Developing a local practice guideline for SMBG in non-insulin treated type 2 diabetes

Neil Brown, John Morrissey

Self-monitoring of blood glucose (SMBG) is a routine part of diabetes self-management but its value in people with non-insulin treated diabetes remains unclear. This article reports on the development of a local guideline based on published research and the results of a local audit of individuals' use of SMBG. Analysis of the audit results supports SMBG as a useful addition to HbA_{1c} testing in individuals with type 2 diabetes treated with oral antidiabetes drugs. SMBG does need to be targeted but it does not need to be frequent; consequently, its cost can be kept within affordable limits.

Article points

1. This article reports on an audit of people with type 2 diabetes at Yardley Green Medical Centre (YGMC), Birmingham, which was undertaken to inform a local practice guideline with regard to SMBG recommendations that were robust, evidence-based and cost-effective.
2. The authors have calculated that with appropriate targeting and restrictions on inappropriate use, YGMC can offer SMBG to all of the non-insulin but pharmacologically-treated type 2 diabetes population at the practice without any increase in cost.

Key words

- Audit
- Local guidelines
- Self-monitoring of blood glucose

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Self-monitoring of blood glucose (SMBG) is strongly recommended for the vast majority of people treated with insulin (NICE, 2004; National Collaborating Centre for Chronic Conditions, 2008), however its value in people with non-insulin treated diabetes remains unclear. Guidelines are inconsistent and often fail to address crucial questions about who should test, when and how often.

It is unlikely that SMBG would be controversial were it not so expensive. In the NHS it is the responsibility of clinicians to recommend interventions that are both clinically effective and good value for money.

This article reports on an audit of people with type 2 diabetes at Yardley Green Medical Centre (YGMC), Birmingham, which was undertaken to inform a local practice guideline with regard to SMBG recommendations that were robust, evidence-based and cost-effective.

SMBG: The evidence for and against

The strongest evidence for the use of SMBG in people with non-insulin treated diabetes is derived from two randomised controlled studies that found a reduction in mean HbA_{1c} of 0.3% in favour of self-testing (Schwedes et al, 2002; Guerici et al, 2003). However, there were significant methodological flaws in both studies that may have biased the results in this direction.

Additional evidence in favour of SMBG in people with diabetes regardless of pharmacological therapy is derived from two cohort studies that used uptake of testing strips as a surrogate for frequency of testing and found higher uptake to be associated with better glycaemic control (Karter et al, 2001; 2006). In addition, a retrospective cohort study reported fewer microvascular and macrovascular events in those with non-insulin treated type 2 diabetes who performed SMBG (Martin et al, 2006).

The first two of these studies, however, were carried out in the USA and the third in Germany,

Page points

1. A cautious conclusion from the published evidence is that the effect of self-monitoring of blood glucose (SMBG) on HbA_{1c} level is small but possibly not negligible, that its influence is difficult to disentangle from other patient and lifestyle factors, and that benefits other than HbA_{1c} reduction cannot be ruled out.
2. From the practice diabetes register the following data were retrieved for all known people with type 2 diabetes: known duration of diabetes, whether they were performing SMBG or not, current treatment regimen, mean HbA_{1c} level over the preceding 12 months, and recorded complications.
3. On the audit date, 458 individuals were included on the Yardley Green Medical Centre diabetes register.
4. The primary outcome was whether people who performed SMBG achieved better glycaemic control.

where SMBG is either self- or insurance-funded. The results may simply indicate that those who make healthy lifestyle choices (or who have the financial resources to do so), such as SMBG also experience better glycaemic control and more favourable diabetes outcomes.

Evidence against any major benefit from SMBG is derived from three randomised controlled trials (Davidson et al, 2005; Farmer et al, 2007; O'Kane et al, 2008). In all three, a greater reduction in mean HbA_{1c} was demonstrated in the SMBG group compared with the control group but failed to reach statistical significance. Two cohort studies demonstrated that across all treatment modalities there was no relationship between frequency of SMBG and glycaemic control and that SMBG was associated with a 79% increase in cardiovascular mortality in non-insulin treated participants (Davis et al, 2006; 2007).

Interpretation is rendered more difficult because the behaviour of people in control groups in randomised controlled trials can be influenced by the fact they are participating in a study (Hawthorne effect). In all three of the negative trials (Davidson et al, 2005; Farmer et al, 2007; O'Kane et al, 2008), glycaemic control also improved in the control groups. This may have limited the opportunity to demonstrate significant benefit from SMBG.

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Current NICE guidance in England and Wales suggests that SMBG should be offered to those on oral antidiabetes therapy for the avoidance of hypoglycaemia and to assess glycaemic control after treatment changes and during intercurrent illness; however, its continued benefit should be reassessed periodically (National Collaborating Centre for Chronic Conditions, 2008).

The audit

Aims

To assist in the development of SMBG recommendations for local use, the authors aimed to determine whether:

- There was any association between SMBG and glycaemic control as judged by HbA_{1c} level in the practice population at YGMC.
- The frequency and timing of SMBG tests had any influence on glycaemic control.
- There was any relationship between performing SMBG and the prevalence of diabetes complications.

Methods

From the practice diabetes register the following data were retrieved for all known people with type 2 diabetes: known duration of diabetes, whether they were performing SMBG or not, current treatment regimen, mean HbA_{1c} level over the preceding 12 months, and recorded complications. In addition, a postal survey of those who performed SMBG was carried out, primarily to determine their current practice in timing and frequency of testing.

On the audit date, 458 individuals were included on the YGMC diabetes register. Excluded from analysis were 41 people because they were either under 17 years of age, had joined the practice within the past 12 months, had diabetes of less than 1 year's known duration or were receiving palliative care in a nursing home. Of the 417 included, 210 were performing SMBG and 207 were not. A total of 176 of the people performing SMBG (84%) responded to the questionnaire.

The 417 participants were stratified into four cohorts according to their antidiabetes therapy: those on non-pharmacological treatment; those using metformin or a thiazolidinedione or both in combination, who would be at low risk of hypoglycaemia; those treated with a sulphonylurea, with or without other antidiabetes agents, who would be at significant risk of hypoglycaemia; and those on insulin. Since the focus of this audit was on the value, or otherwise, of SMBG in non-insulin treated people this last cohort was not considered further.

Results

The primary outcome was whether people who performed SMBG achieved better glycaemic control (*Table 1*). There was a tendency towards better glycaemic control in those who performed

SMBG. In the non-pharmacologically treated and sulphonylurea-treated cohorts, mean HbA_{1c} level was slightly lower in those who performed SMBG. In all three cohorts, more people in the SMBG group achieved the lowest QOF indicator for HbA_{1c}, which, at the time, was ≤7.5% (≤58 mmol/mol). However, because of small numbers, none of these differences were statistically significant. But even if this association is real, it cannot be assumed that SMBG was necessarily responsible for the improved glycaemic control – the link could simply be motivation. It is reasonable to hypothesise that individuals who are more motivated to control their diabetes are more likely to undertake SMBG.

It is noteworthy that glycaemic control was best in the non-pharmacologically treated cohort, less good in those treated with metformin or a thiazolidinedione or both in combination, and worst in the sulphonylurea cohort. The likely explanation is known duration of diabetes. In the non-pharmacologically treated cohort, only 38% had a known duration of diabetes greater than 5 years. This figure was 47% in the metformin/thiazolidinedione cohort and 81% in the sulphonylurea cohort.

The existence of any association between glycaemic control and self-reported frequency and timing of SMBG was also investigated. With respect to frequency of SMBG in the non-pharmacologically treated cohort, those who performed more than 12 tests per month had a slightly higher mean HbA_{1c} level than those who performed fewer. In the metformin and sulphonylurea cohorts, frequent testers had a lower mean HbA_{1c} level than infrequent but the differences were small.

Arguably more illuminating was a possible association between timing of SMBG and glycaemic control, the results of which are shown

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1. In the larger sulphonylurea cohort, mean HbA_{1c} level was lower in those testing both before and after meals, compared with those testing only before meals, and considerably more people achieved the lowest QOF indicator for HbA_{1c}.
2. Across all treatment groups, there was a trend towards better glycaemic control as judged by HbA_{1c} level in those who performed self-monitoring of blood glucose.

in *Table 2*. Data for the non-pharmacologically treated and metformin cohorts are difficult to interpret because of very small numbers. However, in the larger sulphonylurea cohort, mean HbA_{1c} level was lower in those testing both before and after meals, compared with those testing only before meals, and considerably more people achieved the lowest QOF indicator for HbA_{1c} (≤7.5% [≤58 mmol/mol]) (71% pre-prandial plus postprandial versus 44% pre-prandial only). This cannot be explained on the basis of motivation since it probably requires little more motivation to test after meals as well as before. However, these differences did not reach statistical significance.

Analysis of the data on diabetes complications yielded little more than the expected increase in prevalence of complications with longer duration of diabetes. For this reason, complications were least prevalent in the non-pharmacologically treated cohort, most prevalent in the sulphonylurea cohort, and the metformin cohort was intermediate. Interestingly, within each treatment cohort the prevalence of complications was greater in those who used SMBG than in those who did not. A likely explanation is that the presence of complications provided an additional incentive to control blood glucose and therefore to use SMBG.

Key findings

Across all treatment groups, there was a trend towards better glycaemic control as judged by HbA_{1c} level in those who performed SMBG. This was most apparent in the sulphonylurea cohort in whom the improvement in HbA_{1c} was precisely that found in the two controlled trials cited previously: 0.3% (Schwedes et al, 2002; Guerici et al, 2003).

The timing of testing appeared to have at least as much influence on glycaemic control as

Table 1. Glycaemic control by self-monitoring of blood glucose (SMBG) and treatment status.

	SMBG			Not SMBG		
	Number of participants	Mean HbA_{1c} (% [mmol/mol])	% of participants with HbA_{1c} ≤7.5% (≤58 mmol/mol)	Number of participants	Mean HbA_{1c} (% [mmol/mol])	% of participants with HbA_{1c} ≤7.5% (≤58 mmol/mol)
Non-pharmacological therapy	12	6.12 [43]	100%	79	6.35 [45]	94%
Metformin and/or a thiazolidinedione	38	7.00 [53]	84%	77	7.04 [53]	78%
Sulphonylurea alone or with other therapy	78	7.57 [60]	58%	48	7.88 [63]	42%
Total	**128**			**204**		

Table 2. Glycaemic control by timing of self-monitoring of blood glucose (SMBG) and treatment status.

	Before meals only			Before and after meals		
	Number of participants	Mean HbA_{1c} (% [mmol/mol])	% of participants with HbA_{1c} ≤7.5% (≤58 mmol/mol)	Number of participants	Mean HbA_{1c} (% [mmol/mol])	% of participants with HbA_{1c} ≤7.5% (≤58 mmol/mol)
Non-pharmacological therapy	4	6.5 [48]	100%	4	6.1 [43]	100%
Metformin and/or a thiazolidinedione	13	6.81 [51]	92%	13	6.78 [51]	100%
Sulphonylurea alone or with other therapy	36	7.55 [58]	44%	28	7.47 [58]	71%
Total	**53**			**45**		

its frequency. Those who included post-prandial testing tended to have better control than those who relied on fasting and pre-prandial tests. However, there was little additional benefit from testing more than three times each week.

In the absence of compelling evidence of benefit, it is difficult to advocate more expenditure on SMBG in people with non-insulin treated diabetes. However, there are several reasons, other than a reduction in HbA_{1c}, why such individuals might find it useful.

Type 2 diabetes is frequently asymptomatic. Motivation to change lifestyle will not come easily to people who feel perfectly well and SMBG may help to provide that motivation. One participant in a qualitative study remarked that "glucose testing made an invisible illness visible" (Peel et al, 2004). Awareness of the true blood glucose level is likely to be of more value than reliance on non-specific subjective symptoms of tiredness and lethargy to motivate behaviour change.

The authors suggest that the role of SMBG in non-insulin treated diabetes is to:

- Identify hyperglycaemic excursions that may require treatment modification.
- Identify effects of lifestyle on glycaemia, for example diet and exercise.
- Identify potential hypoglycaemia risk.
- Identify whether subjective symptoms, such as tiredness and fatigue, have a biochemical origin that may require treatment modification.
- Motivate behaviour change.

Recommendations

People treated non-pharmacologically

- HbA_{1c} test every 4 months (target <6% [<42 mmol/mol]).
- Normally no SMBG.

People treated with metformin, a thiazolidinedione or both in combination

- HbA_{1c} test every 4 months.
- SMBG two tests each week targeted at two hours after breakfast and 4 hours after the main carbohydrate meal (target 4–7.5 mmol/L).

People treated with a sulphonylurea with or without other agents

- HbA_{1c} test every 4 months.
- SMBG three tests each week targeted at 2 hours after breakfast and 4 hours after the main carbohydrate meal (target 4–7.5 mmol/L); also, fasting blood glucose test to check for risk of nocturnal hypoglycaemia (target 4–6 mmol/L).

Packaging

- To ensure that test strips do not go out of date with less frequent testing, only individually packed strips should be supplied to people with non-insulin treated diabetes.

Conclusion

SMBG is a useful addition to HbA_{1c} testing in people with type 2 diabetes treated with oral antidiabetes agents. It does not need to be frequent but does need to be targeted. The authors have calculated that with appropriate targeting and restrictions on inappropriate use, YGMC can offer SMBG to all of the non-insulin but pharmacologically-treated type 2 diabetes population at the practice without any increase in cost. ■

Davidson MB, Castellanos M, Kain D, Duran P (2005) *Am J Med* **118**: 422–5

Davis WA, Bruce DG, Davis TM (2006) *Diabetes Care* **29**: 1764–70

Davis WA, Bruce DG, Davis TM (2007) *Diabetologia* **50**: 510–15

Farmer A, Wade A, Goyder E et al (2007) *BMJ* **335**: 132

Guerici B, Drouin P, Grangé V et al (2003) *Diabetes Metab* **29**: 587–94

Karter AJ, Ackerson LM, Darbinian JA et al (2001) *Am J Med* **111**: 1–9

Karter AJ, Parker MM, Moffet HH et al (2006) *Diabetes Care* **29**: 1757–63

Martin S, Schneider B, Heinemann L et al (2006) *Diabetologia* **49**: 271–8

NICE (2004) *Type 1 Diabetes: Diagnosis and Management of Type 1 Diabetes in Children, Young People and Adults.* NICE, London

National Collaborating Centre for Chronic Conditions (2008) *Type 2 Diabetes: National Clinical Guideline for Management in Primary and Secondary Care (Update).* Royal College of Physicians, London

O'Kane MJ, Bunting B, Copeland M et al (2008) *BMJ* **336**: 1174–7

Peel E, Parry O, Douglas M, Lawton J (2004) *Br J Gen Pract* **54**: 183–8

Schwedes U, Siebolds M, Mertes G et al (2002) *Diabetes Care* **25**: 1928–32

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