Autocontrollo negoziato, partecipato, strutturato nel "paziente Ramadan"

Monitoraggio

E' una procedura attraverso la quale si osserva e registra un determinato comportamento.

Già il fatto di seguire giornalmente un aspetto di sé produce un cambiamento nel comportamento verso il miglioramento, strettamente correlato alla frequenza dell'osservazione e registrazione

Questo fenomeno prende il nome di REACTIVITY

New Evidence Demonstrates That Self-Monitoring of Blood Glucose Does Not Improve Outcomes in Type 2 Diabetes—When This Practice Is Not Applied Properly

Journal of Diabetes Science and Technology
Volume 2, Issue 3, May 2008
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David C. Klonoff, M.D., FACP

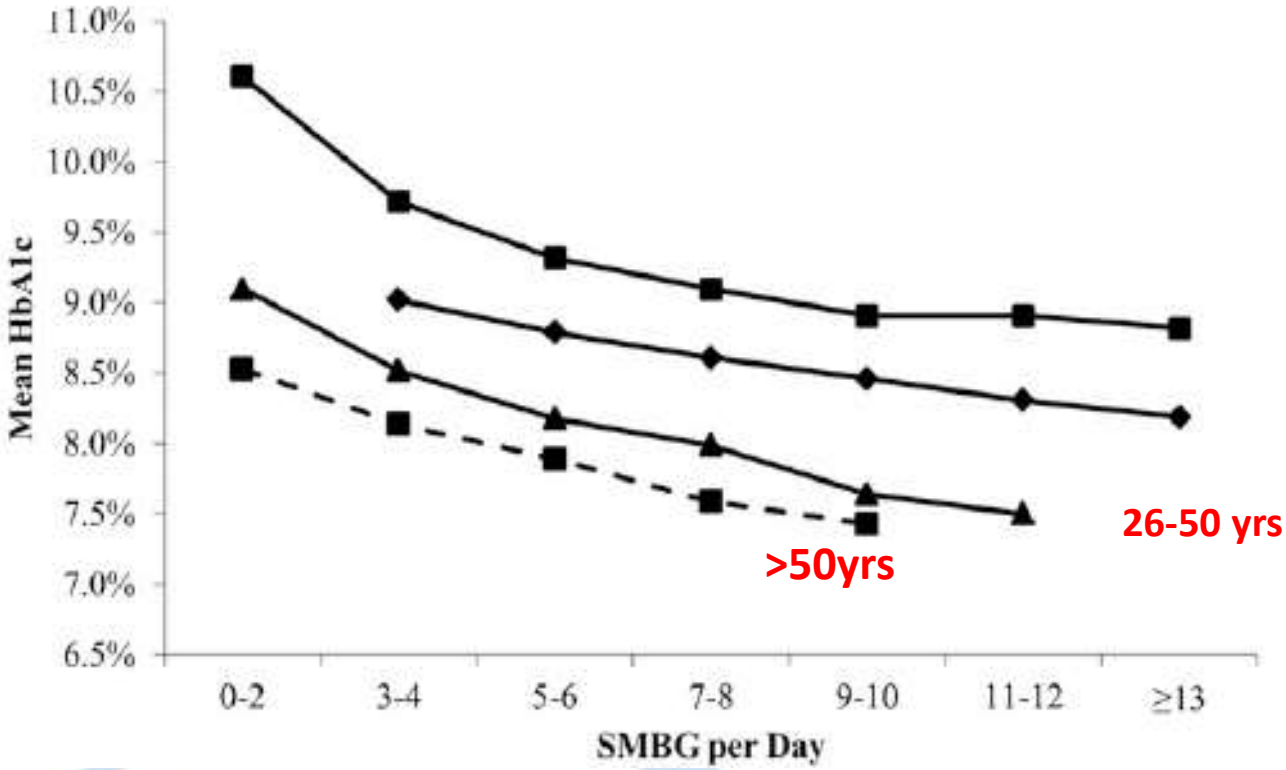
Fare

Interpretare

Agire

Responsibilities of the Patient in Order to Appropriately Perform, Interpret, and Act upon SMBG Information
1. Accurately perform SMBG according to a prescribed regimen
2. Recognize confounding factors that can degrade monitor performance
3. Understand appropriate timing and testing sites for monitoring
4. Interpret SMBG results relative to predetermined target levels
5. See a connection between out-of-range results and lifestyle (e.g., eating, exercise, stress) or medication dosing
6. Possess the knowledge to make adjustments in therapy
7. Act consistently upon an action plan for responding to deviant glucose levels
8. Accurately record SMBG test results on paper or electronically
9. For electronic recording, accurately program the date, time, and events into the monitor
10. Rely more on SMBG readings than subjective sensations of well-being

Evidence of a Strong Association Between Frequency of Self-Monitoring of Blood Glucose and Hemoglobin A_{1c} Levels in T1D Exchange Clinic Registry Participants



Diabetes Care 36:2009-2014, 2013

A higher number of SMBG measurements per day was strongly associated with a lower HbA1c level with the association being present in all age-groups and in both insulin pump and injection users (20,555 participants)

Self-monitoring of blood glucose in type 2 diabetes: systematic review

C Clar, K Barnard, E Cummins, P Royle and N Waugh
for the Aberdeen Health Technology Assessment Group

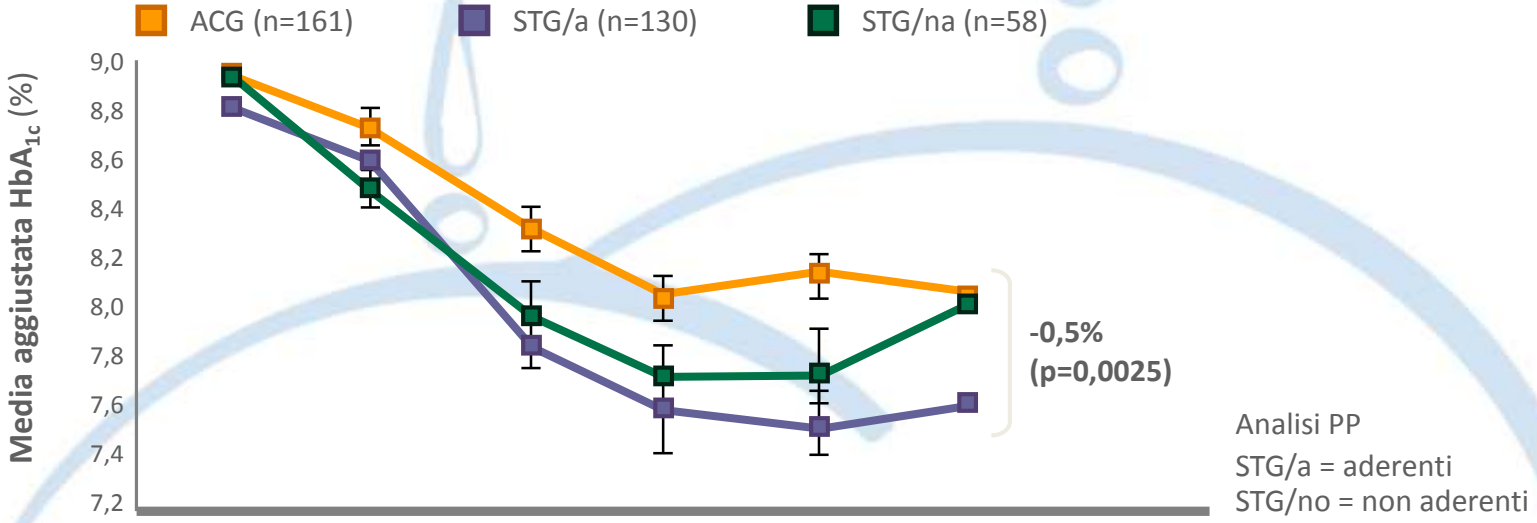
Le evidenze hanno suggerito che l'automonitoraggio glicemico presenta una **limitata efficacia clinica nel migliorare il controllo glicemico in pazienti con DMT2 in terapia con ipoglicemizzanti orali** o con la sola terapia nutrizionale, ed è pertanto improbabile che esso risulti *cost-effective*. L'automonitoraggio della glicemia può migliorare il controllo glicemico **solo** nel contesto di **un appropriato programma di educazione** – **sia per i pazienti che per i medici e gli infermieri** – che insegni a rispondere ai valori rilevati in termini di variazioni dello stile di vita e del trattamento

Clar C et al, Helath Technol Assess 2010; 14 (12): 1-140.

Studio Structured Testing Program (STeP)

- 552 pazienti con DMT2 non trattati con insulina, con inadeguato controllo glicemico (HbA_{1c} ≥7,5%)
- Programma strutturato di monitoraggio della glicemia (Structured testing protocol, STG):
  - Profilo glicemico a 7 punti per 3 giorni consecutivi ogni tre mesi
  - Tutti i soggetti sottoposti a STG hanno ricevuto istruzioni standardizzate sull'automonitoraggio glicemico e sul riconoscimento e l'interpretazione dei pattern.
  - I medici del gruppo STG hanno ricevuto un algoritmo con le strategie terapeutiche suggerite in risposta ai pattern di glicemia osservati
- Active control (ACG), istruzioni standardizzate per l'automonitoraggio della glicemia

Variazione media dell'A1c



Polonsky W et al, Diabetes Care 2011; 34: 262-7.

Studio Structured Testing Program (STeP)

L'automonitoraggio glicemico strutturato promuove un controllo glicemico significativamente migliore nel tempo in pazienti con DMT2 non trattati con insulina, **quando sia i pazienti che i medici collaborano nella raccolta, nell'interpretazione e nell'adeguato utilizzo dei valori di glicemia rilevati**

Polonsky W et al, Diabetes Care 2001; 34: 262-7.

ROSES: role of self-monitoring of blood glucose and intensive education in patients with Type 2 diabetes not receiving insulin. A pilot randomized clinical trial

Patients were instructed to measure their blood glucose levels according to the following weekly schedule:

1st day: before and 2 h after breakfast;
3rd day: before and 2 h after lunch;
5th day: before and 2 h after dinner.

This pattern was repeated 2 weeks every month

Studio Roses: efficacia dell'automonitoraggio della glicemia e di un approccio educativo intensivo nei pazienti con diabete di tipo 2 non trattati con insulina

- Sperimentazione clinica controllata e randomizzata dalla durata di 26 settimane che ha l'obiettivo di valutare l'efficacia dell'SMBG associato con uno specifico approccio educativo, rispetto alla Cura Standard (CS) in pazienti DMT2 trattati con ipoglicemizzanti orali e che non abbiano mai utilizzato l'SMBG.
- **Il programma di educazione intensiva ha previsto** incontri trimestrali, focalizzati su come effettuare l'SMBG, come **modificare la dieta e l'attività fisica in base ai livelli di glicemia**, quali azioni intraprendere in caso di valori anomali, e contatti telefonici mensili per verificare il raggiungimento dei target terapeutici.
- Dopo 6 mesi, i valori di HbA_{1c} erano di 6,6±0,8 nel braccio SMBG e di 7,2±0,5 in quello CS (differenza assoluta tra i bracci -0,7±0,2; p=0,01).

SMBG = Self-Monitoring of Blood Glucose

L'AUTOCONTROLLO COME STRUMENTO EDUCATIVO

Monitoring of glycemic status, as performed by patients and health care providers, is considered a cornerstone of diabetes care. Results of monitoring are used to assess the efficacy of therapy and to make adjustments in diet, exercise, and medications in order to achieve the best possible blood glucose control.

- Il monitoraggio della glicemia serve al medico e al paziente per verificare **l'adeguatezza della terapia** e modificarla in modo appropriato

- L'autocontrollo serve al paziente:
  - per avere un **feedback in tempo reale** del proprio stato glicemico
  - valutare **l'impatto dell'alimentazione e dell'attività fisica**
  - poter prendere **decisioni opportune** circa il proprio stile di vita

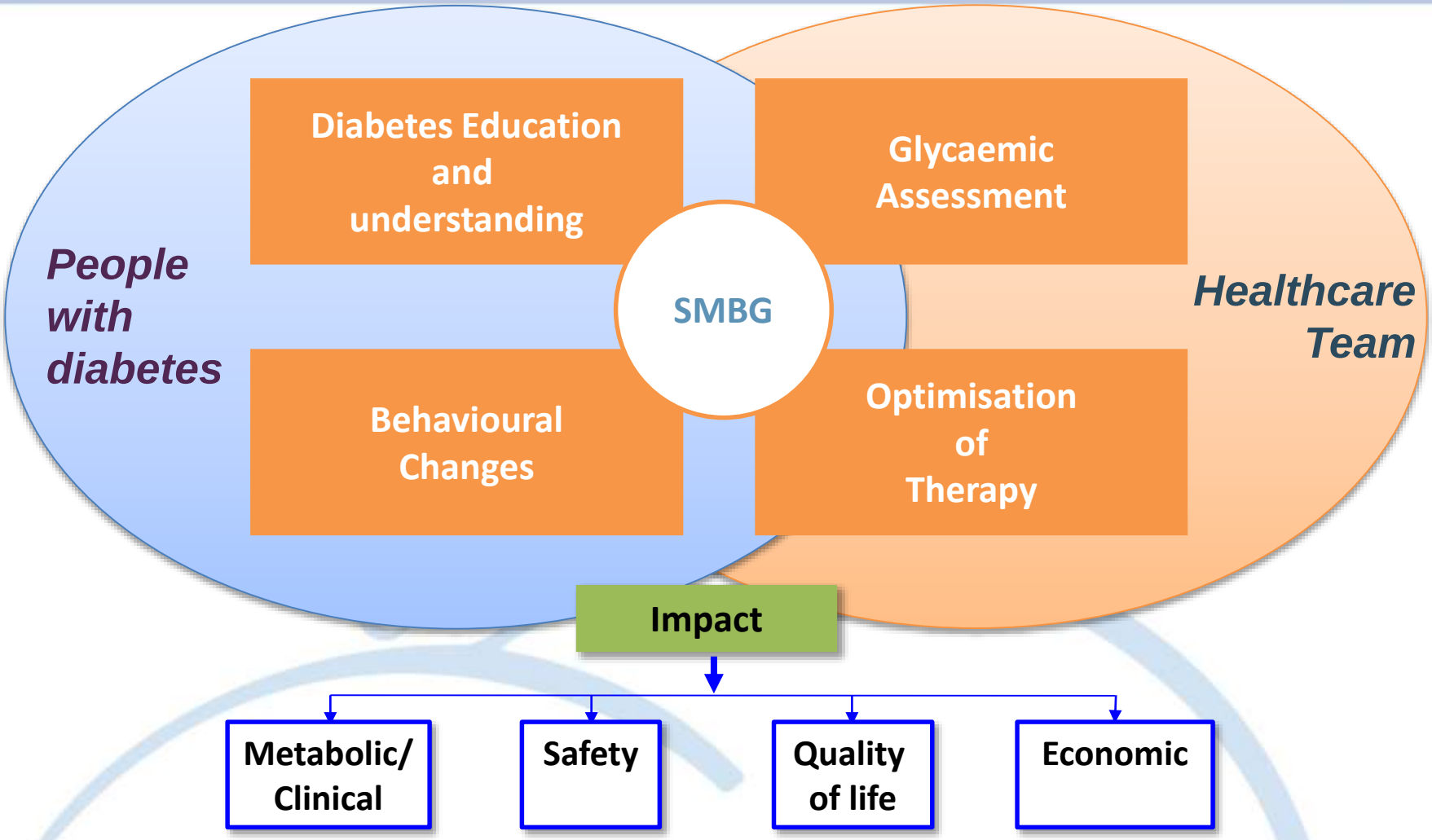
However, there is a general feeling that SMBG readings are a very important educational tool. It could be that reason that the ACE stated on 2 February 2005 that:

"SMBG readings, when performed with sufficient frequency allow patients and their healthcare professionals to make informed decisions about lifestyle choices and adjustment in pharmacology therapy."

More important is, perhaps, the second part of the statement:

"SMBG can also provide on-going feed back to patients about their nutrition and physical activity".

Goldstein D et al, Diabetes Care 2004; 27 (suppl 1): S91-3.



Guideline on Self-Monitoring of Blood Glucose in Non-Insulin Treated Type 2 Diabetes, IDF 2009, page 28

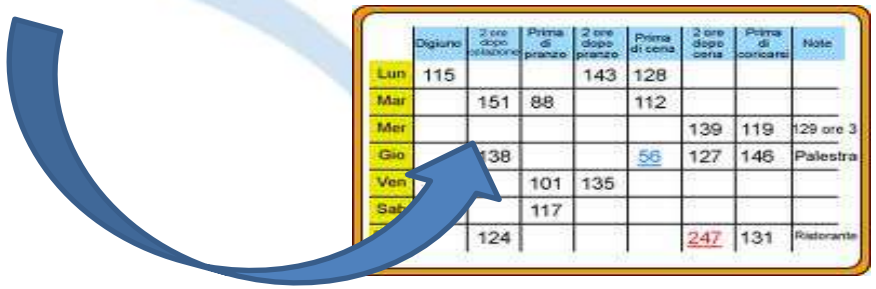
Obiettivo condiviso

essere in grado di capire la relazione tra comportamenti e i risultati ottenuti, confrontandosi continuamente con se stesso

essere attento ai propri progressi

diventare responsabile delle proprie azioni





	Digiuno	2 ore dopo colazione	Prima di pranzo	2 ore dopo pranzo	Prima di cena	2 ore dopo cena	Prima di coricarsi	Note
Lun	115			143	128			
Mar		151	88		112			
Mer						139	119	129 ore 3
Gio		138			56	127	146	Palestra
Ven			101	135				
Sab			117					
		124				247	131	Ristorante

A Population-Based Study of Diabetes and Its Characteristics During the Fasting Month of Ramadan in 13 Countries

Results of the Epidemiology of Diabetes and Ramadan 1422/2001 (EPIDIAR) study

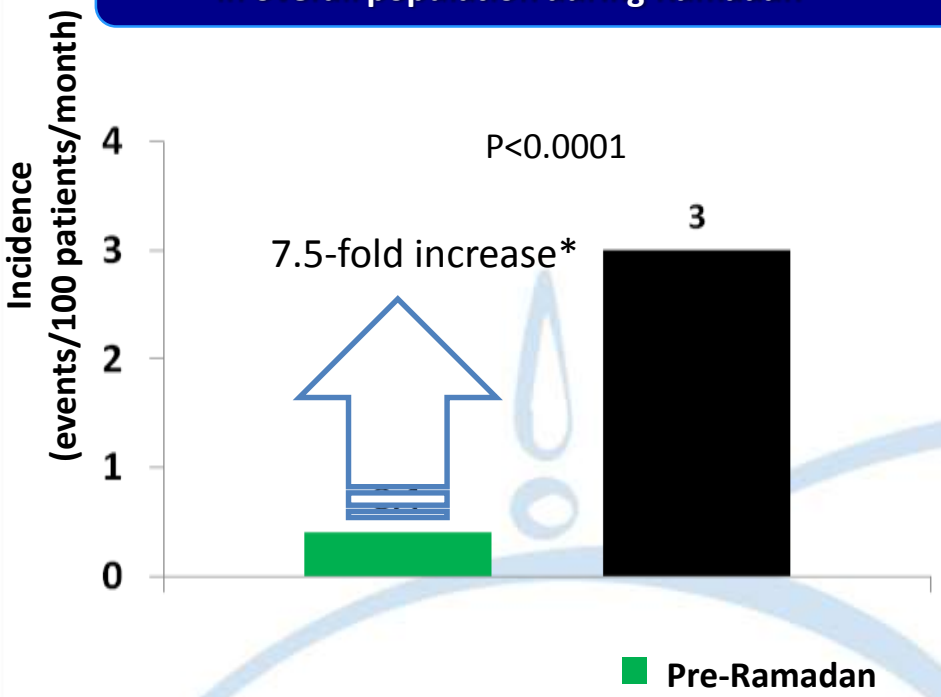
Table 3—*Number of severe glycemic complications per month*

	Type 1 diabetes			Type 2 diabetes		
	Before Ramadan	During Ramadan	*P*	Before Ramadan	During Ramadan	*P*
Overall population						
Severe hypoglycemia	0.03 ± 0.1	0.14 ± 0.6	0.0174	0.004 ± 0.02	0.03 ± 0.28	<0.0001
Severe hyperglycemia/ketoacidosis	0.05 ± 0.08	0.16 ± 0.51	0.1635	0.01 ± 0.05	0.05 ± 0.35	<0.0001
Patients who fasted ≥15 days						
Severe hypoglycemia	0.02 ± 0.05	0.12 ± 0.48	0.9896	0.003 ± 0.02	0.02 ± 0.22	0.0034
Severe hyperglycemia/ketoacidosis	0.05 ± 0.08	0.15 ± 0.51	0.6701	0.009 ± 0.04	0.04 ± 0.30	0.0015

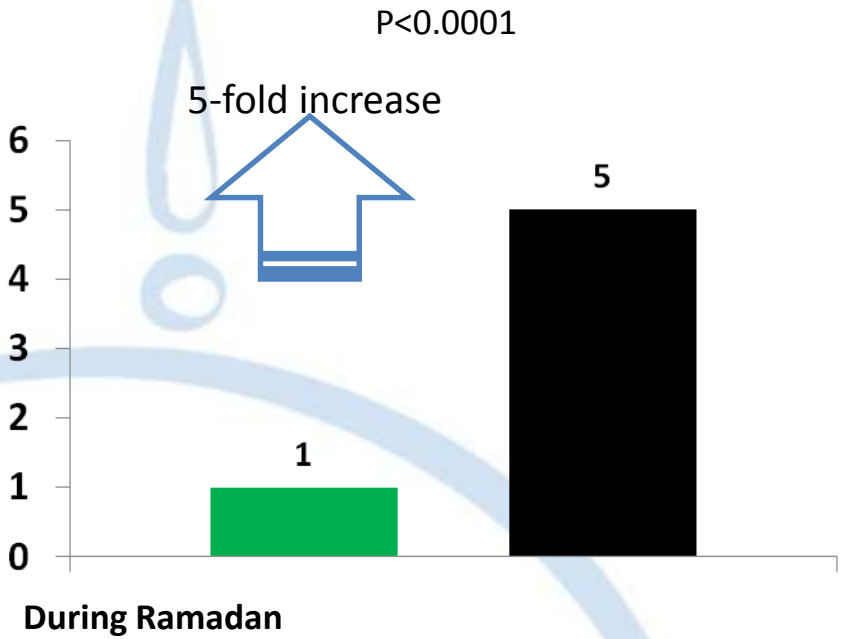
Data are means ± SD.

11,173 pazienti con diabete tipo 2; 78.7% ha digiunato per almeno 15 giorni[1]

Higher risk of severe hypoglycaemic events† in overall population during Ramadan‡[1,2]



Higher risk of severe hyperglycaemic events† in overall population during Ramadan‡[1,2]



†Events requiring hospitalization in overall population with T2DM; ‡compared with previous months

* There was a 7.5 fold difference of hypoglycaemia in overall population fasting during Ramadan. For patients who fasted for ≥ 15 days difference was, 6.7 fold

EPIDIAR = EPIdemiology of DIAbetes and Ramadan; T2DM = type 2 diabetes mellitus

[1]Salti I, et al. Diabetes Care 2004;27:2306–11; [2]Al-Arouj M, et al. Diabetes Care 2010;33:1895–902

A Population-Based Study of Diabetes and Its Characteristics During the Fasting Month of Ramadan in 13 Countries

Results of the Epidemiology of Diabetes and Ramadan 1422/2001 (EPIDIAR) study

The overall incidence of hypoglycemic events was rather low. This may be due to unawareness of symptoms by the patient, limited use of intensive therapies, insufficient monitoring, or restriction of the definition to hospitalization.

Misurano la concentrazione del glucosio nel liquido interstiziale, attraverso un sensore a forma di ago (1 valore ogni 5 minuti) o attraverso una fibra microdialitica, basandosi sul principio che questo sia in equilibrio con il versante ematico. Il *lag-time* necessario per il bilanciamento tra i 2 comparti è tra 4 e 10 minuti

RETROSPETTIVO





REAL TIME





GlucoWatch® Biographer



AutoSensor









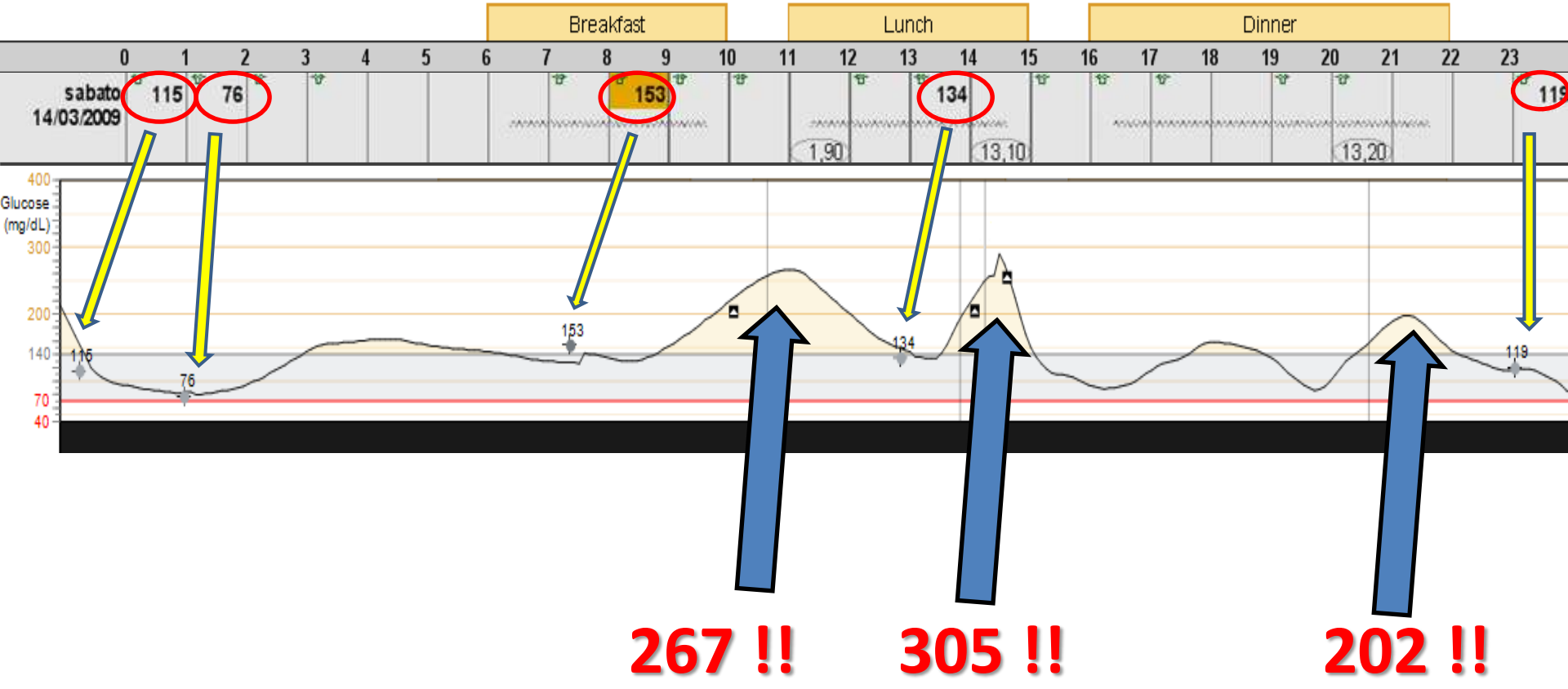


“Dall’automonitoraggio glicemico capillare al Monitoraggio in continuo della glicemia”

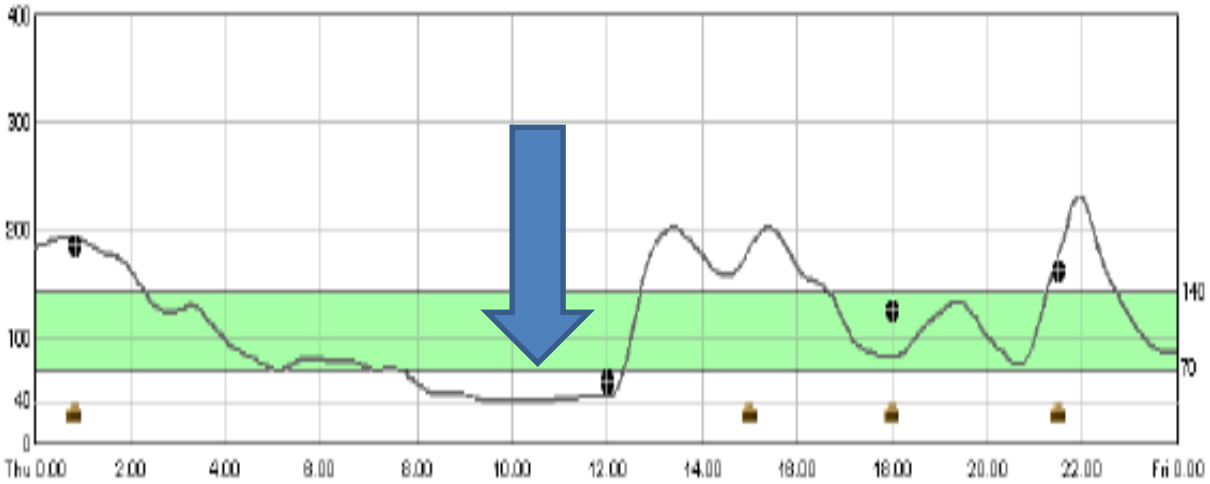
Gerard Reach. Glucose monitoring: from the fingertips to continuous monitoring.
Symposium: Insulin Delivery Devices and Glucose Sensors. 18th IDF Congress; Paris, France 2003

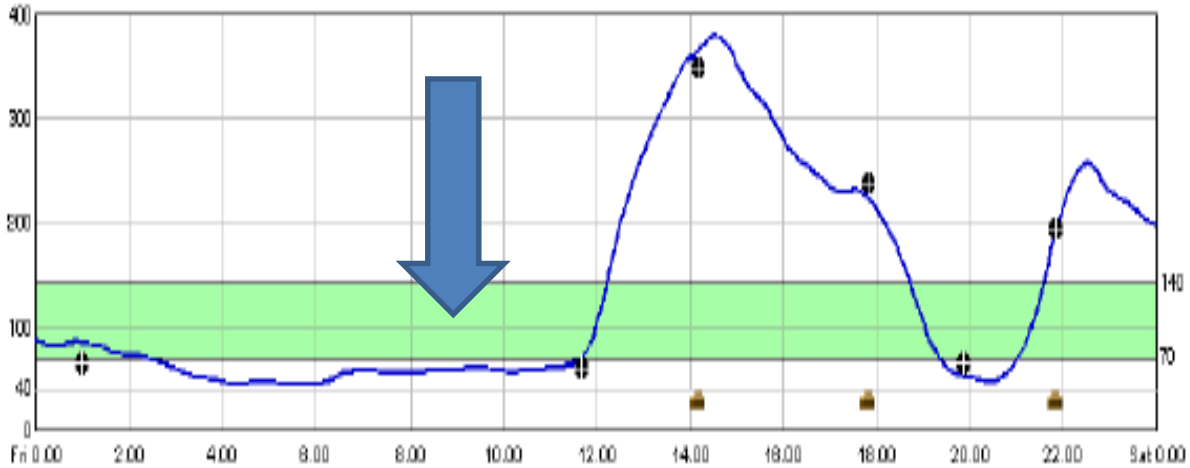
- E’ discontinuo
- Non fornisce informazioni durante la notte
- Non informa dell’occorrenza di possibili eventi ipoglicemici o iperglicemici
- Non fornisce un quadro completo dell’andamento glicemico
- Necessita di una goccia di sangue ogni volta

ESEMPIO – 1 : HbA1c 8%

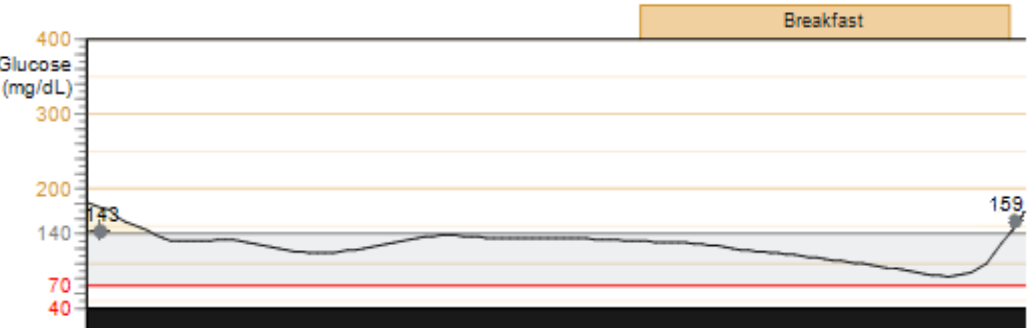


IPOGLICEMIA INAVVERTITA





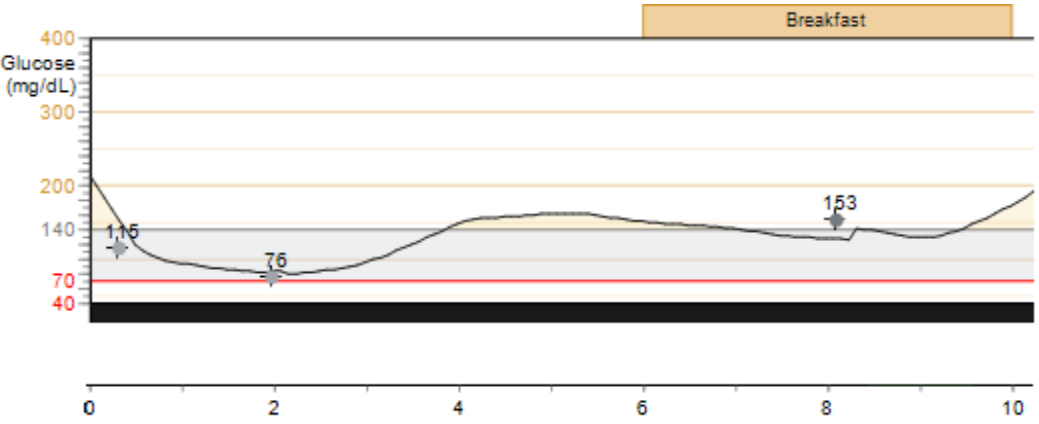
ESEMPIO –2: profilo notturno



159 mattino: **Normale**

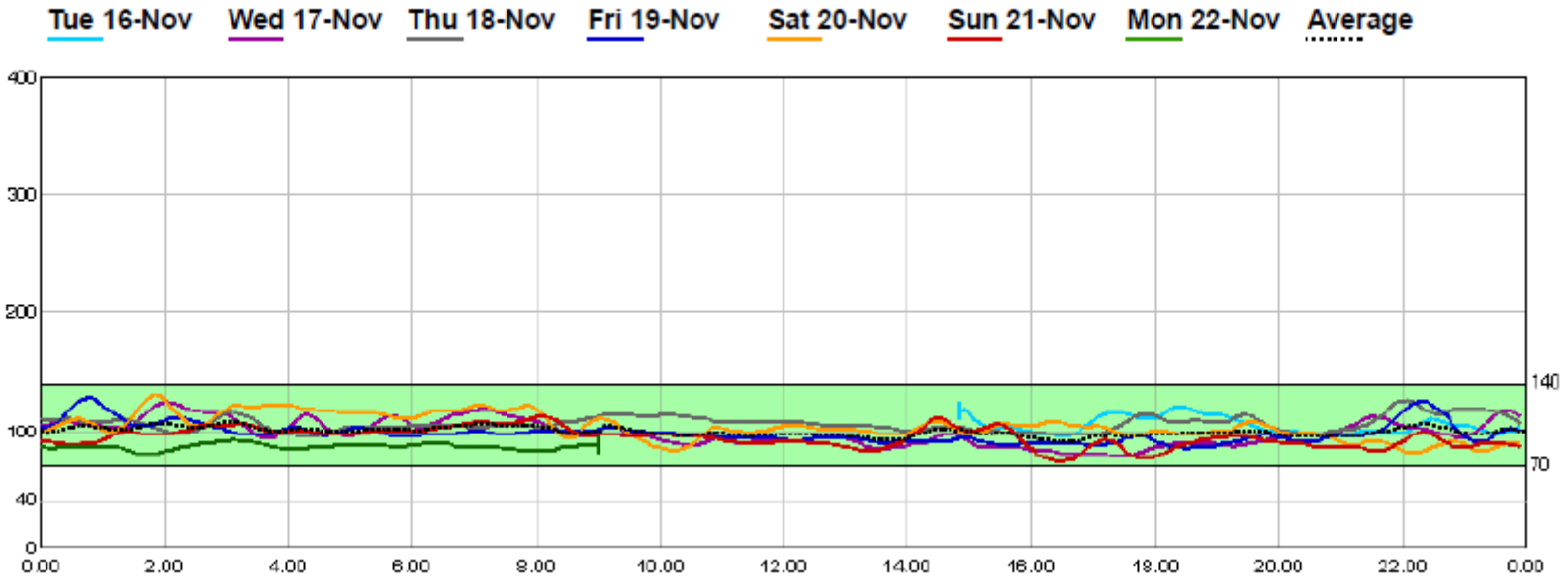


157 mattino: **Iperglicemia**



153 mattino: **Ipoglicemia**

Sensor Data (mg/dL)



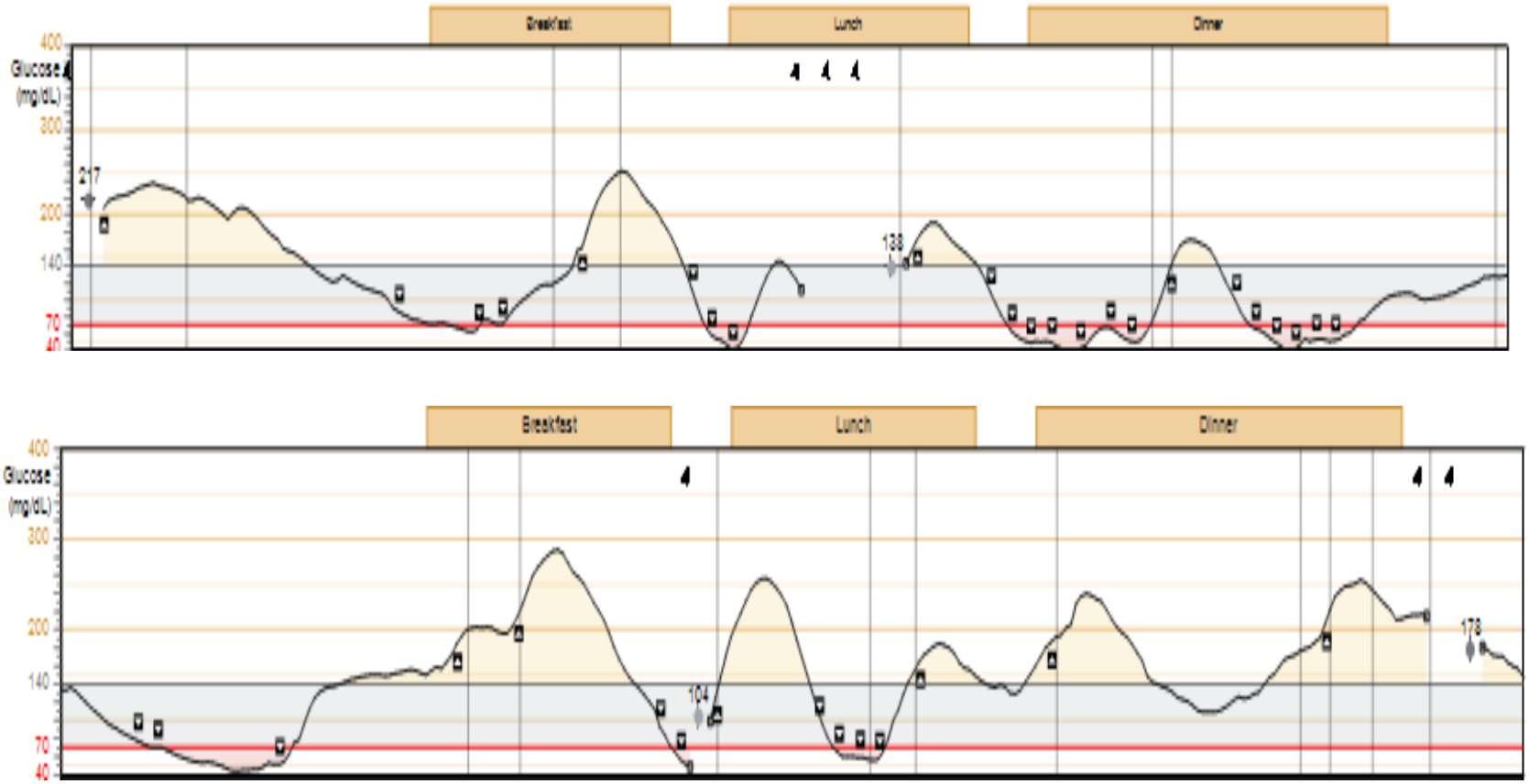
	Tue 16-Nov	Wed 17-Nov	Thu 18-Nov	Fri 19-Nov	Sat 20-Nov	Sun 21-Nov	Mon 22-Nov	Average / Total
# Sensor Values	110	288	288	288	288	288	109	1.659
Highest	120	124	126	127	130	112	92	130
Lowest	95	78	95	84	81	73	79	73
Average	105	98	106	97	103	94	86	99
Standard Dev.	7	11	6	9	11	8	2	10
MAD %	6,2	3,7	4,2	5,8	6,4	0,0	N/A	4,7
Correlation	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
# Valid Calibrations	3	4	3	3	2	1	0	16
Designation					X	X	C	

X: Use Clinical Judgment S: No Sensor Data C: No Calibration BG's

Excursion Summary (mg/dL/day)

	Tue 16-Nov	Wed 17-Nov	Thu 18-Nov	Fri 19-Nov	Sat 20-Nov	Sun 21-Nov	Mon 22-Nov	Average / Total
# Excursions	0	0	0	0	0	0	0	0
# High Excursions	0	0	0	0	0	0	0	0
# Low Excursions	0	0	0	0	0	0	0	0
AUC Above Limit	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0
AUC Below Limit	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

GRAVIDANZA: HbA1c=5.9!!

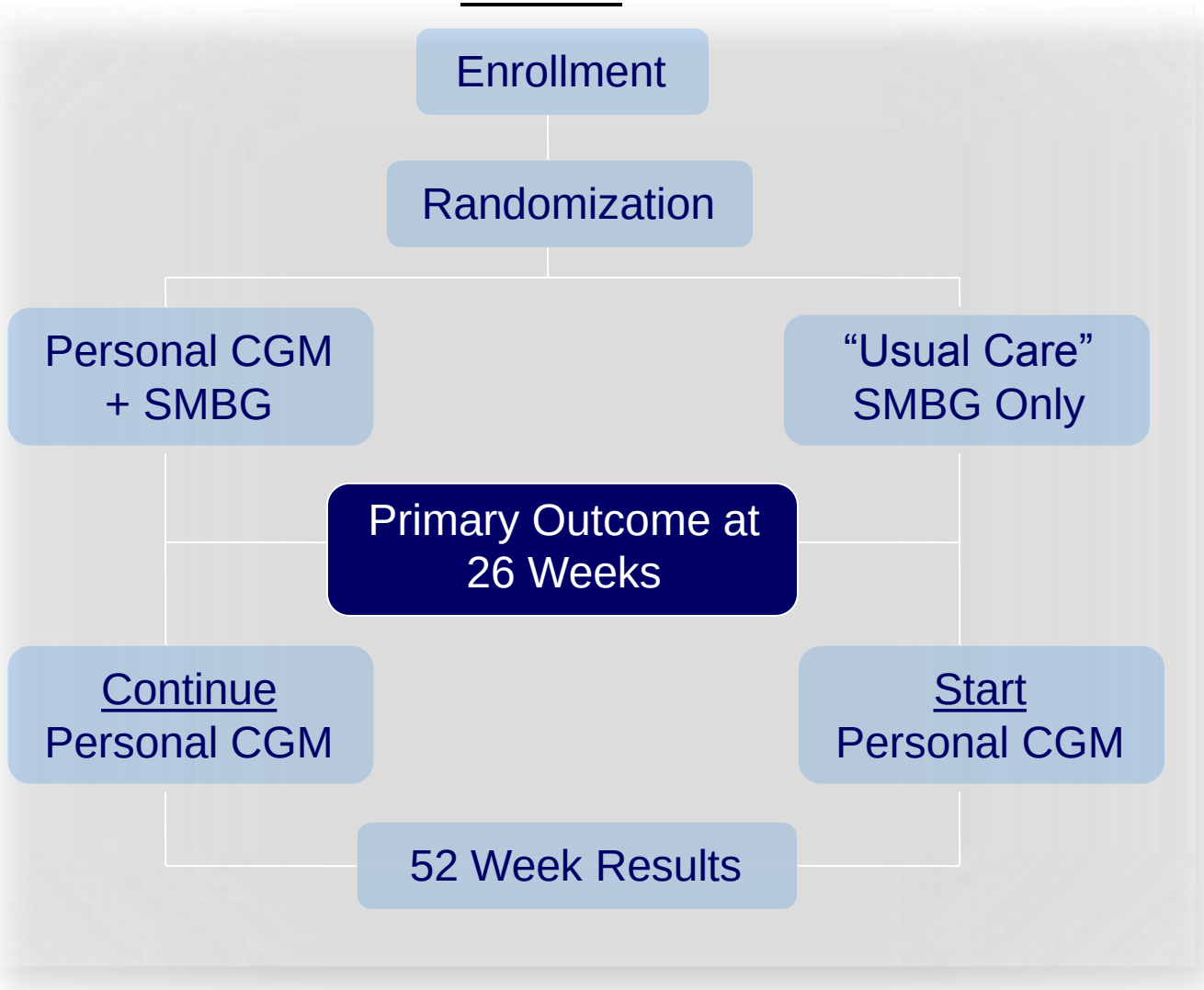


Indicazioni per il monitoraggio continuo

- **Valori elevati di HbA 1c**
- **Discrepanza tra HbA1c e valori all'autocontrollo**
- **Ipoglicemia e/o Iperglicemie asintomatiche *(Il monitoraggio continuo della glicemia dimostra che gli episodi ipoglicemici sono il* 250% *rispetto autocontrollo)***
- **Episodi iperglicemici / periodo postprandiale**
- **Fenomeno alba**
- **Automonitoraggio frequente (>10 controlli al giorno)**
- **Fenomeno del tramonto**
- **Bambini**
- **Gravidanza**
- **Variabilità glicemica**
- **Valutazione modifiche terapeutiche-Inizio di un nuovo trattamento**
- **Diabete instabile (frequenti ospedalizzazioni)**

Study Design & Methods

Study Results Reflect Outcomes After 6 Months

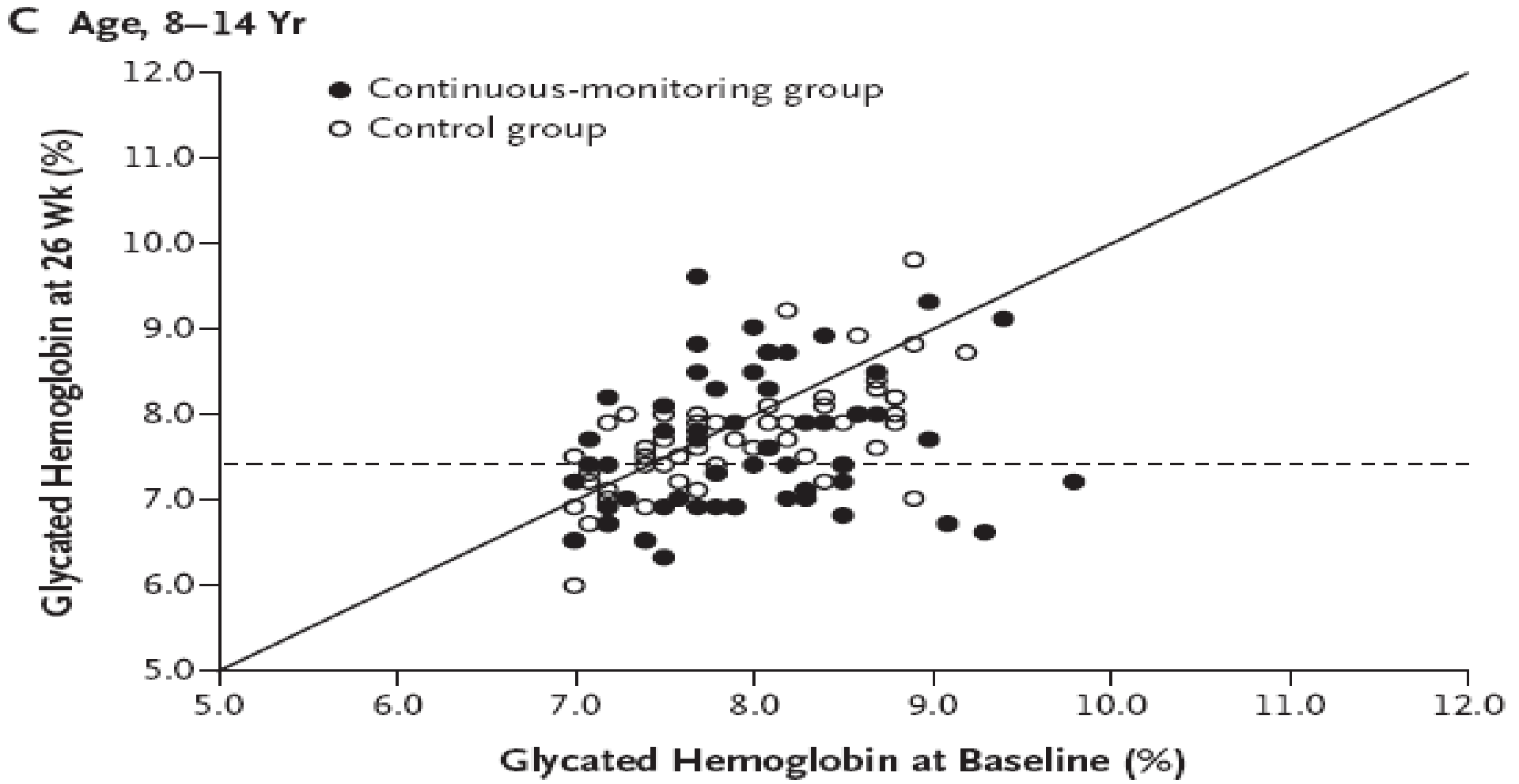


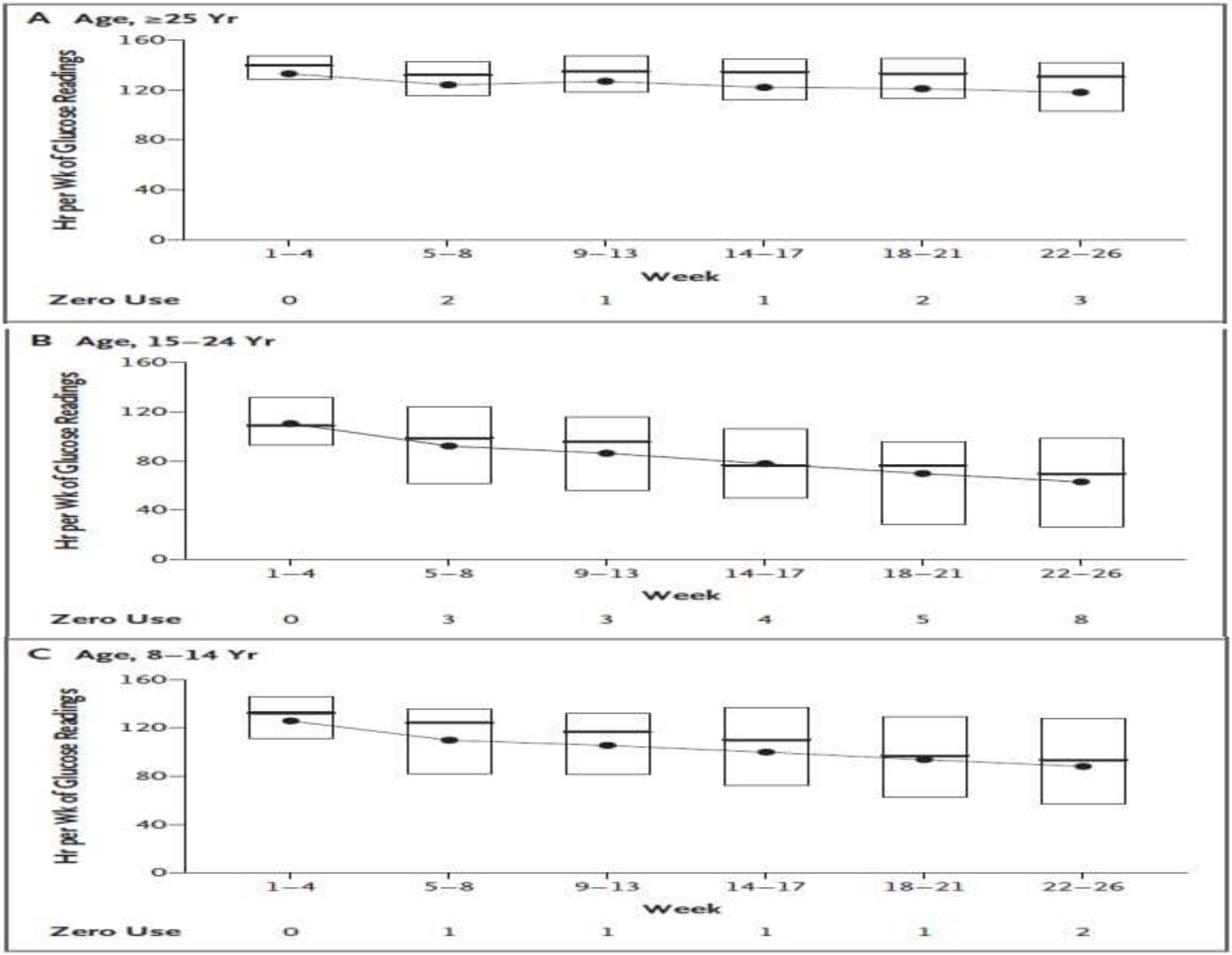
The JDRF CGM Study Group. N Engl J Med 2008;359:1464-76.

CGMS in T1DM: effect on HbA1c

Continuous glucose monitoring and intensive treatment of type 1 diabetes

(JDRF, NEJM, 2008)




A Age, ≥25 Yr
Hr per Wk of Glucose Readings
160
120
80
40
0
1–4
5–8
9–13
14–17
18–21
22–26
Week
Zero Use
0
2
1
1
2
3
B Age, 15–24 Yr
Hr per Wk of Glucose Readings
160
120
80
40
0
1–4
5–8
9–13
14–17
18–21
22–26
Week
Zero Use
0
3
3
4
5
8
C Age, 8–14 Yr
Hr per Wk of Glucose Readings
160
120
80
40
0
1–4
5–8
9–13
14–17
18–21
22–26
Week
Zero Use
0
1
1
1
1
2

Ramadan Fasting: A Study of Changes in Glucose Profiles Among Patients With Diabetes Using Continuous Glucose Monitoring

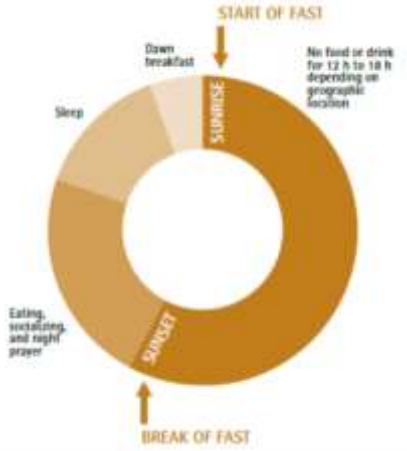
Grande variabilità
inter e intra individuale

correlata al momento della giornata, al tipo di alimenti introdotti, alle modifiche di terapia

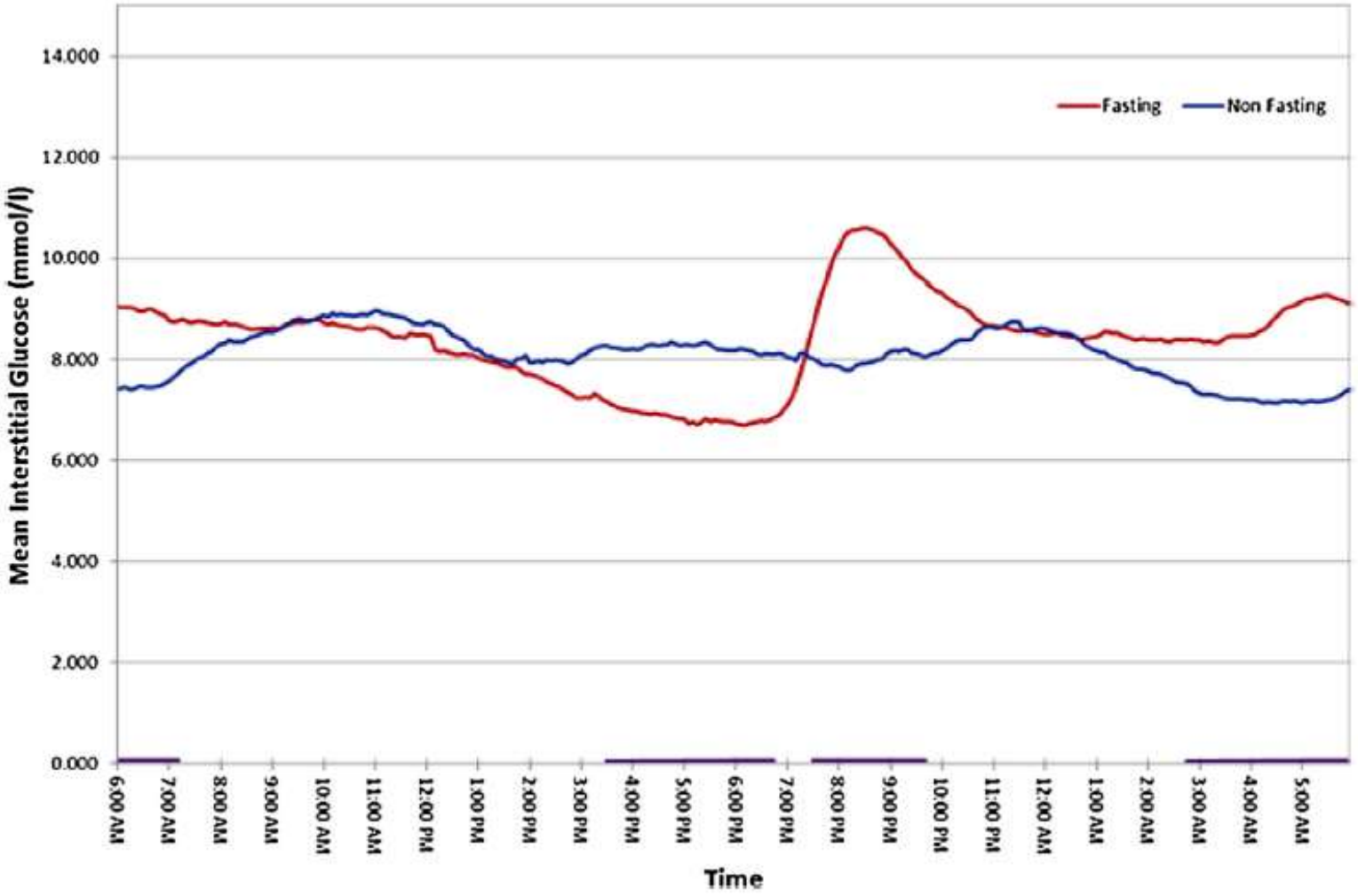
We have explored changes in glucose profiles of patients with type 2 diabetes in a prospective observational study using continuous glucose monitoring (CGM; Medtronic MiniMed CGMS Gold). This was performed for at least 3 consecutive days during Ramadan (2). Nonfasting CGM for the same length of time was obtained on each patient either before or after Ramadan. A mean CGM curve for all patients was obtained during and outside the Ramadan fasting period (3).

NADER LESSAN, MRCP, MD[1]
HAYDAR HASAN, MD[2]
MAHA T. BARAKAT, MRCP[1]

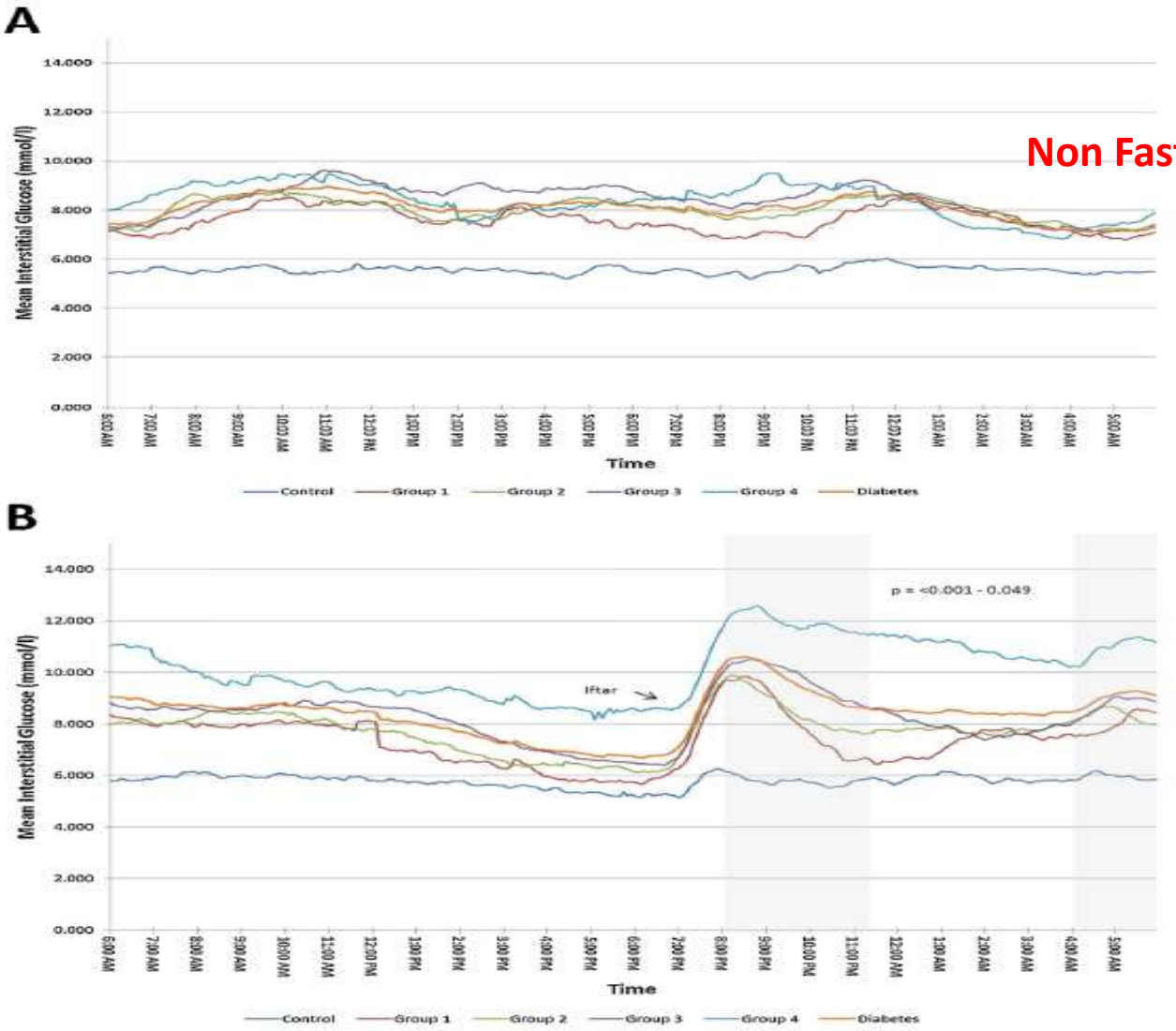
DIABETES CARE, VOLUME 35, MAY 2012



CGMS in RAMADAN



CGMS in RAMADAN



Non Fasting

Fasting

The major glucose rise at iftar time—likely to be greater in patients with poor control—may be related to consumption of sweet and carbohydrate rich food used to break the fast. Other factors including the delay in timing of the medication and hormonal changes of fasting may also contribute to this phenomenon

NADER LESSAN, MRCP, MD[1]
HAYDAR HASAN, MD[2]
MAHA T. BARAKAT, MRCP[1]

DIABETES CARE, VOLUME 35, MAY 2012

Recommendations for Management of Diabetes During Ramadan

Update 2010

Frequent monitoring of glycemia. It is essential that patients have the means to monitor their blood glucose levels multiple times daily. This is especially critical in patients with type 1 diabetes and in patients with type 2 diabetes who require insulin.

Diabetes Care 2014;37:e68–e69 | DOI: 10.2337/dc13-2277

Beliefs of People With Diabetes About Skin Prick During Ramadan Fasting

Shabeen Naz Masood,[1] Muhammad Adil Sheikh,[2] Yasir Masood,[3] Rubina Hakeem,[4] and A. Samad Shera[5]

Studio retrospettivo osservazionale sulle credenze e la pratica dell'autocontrollo durante il Ramadan in Pakistan
Associazione Pazienti e Università di Karaki

860 persone, età 51,5 +- 13,8
91% con diabete tipo 2, di questi il 40% insulinotrattati
Questionario a domande chiuse

Il 77% non fa autocontrollo, nella paura di dovere interrompere il Ramadan
Il 40% degli insulino trattati non ha mai eseguito autocontrollo durante il mese di digiuno

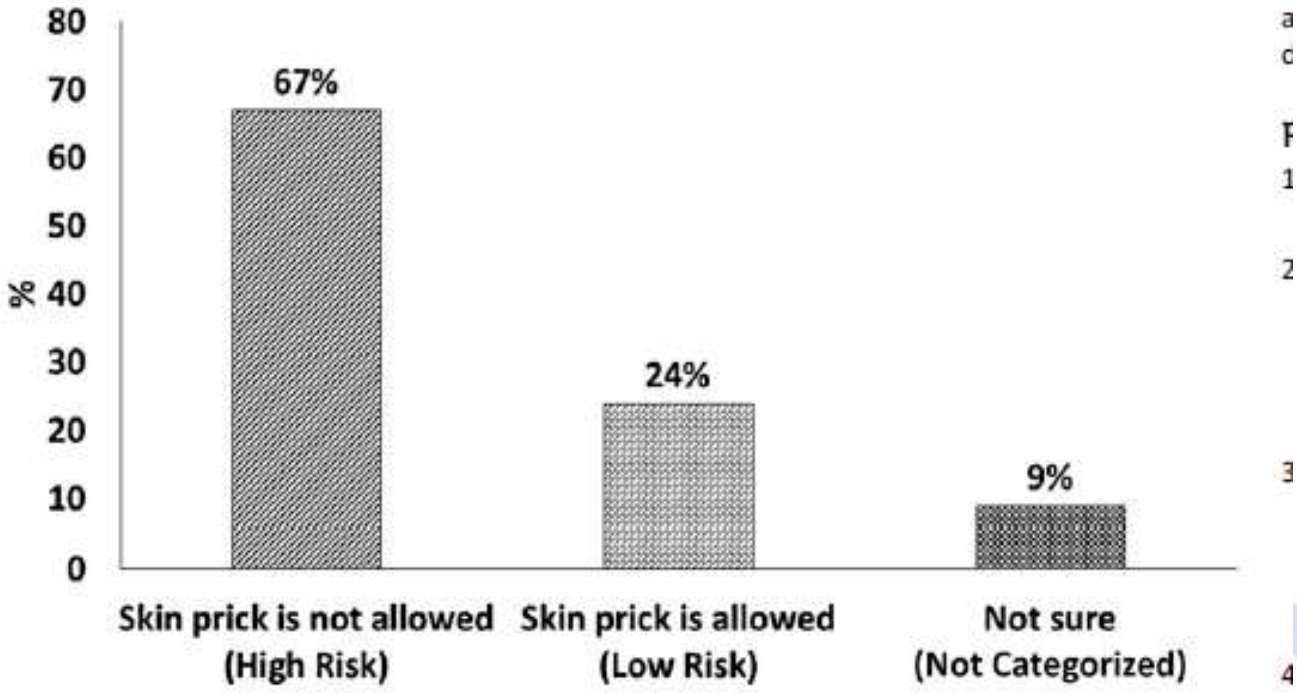


Figure 1—Risk-based categorization of people with diabetes according to their belief about skin prick during Ramadan fasting.

Il 44% non ha fatto percorsi educativi alla gestione del diabete e Ramadan

DIABETICMedicine

DOI: 10.1111/j.1464-5491.2011.03563.x

Article: Treatment

Ramadan Prospective Diabetes Study: the role of drug dosage and timing alteration, active glucose monitoring and patient education

M. Y. Ahmedani[1], M. S. Haque[1], A. Basit[1], A. Fawwad[2] and S. F. D. Alvi[2]

[1]Department of Medicine and [2]Research Department, Baqai Institute of Diabetology and Endocrinology, Baqai Medical University, Karachi, Pakistan

Accepted 17 December 2011

All subjects with Type 1 or Type 2 diabetes who gave a history of fasting in the previous year, and who showed intention to fast for at least 15 days in the coming Ramadan, were considered eligible to participate and were recruited in to the study.

	Male	Female	Overall	*P*-value*
n	58	52	110	
Age (years)	51.63 ± 11.47	48 ± 12.09	49.96 ± 11.85	0.127
Duration of diabetes (years)	11.56 ± 7.34	10.94 ± 6.76	9.91 ± 7.01	0.723
Type 1 diabetes	1 (1.7%)	2 (3.8%)	3 (2.72%)	
Type 2 diabetes	57 (98.3%)	50 (96.2%)	107 (97.27%)	0.495
BMI (kg/m^2)	27.06 ± 4.53	29.42 ± 5.45	28.18 ± 5.1	0.018
Systolic blood pressure (mmHg)	127.38 ± 19.15	126.08 ± 27.88	126.78 ± 23.48	0.777
Diastolic blood pressure (mmHg)	78.54 ± 10.4	78.61 ± 9.4	78.58 ± 9.91	0.972
HbA_{1c}				
mmol/mol	80 ± 5	80 ± 2	80 ± 3	0.955
%	9.46 ± 2.62	9.43 ± 2.33	9.45 ± 2.47	
Cholesterol (mmol/l)	4.62 ± 0.91	4.70 ± 1.17	4.65 ± 1.03	0.737
HDL (mmol/l)	0.94 ± 0.19	0.99 ± 0.19	0.97 ± 0.19	0.282
LDL (mmol/l)	2.79 ± 0.71	3.01 ± 0.93	2.88 ± 0.82	0.287
Triglycerides (mmol/l)	1.77 ± 1.01	2.07 ± 1.04	1.90 ± 1.03	0.245
Type of treatment				
Oral hypoglycaemic agents	17 (29.31%)	19 (36.53%)	36 (32.7%)	0.472
Insulin	18 (31.03%)	11 (21.15%)	29 (26.36%)	
Oral hypoglycaemic agents + insulin	23 (39.65%)	22 (42.3%)	45 (40.90%)	

Table 1 Schedule of blood glucose readings recorded on consecutive days

	First reading	Second reading
Set 1	Pre-dawn (before Sehar)	Pre-dusk (before Iftar)
Set 2	Two hours post-dawn (after Sehar)	Two hours post-dusk (after Iftar)
Set 3	Midday	Two hours post-dusk (after Iftar)
Set 4	Midday	Pre-dawn (before Sehar)
Set 5	Pre-dusk (before Iftar)	Two hours post-dusk (after Iftar)

		Pre-dawn (before Sehar)	Post-dawn (after Sehar)	Midday	Pre-dusk (before Iftar)	Post-dusk (after Iftar)
Hypoglycaemia (mmol/l)	< 2.22	0	0	0	0	1
	2.22–3.05	7	2	5	5	2
	3.11–3.88	21	3	14	13	9
	Total	28	5	19	18	12
Hyperglycaemia (mmol/l)	11.11–13.88	139	42	74	36	115
	13.94–16.66	73	20	24	5	65
	> 16.66	49	14	23	7	46
	Total	261	76	121	48	226

The highest frequencies of hypo- and hyperglycaemic episodes were observed pre-dawn. None of the patients developed diabetic ketoacidosis or hyperglycaemic hyperosmolar state.

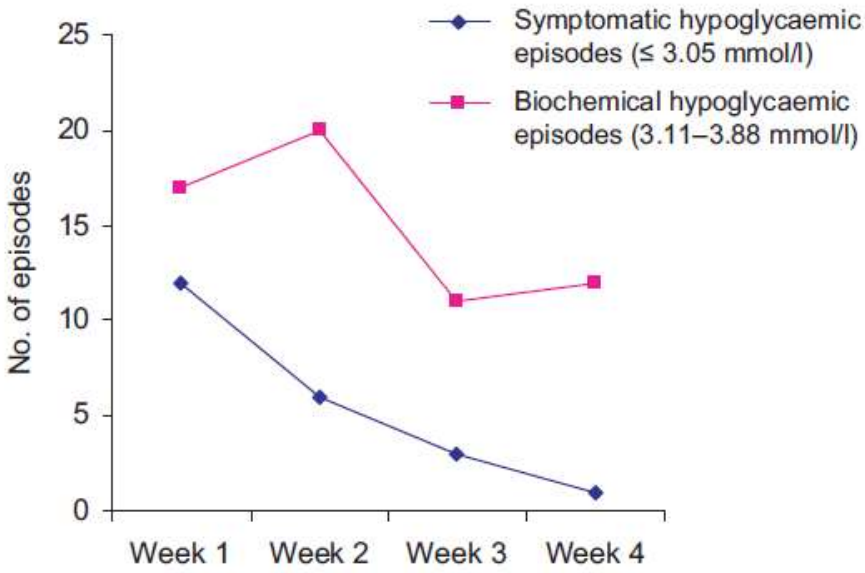


FIGURE 2 Symptomatic and biochemical hypoglycaemic episodes over the whole month

Active glucose monitoring throughout the holy month of Ramadan enabled us to pick up more hypoglycaemic episodes (60 episodes) that were asymptomatic and did not require active intervention. However, out of 22 episodes of symptomatic hypoglycaemia, 18 episodes occurred in three patients who had poor glycaemic control pre-Ramadan and their drug dosages and timings were not altered during Ramadan by their respective treating physicians. Hence, it may be beneficial to alter and adjust drug dose and timing during Ramadan even in patients with poor glycaemic control.

In this prospective study from Pakistan, we observed that, with active glucose monitoring, alteration of drug dosage and timing, dietary counselling and patient education, the majority of the patients did not have any serious acute complications of diabetes during Ramadan. Symptomatic hypoglycaemic episodes occurred in seven patients with only one patient having an episode of severe hypoglycaemia. Although hyperglycaemic episodes occurred more than hypoglycaemic episodes, none of the patients developed diabetic ketoacidosis or hyperglycaemic hyperosmolar state and none required hospitalization. Based on these findings, it seems that the composite effect of the above modifications can enable patients with diabetes to fast without major complications.


Preparing for
Ramadan

Education of patients is the cornerstone of safe fasting, which is needed on both an individual and large-scale level, and this is the responsibility of diabetes care team members.

TARIK A. ELHADD, MD
ABDULLAH A. AL-AMOUDI, MD

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DIAlogue
Diabete e relazioni transculturali

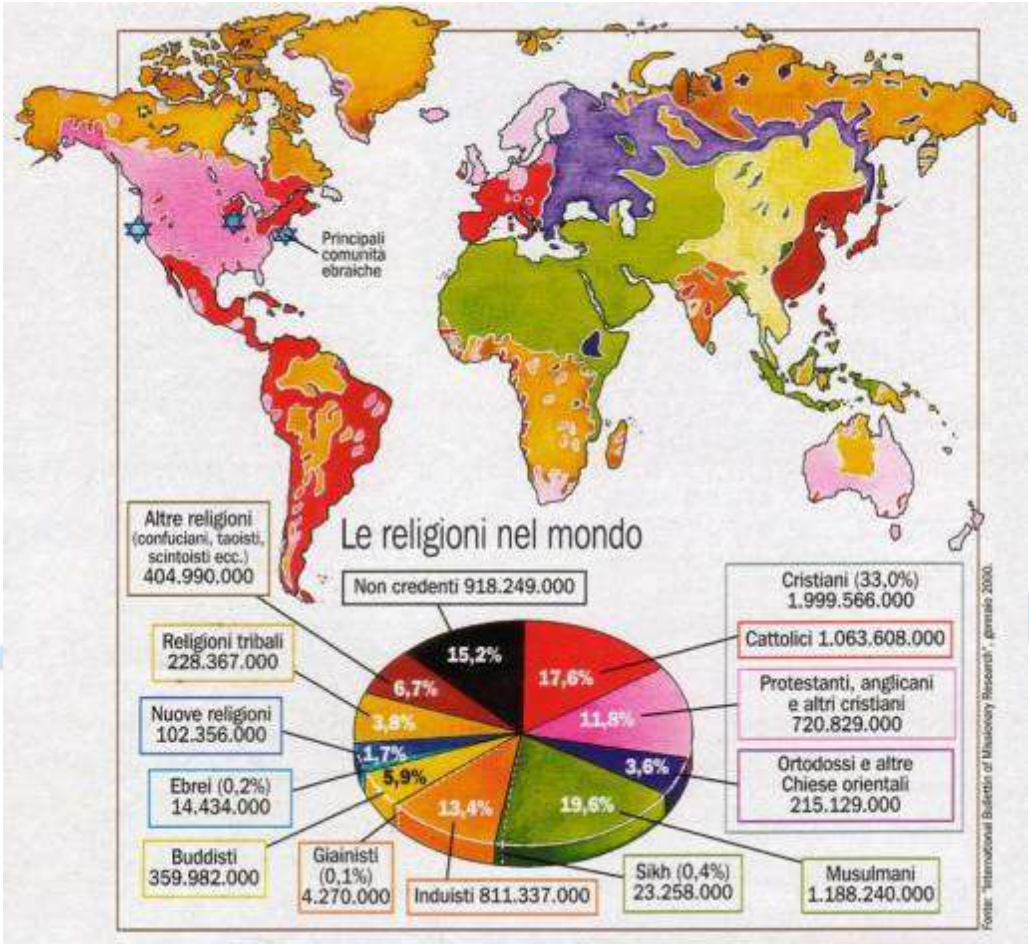




Le Quattro Aree Educative

- Programmazione dei pasti e valutazioni dietetiche
- Esercizio fisico
- Monitoraggio glicemico
- Riconoscimento e gestione delle complicanze

Differenze culturali, ambientali, sociali ed economiche



Counseling



- **Empatia**
- **Ascolto attivo**
- **Comunicazione non direttiva**
- **Autoconsapevolezza**



DIARIO DEL MESE RAMADAN

di .....

DATA:_____

PASTO	ALIMENTI	QUANTITA'	GLICEMIA PRE PASTO	GLICEMIA 2 ORE DOPO	GLICEMIA OCCASIONALE (ora)	INSULINA U.I.	ATTIVITA' FISICA/PREGHIERA (intensità: +/++/+++)
SUHUR (pasto consumato prima del sorgere del sole) ORE:							
EVENTUALE ROTTURA DEL DIGIUNO ORE:							
IFTAR (pasto dal tramonto alla rottura del digiuno) ORE:							
ORE:							
ORE:							