Structured episodic monitoring: A novel approach to SMBG in type 2 diabetes

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The usefulness of self-monitoring of blood glucose (SMBG) in people with type 2 diabetes has been hotly debated recently. This article is the outcome from a recently held roundtable meeting. At this meeting, a number of key opinion leaders from the world of primary and secondary care in the UK debated the usefulness of SMBG per se, in which patient groups and, particularly, a novel tool that facilitates episodic monitoring of blood glucose. In this article we present key evidence for the use of SMBG in people with type 2 diabetes, followed by suggested usage of the novel tool to conduct episodic monitoring of blood glucose.

Article points

1. Self-monitoring of blood glucose (SMBG) can improve a patient's diabetes management in one of two ways: by improving glycaemic control; enabling the individual to attain a better understanding of their diabetes, therefore, improving their attitude toward the condition.
2. Episodic monitoring of blood glucose may help empower people with diabetes to use SMBG in a clinically and cost effective manner.

Key words
- Self-monitoring of blood glucose (SMBG)
- Episodic monitoring of blood glucose
- Cost-effectiveness

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It is well known that diabetes is a progressive condition that requires constant observation by the person with the condition and the healthcare professional. Blood glucose monitoring enables both parties to make informed lifestyle and therapeutic regimen choices, with the ultimate aim of slowing or preventing the condition's progression to serious complications such as microvascular disease.

Good long-term glycaemic control, as measured by HbA_{1c}, is important for preventing diabetic complications, HbA_{1c} has therefore been the traditional target for reducing associated risks; however, there has recently been an evidence-based shift toward also addressing short-term glycaemic variability, such as raised postprandial blood glucose levels, as well as fasting blood glucose alongside HbA_{1c}. Indeed, in late 2007, the International Diabetes Federation (IDF) published its *Guideline for Management of Postmeal Glucose* in order to increase the awareness of the role that postprandial blood glucose levels play in the development of macrovascular disease.

SMBG: A discussion

Healthcare professionals often make changes to therapeutic regimens using the patient's HbA_{1c}

Page points

1. Good long-term glycaemic control, as measured by HbA_{1c}, is important for preventing diabetic complications.
2. HbA_{1c} has therefore been the traditional target for reducing associated risks.
3. However, there has recently been an evidence-based shift toward addressing short-term glycaemic variability, such as raised postprandial blood glucose levels, as well as fasting blood glucose alongside HbA_{1c}.
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levels alone. However, the growing evidence-base suggests that a stable and under-target HbA_{1c} level can belie fluctuating daily blood glucose levels. Therefore, self-monitoring of blood glucose (SMBG) data should also form an integral part of any decision to modify or change existing therapies.

SMBG can improve a patient's diabetes management in one of two ways. Firstly, by helping to improve glycaemic control. Secondly, SMBG can enable the individual to attain a better understanding of their diabetes, therefore, increasing their positive contribution towards controlling their blood glucose levels or condition.

SMBG: The evidence for

Below are summaries of a selection of key studies that aimed to assess the clinical effectiveness of self-monitoring of blood glucose. A cost-effectiveness analysis is also discussed.

ROSSO

Martin et al (2006) conducted a study to address how SMBG affects diabetes-related morbidity and mortality. ROSSO (Retrolective Study 'Self-monitoring of Blood Glucose and Outcome in Patients with Type 2 Diabetes') was a Germany-based multicentre, retrospective, comparative, epidemiological cohort study. Data were collected from 3268 patients' medical records, from 192 primary care practices from across Germany. All 3268 medical records had the following recorded:

- age
- sex
- diabetes therapy, including SMBG. Both for the time of diagnosis of diabetes and for at least 1 subsequent year.

No one diagnosed with diabetes before the age of 45 years was included in the study.

Predefined study endpoints were morbidity and all-cause mortality. Morbidity was defined as myocardial infarction, stroke, foot amputation, blindness in one or both eyes, or end-stage renal failure requiring haemodialysis.

The records were assigned to one of two groups: those self-monitoring their blood glucose (SMBG group; n=1789) and those not (non-SMBG group; n=1479). The SMBG group had been self-monitoring for at least 12 months.

Each study participant was followed up for a maximum of 8 years (mean 6.5 years): to study withdrawal (such as following a fatal event) or to study end (2003).

ROSSO conclusions

Potential confounders such as age, sex and concomitant disease at diagnosis were corrected prior to final statistical analyses. Hazard ratios demonstrated that SMBG, despite an increase in microvascular events, was associated with a 32% reduction in combined non-fatal endpoints. SMBG was also significantly associated with a 51% reduction in mortality.

The SMBG study

Schwedes et al (2002) aimed to assess the effect of meal-related SMBG on glycaemic control and well-being in insulin naive people with type 2 diabetes. The study participants were randomised to one of the two following groups.

- SMBG plus standardised counselling.
- SMBG plus non-standardised counselling.

The study authors concluded that meal-related SMBG within a structured programme (which aims to educate the individual on how best to apply their SMBG results to any antidiabetic therapy they may be on) has a significant positive effect on glycaemic control in insulin naive people with type 2 diabetes. The data also demonstrated that structured SMBG also has beneficial effects on general well-being, particularly related to reported levels of depression.

The QuED Project

The Italian *Qualita ed Esito in Diabetologia* (QuED; Franciosi et al, 2001) Project assessed the association of the frequency of self-monitoring of blood glucose with glycaemic control and quality of life. This was a large multi-centre study with 3567 participants who were recruited from the primary and secondary care sectors. All patients were considered eligible for this study, irrespective of age, duration of diabetes and treatment. Of all recruited, 2968 completed a questionnaire. Relevant information, regarding SMBG and its associated outcomes, were available for 2855 of the 'completers'.

This study found a positive correlation between

an increased frequency of self monitoring and better glycaemic control in those treated with insulin. In those not treated with insulin a higher HbA_{1c} was observed with an increased frequency of SMBG.

The QuED project is an Italy-wide initiative aimed at assessing the relationship between the quality of care delivered to people with type 2 diabetes and subsequent outcomes.

SMBG: The evidence against

DiGEM study

Farmer et al (2007), in a primary-care-based study, found use of SMBG to have no more effect on glycaemic control over non-usage in people with type 2 diabetes on oral antidiabetic therapy. The DiGEM (Diabetes Glycaemic Education and Monitoring) study assessed HbA_{1c} levels over a period of 12 months. However, the authors rightly point out that the patient's view was largely absent in discussions on self monitoring in type 2 diabetes. While self testing of blood glucose can empower people, it is often viewed as a complex procedure. Finger pricks can be painful, and the possible repeated confrontations with unexpected outcomes and 'poor' results may lead to frustration and guilt. These negative effects on patients' well-being are probably responsible, to a large extent, for the low adherence to self monitoring seen in people with both type 1 and type 2 diabetes.

ESMON study

The ESMON (Efficacy of self monitoring of blood glucose in patients with newly diagnosed type 2 diabetes) study concluded that SMBG is associated with higher scores on a depression subscale in people newly diagnosed with type 2 diabetes (O'Kane et al, 2008). The study was a prospective randomised controlled trial of self monitoring versus no monitoring. A total of 184 people were randomised to receive SMBG intervention or not, they were assessed at 3-monthly intervals over 1 year in a hospital setting. Main outcome measures included between group HbA1c differences, psychological indices, BMI, use of oral hypoglycaemic drugs and reported hypoglycaemic rates.

No significant differences were observed between the two groups at any time during the study. Similarly no differences were observed in use of oral hypoglycaemic drugs, BMI and reported hypoglycaemic events. However, the authors did observe a 6% higher score on the depression subscale of the well-being questionnaire.

SMBG: Cost-effectiveness

Tunis et al (2008) designed a computer model to assess the cost-effectiveness of regular SMBG (1 to 3 times a day) versus no SMBG for people with type 2 diabetes treated with oral antihyperglycaemic drugs. The model was designed to address whether the immediate cost of performing SMBG regularly was offset by the long-term complications of the condition. The model predicted clinical and economic outcomes over 40-year period in order to 'mimic' the natural progression of diabetes over years. Outcomes were measured in increased life expectancy and quality-adjusted life-years (QALYs).

Life expectancy and QALYs were improved with once-daily blood glucose testing. Thrice-daily blood glucose testing was associated with further improvements in both indicators.

The model was also able to predict changes in relative risk of diabetes complications with an increasing frequency of SMBG. The relative risk of end-stage renal disease was reduced the most. The relative risks of a first stroke and a first amputation were the only two complications that showed a very slightly increase with an increased frequency of SMBG. A total of 16 risks were analysed. These included specific cardiovascular complications, aspects of renal disease, specific eye complications and lower limb complications.

Structured episodic monitoring of blood glucose

Although there is much evidence demonstrating the benefits of SMBG in people with type 2 diabetes, across the UK, many primary care trusts have been imposing restrictions on the number of blood glucose test strips. With specific reference to a novel paper-based tool (the Accu-Chek 360° View tool) the faculty at this roundtable meeting discussed and here present guidance for 'using

Page points

1. Meal-related SMBG within a structured programme (which aims to educate the individual on how best to apply their SMBG results to any antidiabetic therapy they may be on) has a significant positive effect on glycaemic control in insulin naive people with type 2 diabetes.
2. Daily self-monitoring of blood glucose is associted with improvements in quality-adjusted life-years and life expectancy.

Page points

1. In order to check whether any diabetes medication is having the desired therapeutic effect, SMBG is an essential tool that allows both the person with diabetes and the clinician valuable day-to-day information into the results of the individual's lifestyle or prescribed medication, or both.
2. There was a consensus among the faculty that SMBG has major benefits for people with type 2 diabetes, provided it is linked to a structured education programme and the individual is using the result in a constructive way.

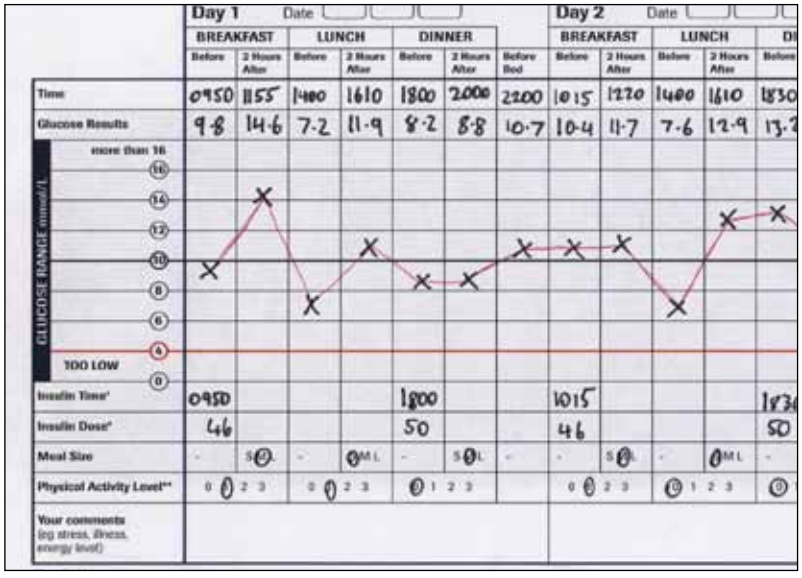
this novel SMBG tool and in whom it may provide the greates benefits'.

The faculty believe that HbA_{1c} need not be the sole indicator to modify or change any treatment regimen, rather a fuller picture may be necessary. Therefore, the faculty recommend episodic monitoring of blood glucose levels prior to a consultation between the patient and the clinician, especially for the patient who self monitors habitually with no action taken as a result. This is highlighted in the newly published NICE guidance for type 2 diabetes, which focuses heavily on structured education in combination with monitoring to enable individuals to take action based on their SMBG test results.

Monnier et al (2007) concluded that postprandial blood glucose levels affect HbA_{1c} levels as much as fasting blood glucose levels and should, therefore, inform any treatment regimens. With this in mind, Roche Diagnostics developed (and are currently trialling in a multinational trial) the Accu-Chek 360° View tool. This is a simple paper based tool that allows people with type 2 diabetes to note their SMBG results, food intake and any physical activity taken, over a period of three consecutive days. The patient will be instructed to complete the tool in the week prior to his or her diabetes consultation. This will supply the data needed for the healthcare professional and the patient to make appropriate changes to the treatment regimen while formulating a joint care plan.

Figure 1 illustrates the part of the tool where individuals complete their SMBG results. One can see that such a tool can provide a very clear indication as to the patient's day-to-day blood glucose control. The recorded data can allow informed treatment regimen choices to be made; through the 'food and drink intake' part of the tool a discussion can be facilitated between the patient and the clinician regarding the patient's lifestyle (*Figure 2*).

Figure 1. The Accu-Chek 360° View tool. This side of the paper-based tool allows the person with diabetes to record his or her blood glucose levels for three consecutive days in order for both, the patient and the clinician, to gain a better understanding of glycaemic control.



Education

In order to check whether any diabetes medication is having the desired therapeutic effect, SMBG is an essential tool that allows both the person with diabetes and the clinician valuable day-to-day information into the results of the individual's lifestyle or prescribed medication, or both. There was a consensus among the faculty that SMBG can have major benefits for people with type 2 diabetes, provided it is linked to a structured education programme and the individual is using the result in a constructive way. Given that there is strong evidence to prove that the major cost from diabetes to the NHS is due to caring for people with complications as a result of their diabetes it seems somewhat strange that we are restricting the very tool that enables people with diabetes to self manage their condition and prevent such costly complications both in terms of financial cost and possibly the deterioration in quality of life.

The Accu-Chek 360° View tool: A discussion

The tool provides the clinician with a short and precise snapshot of his or her patient's blood glucose control in order to inform any intervention decisions. The faculty believe that the tool may be useful for the following groups of people with type 2 diabetes (these groups and how effective the tool could be for them are discussed more fully later).

- Newly diagnosed people.
- Those with HbA_{1c} levels over the agreed target (this will generally be ~7%).
- Women planning a pregnancy.
- Women who are pregnant.

- Those with hypoglycaemia unawareness.
- Those on oral agents likely to induce hypoglycaemia, particularly sulphonylureas.
- Prior to initiating insulin therapy.
- Those treated with insulin.
- Those who take appropriate action based on the results, particularly during times of illness and prior to any hospital visits.

The newly diagnosed

This is one of the two most controversial groups in whom SMBG was advocated by the faculty. Self-monitoring of blood glucose should be available to all newly diagnosed people at the discretion of the healthcare professional who can evaluate the effectiveness and relevance for the patient at this stage. It can be beneficial by providing an early picture of their postprandial blood glucose levels in order to inform a treatment regimen.

Those with HbA_{1c} levels over the agreed target, this will generally be 7%

Episodic monitoring may aid concordance in this group with the collection of information on daily blood glucose control, which could be used by the clinician in working with the individual as to how to improve control. Such a visualisation of blood glucose control as is offered by this tool may also help the patient understand how their lifestyle is impacting on blood glucose levels.

Women planning a pregnancy and those already pregnant

There is much evidence demonstrating the detrimental effects of poor glycaemic control on pregnancy outcomes, with many births being premature and of low weight, for example. Therefore, in this group, any tool that facilitates SMBG in order to allow the assessment of glycaemic control will be of benefit; even in women treated with oral hypoglycaemic agents but not insulin. A formal assessment of the tool in a hospital-based diabetes clinic specialising in antenatal care could be of immense value.

Those with hypoglycaemia unawareness

Quite simply, people who are unaware of any hypoglycaemia, blood glucose monitoring will be of clinical benefit. SMBG in this group allows a quick visual indication of when hypoglycaemic episodes may be occurring. Although not specific to this tool, SMBG may enable people to return to driving if they have had to stop due to hypoglycaemia unawareness.

Those on oral agents likely to induce hypoglycaemic

This is the other of the two most controversial group in which to use any self monitoring of blood glucose tools, including blood glucose meters. However, the faculty cannot express how important it is to facilitate an understanding by the patient of their diabetes, and its progressive nature. It can be argued that episodic monitoring will be cost-effective in this patient group as it 'self-restricts' the use of blood glucose testing strips. SMBG is more accepted as routine if there is any risk of hypoglycaemia.

Prior to initiating insulin therapy

Many patients see insulin initiation as a 'failure' on their part in managing their diabetes. It is therefore imperative that the clinician helps them to understand that the condition is progressive. Episodic monitoring may help the patient observe this gradual progression, and when the time comes, to understand why insulin must be initiated.

Page points

1. People newly diagnosed with type 2 diabetes can benefit from SMBG, provided structured education has been provided and the individual is able to use the SMBG results to gain a better understanding of his or her diabetes.
2. SMBG and, more specifically, episodic monitoring will be of benefit in making insulin dose adjustments based on such sporadic testing as is required by monitoring episodically.

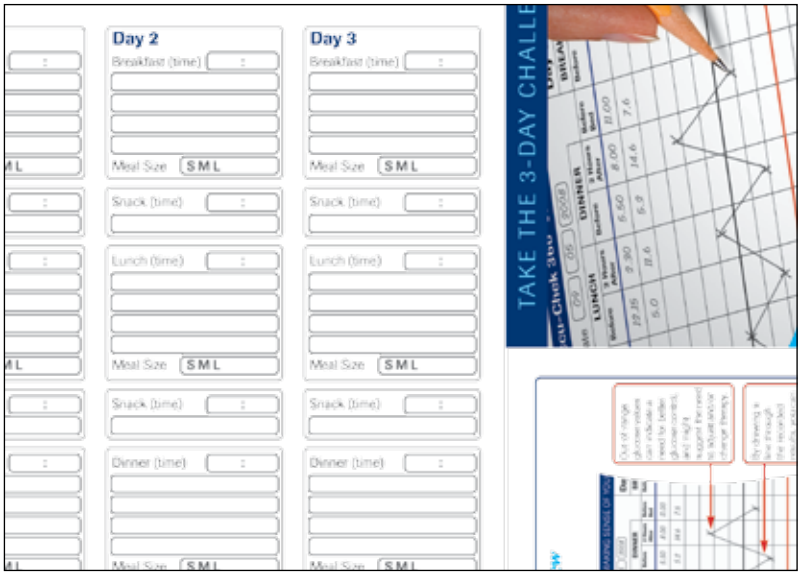


Figure 2. The Accu-Chek 360° View tool. This side of the paper based tool allows the person with diabetes to record his or her food and drink intake, thus giving an indication of possible reasons for any unexplained fluctuations in blood glucose levels.

Those treated with insulin

The faculty were unanimous in deciding that SMBG and the Accu-Chek 360° View tool, by allowing the visualisation blood glucose level patterns, will be of benefit in assessing whether more self-monitoring may be necessary. The tool may also help those monitor infrequently or not at all.

During dose titrations or addition of oral therapy

Similarly with initiating insulin, episodic monitoring at such a time will allow the patient to understand any changes to oral antihyperglycaemic treatments that may be necessary to improve diabetes control. These changes can be increasing the dose of metformin, or the addition of a second or third oral agent.

Those undergoing non-diabetes changes in their lives

Stress such as that caused by exams or a death of a close one may also affect glycaemic control. The problem the clinician may come across is that of "I've got other things to be thinking of right now". However, it is our duty to offer all tools available to us to all patients and at all times, as long as they are adhered to and relevant treatment changes are made as a result of the recorded data, that the 360 tool provides.

'We believe that providing a simple paper-based tool that permits episodic monitoring of blood glucose, particularly within the week prior to a medical appointment, will help empower people with diabetes to use self-monitoring of blood glucose in a clinically and cost effective manner.'

Discussion

We believe that the perceived cost of SMBG test strips in the UK has, in some way, has contributed to the aforementioned strip rationing. However, the recently published NICE guidelines on type 2 diabetes states that blood glucose monitoring should be available to all newly diagnosed people with type 2 diabetes as part of their structured education plan. The faculty stressed the importance of such education to back up monitoring. Any patient who is capable of understanding results and are confident of subsequently acting upon them should be allowed to access prescribed test strips, regardless of existing medication. More frequent monitoring is required for those who are taking medication that could cause hypoglycaemic episodes, such as sulphonylureas and insulin. The frequency and targets to be met should be an informed joint decision made by the person with diabetes and the healthcare professional.

As well as the debate on the clinical effectiveness of SMBG, its cost-effectiveness has also been debated (Simon et al, 2008, for example); however, the majority of those who self-monitor of those who self-monitor their blood glucose are insulin treated. We believe that the long-term costs associated with diabetes' comorbidities and complications is much higher than those associated with the condition's treatment.

We believe that providing a simple paper-based tool that permits episodic monitoring of blood glucose, particularly within the week prior to a medical appointment, will help empower people with diabetes to use self-monitoring of blood glucose in a clinically and cost effective manner.■

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