



## **Auto-Vigilância na Diabetes tipo 2 Revisão das Recomendações Internacionais**



Carlos Martins  
Médico de Família  
Faculdade de Medicina UP

## Sumário

- **Recomendações internacionais**
- **Olhar para a evidência científica**
- **Reflexões**

### **Abreviaturas:**

**AMG** = auto-monitorização da glicemia

**SMBG** = self-monitoring of blood glucose



## **Faz sentido usar a AMG nos pacientes com DM tipo 2 não insulino-ttdos?**



Carlos Martins  
Médico de Família  
Faculdade de Medicina UP

- P – Diabéticos tipo 2 (não insulino-ttdos)**
- I – AMG**
- C – AMG vs cuidados habituais**  
**AMG + programa educacional vs AMG**
- O – diminuição HgA1C**  
**diminuição da morbi-mortalidade**  
**melhoria da qualidade de vida**

ADA 2010

## Self-monitoring of blood glucose (SMBG) – Recommendations

- Three or more times daily for patients using multiple insulin injections or insulin pump therapy. **(A)**
- For patients using less frequent insulin injections, **noninsulin therapies**, or medical nutrition therapy alone, **SMBG may be useful** as a guide to the success of therapy. **(E)**
- To achieve postprandial glucose targets, postprandial **SMBG may be** appropriate. **(E)**
- When prescribing **SMBG**, ensure that patients receive **initial instruction** in, and routine follow-up evaluation of, **SMBG** technique and their ability to use data to adjust therapy. **(E)**



DiabetesCare

Table 1 —ADA evidence grading system for clinical practice recommendations

Level of evidence	Description
A	<p>Clear evidence from well-conducted, generalizable, randomized controlled trials that are adequately powered, including:</p> <ul style="list-style-type: none"><li>• Evidence from a well-conducted multicenter trial</li><li>• Evidence from a meta-analysis that incorporated quality ratings in the analysis</li></ul> <p>Compelling nonexperimental evidence, i.e., "all or none" rule developed by Center for Evidence Based Medicine at Oxford</p> <p>Supportive evidence from well-conducted randomized controlled trials that are adequately powered, including:</p> <ul style="list-style-type: none"><li>• Evidence from a well-conducted trial at one or more institutions</li><li>• Evidence from a meta-analysis that incorporated quality ratings in the analysis</li></ul>
B	<p>Supportive evidence from well-conducted cohort studies:</p> <ul style="list-style-type: none"><li>• Evidence from a well-conducted prospective cohort study or registry</li><li>• Evidence from a well-conducted meta-analysis of cohort studies</li></ul> <p>Supportive evidence from a well-conducted case-control study</p>
C	<p>Supportive evidence from poorly controlled or uncontrolled studies</p> <ul style="list-style-type: none"><li>• Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results</li><li>• Evidence from observational studies with high potential for bias (such as case series with comparison to historical controls)</li><li>• Evidence from case series or case reports</li></ul> <p>Conflicting evidence with the weight of evidence supporting the recommendation</p>
E	<p>Expert consensus or clinical experience</p>



DiabetesCare

ADA 2010

## Self-monitoring of blood glucose (SMBG) – Recommendations

- Three or more times daily for patients using multiple insulin injections or insulin pump therapy. **(A)**
- For patients using less frequent insulin injections, **noninsulin therapies**, or medical nutrition therapy alone, **SMBG may be useful** as a guide to the success of therapy. **(E)**
- To achieve postprandial glucose targets, postprandial **SMBG may be** appropriate. **(E)**
- When prescribing **SMBG**, ensure that patients receive **initial instruction** in, and routine follow-up evaluation of, **SMBG** technique and their ability to use data to adjust therapy. **(E)**



DiabetesCare

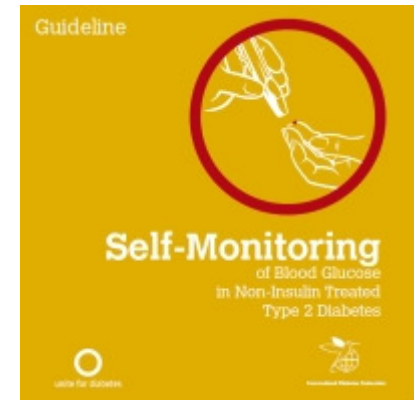


**Recomendações**  
Guidelines

*Revista Portuguesa de Diabetes. 2009; 4 (4): 168-177*

## **Recomendações para a Auto-monitorização da Glicemia na Diabetes Tipo 2 Não Insulino-tratada\***

*C. Pina e Brito, R. Duarte*



## IDF 2009

1. A AMG deverá ser utilizada apenas... diabéticos/ cuidadores com conhecimentos, as **capacidades** de ajuste da terapêutica.
2. Considerada na **altura do diagnóstico**, para aumentar a compreensão da diabetes, como parte da educação do indivíduo, e para facilitar uma iniciação atempada do tratamento e a sua optimização...
3. Os protocolos de AMG deverão ser **individualizados**.
4. Objectivos **acordados** com os diabéticos
5. Requer um procedimento **fácil**...

# TYPE 2 DIABETES

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

## NICE, 2008 – RECOMMENDATIONS

**R22 - Offer to a person newly diagnosed with Type 2 diabetes only as an integral part of his or her self-management education.**

**R23 - Self-monitoring of plasma glucose should be available:**

- to those on insulin treatment
- to those on oral glucose lowering medications to provide information on hypoglycaemia
- to assess changes in glucose control resulting from medications and lifestyle changes
- to monitor changes during intercurrent illness
- to ensure safety during activities, including driving.

# TYPE 2 DIABETES

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

## **NICE, 2008 – RECOMMENDATIONS**

**R24 - Assess at least annually and in a structured way**

**E o que nos diz a evidência científica?**

## E o que nos diz a evidência científica?

### **Estudos observacionais que demonstram benefício:**

Karter, AJ, Ackerson, LM, Darbinian, JA, et al. Self-monitoring of blood glucose levels and glycemic control: the Northern California Kaiser Permanente Diabetes registry. *Am J Med* 2001; 111:1.

Karter, AJ, Parker, MM, Moffet, HH, et al. Longitudinal study of new and prevalent use of self-monitoring of blood glucose. *Diabetes Care* 2006; 29:1757.

## E o que nos diz a evidência científica?

### **Estudos observacionais que não demonstram benefício:**

Faas, A, Schellevis, FG, van Eijk, JT. The efficacy of self-monitoring of blood glucose in NIDDM subjects. *Diabetes Care* 1997; 20:1482.

Harris, MI. Frequency of blood glucose monitoring in relation to glycemic control in patients with type 2 diabetes. *Diabetes Care* 2001; 24:979.

Davis, WA, Bruce, DG, Davis, TM. Is self-monitoring of blood glucose appropriate for all type 2 diabetic patients? The Fremantle Diabetes Study. *Diabetes Care* 2006; 29:1764.

Franciosi, M, Pellegrini, F, De Berardis, G, et al. Self-monitoring of blood glucose in non-insulin-treated diabetic patients: a longitudinal evaluation of its impact on metabolic control. *Diabet Med* 2005; 22:900.

# E o que nos diz a evidência científica?

## Uma meta-análise: sem benefício

Coster, S, Gulliford, MC, Seed, PT, et al. Self-monitoring in Type 2 diabetes mellitus: a meta-analysis. Diabet Med 2000; 17:755-61.

# E o que nos diz a evidência científica?

## Uma revisão sistemática de 6 RCTs:

Welschen LMC, Bloemendal E, Nijpels G, Dekker JM, Heine RJ, Stalman WAB, Bouter LM. Self-monitoring of blood glucose in patients with type 2 diabetes mellitus who are not using insulin. *Cochrane Database of Systematic Reviews* 2005, Issue 2.



**THE COCHRANE LIBRARY**

Independent high-quality evidence for health care decision making

## Uma revisão sistemática de 6 RCTs: 2 em 6 redução de Hg A1C%

### Main results

...Because of the differences in patient characteristics, interventions and outcomes between the studies, it was **not possible to perform a meta-analysis**.

The methodological **quality** of studies was **low**.

**Two of the six** studies reported a significant lowering effect of self-monitoring of blood glucose on HbA1c.

However, one of these studies had a co-intervention with education on diet and lifestyle. There were few data on the effects of other outcomes and these effects were not statistically significant.

## Uma revisão sistemática de 6 RCTs: redução ligeira de Hg A1C%

### Authors' conclusions

SMBG **might be effective** in improving glycaemic control

To assess the potential beneficial ... a well-designed randomised controlled trial is required:

**quality of life,  
well-being and patient satisfaction,  
and provide adequate education to the patient.**

## E o que nos diz a evidência científica?

### 2 RCTs adicionais: sem redução na Hg A1C%

Farmer, A, Wade, A, Goyder, E, et al. Impact of self monitoring of blood glucose in the management of patients with non-insulin treated diabetes: open parallel group randomised trial. [BMJ 2007](#); 335:132.

O'Kane, MJ, Bunting, B, Copeland, M, Coates, VE. Efficacy of self monitoring of blood glucose in patients with newly diagnosed type 2 diabetes (ESMON study): randomised controlled trial. [BMJ 2008](#); 336:1174.

- maior risco de depressão...

## E a perspectiva dos pacientes?

Peel E, Parry O, Douglas M et al. Blood glucose self-monitoring in non-insulin-treated type 2 diabetes: a [qualitative study](#) of patients' perspectives. *British Journal of General Practice* 2004;54(500):183–188.

## E a perspectiva dos pacientes?

### **Pros of self-monitoring:**

- provides a heightened **awareness** of, and evidence of, the condition when readings are within advised guidelines and fluctuations are easily interpretable.
- the positive role in their diabetes management... **personal gratification**
- cultivates **independence** from health services and enhances self-regulation

## E a perspectiva dos pacientes?

### Cons of self-monitoring:

- raise **anxiety** about readings
- blood glucose parameters were found to be **problematic**... contradictory ...
- lack of awareness** as to how to manage hyperglycaemia
- increased **self-responsibility**, **self-blame** and negative emotional reactions
- **adversely** effecting **adherence** to diabetic regimens
- healthcare **professionals** were not interested in readings

## E o custo-benefício?

Simon, J, Gray, A, Clarke, P, et al. Cost effectiveness of self monitoring of blood glucose in patients with non-insulin treated type 2 diabetes: economic evaluation of data from the DiGEM trial. BMJ 2008; 336:1177.

### Conclusions

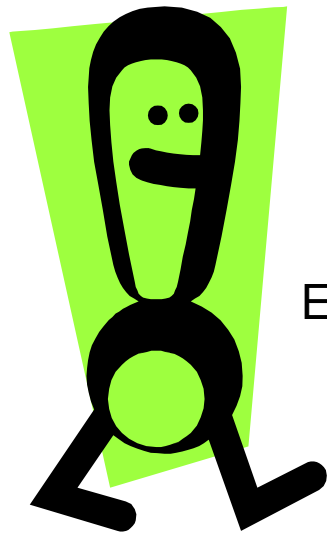
SMBG...

associated with **higher costs and lower quality of life** in patients with non-insulin treated type 2 diabetes.

In light of this, and **no clinically significant differences in other outcomes**,...

**unlikely to be cost effective** in addition to standardised usual care.

**E o que fazer na prática?**



AMG  
Estilo de vida

Medicação



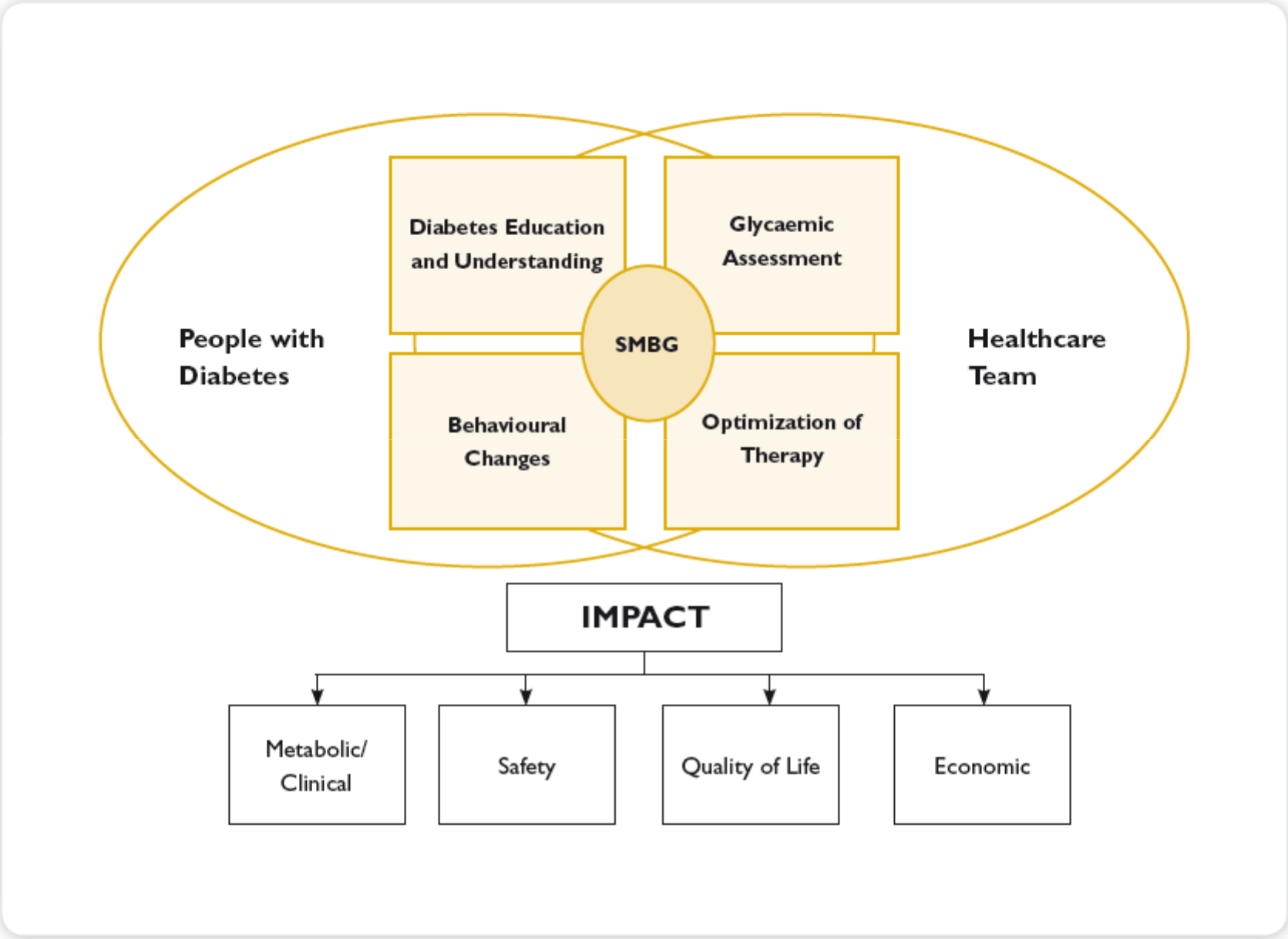
Estilo de vida

Medicação



AMG

**SMBG as a Component of the Education/Treatment Programme**





**Em resumo...**

**AMG pode nem ser necessária.**

**AMG pode ser útil.**

**Evidência... muito frágil.**

**Obrigado pela vossa atenção 😊**

☐ 8.4.2. Antidiabéticos orais

- ( ACARBOSE ✓
- ( GLIBENCLAMIDA AMG
- ( GLIBENCLAMIDA + METFORMINA AMG
- ( GLICLAZIDA AMG
- ( GLIMEPIRIDA AMG
- ( GLIPIZIDA AMG
- ( METFORMINA ✓
- ( METFORMINA + PIOGLITAZONA ✓
- ( METFORMINA + ROSIGLITAZONA ✓
- ( METFORMINA + SITAGLIPTINA ✓
- ( METFORMINA + VILDAGLIPTINA ✓
- ( NATEGLINIDA AMG
- ( PIOGLITAZONA ✓
- ( ROSIGLITAZONA ✓
- ( SITAGLIPTINA ✓
- ( VILDAGLIPTINA ✓



**Em resumo...**

**AMG pode nem ser necessária.**

**AMG pode ser útil.**

**Evidência... muito frágil.**

**Obrigado pela vossa atenção 😊**

**Table 3. Guidelines for glycaemic control in T2DM**

	<b>IDF</b> <sup>(52,53)</sup>	<b>AACE</b> <sup>(60)</sup>	<b>ADA</b> <sup>(61)</sup>
HbA <sub>1c</sub> (%)	<6.5	≤6.5	<7.0
Fasting/preprandial glucose (mmol/L / mg/dL)	<6.0 / <110	<6.0 / <110	3.9-7.2 / 70-130
2-h postprandial glucose (mmol/L / mg/dL)	<7.8 / <140	<7.8 / <140	<10.0 / <180*

\*ADA recommends that postprandial glucose measurements should be made 1–2 h after the beginning of the meal.

**Figure 2. Examples of focused SMBG regimens**

*5-point profile*

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

*7-point profile*

	Pre-Breakfast	Post-Breakfast	Pre-Lunch	Post-Lunch	Pre-Supper	Post-Supper	Bedtime
Monday							
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							
Saturday							
Sunday							

**'Staggered' SMBG regimen**

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

### *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							

### 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.

### Detection of asymptomatic hypoglycaemia

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

Pre-lunch and pre-supper SMBG can be used to detect asymptomatic hypoglycaemia <sup>(85)</sup>.

**Table 1A. Summary of key observational studies**

Study	Description of purpose	Findings/comments
Fremantle Diabetes Study <sup>(31)</sup>	<ul style="list-style-type: none"> <li>■ Assessed whether SMBG is an independent predictor of improved outcome in a community-based cohort of T2DM patients</li> <li>■ Used longitudinal data from 1,280 T2DM participants (70% ongoing SMBG users at baseline) and a subset of 531 individuals who attended annual assessments over a 5-year period</li> </ul>	<ul style="list-style-type: none"> <li>■ SMBG was associated with a 48% decreased risk of cardiovascular mortality in insulin-treated patients, but a 79% increased risk in non-insulin-treated patients</li> <li>■ Time-dependent SMBG was independently associated with a 48% reduced risk of retinopathy in the 5-year cohort</li> </ul> <p><i>'Inconsistent findings relating to the association of SMBG with cardiac death and retinopathy may be due to confounding, incomplete covariate adjustment or chance'</i></p>
Kaiser Permanente <sup>(28)</sup>	<ul style="list-style-type: none"> <li>■ Assessed longitudinal association between SMBG and glycaemic control in diabetic patients from an integrated health plan</li> <li>■ Followed 16,091 new SMBG users and 15,347 ongoing users over a 4-year period</li> </ul>	<ul style="list-style-type: none"> <li>■ Greater SMBG frequency among new users was associated with a graded decrease in HbA<sub>1c</sub> (relative to non-users) regardless of diabetes therapy</li> <li>■ Longitudinal changes in SMBG frequency were related to significant changes in glycaemic control</li> </ul>
QuED <sup>(29)</sup>	<ul style="list-style-type: none"> <li>■ Assessed impact of SMBG on metabolic control in non-insulin-treated T2DM subjects (41% ongoing SMBG users at baseline)</li> <li>■ Followed 1,896 patients over a 3-year period</li> </ul>	<ul style="list-style-type: none"> <li>■ Performance and frequency of SMBG did not predict better metabolic control over 3 years</li> <li>■ Investigators could not identify any specific subgroups for whom SMBG practice was associated with lower HbA<sub>1c</sub> levels during the study</li> </ul>
ROSSO <sup>(30)</sup>	<ul style="list-style-type: none"> <li>■ Investigated relationship of SMBG with disease-related morbidity and mortality</li> <li>■ Followed 3,268 patients from diagnosis of T2DM between 1995 and 1999 until end of 2003 (mean follow-up 6.5 years) retrospectively from medical records</li> </ul>	<ul style="list-style-type: none"> <li>■ SMBG was associated with decreased diabetes-related severe morbidity and all-cause mortality</li> <li>■ This association was also seen in subgroup of non-insulin-treated patients</li> <li>■ Medical records contained data on some biochemical parameters, retinopathy and neuropathy for only a small proportion of patients</li> </ul>

**Table 1B. Summary of key randomized controlled trials**

Study	Description of purpose	Findings/comments
King-Drew Medical Center Trial <sup>(20)</sup>	<ul style="list-style-type: none"> <li>■ Randomized, single-blind study designed to determine whether SMBG improves HbA<sub>1c</sub> in non-insulin-treated T2DM patients</li> <li>■ Clinical management decisions were blinded to SMBG data and use</li> <li>■ 89 non-insulin-treated T2DM patients were followed for 6 months</li> </ul>	<ul style="list-style-type: none"> <li>■ At 6 months, differences in decrease in HbA<sub>1c</sub> levels were not statistically significant</li> </ul> <p><i>The rapid upgrading of medication every two weeks if goals were not met may have obscured the potential of SMBG for supporting self-management</i></p>
ESMON <sup>(33)</sup>	<ul style="list-style-type: none"> <li>■ Prospective randomized controlled trial assessed the effect of SMBG vs no monitoring on glycaemic control and psychological indices in patients with newly diagnosed T2DM</li> <li>■ Evaluated 184 non-insulin-treated patients with no previous use of SMBG over 12 months</li> </ul>	<ul style="list-style-type: none"> <li>■ There were no significant differences in HbA<sub>1c</sub> between groups at any time point</li> <li>■ SMBG was associated with a 6% higher score on the depression subscale of the well-being questionnaire</li> </ul> <p><i>The major improvement of mean HbA<sub>1c</sub> levels in the control group, from 8.6 to 6.9% indicates a dominant role of medication in disease management</i></p>
DINAMIC <sup>(19)</sup>	<ul style="list-style-type: none"> <li>■ Multicentre, randomized, parallel-group trial was designed to determine if therapeutic management programmes for T2DM that included SMBG result in greater reductions in HbA<sub>1c</sub> compared with programmes without SMBG in non-insulin-treated patients</li> <li>■ Followed 610 T2DM patients with early or mild diabetes receiving an identical oral anti-diabetic therapy regimen with gliclazide for 27 weeks</li> </ul>	<ul style="list-style-type: none"> <li>■ There was a major decrease of HbA<sub>1c</sub> which was significantly larger in the SMBG group than the control group</li> <li>■ The incidence of symptomatic hypoglycaemia was lower in the SMBG group</li> </ul> <p><i>The major improvement of HbA<sub>1c</sub> levels in the control group from 8.1 to 7.2% indicates a dominant role of medication in disease management</i></p>

Study	Description of purpose	Findings/comments
German-Austrian <sup>(22)</sup>	<ul style="list-style-type: none"> <li>■ Prospective, multicenter, randomized controlled study Investigated the effect of meal-related SMBG on glycaemic control and well-being in non-insulin-treated T2DM subjects</li> <li>■ Followed 250 non-insulin-treated T2DM patients for 6 months</li> </ul>	<ul style="list-style-type: none"> <li>■ In per-protocol analysis (n=223) use of SMBG significantly reduced HbA<sub>1c</sub> levels</li> <li>■ SMBG use resulted in a marked improvement of general well-being with significant improvements in the subitems depression and lack of well-being</li> </ul> <p><i>The benefit of intense patient care is evident but the contribution of intense vs SMBG cannot be assessed</i></p>
DIGEM <sup>(18)</sup>	<ul style="list-style-type: none"> <li>■ Three-arm, open, parallel group randomized trial designed to determine whether SMBG alone, or with instruction in incorporating results into self-care, is more effective than standardized usual care in improving glycaemic control in non-insulin-treated T2DM patients</li> <li>■ Followed 453 patients with a mean HbA<sub>1c</sub> level of 7.5% for a median duration of 1 year.</li> </ul>	<ul style="list-style-type: none"> <li>■ At 12 months the differences in HbA<sub>1c</sub> level between the three groups were not statistically significant</li> <li>■ Investigators concluded that evidence is not convincing of an effect of SMBG, with or without instruction in incorporating findings into self-care, compared with usual care in reasonably well controlled non-insulin-treated patients with type 2 diabetes.</li> </ul>