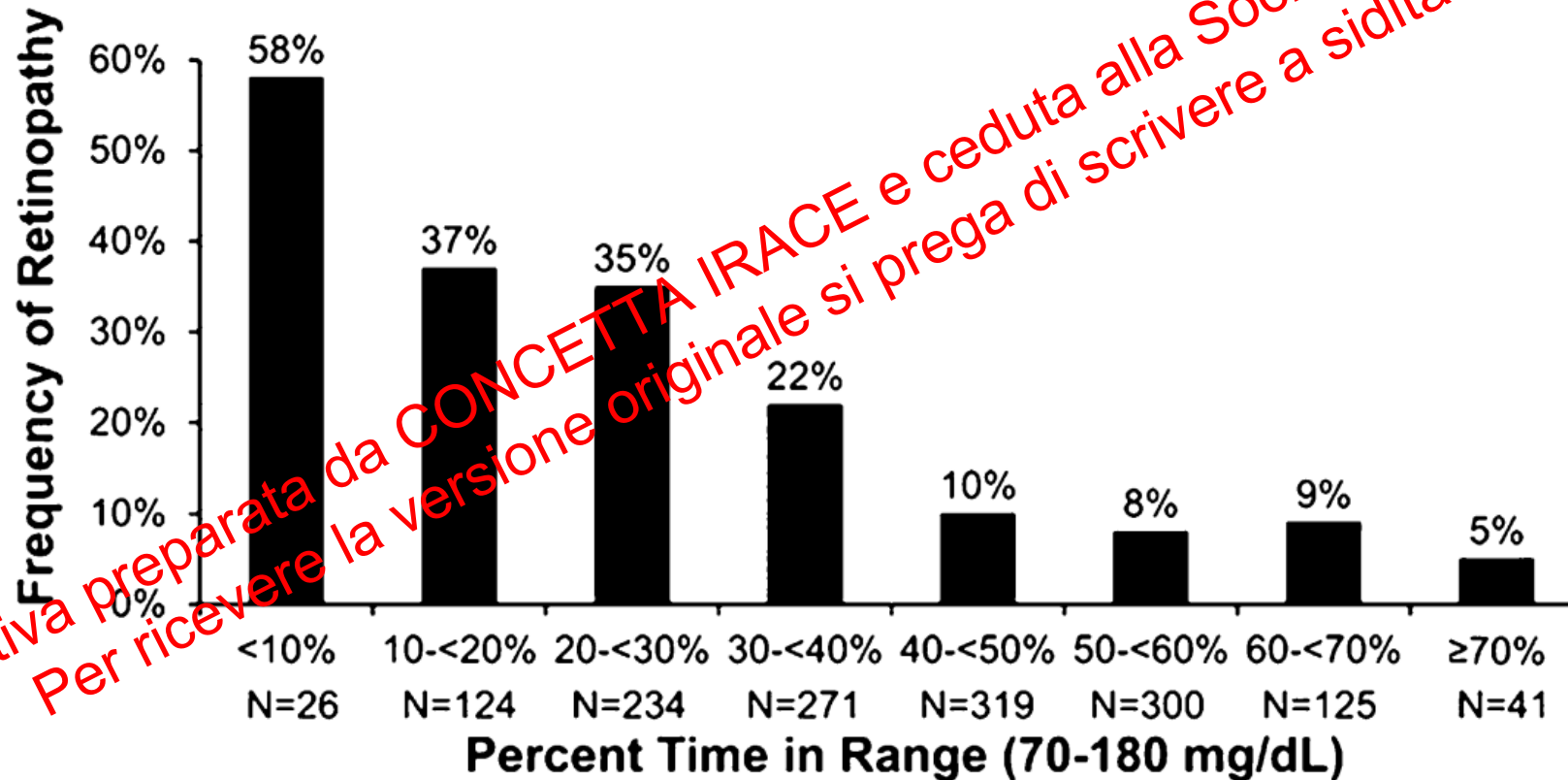
Validation of Time in Range as an Outcome Measure for Diabetes Clinical Trials

Diabetes Care 2019;42:400–405 | <https://doi.org/10.2337/dc18-1444>

Roy W. Beck,¹ Richard M. Bergenstal,²
Tonya D. Riddlesworth,¹ Craig Kollman,¹
Zhaomian Li,¹ Adam S. Brown,³ and
Kelly L. Close⁴

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Frequency of development of *retinopathy* according to the level of TIR computed from quartely seven-point blood glucose testing



Reduction in Diabetic Ketoacidosis and Severe Hypoglycemia in Pediatric Type 1 Diabetes During the First Year of Continuous Glucose Monitoring: A Multicenter Analysis of 3,553 Subjects From the DPV Registry

Table 1—Comparison of clinical outcomes at baseline with outcomes assessed during the first 6 months of CGM use and during months 6–12 after CGM initiation

	Baseline	Follow-up 1 (months 2–6)	<i>P</i>	Follow-up 2 (months 6–12)	<i>P</i>
HbA_{1c}					
%	7.58 (6.95–8.23)	7.47 (6.89, 8.13)	<0.0001	7.48 (6.91, 8.18)	<0.0001
mmol/mol	59.3 (52.5, 66.5)	58.2 (51.8, 65.4)		58.2 (52.0, 65.9)	
Percentage of subjects with HbA _{1c} <7.5% (<58 mmol/mol)	41.1	52.3	<0.0001	50.5	<0.0001
DKA					
Percentage of subjects with at least 1 event	1.0	0.5	0.0055	0.5	0.0143
Event rate, events/100py (95% CI)	2.0 (1.4–2.9)	1.2 (0.7–1.9)	0.06	1.1 (0.7–1.7)	0.0254
SH					
Percentage of subjects with at least 1 event	3.4	1.8	<0.0001	2.6	0.0366
Event rate, events/100py (95% CI)	9.3 (7.3–11.8)	6.9 (5.1–9.5)	0.13	8.6 (6.4–11.4)	0.66
SH with coma/convulsion					
Percentage of subjects with at least 1 event	1.4	0.5	<0.0001	0.8	0.0153
Event rate, events/100py (95% CI)	2.5 (1.9–3.4)	1.2 (0.7–1.9)	0.0062	1.8 (1.2–2.6)	0.15

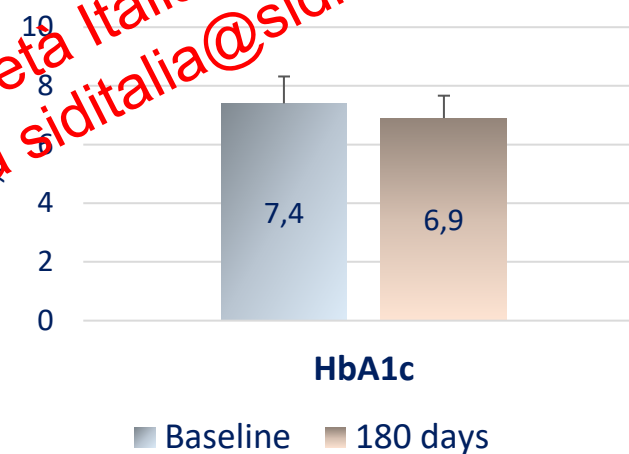
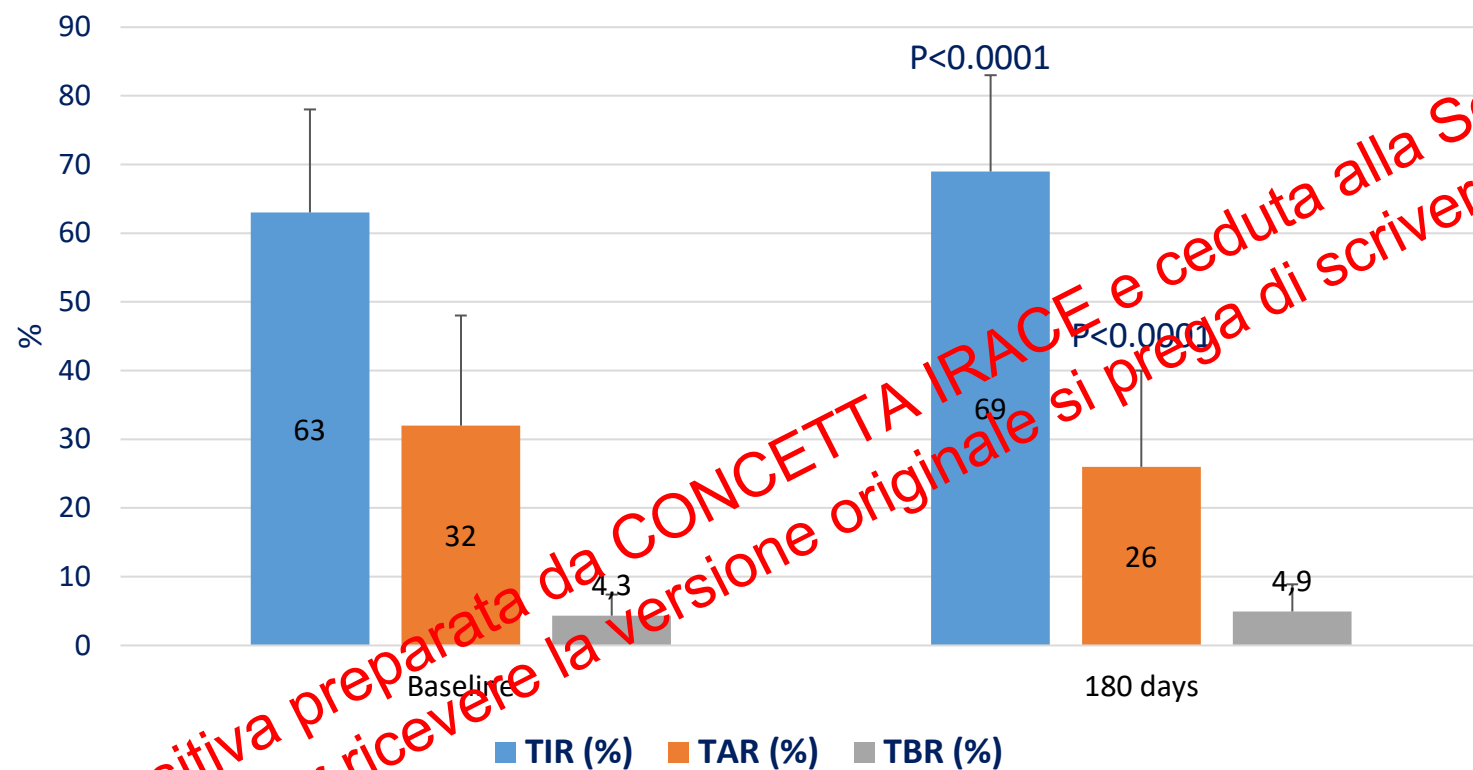
Improved Time in Range Over 1 Year Is Associated With Reduced Albuminuria in Individuals With Sensor-Augmented Insulin Pump–Treated Type 1 Diabetes

	Month					Change from baseline	P value
	0	3	6	9	12		
Days from baseline	0 ± 0	103 ± 25	193 ± 27	289 ± 28	392 ± 33		
HbA _{1c} , mmol/mol	76.0 ± 12.5	69.8 ± 11.7	64.0 ± 11.4	62.6 ± 13.5	61.8 ± 11.4	−14.4 (−17.4; −10.5)	<0.0001
HbA _{1c} , %	9.1 ± 1.1	8.5 ± 1.1	8.0 ± 1.0	7.9 ± 1.2	7.8 ± 1.0	−1.3 (−1.6; −0.96)	
UACR*, mg/g	95.8 ± 3.7	93.5 ± 3.5	70.1 ± 4.4	65.6 ± 4.0	76.3 ± 3.8	−15 (−38; 17)	0.049
MAP†, mmHg	98.9 ± 9.7	96.2 ± 14.0	94.3 ± 11.9	96.6 ± 9.8	97.9 ± 12.4	−1.9 (−6.3; 2.5)	0.90
BMI, kg/m ²	27.5 ± 5.1	27.6 ± 5.5	27.7 ± 5.1	27.5 ± 5.2	27.4 ± 5.6	0.3 (−0.2; 0.7)	0.18
CGM uploads, N	26	24	24	25	22		
CGM readings, %	81 ± 31	63 ± 30	55 ± 20	61 ± 32	78 ± 51		
CGM readings, h	116 ± 45	961 ± 462	1,717 ± 623	1,403 ± 732	1,938 ± 1,267		
%TAR ₂	18 ± 13	15 ± 12	10.4 ± 8.7	11.5 ± 10	9.0 ± 7.7	−7.0 (−10.9; −3.3)	0.002
%TAR ₁	42.3 ± 16.9	40.7 ± 19.4	42.5 ± 17.2	38.8 ± 18.2	32.3 ± 14.4	−7.4 (−12.9; −1.9)	<0.0001
%TIR	46.9 ± 20.1	47.1 ± 19.0	53.5 ± 20.0	57.9 ± 19.9	64.3 ± 13.4	13.2 (6.2; 20.2)	0.0003
%TBR ₁	40.7 ± 12.5	3.2 ± 9.8	4.0 ± 11.4	3.3 ± 5.1	3.4 ± 2.6	−6.3 (−11.1; −1.6)	0.008
%TBR ₂	3.3 ± 1.8	0.2 ± 0.3	0.3 ± 0.3	0.4 ± 0.4	0.6 ± 0.7	−2.7 (−3.8; −1.9)	<0.0001
Mean _{SG} , mmol/L	9.6 ± 1.8	10.3 ± 1.6	9.7 ± 1.4	9.4 ± 1.6	8.9 ± 1.3	−0.5 (−1.02; −0.03)	0.0001
SD _{SG} , mmol/L	4.0 ± 1.0	3.2 ± 0.5	3.1 ± 0.4	3.2 ± 0.5	3.2 ± 0.6	−0.7 (−1.0; −0.4)	<0.0001
CV _{SG} , %	41.9 ± 8.4	31.1 ± 3.9	32.4 ± 3.7	34.2 ± 3.6	36.3 ± 4.6	−5.6 (−8.1; −3.1)	<0.0001
GMI _{SG} , mmol/mol	58.0 ± 8.2	61.2 ± 7.6	58.2 ± 6.5	57.0 ± 7.3	54.4 ± 6.0	−2.5 (−4.8; −0.1)	0.0001

Clinical use of a 180-day implantable glucose sensor improves glycated haemoglobin and time in range in patients with type 1 diabetes*

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Roberta Assaloni MD⁴ | Barbara Brunato MD⁴ | Dario Pitocco MD⁵ |
Linda Tartaglione MD⁵ | Sergio Di Molfetta MD⁶ | Angelo Cignarelli MD⁶  |
Luigi Laviola MD⁶ | Giuseppe Citro MD⁷ | Elisabetta Lovati MD⁸ |
Agostino Gnasso MD² | Katherine S Tweden PhD⁹  | Francine R Kaufman MD⁹

HbA1c and CGM metric changes

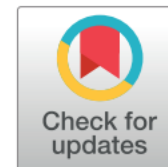




Effects of Continuous Glucose Monitoring on Metrics of Glycemic Control in Diabetes: A Systematic Review With Meta-analysis of Randomized Controlled Trials

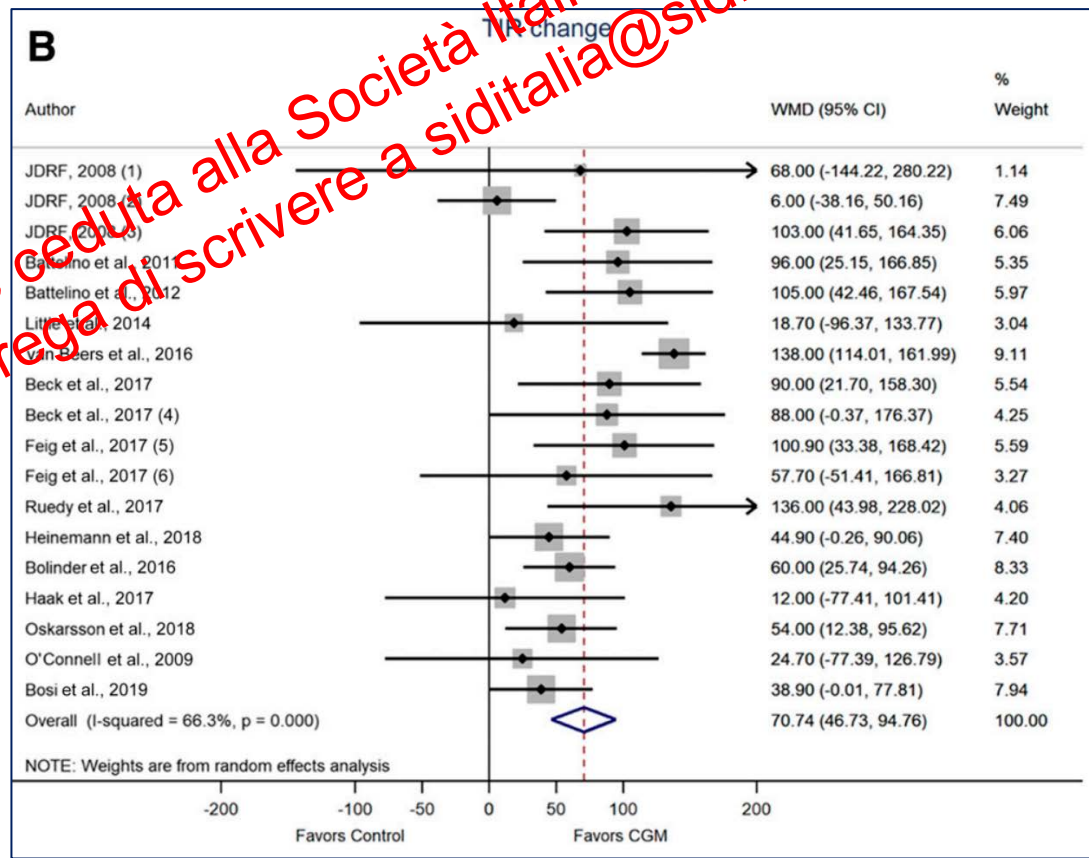
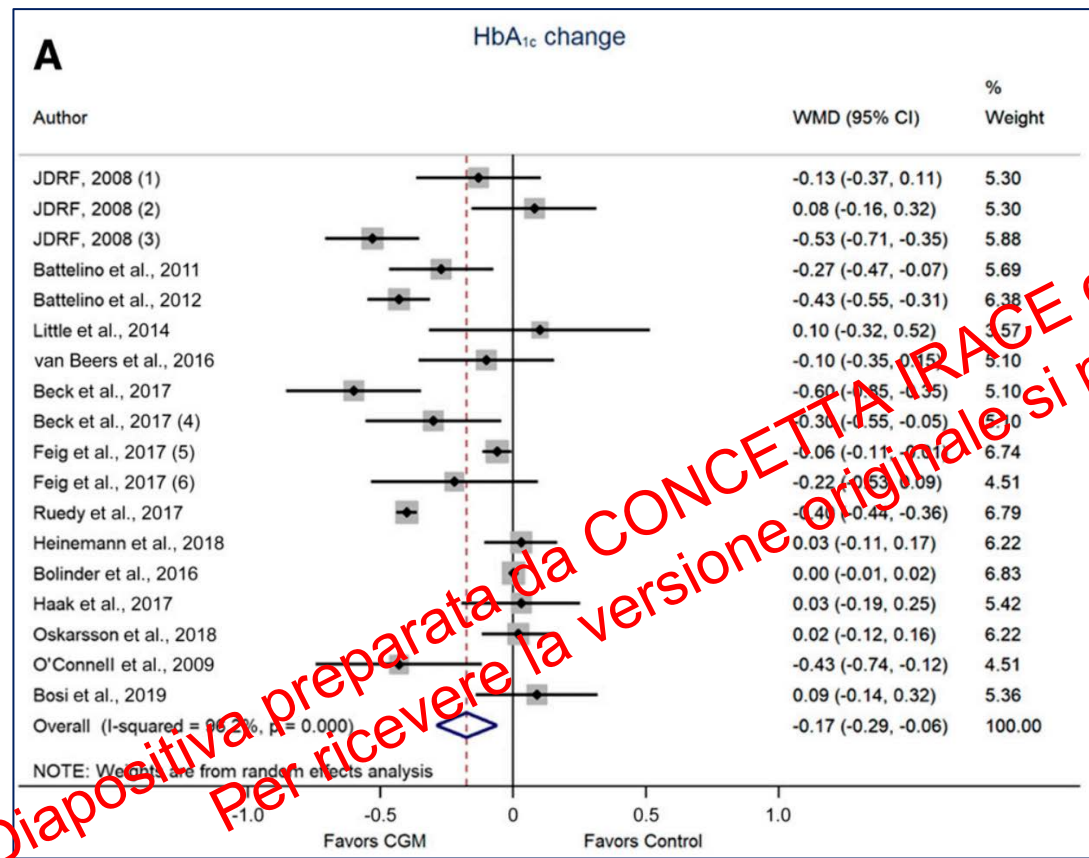
Diabetes Care 2020;43:1146–1156 | <https://doi.org/10.2337/dc19-1459>

Marilda Maiorino,^{1,2} Simona Signoriello,³
Antonietta Maio,² Paolo Chiodini,³
Giuseppe Bellastella,^{1,2}
Lorenzo Scappaticcio,^{1,2} Miriam Longo,²
Dario Giugliano,^{1,2} and
Katherine Esposito^{2,4}



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Forest plots of meta-analysis for HbA1c (A) and TIR (B) change from baseline in all 16 comparisons



CGM: Recommendation

- **rtCGM: Adults with Type 1 diabetes** who are not meeting glycemic targets, or have hypoglycemia or unawareness hypoglycemia
 - to **lower A1C** levels
 - To **reduce hypoglycemia [A]**;
- **rtCGM** may be used effectively to improve A1C levels, time in range, and neonatal outcomes in **pregnant women with type 1 diabetes. B**
- **isCGM: Adults with Type 1 diabetes** who are not meeting glycemic targets, or have hypoglycemia or unawareness hypoglycemia
 - to **lower A1C** levels
 - To **reduce hypoglycemia [C]**.

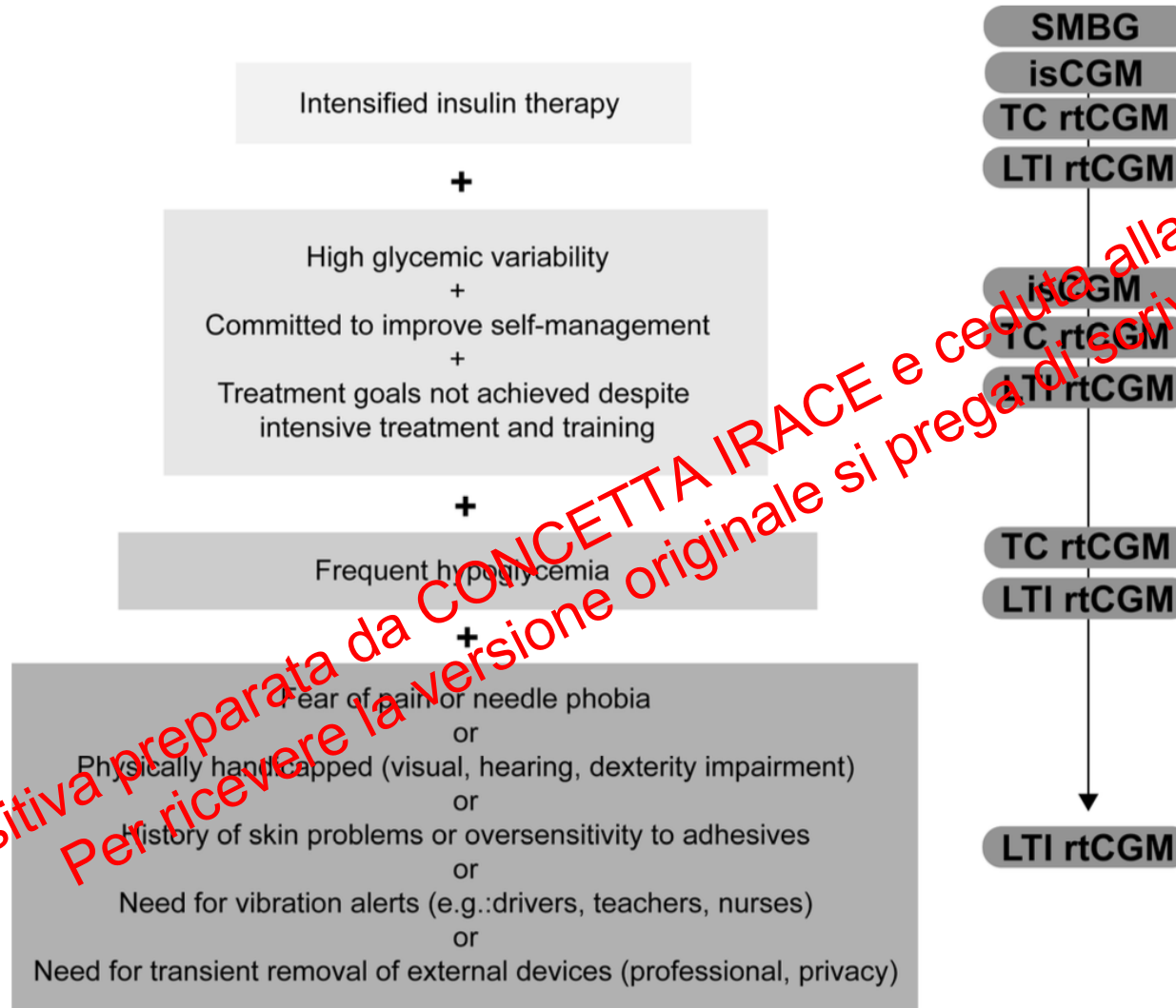


ORIGINAL ARTICLE

Clinical Practice Recommendations on the Routine Use of Eversense, the First Long-Term Implantable Continuous Glucose Monitoring System

Dorothee Deiss, MD,¹ Agnieszka Szadkowska, MD,² Debbie Gordon, MD,^{3,4} Akhila Mallipedhi, MD,⁵ Ingrid Schütz-Fuhrmann, MD,⁶ Eva Aguilera, MD,⁷ Corina Ringsell, Dr,⁸ Christophe De Block, MD,^{9,*} and Concetta Irace, MD^{10,*}

Decision tree for glucose monitoring



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Flat, narrow, in range

GIORNI ▼	ORA DEL GIORNO ▼	EVENTI ▼	UTILIZZO ▼
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