

Dall'Automonitoraggio glicemico all'ottimizzazione della terapia insulinica per migliorare gli esiti di cura

Giorgio Grassi



The image shows the cover of a brochure for a national training course. The background is a landscape with green fields and trees with yellow autumn foliage. At the top left is the AMD logo (Associazione Medici Diabetologi) with the year 1974. To its right is a smaller logo with the word 'subito' and a group of people. Below these is the 'subito!no' logo. The main title is 'Corso di Formazione Nazionale AMD'. Below that is the text: 'MISURARE (... subito!no ... MISURA...) I PROCESSI DI SALUTE ED ASSISTENZIALI PER MIGLIORARE GLI OUTCOME DI SALUTE E DI CURA'. At the bottom, the location is 'Locanda del Sant'Uffizio Cioccaro di Penango - Asti' and the dates are '10-11-12 novembre 2011'.

AMD
1974
ASSOCIAZIONE
MEDICI
DIABETOLOGI

subito!
no

subito!
no

Corso di Formazione
Nazionale AMD

MISURARE (... subito!no ... MISURA...)
I PROCESSI DI SALUTE ED ASSISTENZIALI
PER MIGLIORARE GLI OUTCOME
DI SALUTE E DI CURA

Locanda del Sant'Uffizio
Cioccaro di Penango - Asti

10-11-12 novembre
2011



- L'autocontrollo glicemico non continuativo è potenzialmente utile per la persona con diabete tipo 2 in terapia orale o dietetica, ma non sono disponibili chiare evidenze di efficacia sul controllo glicemico. (**Livello della prova VI, Forza della raccomandazione C**)

- Per ottenere un buon controllo glicemico e raggiungere gli obiettivi glicemici post-prandiali può essere utile l'autocontrollo glicemico post-prandiale. (**Livello della prova VI, Forza della raccomandazione B**)

Standard italiani per la cura del diabete mellito, Diabete Italia, AMD, SID, 2007-2010



- È necessario istruire il paziente all'autocontrollo glicemico, valutare periodicamente la correttezza dell'utilizzo del glucometro e la capacità di modificare la terapia sulla base dei valori misurati, eventualmente facendo uso di un algoritmo condiviso. (Livello della prova VI, Forza della raccomandazione B)

- L'istruzione all'autocontrollo glicemico deve inserirsi in un programma educativo condotto e controllato a medio-lungo termine da personale infermieristico con esperienza in campo diabetologico. (Livello della prova VI, Forza della raccomandazione B)

Standard italiani per la cura del diabete mellito, Diabete Italia, AMD, SID, 2007-2010

Quali i vantaggi dell'autocontrollo per la gestione del rapporto con la “malattia” e la sua “conduzione”

- Nel diabete in terapia insulinica l'autocontrollo è strumento di gestione della terapia
- Per tutti i diabetici l'autocontrollo può “educare” ad una miglior gestione e valorizzare l'intervento sullo “stile di Vita”

TYPE 2 DIABETES

National clinical guideline for management
in primary and secondary care (update)

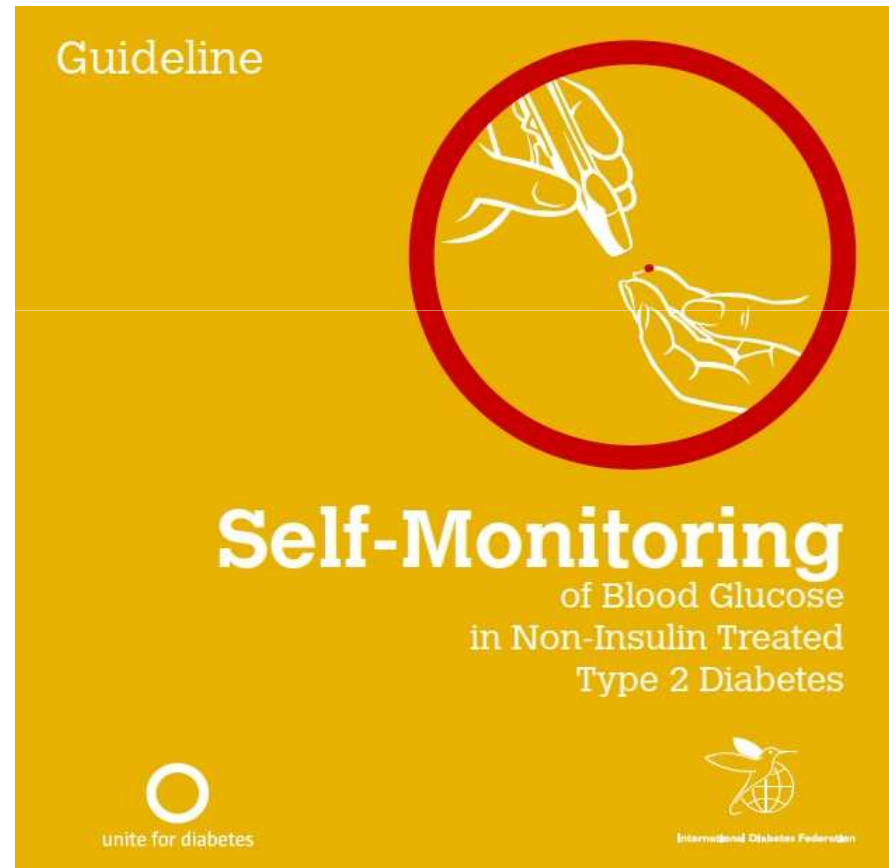
- Recent information from the Health Commission survey in 2007 suggests that only 11% of people with Type 2 diabetes report being offered structured education (Healthcare Commission. *Managing diabetes: improving*

services for people with diabetes. London: Commission for Healthcare Audit and Inspection, 2007).

This suggests that the majority of healthcare providers have found it difficult to implement and resource quality education programmes that meet these standards.

Type 2 diabetes: national clinical guideline for management in primary and secondary care (update). London: Royal College of Physicians, 2008.

Automonitoraggio glicemico ed avvio terapia insulinica



DIABETES TECHNOLOGY & THERAPEUTICS
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DOI: 10.1089/dia.2011.0163

Original Article

Telecare Provides Comparable Efficacy to Conventional Self-Monitored Blood Glucose in Patients with Type 2 Diabetes Titrating One Injection of Insulin Glulisine—the ELEONOR Study

Stefano Del Prato, M.D.,¹ Antonio Nicolucci, M.D.,² Augusto C. Lovagnini-Scher, M.D.,³
Salvatore Turco, M.D.,⁴ Sergio Leotta, M.D.,⁵ and Giacomo Vespasiani, M.D.,⁶
on behalf of the ELEONOR Study Group

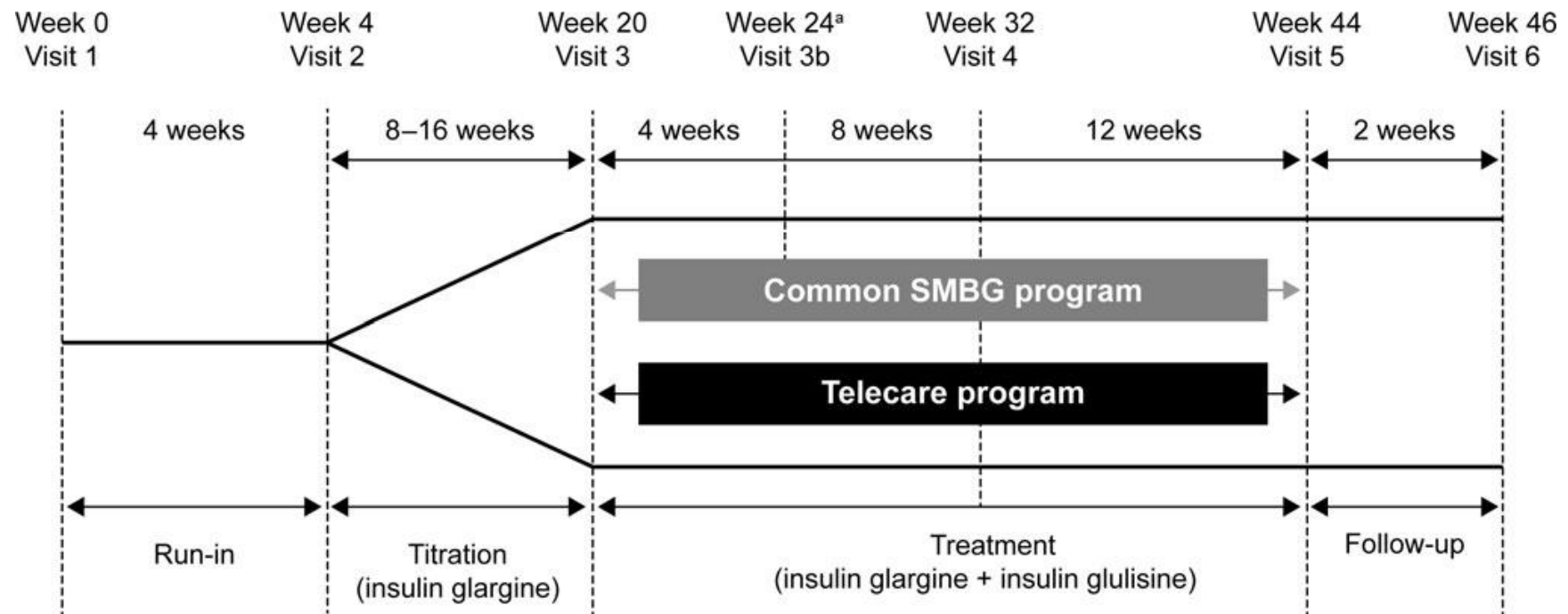
Insulin Titration in Type 2 diabetic patients

Diabetes, Obesity and Metabolism 13: 1020–1027,
2011.

Effects of initiation and titration of a single pre-prandial dose of insulin glulisine while continuing titrated insulin glargine in type 2 diabetes: a 6-month 'proof-of-concept' study

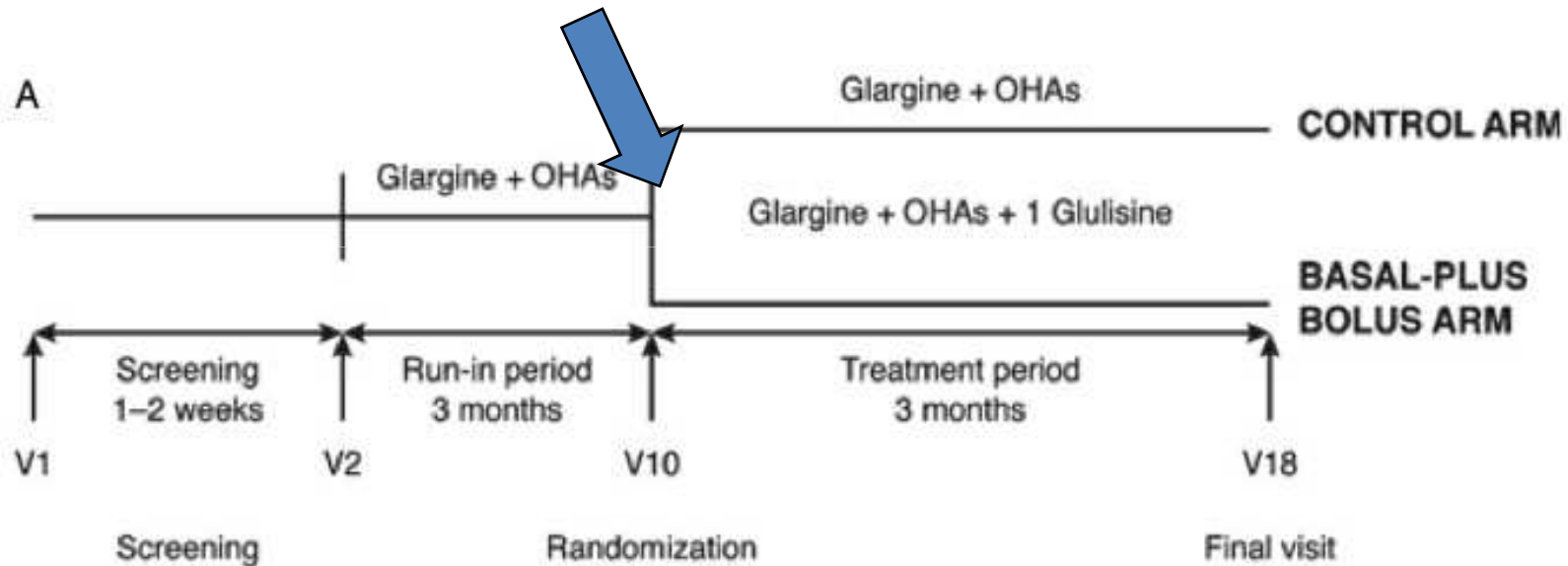
Basal-Plus: prandial insulin titration

The treatment phase began when a patient achieved FPG < 7 mmol/L (126 mg/dl), after 8, 12, or 16 weeks of the titration phase



Basal-Plus: prandial insulin titration

RANDOMIZZATI SE A1C $\geq 7\%$



United Kingdom Prospective Diabetes Study (UKPDS) Glucose Study 2

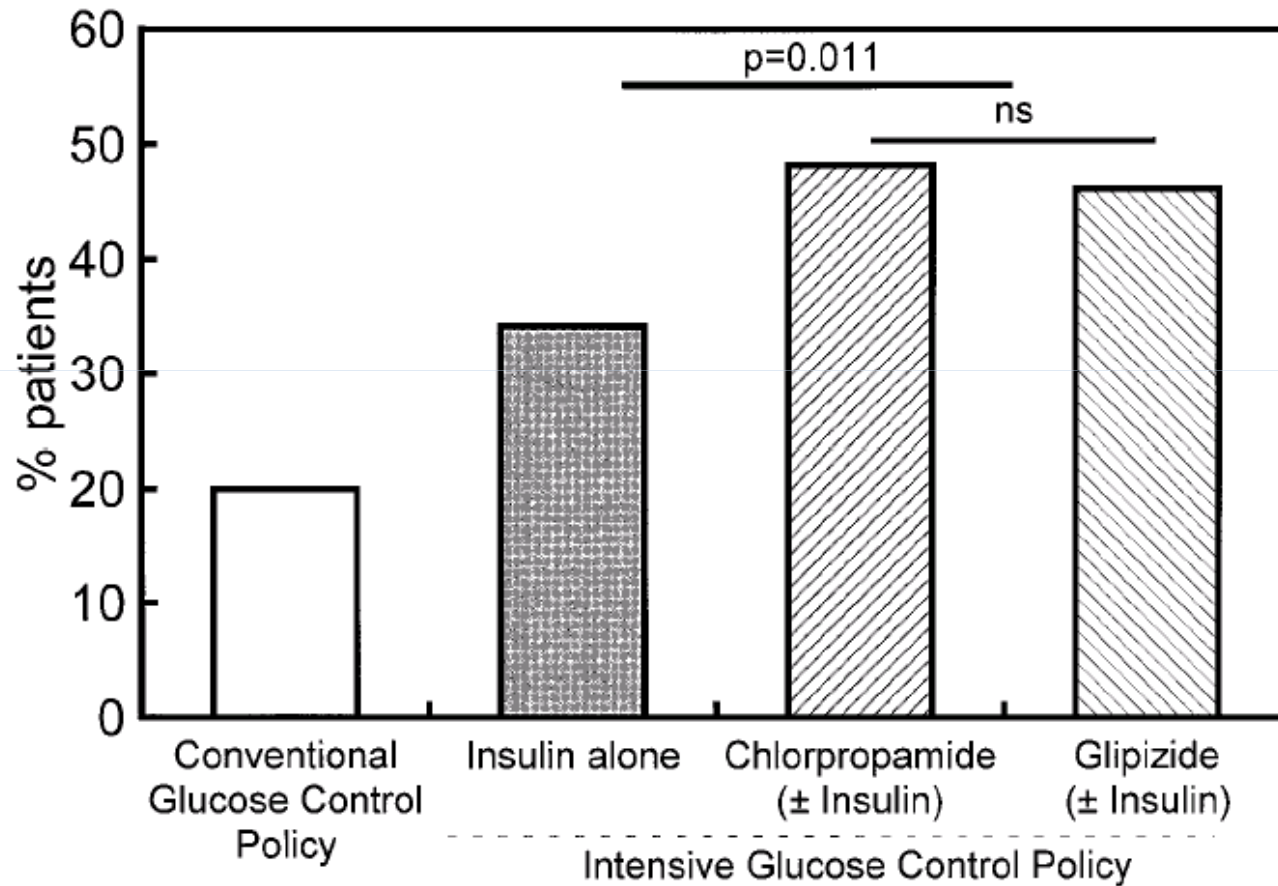
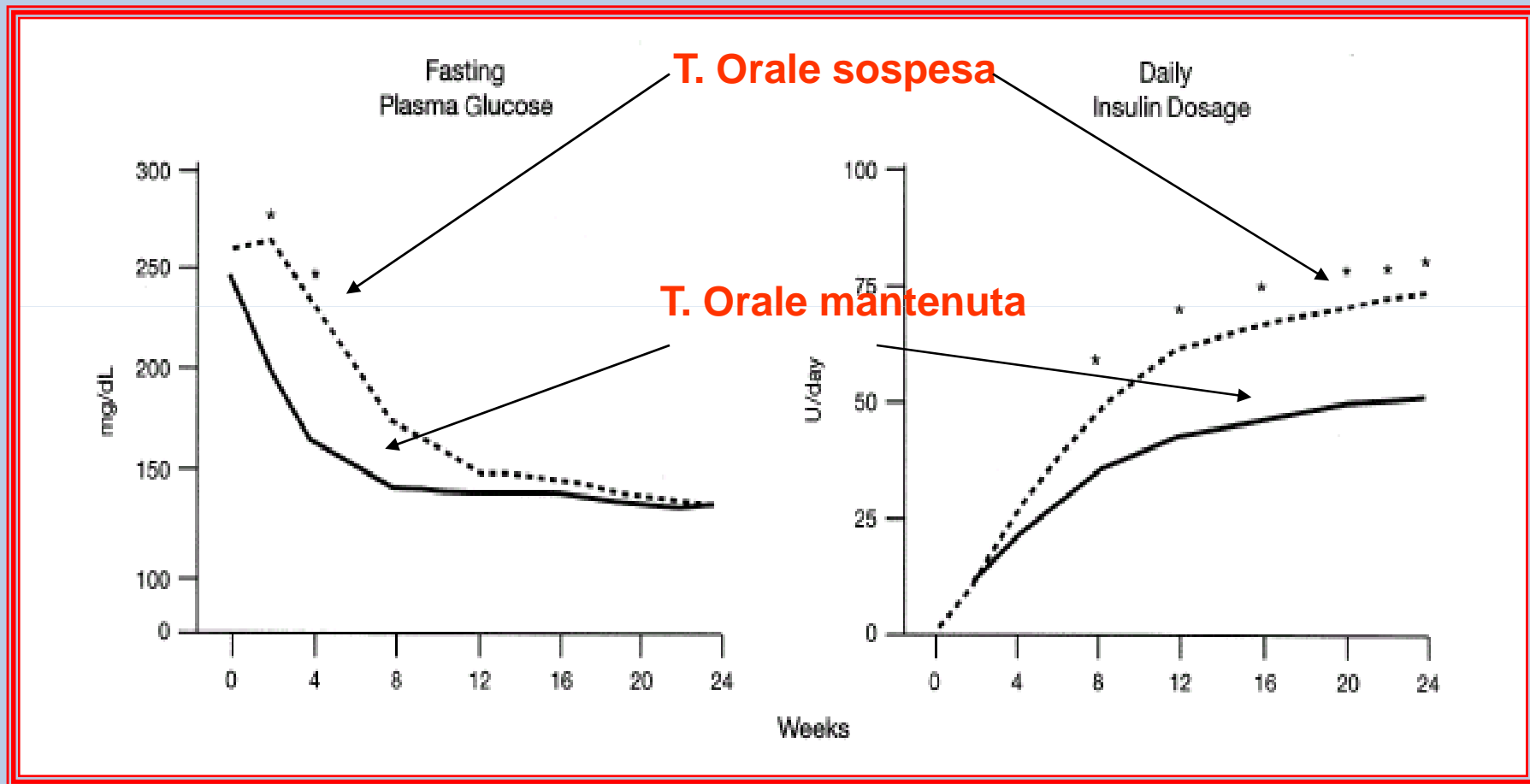


Figure 4—Proportion (%) of patients achieving HbA_{1c} <7% at 6 years.

Mantenere la terapia orale all' avvio dell' insulina



Diabetes Care. 1998;21: 1052-1057

Eleonor Study: Titolazione Basale

TABLE 1. ALGORITHMS FOR THE TITRATION OF INSULIN GLARGINE AND INSULIN GLULISINE

<i>Titration algorithm</i>	<i>Dose</i>
Basal insulin algorithm (mean FPG values from preceding 2 days) ^a	
Starting daily dose	10 U
> 10 mmol/L 180 mg/dl	+6 U
8.9–10 mmol/L 160-180 mg/dl	+5 U
7.8–8.8 mmol/L 140-159 mg/dl	+4 U
6.7–7.7 mmol/L 120-139 mg/dl	+2 U
5.6–6.6 mmol/L 100-119 mg/dl	+1 U
3.9–5.5 mmol/L 70-99 mg/dl	No change
<3.9 mmol/L <70 mg/dl	-2 U

Improvement of glycemic control in subjects with poorly controlled type 2 diabetes: comparison of two treatment algorithms using insulin glargine. Export

by: [Melanie Davies](#), [Fred Storms](#), [Simon Shutler](#), [Monique Bianchi-Biscay](#), [Ramon Gomis](#), [ATLANTUS Study Group](#)

Diabetes care, Vol. 28, No. 6. (June 2005), pp. 1282-1288.

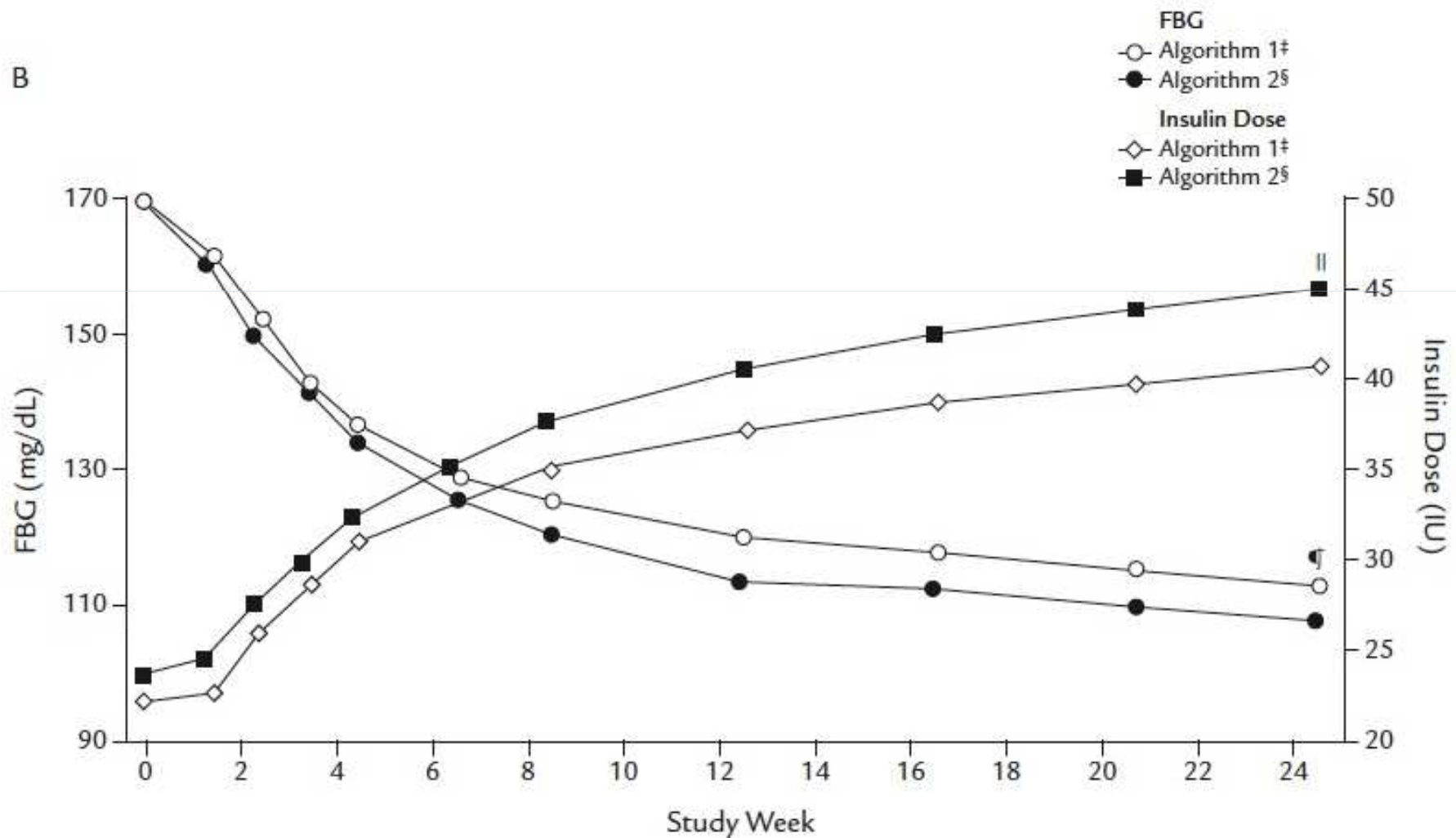
Mean FBG for the previous 3 consecutive days	Increase in daily basal insulin glargine dose (IU)*	
	Algorithm 1: titration at every visit; managed by physician†	Algorithm 2: titration every 3 days; managed by subject†
≥100 mg/dl and <120 mg/dl (≥5.5 mmol/l and <6.7 mmol/l)	0–2 (at the discretion of the investigator)‡	0–2 (at the discretion of the investigator)‡
≥120 mg/dl and <140 mg/dl (≥6.7 mmol/l and <7.8 mmol/l)	2	2
≥140 mg/dl and <180 mg/dl (≥7.8 mmol/l and <10 mmol/l)	4	2
≥180 mg/dl (≥10 mmol/l)	6–8 (at the discretion of the investigator)‡	2

*Target FBG ≤100 mg/dl (≤5.5 mmol/l). †Reviewed by physician at each visit, either in person or over the telephone; titration occurred only in the absence of blood glucose levels <72 mg/dl (<4.0 mmol/l). ‡Magnitude of daily basal dose was at the discretion of the investigator.

Improvement of glycemic control in subjects with poorly controlled type 2 diabetes: comparison of two treatment algorithms using insulin glargine. Export

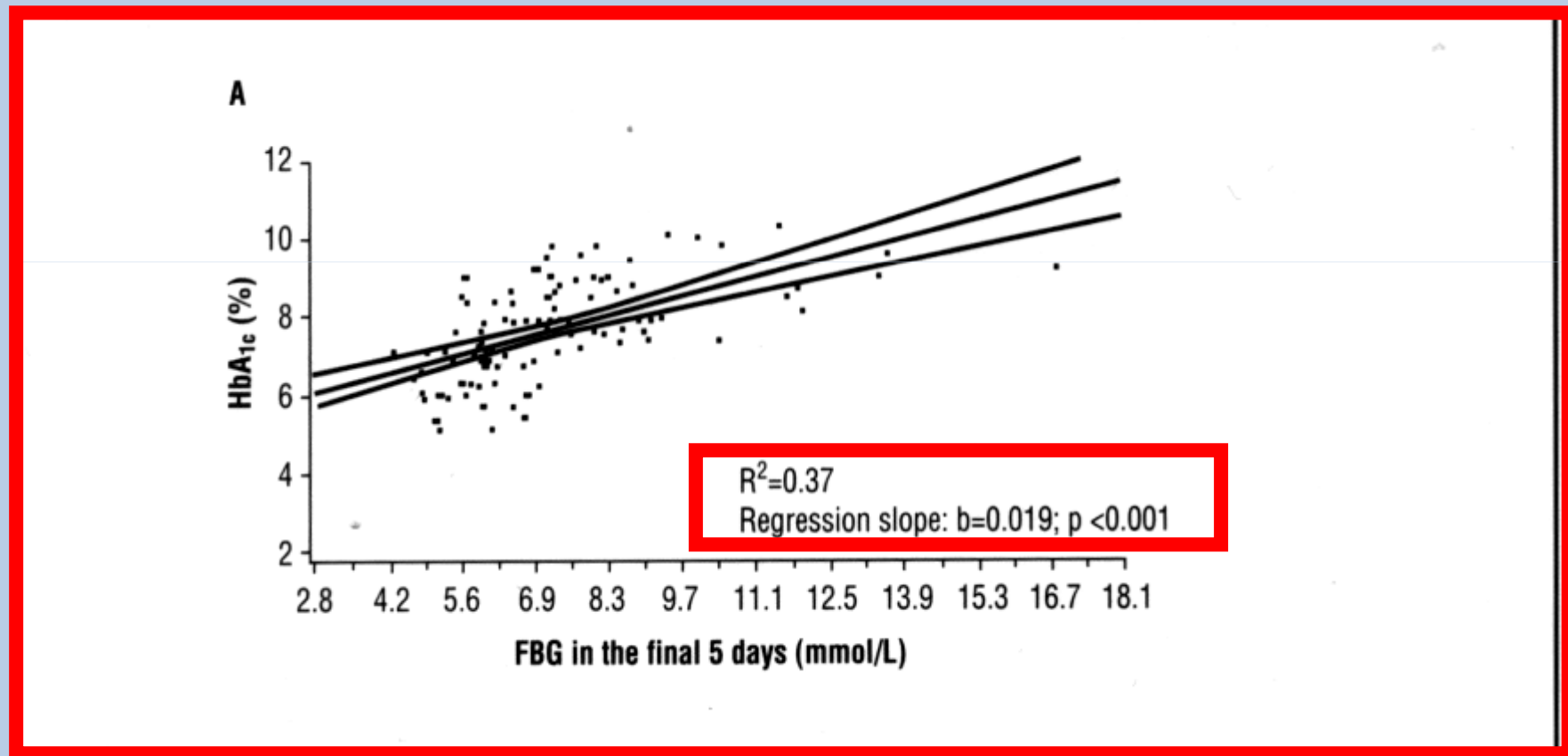
by: [Melanie Davies](#), [Fred Storms](#), [Simon Shutler](#), [Monique Bianchi-Biscay](#), [Ramon Gomis](#), [ATLANTUS Study Group](#)

Diabetes care, Vol. 28, No. 6. (June 2005), pp. 1282-1288.



Aggiustamento della terapia: utilizzo della glicemia al risveglio

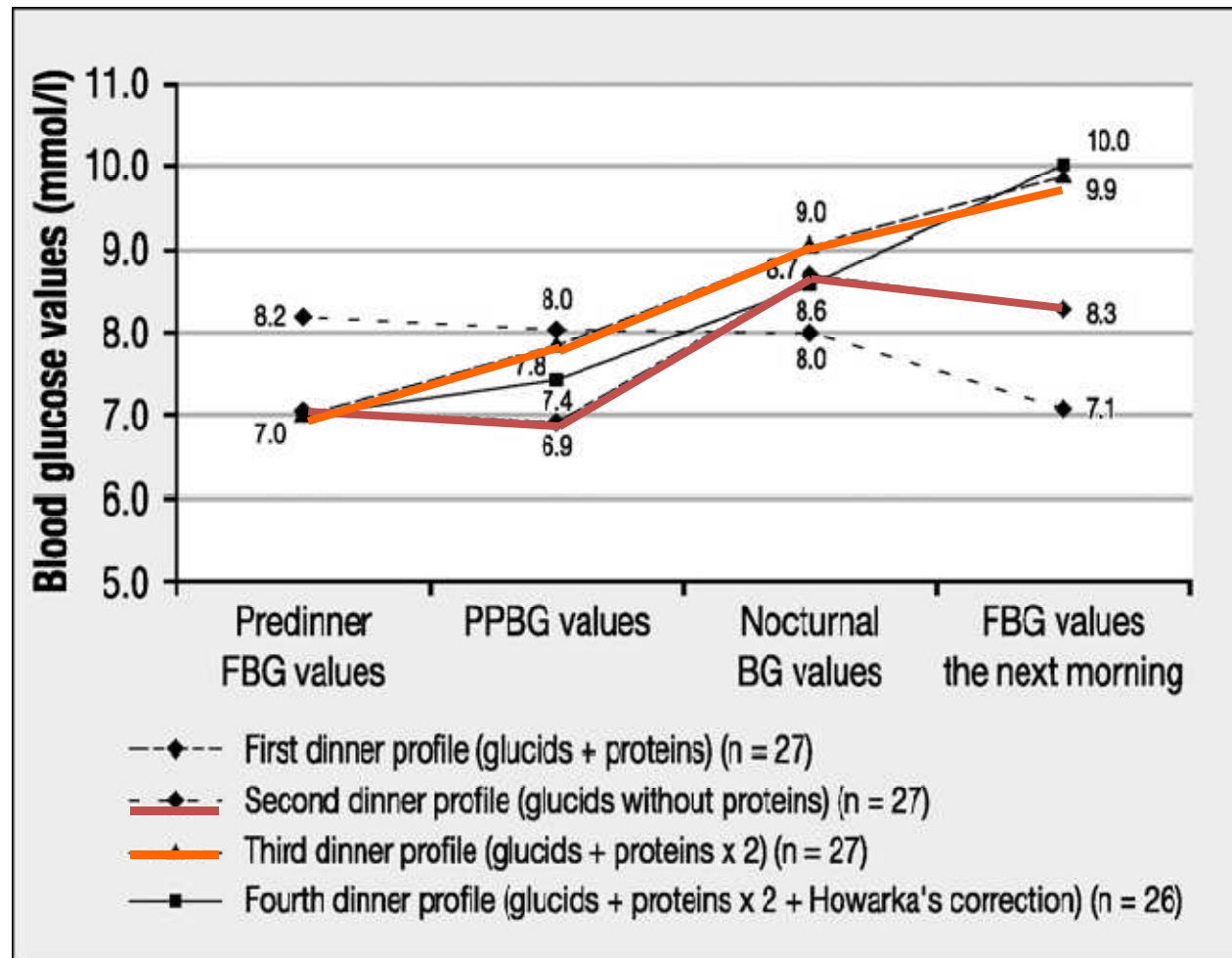
Haupt A, et al diabetologia 2004; 47 (suppl 2): A743



Real-life application and validation of flexible intensive insulin-therapy algorithms in type 1 diabetes patients[☆]

S. Franc^{a,b,*}, D. Dardari^{a,b,1}, B. Boucherie^{a,b}, J.-P. Riveline^{a,b}, M. Biedzinski^{a,b}, C. Petit^{a,b},
E. Requeda^a, P. Leurent^c, M. Varroud-Vial^a, G. Hochberg^a, G. Charpentier^{a,b}

La conoscenza del puro dato glicemico non è sufficiente



Automonitoraggio glicemico ed avvio terapia insulinica

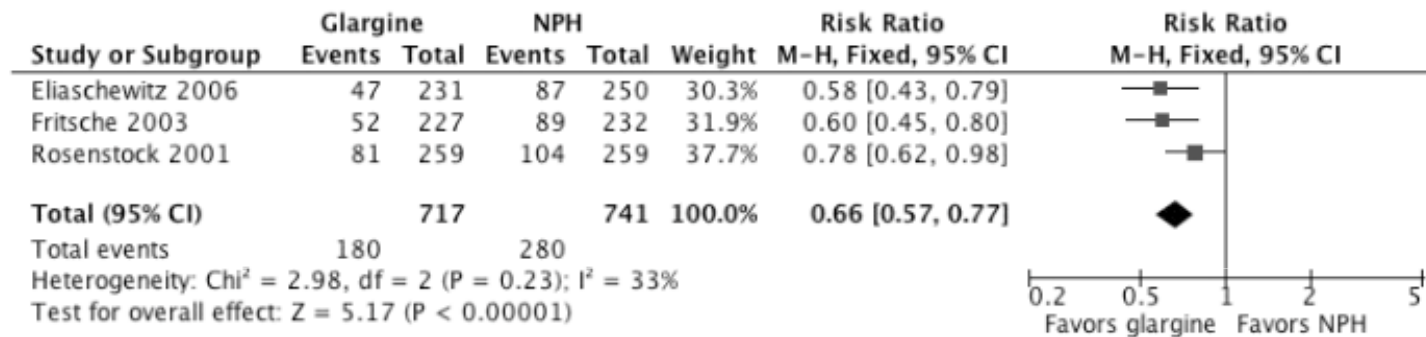
Detection/assessment of fasting hyperglycaemia

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

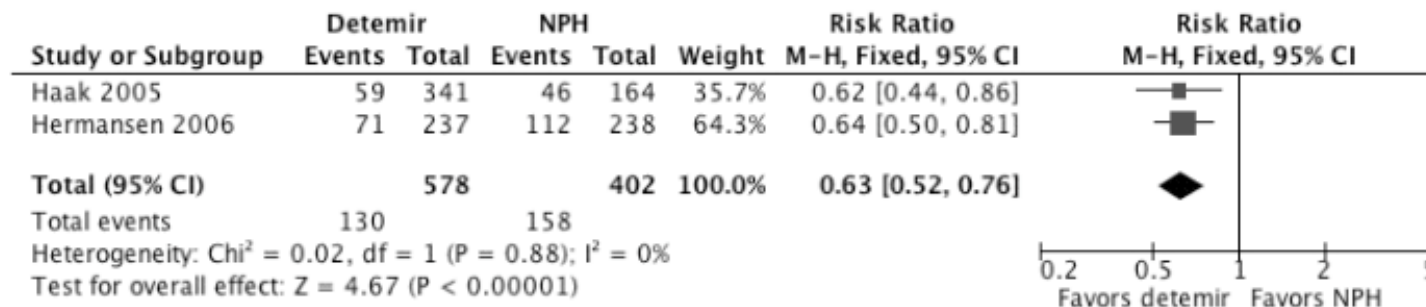
Bedtime and morning fasting SMBG can be used to identify fasting and assess fasting hyperglycaemia.

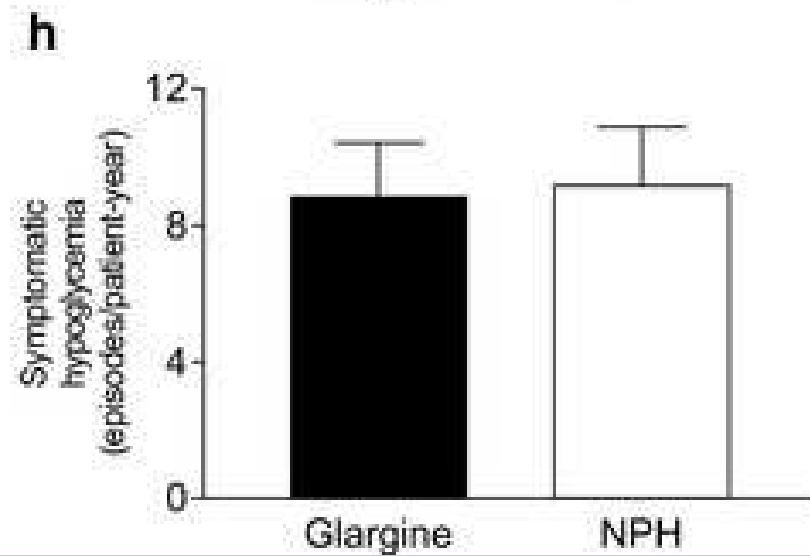
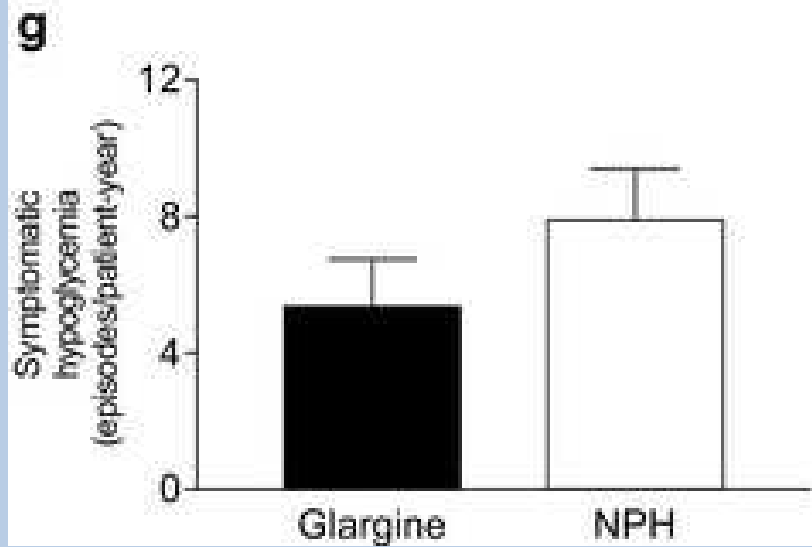
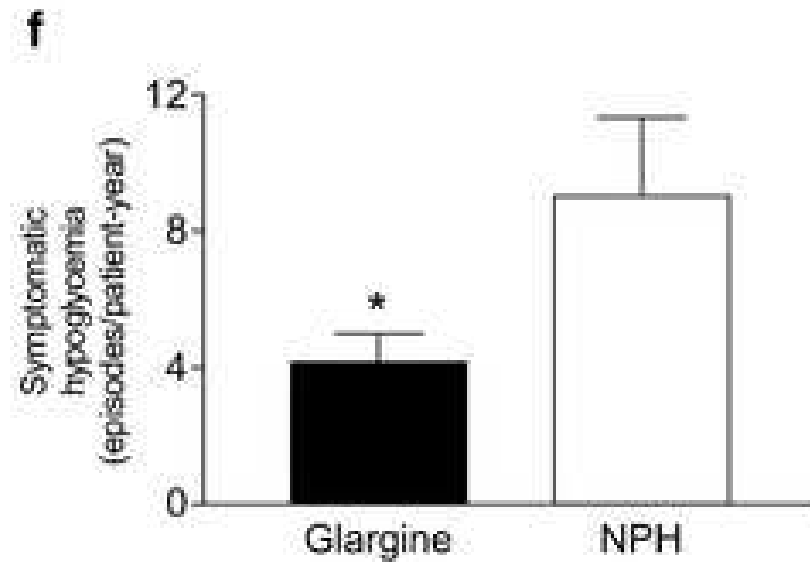
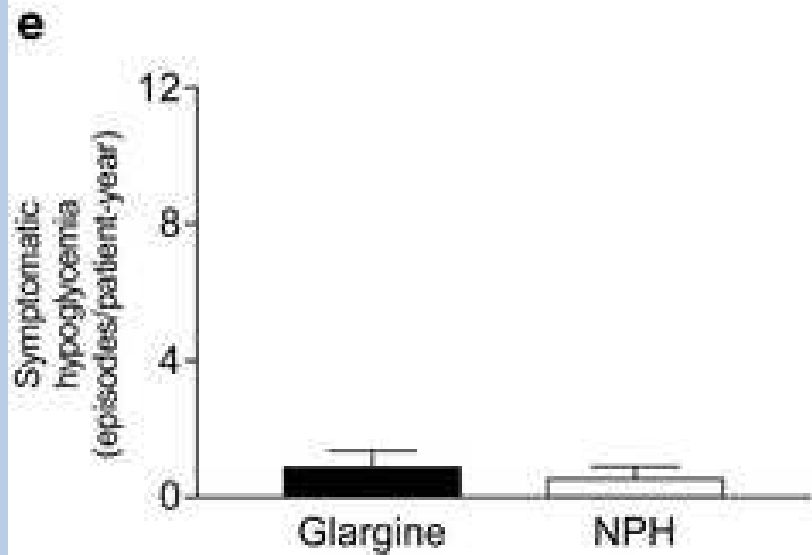
Comparison of nocturnal hypoglycemic risk with long-acting insulin analogs (a) glargine and (b) detemir versus NPH insulin.⁵¹ From Horvath K, et al. Long-acting insulin analogues versus NPH insulin (human isophane insulin) for type 2 diabetes mellitus. Cochrane Database Syst Rev 2007;(2):CD005613.)

A



B

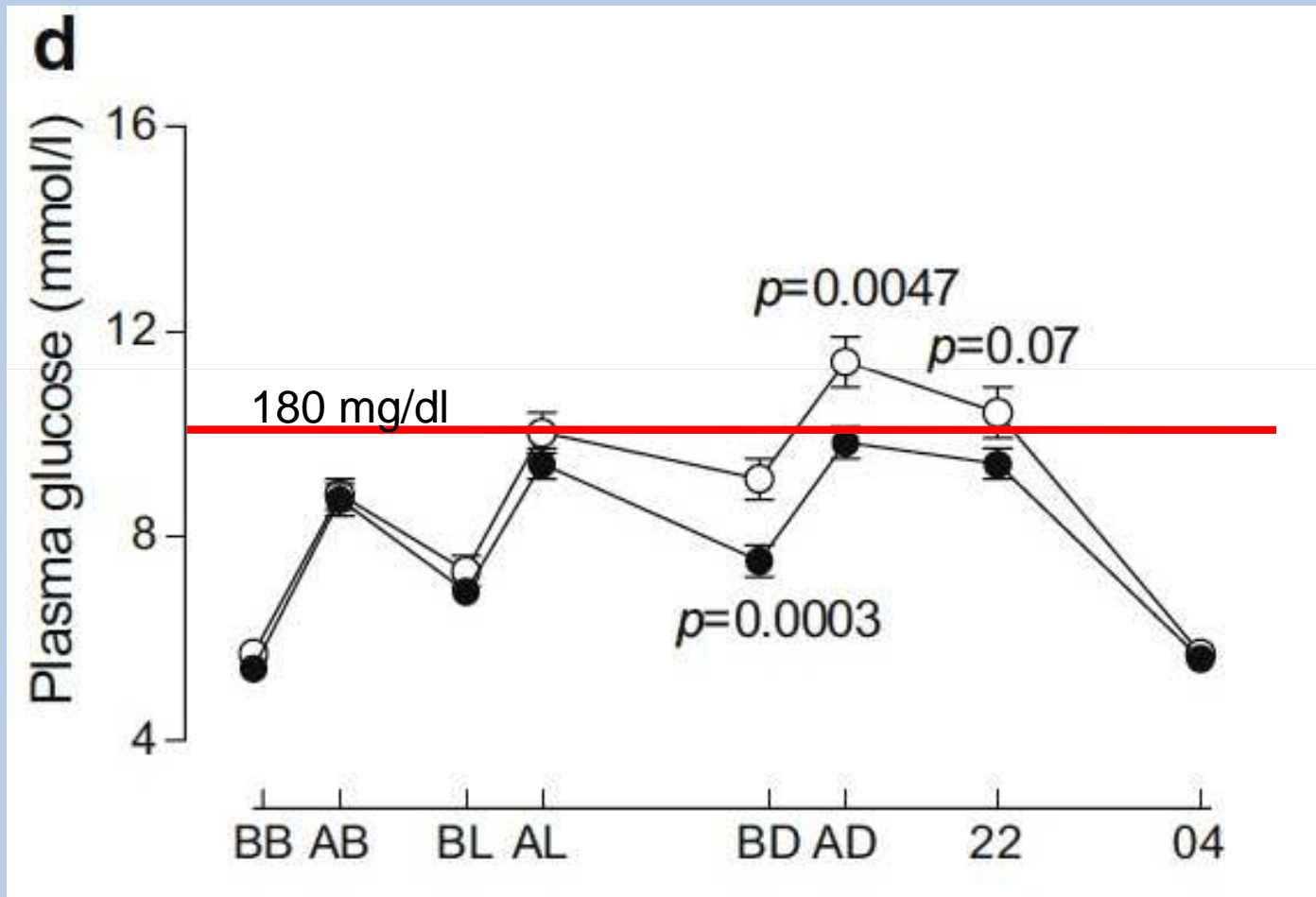




- La titolazione è fattibile con diversi modelli più o meno intensivi
- La titolazione permette il raggiungimento di un target in un periodo di tempo che rientra nelle indicazioni attuali (3-4 mesi)
- Richiede risorse ed organizzazione dell'attività
- Coinvolge in modo attivo il paziente

- Gli studi sono di breve durata
- L'insulinizzazione basale guarda al dato della glicemia a digiuno e A1c non al controllo della glicemia post-prandiale
- Alla luce dei recenti trial (ACCORD ADVANCE) riconsiderare il target

Oltre la Basale: Lanmet study



At 36 weeks, mean HbA1c was 7.14 ± 0.12 (Glargine) and $7.16 \pm 0.14\%$, (NPH)

TABLE 2. STARTING PRANDIAL INSULIN DOSE AND ADJUSTMENTS ALGORITHM

<i>Initiation dose of prandial insulin</i>	
<i>Methods</i>	<i>Initial dose</i>
Fixed initial dose ²¹	4 U
Based on level of postprandial glucose values ²⁰	Glucose values (mmol/L)/2 (1 mmol/L = 18 mg/dL)
Based on patient's weight ²⁶	0.05 U/kg
Based on previous basal insulin dose ²⁷	10% of basal insulin dose
<i>Adjustment algorithm</i>	
<i>Methods</i>	<i>Recommendations</i>
Fixed-increments based on postprandial glucose values above target ²¹	Postprandial glucose value >140 mg/dL: increase +1 U
Based on postprandial glucose values ²⁰	Between 136 and 153 mg/dL: increase +1 U Between 154 and 180 mg/dL: increase +2 U > 180 mg/dL: increase +3 U
Based on previous prandial insulin dose if postprandial glucose values are above target ²⁷	Dose ≤10 U: increase +1 U Dose 11–20 U: increase +2 U Dose >20 U: increase +3 U

The frequency of dose adjustments should be individualized, but changes can be done every 3 days or weekly. Patients should be trained in self-dose adjustments.

Eleonor Study:Titolazione Prandiale

Prandial insulin algorithm (mean PPPG values from preceding 2 days)^b

Starting dose at the meal with the highest postprandial point	0.05 U/kg
>7.8 mmol/L >140 mg/dl	+2 U
7.5–5.6 mmol/L 139-100 mg/dl	No change
<5.6 mmol/L <100 mg/dl	-2 U

^aTitration target was fasting plasma glucose (FPG) <5.6 mmol/L.

^bTitration target postprandial plasma glucose (PPPG)=7.8–5.6 mmol/L.

Basal-Plus: prandial insulin titration

Russia and United Kingdom

Calculation of the initial dose of insulin glulisine for the first injection:

Dose of insulin glulisine prior to the main meal = PPBG of the main meal in mmol/l divided by 2

Treat to target: PPBG \leq 135 mg/dl (7.5 mmol/l)

PPBG \leq 135 mg/dL (7.5 mmol/l)

No change

135 mg/dl (7.5 mmol/l) < PPBG \leq 153 mg/dl (8.5 mmol/l)

+1 U

153 mg/dl (8.5 mmol/l) < PPBG \leq 180 mg/dl (10 mmol/l)

+2 U

PPBG > 180 mg/dl (10 mmol/l)

+3 U

At the discretion of the investigator, small decreases of 1 U of the dose of insulin glulisine are permitted in case of hypoglycaemia

United States

Calculation of the initial dose of insulin glulisine for the first injection:

6 U prior to the main meal. At the same time, the insulin glargine dose was reduced by 6 U and then titrated again the next week

Treat to target: 100 mg/dl (5.6 mmol/l) < BG* \leq 120 mg/dl (6.7 mmol/l)

120 mg/dl (6.7 mmol/l) < BG* \leq 140 mg/dl (7.8 mmol/l)

+1 U

140 mg/dl (7.8 mmol/l) < BG* \leq 180 mg/dl (10 mmol/l)

+2 U

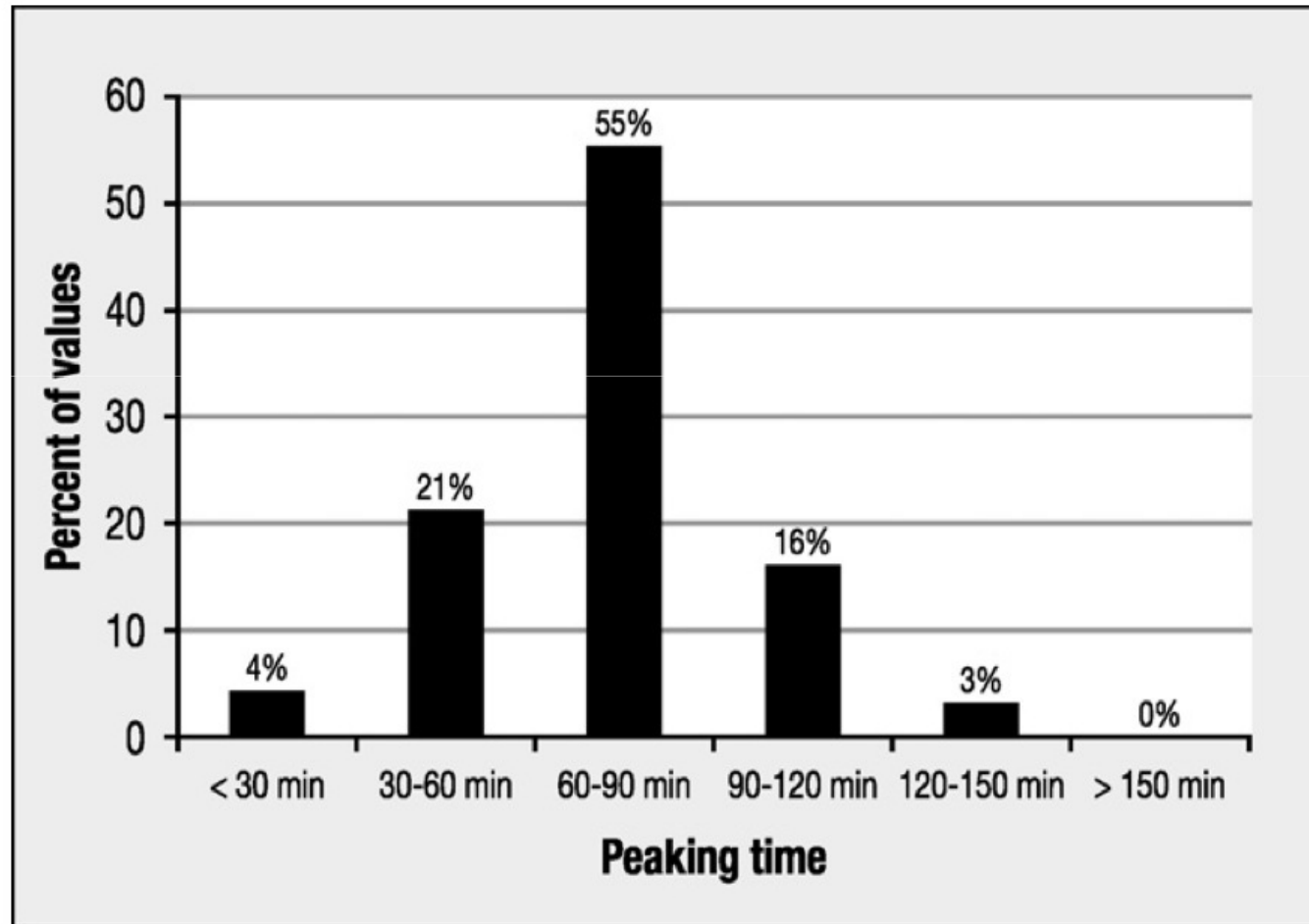
BG* > 180 mg/dl (10 mmol/l)

+2 U

At the discretion of the investigator, small decreases of 1 U of the dose of insulin glulisine are permitted in case of hypoglycaemia

Titration of the prandial dose of insulin glulisine was performed once a week using one of two different algorithms

Insulina Prandiale: picco insulinico



Role of Paired-Meal SMBG

L. Jovanovic *The Diabetes Educator* 2009 35: 1023

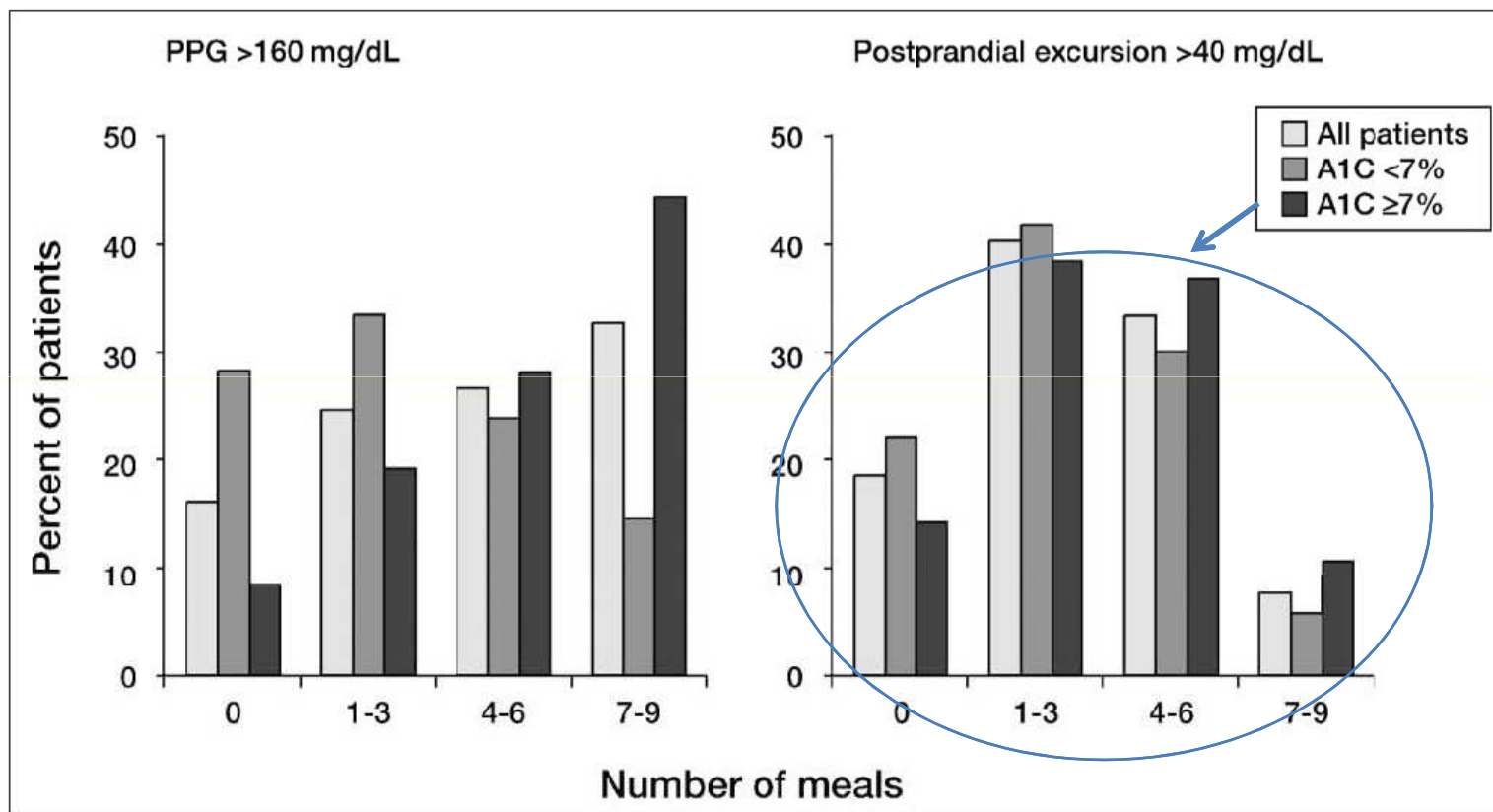
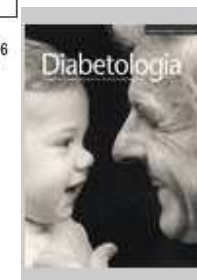


Figure 1. Frequency of PPG >160 mg/dL and glucose excursions >40 mg/dL over 3 days (9 meals) in 3284 noninsulin-treated types 2 diabetes patients.⁶ Source: Bonora E, Corrao G, Bagnardi V, et al. Prevalence and correlates of postprandial hyperglycaemia in a large sample of patients with type 2 diabetes mellitus. *Diabetologia*. 2006;49:846-854. Adapted with permission from Springer-Verlag.



Automonitoraggio glicemico ed avvio terapia insulinica

Meal-based testing

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

Testing in Pairs

Name _____ Date of Birth _____
(For your healthcare provider's records)

The American Diabetes Association (ADA) and American College of Endocrinology (ACE) recommend:

	ADA	ACE
Before meal	70–130 mg/dL	<110 mg/dL
After meal	<180 mg/dL 1–2 hours after the start of the meal	<140 mg/dL 2 hours after the start of a meal

What do I want to learn?

Day	Before	After	Change	Notes:
1				
2				
3				
4				
5				
6				
7				

Schwedes, U., Siebolds, M., Mertes, G., SMBG Study Group, Nov. 2002. Meal-related structured self-monitoring of blood glucose: effect on diabetes control in non-insulin-treated type 2 diabetic patients. *Diabetes care* 25 (11), 1928-1932.

URL <http://view.ncbi.nlm.nih.gov/pubmed/12401734>

Documento di consenso del Gruppo di lavoro AMD: Terapia personalizzata

Iperglicemia preprandiale

- >60% delle rilevazioni glicemiche indicative di iperglicemia
- Target 70-130 mg/dl

Iperglicemia postprandiale

- >60% delle rilevazioni glicemiche indicative di iperglicemia
- Target < 180 mg/dl mg/dl

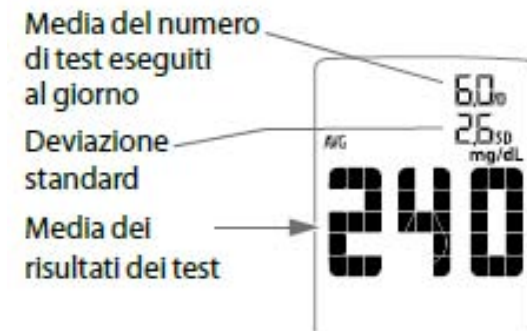
Commento:

Strumenti che esprimano con facilità ed in modo differenziato
Indicatori di iperglicemia nelle diverse fasce: preprandiale,
Post-prandiale

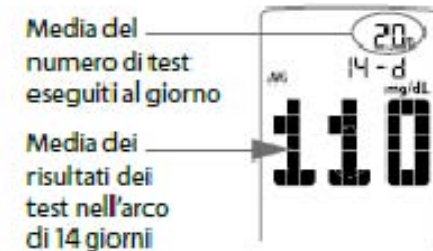
Il glucometro: Componenti per il successo dell'autocontrollo

- Motivazione
- Indicazioni semplici e chiare fornite attraverso un efficace educazione
- Accuratezza
- **Glucometri che con immediatezza fornisco dati necessari alla decisione terapeutica per una analisi efficace**

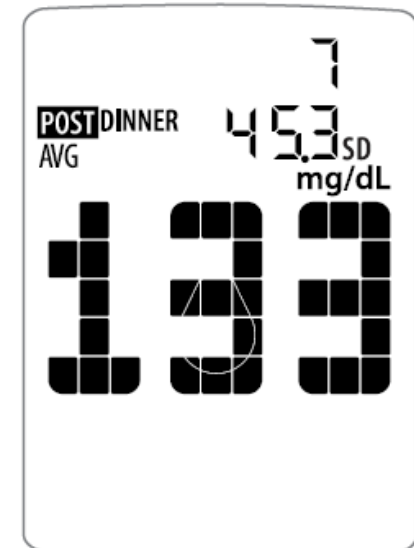
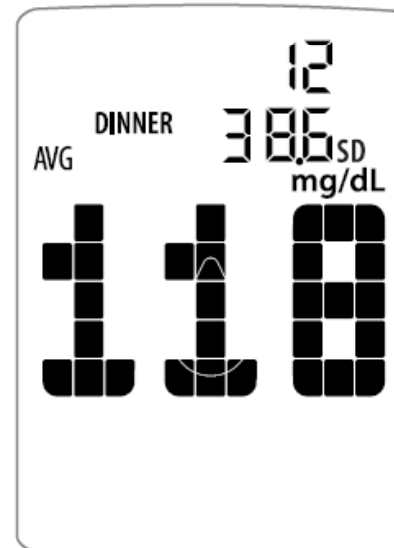
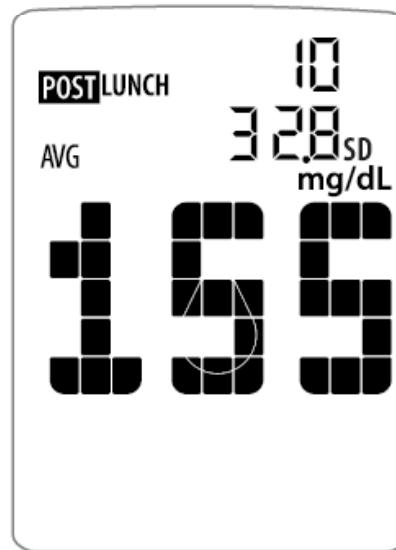
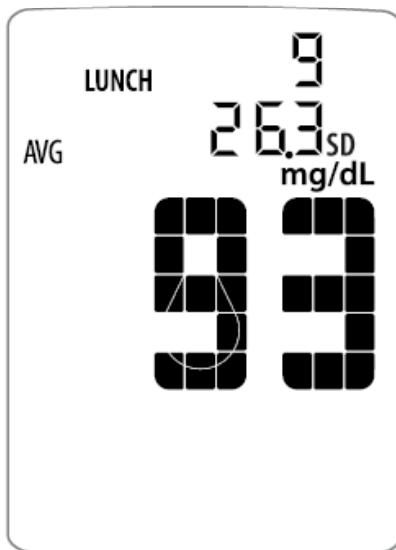
■ **Le statistiche nell'arco di 14 giorni:** La funzione Statistiche consente di confrontare le medie dei risultati del test, le deviazioni standard tra i risultati dei test e la media del numero di test effettuati ogni giorno per i 14 giorni precedenti.



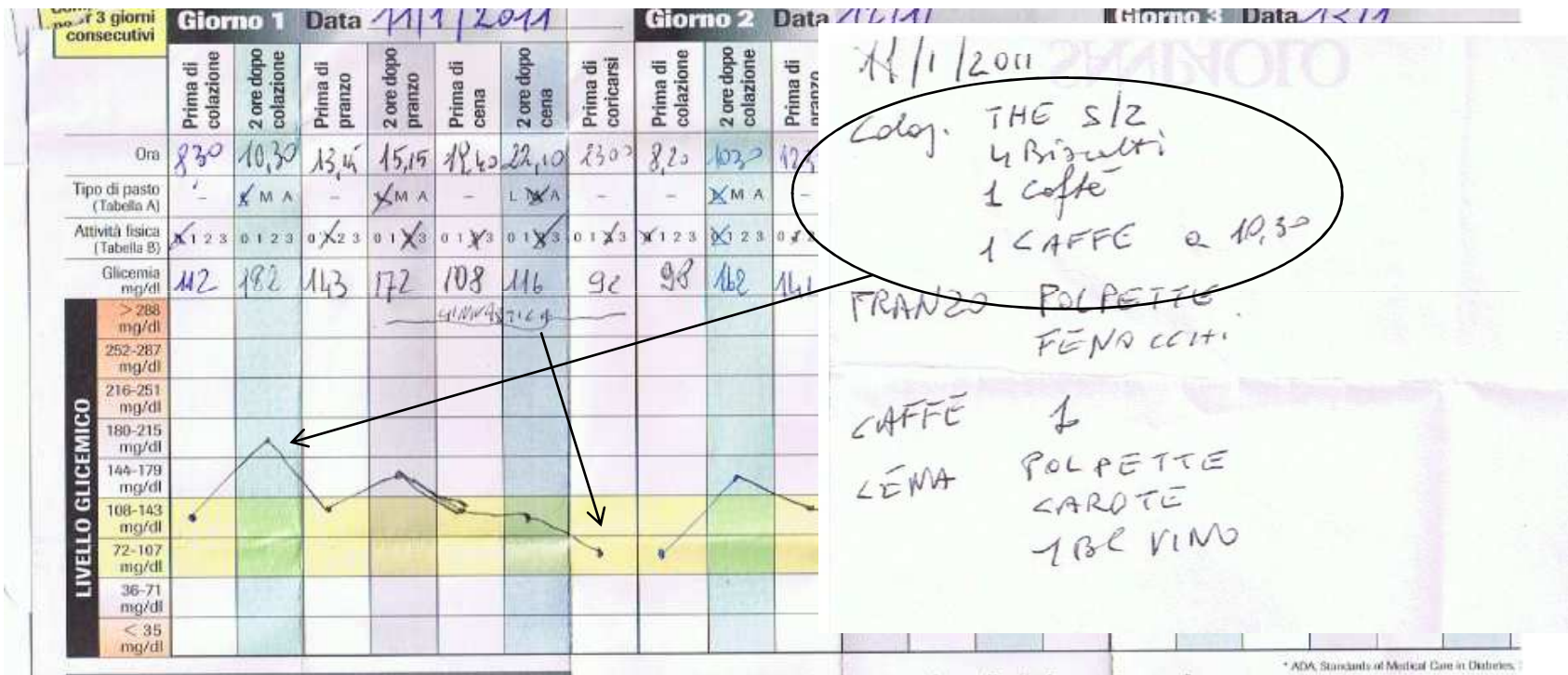
■ **Le medie nell'arco di 14, 30 e 90 giorni:** Queste medie permettono di verificare la variazione dei livelli glicemici alle diverse ore del giorno.



■ **Le medie prima e dopo i pasti e il rilevamento della variabilità glicemica:** Lo strumento suddivide le letture in categorie in base all'esecuzione del test prima o dopo i pasti. Queste medie permettono di verificare la variazione dei livelli glicemici alle diverse ore del giorno.



Diario Integrato



* ADA Standards of Medical Care in Diabetes

Grazie per
l'attenzione !