L' automonitoraggio glicemico nella letteratura e nella pratica clinica: luci e ombre

Automonitoraggio glicemico in generale

Automonitoraggio glicemico postprandiale

HOME MONITORING OF BLOOD-GLUCOSE

Method for Improving Diabetic Control

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Summary   64 diabetic patients measured their own blood-glucose concentration with 'Dextrostix' (Ames) and an 'Eyetone' (Ames) meter. The records made at home by 53 of these patients have shown that this led to a significant improvement in blood-glucose control. A majority (64%) were able to maintain "good" control (80% of blood-glucose recordings equal to or less than 10 mmol/l for periods as long as 478 days). This hitherto unobtainable degree of control of blood-glucose was achieved mostly with conventional insulin regimens of twice-daily 'Actrapid' (Novo Laboratories Ltd.) and 'Leo-Retard' (Leo Laboratories Ltd.). Adjustments of insulin dosage and type were found to be much easier and more predictable than with urine-glucose analysis. No significant complications were encountered. Hypoglycæmic episodes were less frequent. 70% of patients preferred blood-tests to urine tests and 92% would like to buy their own meter "if the price was right." The results suggest that self-monitoring of blood-glucose by diabetics makes possible, for the first time, the achievement of near normoglycæmia. This may reduce the incidence of long-term diabetic complications.

Rappresenta la prima notizia pubblicata su una importante rivista medica che prenda in considerazione l' automonitoraggio glicemico domiciliare come uno strumento per il miglioramento del compenso metabolico e dati i tempi (1978) si trattava di una autentica novità

Epidemiology and determinants of blood glucose self-monitoring in clinical practice[1]

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Studies have found that home monitoring of blood glucose in patients with non-insulin-treated type 2 diabetes does not affect glycemic control [4–7]. Our results seem to confirm the lack of association between glycated hemoglobin levels and SMBG practice also for type 2 insulin-treated patients.

Similarly, suffering from a major diabetic complication or having a previous history of cardiac or cerebrovascular disease were not predictors of self-monitoring.

Esprime il concetto che la pratica dell' automonitoraggio glicemico domiciliare non è determinato dallo stato dei pazienti, sia che abbiano o non abbiano complicazioni della malattia ed esprime il concetto,contrario al Lancet, che fra automonitoraggio glicemico e livelli di emoglobina glicata non esista una relazione

Evidence for the effectiveness of SMBG

Control of blood glucose

Despite numerous guidelines recommending the use of SMBG, the evidence that SMBG is effective in improving blood glucose control in type 2 diabetes is contradictory.
In 1997, Faas et al published a systematic literature review of studies of SMBG in type 2 diabetes carried out between 1976 and 1996. The review found that many of these studies had methodological deficiencies: of the 77 studies identified, only 11 met the qualitative assessment criteria established by the authors. Of these 11 studies, 4 were uncontrolled prospective studies, 1 was a retrospective study, and 6 were randomized controlled studies. Of the 6 randomized controlled trials, only 1, by Rutten et al, showed a statistically significant improvement in HbA1c with SMBG in type 2 diabetes (reduction of 0.9%, $P < 0.05$).

A more recent meta-analysis found that most of the studies investigating the value of SMBG in glycemic control were poorly conducted, involved small groups of patients and, consequently, were lacking in statistical power. Of 18 studies published between 1990 and 1999, only 8 were randomized, controlled trials (which included the 6 identified by Faas et al).

A metaanalysis of the 4 that compared self-monitoring (urine or SMBG) with no monitoring found selfmonitoring to be associated with a small but non significant decrease in mean HbA1c levels (–0.25%; 95% CI –0.61 to 0.1%; Figure 1) compared with no monitoring.

The authors stated that this result should be viewed with caution, however, due to the limitations of the studies included in the metaanalysis.
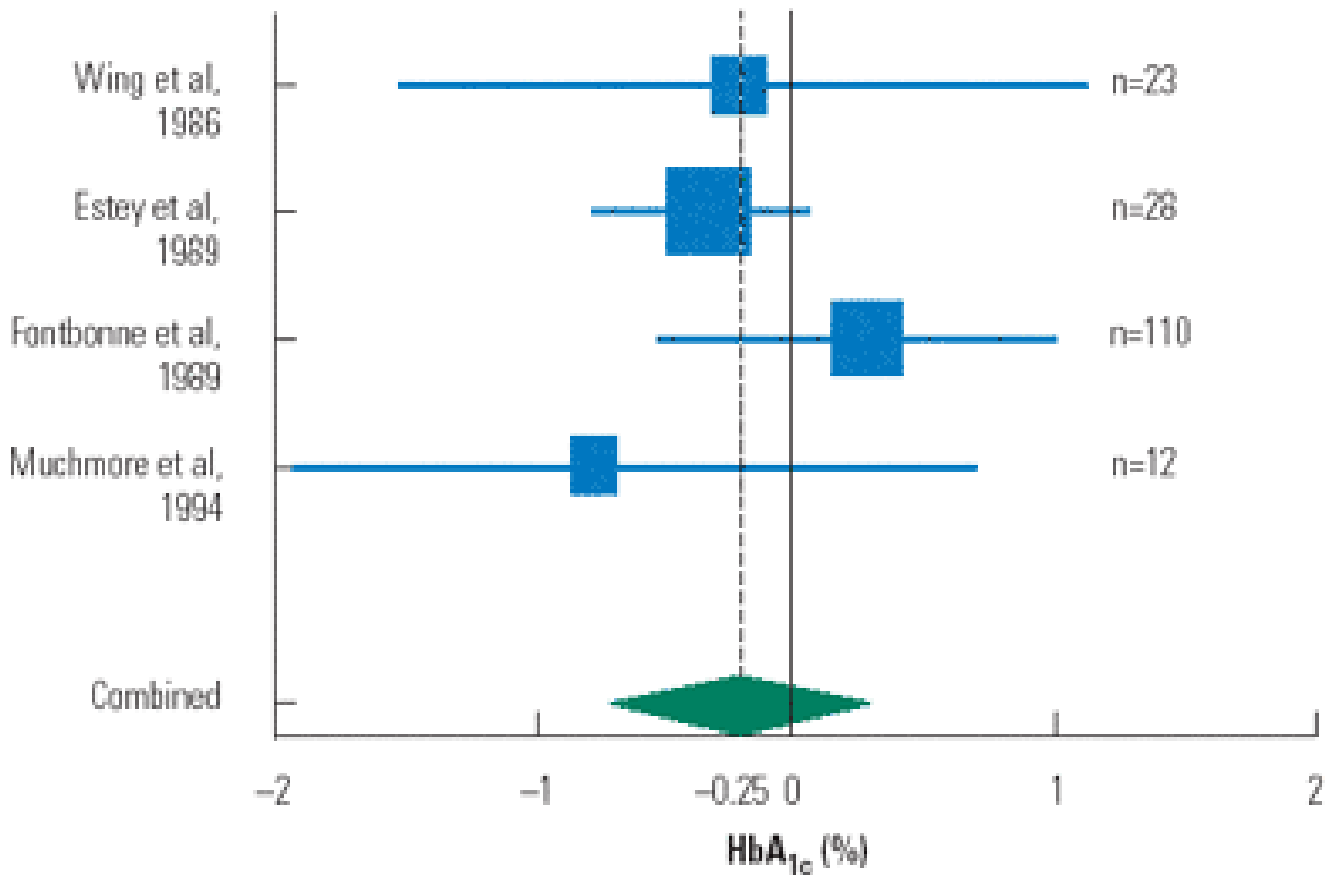
FIGURE 1 *Meta-analysis of self-monitoring (SMBG or urine) compared with no monitoring. (Reproduced with permission from Coster et al.[9])*

La comparazione di studi in cui il monitoraggio (della glicemia o delle urine) rispetto al non monitoraggio ha dato in sintesi risultati molto poveri per quanto attiene al miglioramento della glicata

Although people with diabetes mellitus may prefer blood glucose self-monitoring, evidence does not suggest improved outcomes relative to urine testing

Self-monitoring in type-2 diabetes mellitus

Eight RCT's were initially identified, but two were formally excluded from the meta-analyses. A random effects meta-analysis of data from three studies showed that the difference in glycosylated haemoglobin for those performing self-monitoring of blood glucose compared with those performing urine testing was − 0.03% (95% CI, − 0.5% to + 0.5%). Published information on patient outcomes and the avoidance of

Altra nota a sfavore lo studio di Coster del 2000 in cui si dichiara che, nonostante i pazienti preferiscano il monitoraggio domiciliare glicemico rispetto al monitoraggio delle urine, l' evidenza dello studio non dimostra una superiorità del monitoraggio glicemico rispetto al monitoraggio eseguito sulle urine, ma certamente con costi superiori per il monitoraggio glicemico

BOX 3 Summary of design features for RCTs

- Eight RCTs were identified

- No trial included enough subjects to detect a difference in GHb of $\leq 0.5\%$

- The studies included comparisons of blood testing, urine testing and no testing in patients with type 2 DM

- Interventions were not standardised, patient training and compliance were not addressed systematically and the mean (SD) quality rating was 15.0 (1.7)

- No study required patients to modify their drug therapy in accordance with their self-monitoring results

Vengono elencate le critiche agli studi introdotti nella metanalisi: in nessuno degli 8 studi considerati si è raggiunta una differenza al minimo della significatività per quanto riguarda l' emoglobina glicata; gli interventi non sono stati standardizzati, non c'è stata una istruzione corretta dei pazienti, né è stata monitorata la loro compliance, la cui qualità si è mantenuta ad un livello piuttosto basso. Infine nessuno degli studi ha richiesto ai pazienti di modificare la loro terapia in base ai risultati ottenuti dall' automonitoraggio. E' questo il puntyo debole comune di tutti gli studi esistenti, perché al massimo i pazienti riportano il dato, ma non hanno la minima idea di cosa rappresenti e di quanto valga

BOX 4 Main conclusions of the review of self-monitoring in type 2 DM

- There is no evidence to show that self-monitoring of blood or urine glucose improves blood glucose control measured using GHb or FPG

- There is no evidence that blood glucose monitoring is more effective than urine glucose monitoring in improving blood glucose control

- The studies reviewed had low statistical power and were poorly conducted and reported. Small but clinically relevant effects might not have been detectable

- Patients' perceptions of monitoring were neither completely nor rigorously studied and further work is needed in this area

- Urine testing is less costly than blood testing

- Urine testing is preferred by some patients

Self-monitoring in type 2 DM

At the present time there is insufficient evidence to support the self-monitoring recommendations made by professional and patient organisations. The studies reviewed suggest that the independent effects of self-monitoring on blood glucose control are small, and the effects on patient outcomes have not been documented adequately. RCTs should be carried out to provide a rigorous assessment of:

- the effectiveness of self-monitoring in newly presenting patients with type 2 DM
- the consequences of discontinuing self-monitoring in patients with stable type 2 DM.

COMMENTO ALL' EDITORIALE

In this light, some potentially disruptive results obtained by this systematic review seem less surprising. For example, the lack of evidence that BGSM improves blood glucose control in type-2 diabetes may be explained by the fact that no study required patients to modify their drug therapy in accordance with the BGSM results. This means that the BGSM data were poorly exploited. Moreover, it is apparent from this review that the effectiveness of BGSM in type-1 diabetes is clear only within an overall package of interventions, for which BGSM is a pre-condition.

The final recommendations should, therefore, include a statement that requires associating BGSM with a set of procedures to *effectively use* the monitoring results. If this recommendation is followed in future studies, there is a very good chance that the guidelines on self-monitoring for diabetes care will be clearly justified by clinical evidence.

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Postprandial Blood Glucose

AMERICAN DIABETES ASSOCIATION

glucose metabolism in the liver and peripheral tissues.

The magnitude and time of the peak

In summary, there are insufficient data to determine accurately the relative contribution of the FPG and PPG to HbA_{1c}. It appears that FPG is somewhat better than PPG in predicting HbA_{1c}, especially in type 2 diabetes.

A. Suspected postprandial hyperglycemia. In patients who achieve their pre-meal glucose targets, but whose overall glycemic control as determined by HbA_{1c} is inappropriately high, PPG monitoring and therapy to minimize PPGEs may be beneficial.

B. Monitoring treatment aimed specifically at lowering PPG. In patients with type 1 or type 2 diabetes who are treated with glucose-lowering agents expected primarily to reduce PPG, monitoring may be useful in titrating these treatments or in confirming that patients have responded to the intervention. It is also possible that PPG monitoring may be beneficial to evaluate the effect of changes in nutrition or exercise patterns.

Postprandial Blood Glucose

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glucose metabolism in the liver and peripheral tissues.

The magnitude and time of the peak

B. What is the clinical utility of using measurements of PPG to improve glycemic control? At present, HbA_{1c} measurements are the "gold standard" for assessing long-term glycemic control. The fundamental question to be answered is whether measuring premeal glucose, FPG, or PPG, alone or in combination, will be most helpful in adjusting treatment to achieve HbA_{1c} goals while minimizing hypoglycemia. Although useful insights concerning these issues have been gained from retrospective analyses, definitive answers require intervention studies. These studies should determine whether treatments aimed at controlling FPG and PPG result in lower HbA_{1c} than do treatments that predominantly affect FPG and/or premeal glucose levels.

C. In the presence of equivalent HbA_{1c} values, does an excessive rise in PPG uniquely affect chronic diabetic complications? It is unclear whether excessive excursions of PPG have a significant impact on the development of diabetic microvascular or macrovascular complications independent of HbA_{1c} levels. To address this fundamental question, studies must be designed to control FPG versus PPG levels while aiming to achieve similar and acceptable HbA_{1c} levels.

Self-monitoring of Blood Glucose Levels and Glycemic Control: the Northern California Kaiser Permanente Diabetes Registry*

Andrew J. Karter, PhD, Lynn M. Ackerson, PhD, Jeanne A. Darbinian, MPH,
Ralph B. D'Agostino, Jr, PhD, Assiamira Ferrara, MD, PhD, Jennifer Liu, MS,
Joe V. Selby, MD, MPH

RESULTS: Self-monitoring among patients with type 1 diabetes ($\geq$3 times daily) and pharmacologically treated type 2 diabetes (at least daily) was associated with lower HbA_{1c} levels (1.0 percentage points lower in type 1 diabetes and 0.6 points lower in type 2 diabetes) than was less frequent monitoring (P <0.0001). Although there are no specific recommendations for patients with nonpharmacologically treated type 2 diabetes, those who practiced self-monitoring (at any frequency) had a 0.4 point lower HbA_{1c} level than those not practicing at all (P <0.0001)
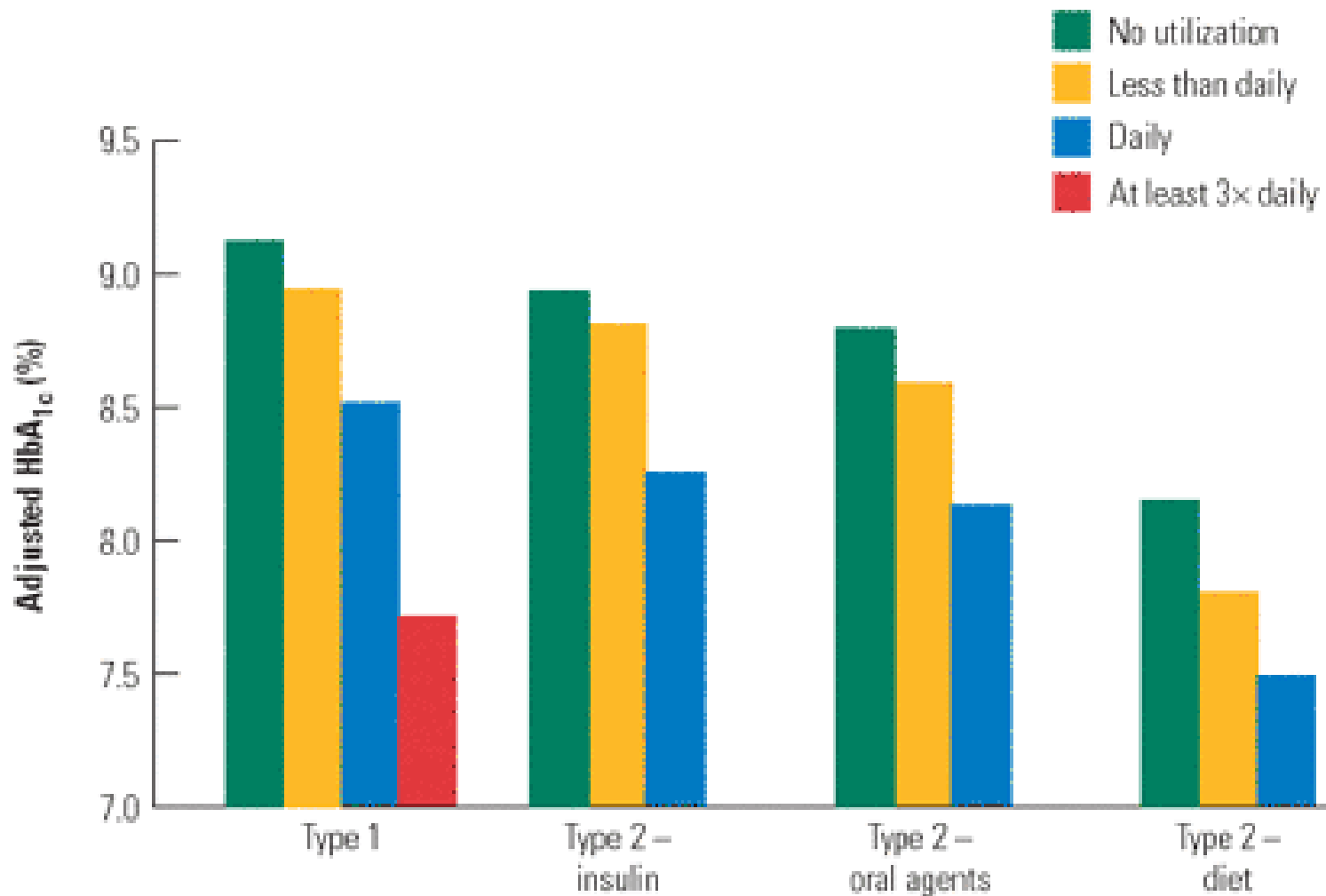
Karter AJ, Ackerson LM, Darbinian JA, et al. *Am J Med*. 2001;111:1–9.

La diapositiva espone graficamente i risultati ottenuti, che si allineano ai risultati del tipo 1 (colonne di sinistra

The relationship between self-monitoring of blood glucose control and glycosylated haemoglobin in patients with type 2 diabetes with and without diabetic retinopathy

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retinopathy ($n = 52$, 19.5%). Results: HbA_{1c} levels at baseline, after 6 and 12 months were $9.09 \pm 2.69\%$, $7.47 \pm 1.78\%$ and $7.12 \pm 1.4\%$, respectively, mean $\pm$ S.D. The values decreased significantly after the education program ($P < .001$ for both values compared with baseline).

Self-control: A Physician's Guide to Blood Glucose Monitoring in the Management of Diabetes

AN *AMERICAN FAMILY PHYSICIAN* MONOGRAPH

Jennifer Mayfield, M.D., M.P.H.;
Stephen Havas, M.D., M.P.H., M.S.; for the
AAFP Panel on Self-monitoring of Blood Glucose

The AAFP Panel on SMBG did not reach consensus regarding the optimal frequency of SMBG in type 2 diabetes, noting that further research is needed. As a general rule, patients whose diabetes is not well controlled should test multiple times per day for several days to produce sufficient data for clinical decision-making. The type of medication and other factors dictate the frequency and timing of testing. For example, more frequent testing may be appropriate for patients who are taking repaglinide or nateglinide or a sulfonylurea, which are more likely to cause hypoglycemia than thiazolidinediones or biguanides. Generally, testing times should monitor times when the medication is most likely to cause hypoglycemia or hyperglycemia in order to inform medication adjustments. Once the patient's diabetes is under control, the panel recommends testing based on the patient's clinical circumstances and the type of oral diabetes medication he or she is taking. This will often be a few times a week, but occasionally will be less frequent.

Blood glucose is usually highest one to two hours after meals. Patients whose preprandial levels have normalized but who have not achieved their overall glycemic goals may benefit from assessment and management of postprandial glucose levels.

Self-monitoring of blood glucose in diabetic patients: from the least common denominator to the greatest common multiple

L Monnier, C Colette, H Lapinski, H Boniface

Schwedes U, Siebolds M, Mertes G, for the SMBG study group. Meal-related structured self-monitoring of blood glucose. Effect on diabetes control in non-insulin-treated type 2 diabetic patients. Diabetes Care, 2002, 25, 1928-32.

Although recent publication have indicated that SMBG in combination with a structured counselling program can produce positive effects on the diabetic control of non-insulin-treated type 2 diabetic patients [13], the efficacy of SMBG in type 2 patients still remains a question of debate

Self-Monitoring of Blood Glucose (SMBG): Considerations for Intensive Diabetes Management

Data suggest that patients with type-2 DM have difficulty achieving the recommended HbA_{1c} goal despite having near-normal to normal FPG levels. These data imply that health care providers should adjust pharmacological treatment to decrease PPG levels for better overall blood glucose management.[13] With recommendations to monitor PPG more closely, SMBG becomes an even more significant part of diabetes care.

TABLE 4 Summary of Requirements for Performing Self-Monitoring of Blood Glucose (SMBG) by Diabetes Type

Type-1 diabetes
- Perform SMBG three or more times per day.
- Adjust intensity of monitoring to intensity of insulin therapy.
- Perform SMBG three or more times every day when multiple doses of insulin are administered every day.

Type-2 diabetes
- The exact frequency is undetermined.
- Perform SMBG at a sufficient rate to reach glucose goals.
- If taking insulin therapy, perform SMBG three or more times each day.

Gestational diabetes mellitus
- Perform SMBG three or more times each day.

Data from the American Diabetes Association;[3] DiPiro JT, et al., 2002;[4] and Mooradian AD, et al., 1998.[5]

Improving glucose management: Ten steps to get more patients with type 2 diabetes to glycaemic goal

S. DEL PRATO,[1] A-M. FELTON,[2] N. MUNRO,[3] R. NESTO,[4] P. ZIMMET,[5] B. ZINMAN[6] ON BEHALF OF *THE GLOBAL PARTNERSHIP FOR EFFECTIVE DIABETES MANAGEMENT**
University of Pisa,[1] Pisa, Italy, Federation of European Nurses in Diabetes,[2] London, UK, Primary Care Diabetes Europe,[3] Surrey, UK, Lahey Clinic,[4] Burlington, MA, USA, International Diabetes Institute,[5] Caulfield, Australia, and Mount Sinai Hospital,[6] University of Toronto, Toronto, Canada

Table 1 Barriers to effective glucose management

Conservative management
- Ineffective diet/exercise initiatives
- Delayed efficacy due to a slow traditional stepwise approach
- Suboptimal healthcare systems impede achievement of glycaemic goals

Lack of perceived efficacy
- Insufficient communication with patient
- Poor adherence to antidiabetic regimens

Lack of knowledge of underlying pathophysiology
- Inappropriate prescription of medication

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Regular self-monitoring of blood glucose by the patient, according to a programme agreed by the healthcare professional (HCP) and patient, also constitutes a key component of diabetes self-management and can improve the proportion of patients achieving their glycaemic targets (14,16,28,29). Given the well-established link between elevated postprandial glucose (PPG) levels and cardiovascular risk (30–32), it is also important that patients monitor PPG and regularly

Self monitoring of blood glucose in type 2 diabetes and long-term outcome: an epidemiological cohort study

3268 pazienti con un follow-up di 8 anni analizzati se eseguivano SMBG almeno per un anno nel corso dello studio (glicemia a digiuno). Il SMBG è stato iniziato prevalentemente in soggetti con peggior compenso metabolico (HbA1c) al baseline.

SMBG was associated with decresed diabetes-related morbidity and all-cause mortality in type 2 diabetes, and this association remained in a subgroup of patients who were not receiving insulin therapy. The differences between the SMBG and non SMBG groups remained after adjustment for patients' or doctors' characteristics
SMBG may be associated with a healthier lifestyle and/or better disease management.

Lavoro recente del 2006 in sui si assiste ad una espressione di netto favore per l' automonitoraggio glicemico come strumento per il raggiungimento del miglior compenso metabolico

Fig. 4 Cox regression analysis: unadjusted and adjusted HR for fatal and non-fatal endpoints for patients using SMBG. Estimates were obtained by Cox regression using a proportional HR model. Adjustments: in Model 1, the factors SMBG, age, sex, concomitant diseases at diabetes diagnosis (hypertension, CHD, history of stroke), laboratory values (fasting blood glucose, triglycerides) and treatment are considered. Model 2 comprises the factors of Model 1 and additional non-disease-related potential confounders, such as qualification of the treating physician (general practitioner, internist), centre size (number of newly diagnosed patients with type 2 diabetes during 1995–1999), centre location (small town, city), patient's habitation (small town, city) and patient's health insurance (public, private). After adjustment for the mentioned confounders, use of SMBG resulted in reduced HR for non-fatal and fatal endpoints

Total study population

	HR	95% CI	
Non-fatal endpoints			
SMBG	0.63	0.50–0.80	*p < 0.001*
SMBG, adjusted model 1	0.67	0.50–0.89	*p = 0.006*
SMBG, adjusted model 2	0.68	0.51–0.91	*p = 0.009*
Fatal endpoints			
SMBG	0.52	0.36–0.76	*p < 0.001*
SMBG, adjusted model 1	0.50	0.32–0.80	*p = 0.004*
SMBG, adjusted model 2	0.49	0.31–0.78	*p = 0.003*

Patients without insulin therapy

	HR	95% CI	
Non-fatal endpoints			
SMBG	0.60	0.44–0.82	*p = 0.001*
SMBG, adjusted model 1	0.71	0.52–0.98	*p = 0.037*
SMBG, adjusted model 2	0.72	0.52–0.9998	*p = 0.0496*
Fatal endpoints			
SMBG	0.54	0.33–0.87	*p = 0.011*
SMBG, adjusted model 1	0.59	0.36–0.96	*p = 0.035*
SMBG, adjusted model 2	0.58	0.35–0.96	*p = 0.035*

0.25   0.5   0.75   1   1.25
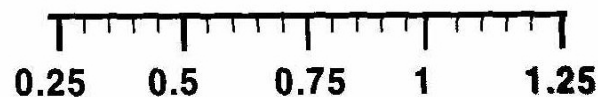
HR (95% CI)

ORIGINAL ARTICLE

Cost-utility analysis in a UK setting of self-monitoring of blood glucose in patients with type 2 diabetes

Andrew J. Palmer[a], Sean Dinneen[b], James R. Gavin III[c], Alastair Gray[d], William H. Herman[e] and Andrew J. Karter[f]

Conclusions: Based on the moderate level of clinical evidence available to date, improvements in glycaemic control with interventions, including SMBG, can improve patient outcomes, with acceptable cost-effectiveness ratios in the UK setting.

Self-monitoring of blood glucose in patients with type 2 diabetes mellitus who are not using insulin (Cochrane Review)

Welschen LMC, Bloemendal E, Nijpels G, Dekker JM, Heine RJ, Stalman WAB, Bouter LM

ABSTRACT

Authors' conclusions: From this review we concluded that self-monitoring of blood glucose might be effective in improving glycaemic control in patients with type 2 diabetes who are not using insulin. To assess the potential beneficial effects of SMBG in these patients a large and well-designed randomised controlled trial is required. This long-term trial should also investigate patient-related outcomes like quality of life, well-being and patient satisfaction, and provide adequate education to the patient to allow SMBG to be effective.

Effect of Self-Monitoring of Blood Glucose in Patients With Type 2 Diabetes Mellitus Not Using Insulin
This study is currently recruiting patients.

Verified by Medical Research Foundation, The Netherlands February 2006

Sponsors and Collaborators:	**Medical Research Foundation, The Netherlands** Langerhans Foundation, the Netherlands
Information provided by:	Medical Research Foundation, The Netherlands
ClinicalTrials.gov Identifier:	NCT00287807

Two treatment protocols are proposed. Treatment A consists of self-monitoring of blood glucose and treatment B consists of usual care. Patients in the A-group are instructed to measure their blood glucose values 4 times a day (1 fasting plasma glucose concentration and 3 post-meal glucose concentrations), two times a week, on one week day, and one weekend day (no more, no less). Patients should record these glucose values in a diary. Patient will get one page with information in Dutch. No further education than for handling the device and interpreting the values is given, so that besides this intervention, there will be no differences compared with the control group like other forms of education.
The duration fo the trial will be 12 months

Study start: February 2006; Expected completion: March 2008
Last follow-up: October 2007; Data entry closure: October 2007

COME E QUANDO CONTROLLARE LA GLICEMIA

- dipende dal tipo di diabete e dal tipo di terapia
- dipende dal compenso glicemico
- non esiste un sistema ottimale per tutti esistono schemi molto personalizzati
- Variazioni in rapporto a differenti direttive dei diversi Piani S.S.Regionali

DIABETE MELLITO TIPO 2 (DEFINIZIONE CLASSICA: NON INSULINO-DIPENDENTE)

✔ Se la terapia insulinica è intensiva (3-4 iniezioni di insulina al giorno) la cadenza dell'autocontrollo deve essere simile a quello effettuato dai diabetici tipo 1

✔ Se la terapia insulinica è meno aggressiva o è associata a quella con le compresse, la frequenza delle misurazioni può essere ridotta. Anche in questo caso si devono intensificare i controlli se variano le abitudini

DIABETE MELLITO TIPO 2 IN TERAPIA ORALE

✔ Solitamente la situazione clinica è poco soggetta a variazioni: sarà sufficiente un profilo glicemico (3-5 misurazioni al giorno negli orari esemplificati nella tabella precedente) ogni 7-10 giorni

✔ Ulteriori controlli saranno aggiunti dopo aver praticato attività fisica o dopo aver assunto cibi particolarmente calorici o non assunti abitualmente

DIABETE MELLITO TIPO 2 IN TRATTAMENTO CON SOLA DIETA

✓ 1 o 2 controlli a settimana, a digiuno e/o 2 ore dopo il pasto principale sono più che sufficienti per stabilire l'andamento della glicemia.

✓ Quando compaiono sintomi come minzione frequente ed abbondante (specie di notte), perdita di peso inspiegabile, malessere generale e astenia che fanno sospettare innalzamento della glicemia, i controlli vanno intensificati prontamente

L'AUTOCONTROLLO DELLA GLICEMIA:

- Non significa "mi curo da solo". Una buona glicemia isolata non equivale ad un buon compenso

- significa cercare di capire, di imparare, di consapevolizzarsi, di responsabilizzarsi verso se stessi e verso gli altri: significa _crescere e essere più liberi_

- significa creare e portare avanti un _contratto sanitario_ con il diabetologo di riferimento (creare strategie di trattamento)

Sommario

A) Nonostante la mancanza di orientamenti condivisi e di indicazioni precise e concordanti, l' automonitoraggio glicemico domiciliare del paziente, ben guidato e controllato dal medico, rappresenta uno dei caposaldi dell' ottimizzazione del compenso glicemico

B) L' automonitoraggio glicemico deve essere parte di un programma di educazione terapeutica strutturata intesa ad utilizzare i dati dell' autocontrollo nel circolo della qualità

C) Per fare questo il paziente deve essere istruito a saper comprendere, interpretare e modificare la terapia in accordo con i valori riscontrati

D) Le terapie moderne del tipo 2 (secretagoghi, analoghi rapidi e di lunga durata) consentono di sfruttare come non mai i dati dell' autocontrollo pre e postprandiale per pilotare il compenso del paziente verso l' ottimizzazione

CONCLUSIONE

La numerosità del campione previsto dal presente protocollo (4500 pazienti) con la mira specificamente centrata sulla glicemia postprandiale e sui suoi determinanti, deve permetterci di aggiungere un importante tassello alla letteratura corrente sull' argomento, ancora tanto variegata e controversa

La brevità del periodo di osservazione (12 giorni) ci permette di fissare un' istantanea sul problema; resta da considerare l' importanza di andare a controllare a distanza quanto i risultati dello studio abbiano potuto incidere sui comportamenti del medico e del paziente e sugli affinamenti di terapia