

Is it worth monitoring blood glucose levels in type 2 diabetes?

Debbie Hicks

Introduction

It is well established that people with diabetes, regardless of type, can reduce the risk of long-term complications by maintaining good glycaemic control (Diabetes Control and Complications Trial [DCCT] Research Group, 1993; UK Prospective Diabetes Study [UKPDS] Group, 1998). Self-monitoring of blood glucose (SMBG) provides immediate feedback to assist in the maintenance of good glycaemic control. However, evidence to support the use of SMBG in the management of type 2 diabetes is only now beginning to emerge. This article examines the evidence base, including the results of a recent large German study (ROSSO), and the new *Global Guideline for Type 2 Diabetes from the International Diabetes Federation*.

Until recently there has been a lack of scientific evidence to support the benefits of self-monitoring of blood glucose (SMBG) in people with type 2 diabetes mellitus. Because of the lack of evidence, SMBG became an easy target for primary care trusts (PCTs; known as primary care organisations [PCOs] in Scotland), who were trying to save money within their pharmacy budgets. As a result, PCTs and PCOs around the UK began to restrict the number of test strips that people with diabetes were allowed to request. Not surprisingly, this served to highlight the inequalities within diabetes care.

This move to restrict the availability of test strips led to the setting up of a Delphi Project to develop a UK-wide consensus on SMBG (Owens et al, 2004; the Delphi process is a method that includes a definition of consensus as a 50% level of agreement). The project aimed to provide guidance on who should be monitoring and the frequency of monitoring. The expected outcome was a framework, available to all healthcare professionals, that would ensure that SMBG not only was used in the most cost-effective way, but would also consider the individual needs of the person with diabetes.

The results of the project were published

in April 2005 (Owens et al, 2005). These showed that people with type 2 diabetes, who were taking blood glucose lowering therapies, should monitor their blood glucose levels regularly to avoid the risk of hypoglycaemia. Hypoglycaemia is more common than generally assumed in people with type 2 diabetes on sulphonylureas (Jennings et al, 1989). Owens et al (2005) said that SMBG should also be encouraged when there are periods of illness, a change in therapy, during steroid therapy, postprandial hyperglycaemia and where regular HbA_{1c} testing is not available.

The key to effective SMBG is education. When a person with diabetes is educated about the benefits of regular SMBG, effective self-management can help to reduce complications and long-term risk (Hampson et al, 2001). On a day-to-day basis, people with diabetes need to understand what the test results mean in terms of lifestyle and treatment, and to know that they have the ability to adjust some factors, such as diet and exercise, accordingly. Where appropriate, people with diabetes should be taught to adjust their treatment according to their test results and to change those lifestyle factors that are directly influencing their blood glucose levels (Gadsby, 2005).

ARTICLE POINTS

1 Evidence to support self-monitoring of blood glucose (SMBG) in type 2 diabetes is mounting.

2 Examples include the ROSSO study from Germany, which has shown that SMBG is useful and cost-effective in the management of type 2 diabetes.

3 The evidence has led the International Diabetes Federation to launch a *Global Guideline for Type 2 Diabetes*, which supports the use of SMBG.

4 The key to effective SMBG is education.

5 It is hoped that the growing body of evidence will help people with type 2 diabetes to gain access to SMBG and thereby achieve optimal care.

KEY WORDS

- Type 2 diabetes
- Self-monitoring of blood glucose
- ROSSO study
- IDF *Global Guideline for Type 2 Diabetes*
- Education

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The ROSSO study

At the 41st Annual Meeting of the European Association for the Study of Diabetes (EASD) in September 2005, the results of the 'Retrospective Study: Self-monitoring of blood glucose and Outcome in people with type 2 diabetes' (ROSSO study) were presented (Martin et al, 2005). This study, which was conducted at the German

Diabetes Center in Dusseldorf, involved data collection from the case notes of 3268 people with type 2 diabetes recruited between November 2003 and June 2004. See Tables 1 and 2 for participant baseline characteristics.

The criterion used to differentiate the SMBG cohort and the 'no SMBG' cohort was that SMBG had to be documented within the medical notes for at least a year. Table 3 shows that the SMBG cohort was a slightly younger and smaller group, but had worse HbA_{1c} and lipid levels than the no SMBG cohort.

The ROSSO study looked at two endpoints: 'combined non-fatal' and 'fatal'.

The combined non-fatal endpoint comprised one or more of the following:

- myocardial infarction
- stroke
- blindness
- haemodialysis
- amputation (foot or lower limb).

The fatal endpoint comprised:

- all-cause mortality.

Results

There were fewer people with non-fatal endpoints in the SMBG cohort (107/1479; 7.2%) than in the no SMBG cohort (186/1789; 10.4%). The difference was statistically significant (P=0.002).

There were fewer people with fatal endpoints in the SMBG cohort (41/1543; 2.7%) than in the no SMBG cohort (79/1725; 4.6%). Again, the difference was statistically significant (P=0.004).

Because of differences in the baseline characteristics of the two cohorts, the Cox regression (proportional hazard rate model) was used to make the groups more comparable.

The results of the study showed that people with type 2 diabetes have a 51% lower risk of reaching a fatal outcome and a 32% lower risk of reaching a non-fatal endpoint. The study therefore demonstrated that SMBG has a long-term protective effect on people with diabetes (Martin et al, 2005).

Discussion

What factors might have influenced the ROSSO study outcomes?

Table 1. Baseline demographics of the ROSSO study participants.

Total number of participants	3268
Mean observation period (years)	6.5
Mean age (years)	
– male	60.0
– female	64.6
Women (%)	51
Retired (%)	55

Table 2. Baseline clinical and laboratory data of ROSSO study participants.

Body mass index (kg/m ²)	29.8
Systolic blood pressure (mmHg)	149
Diastolic blood pressure (mmHg)	87
Fasting blood glucose (mmol/l)	10.4
HbA _{1c} (normalised to 6.1%)	7.7
Creatinine (mmol/l)	88.4
Triglycerides (mmol/l)	2.6
Cholesterol (mmol/l)	6.1
HDL-cholesterol (mmol/l)	1.2
LDL-cholesterol (mmol/l)	3.8

Table 3. Comparison of SMBG and no SMBG cohort baseline clinical and laboratory data.

	SMBG	No SMBG
Number in cohort	1479	1789
Age (years)	60.5	64.0
Body mass index (kg/m ²)	29.9	29.8
Systolic blood pressure (mmHg)	148	150
Diastolic blood pressure (mmHg)	87	87
Fasting blood glucose (mmol/l)	10	8.8
HbA _{1c} (normalised to 6.1%)	8.1	7.2
Triglycerides (mmol/l)	2.8	2.4
Total cholesterol (mmol/l)	6.1	6.1
HDL-cholesterol (mmol/l)	1.2	1.2
LDL-cholesterol (mmol/l)	3.8	3.7

- Education?
- Awareness?
- Motivation?

On questioning, the presenting panel at the EASD clarified that each participant in the study received the usual standard diabetes education provided in Germany by the his/her medical insurance. The SMBG cohort did not receive any extra education other than instruction on the procedure of SMBG.

It is possible that people in the SMBG cohort were more aware of their blood glucose levels, and therefore sought advice sooner from their physicians when their blood glucose levels were outside the target range set for the individual. Without the ability to self-monitor their blood glucose levels, people with diabetes may not be aware that their levels are increasing until they experience overt osmotic symptoms. Unfortunately, persistently high blood glucose levels contribute to long-term complications and poor outcomes.

The ROSSO panel stated that the SMBG cohort had more frequent adjustments to their medication than the no SMBG cohort. As mentioned earlier, involving people with diabetes in the treatment process, and thus enabling them to see the benefits of the treatment regimens, encourages concordance and improves outcomes.

SMBG also allows people with diabetes to experiment with their diet, enabling them to learn how certain foods influence their blood glucose levels, and promotes a feeling of 'being in control'. In addition, SMBG allows people with diabetes to monitor the effect of activity on their blood glucose levels.

Once a person with diabetes is fully engaged with self-care management through education and empowerment, they can achieve improved outcomes for themselves and their families.

Publication of the SMBG consensus statement (Owens et al, 2005) provided healthcare professionals around the UK with a robust framework that supports the effective use of SMBG in people with type 1 or type 2 diabetes. In the author's opinion SMBG can never be used in isolation: it must always be used in conjunction with education to enable people with diabetes to

manage their blood glucose levels.

Moore and McQuay (2005) claim that SMBG provides significant benefit for people with type 2 diabetes, as demonstrated in their recent *Bandolier* article entitled 'Is blood glucose self-monitoring worthwhile in type 2 diabetes?'

Following the presentation of the ROSSO study at the EASD annual meeting, evidence is now accruing to support the use of blood glucose monitoring in the management of people with type 2 diabetes.

During the same meeting, the International Diabetes Federation (IDF) launched its new *Global Guideline for Type 2 Diabetes* (IDF Clinical Guidelines Task Force, 2005). Chapter 8 of the guideline relates to the use of blood glucose monitoring and describes three levels of care that are acceptable throughout the world, based on the individual country's economy. These recommendations are summarised below.

IDF recommendations

Standard care

SM1 (Self-monitoring recommendation 1): SMBG should be available for all newly diagnosed people with type 2 diabetes, as an integral part of self-management education.

SM2: SMBG (using meter and strips) should be available on an ongoing basis to those on insulin treatment.

SM3: SMBG should be considered on an ongoing basis for people using oral hypoglycaemic agents, but not insulin, where it is used:

- to provide information on hypoglycaemia
- to assess glucose excursions due to medications and lifestyle changes
- to monitor changes due to intercurrent illness.

SM4: SMBG should be considered on an intermittent basis for people not using insulin or oral agents, where it is used:

- to assess glucose excursions due to lifestyle changes
- to monitor changes during intercurrent illness.

SM5: Structured assessment of self-monitoring skills, the quality and the use made of the results obtained, and of the equipment used, should be made annually.

PAGE POINTS

1 Persistently high blood glucose levels contribute to long-term complications and poor outcomes.

2 Without SMBG, people with diabetes may not be aware that their blood glucose levels are increasing until they experience overt osmotic symptoms.

3 In the ROSSO study, the SMBG cohort adjusted their medication more frequently than did the SMBG cohort.

4 Involving people with diabetes in the treatment process enables them to see the benefits of the regimen, encourages concordance and improves outcomes.

5 SMBG allows people with diabetes to experiment with their diet and learn how certain foods influence their blood glucose levels, and enables them to see how activity affects their blood glucose levels.

PAGE POINTS

1 The ROSSO study results support the argument that SMBG is useful and cost-effective in people with type 2 diabetes.

2 Further support is provided by the new IDF *Global Guideline for Type 2 Diabetes*, which recommends the use of SMBG for people with type 2 diabetes.

3 The new IDF guideline reinforces earlier work on the development of the SMBG consensus statement and framework published in April 2005.

4 It is hoped that this growing body of evidence will help to ensure that people with diabetes have access to SMBG to enable them to achieve optimal outcomes.

Comprehensive care

SMcI: This would be as for standard care, but SMBG on an ongoing basis could be offered to all people with type 2 diabetes on insulin or oral hypoglycaemic agents.

Minimal care

SMmI: SMBG using meters with strips, or visually read blood glucose strips, should be considered for those on insulin therapy.

Conclusion

The results of the ROSSO study have considerably strengthened the argument that self-monitoring is useful and cost-effective in people with type 2 diabetes. These results, together with meta-analyses of earlier studies (Sarol et al, 2005; Welschen et al, 2005), and an understanding of the role of self-monitoring in promoting optimal use of education and other therapies, have given the IDF the confidence to recommend the use of SMBG in the management of people with type 2 diabetes. The new IDF guideline reinforces earlier work carried out via the Delphi Project in the development of the SMBG consensus statement and framework published in April 2005 (Owens et al, 2005).

It is hoped that this growing body of evidence will help to ensure that people with type 2 diabetes have access to SMBG, as appropriate, to allow them to achieve optimal outcomes. ■

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