

Self-monitoring of blood glucose in type 2 diabetes: systematic review

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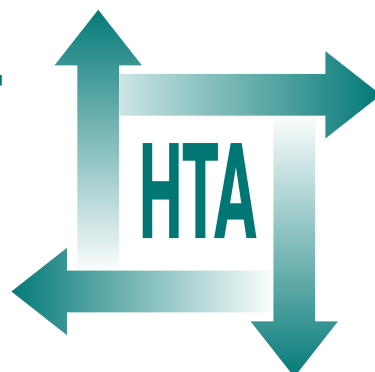
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Executive summary

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Executive summary

Background

The prevalence of type 2 diabetes (T2DM) has been rising in the UK, and around 4% of the population now have the condition.

Good control of blood glucose level is important in preventing or delaying the complications of T2DM, such as heart disease, peripheral vascular disease, visual loss and renal failure.

However, many people with T2DM do not have good control of their blood glucose.

The usual method for monitoring glycaemic control is by measuring glycated haemoglobin, or HbA_{1c}, which gives an average of the blood glucose over 3 months. If it is high then control needs to be improved. The National Institute for Health and Clinical Excellence (NICE) recommends that most people with T2DM should aim to keep their HbA_{1c} level at 6.5% or under, though targets should be tailored to the individual.

However, HbA_{1c} level does not tell patients what their blood glucose is doing on a day-to-day basis. Self-monitoring by testing for urinary glucose is one way of checking when blood glucose is high, but is only a rough guide. A more accurate measure can be obtained by blood testing, which is done by pricking the skin to get a drop of blood, putting that blood on a testing strip, and reading the result with a small meter. This can be done at different times of day, before or after meals, or before or after physical activity.

Meters are cheap (about £14), and the NHS requires manufacturers to provide them free of charge if needed, so the main cost is the test strips, at about £14 for a pack of 50.

Main question

Is self-monitoring of blood glucose worthwhile in people with T2DM who are not treated with insulin or who are on only basal insulin in combination with oral agents, in terms of glycaemic control, hypoglycaemia, quality of life (QoL) and other

relevant outcomes, and cost per quality-adjusted life-year (QALY)?

Methods

Review of systematic reviews published since 1996, and a systematic review and meta-analyses of randomised controlled trials (RCTs) identified from the reviews, and from searches for more recent trials. Review of qualitative and economic studies.

Search strategy

- Electronic databases: including The Cochrane Library [all sections] (Issue 2, 2009), MEDLINE (1996–April 2009), EMBASE (1996–April 2009), PsycINFO (1996–April 2009), Web of Science – limited to meeting abstracts (1996–April 2009).
- Websites of the European Association for the Study of Diabetes (EASD), the American Diabetes Association (ADA) and Diabetes UK searched for meeting abstracts in April 2009.
- Websites of the US Food and Drug Administration (FDA), the Medicines and Healthcare Products Regulatory Agency (MHRA), Self-Monitoring of Blood Glucose (SMBG) International Working Group, Current Controlled Trials, and ClinicalTrials.gov
- Contact with experts in the field.
- Scrutiny of bibliographies of retrieved papers.

The searches were limited to the English language and to articles published since 1996, due to the number of recent good quality systematic reviews and in order to reflect current meter technologies. The search strategy did not include limits for study design, as all types of studies were screened manually for potential inclusion.

Results

Systematic reviews

We found 11 systematic reviews published in the last 10 years, most in the last few years. Most were of good quality. They contained from three to 13 RCTs out of a total of 20. Their conclusions on

glycaemic control varied, with some saying there was no benefit, others saying there was benefit, and some saying that there was no conclusive evidence of benefit. Much of the apparent disagreement may arise from the level of HbA_{1c} that was considered to prove benefit, since the differences in meta-analysis were often of the order of 0.2%, which can be statistically significant, but not clinically important. There was some evidence that studies in which patients were given feedback in response to SMBG values and/or in which SMBG results were used to modify therapeutic regimens were more effective than those without feedback or use of SMBG for therapy modification. Effects also tended to be larger for patients with higher baseline HbA_{1c} values.

Randomised controlled trials

We found 26 RCTs, ranging in size from under 30 to over 800 patients, and in duration from 12 weeks to 30 months. Only four trials scored highly on quality assessment. Components of the SMBG interventions were not well described in many cases. Half of the trials reported a reduction in HbA_{1c} level, and all those that did find favourable results included an educational component and/or feedback.

Ten trials compared 'simple' SMBG with no SMBG, and found a reduction in HbA_{1c} level of 0.21%, which was statistically significant but of doubtful clinical significance. Four trials of 'enhanced' SMBG (for example with education, feedback, etc.) showed a bigger reduction in HbA_{1c} level – 0.52% compared with no-SMBG. When SMBG enhanced with an educational or feedback component was compared to simple SMBG (five trials), there was an HbA_{1c} reduction of 0.2%, however, this was not statistically significant.

Three RCTs showed no difference between SMBG and urine testing.

Differences in the frequency of hypoglycaemic episodes were inconsistent. There was no difference in weight or body mass index (BMI). There was no increase in medication changes with SMBG versus no SMBG, which may explain why HbA_{1c} is not improved. Few studies examined quality of life (QoL), but the two best ones for this outcome [both from the UK, DiGEM (Diabetes Glycaemic Education and Monitoring) and ESMON (Efficacy of Self MONitoring of blood glucose in newly diagnosed type 2 diabetes trial)] reported a net

adverse effect on anxiety and/or depression. Results from other studies were less clear cut.

Observational studies

There were 36 relevant observational studies. These are more prone to bias, from confounding factors, and association does not necessarily mean cause. Eighteen showed no difference in HbA_{1c} level, 12 showed a reduction (but often very small), and some showed an increase in HbA_{1c} level on SMBG, which may be because SMBG was started as a result of poor glycaemic control.

Qualitative studies

The qualitative studies had some fairly consistent messages:

- There was a lack of education in how to interpret and use the data from SMBG.
- In some patients, SMBG caused adverse psychological effects, including depression and self-chastisement, whereas others found it a useful tool for reassurance, assessing effects of behaviour and empowerment.
- There was a lack of education in how to interpret and use the data from SMBG.
- There was a lack of interest in the results from health-care professionals (HCPs).
- Failure to act on the results was common.

The cost-effectiveness literature

There was a mixture of studies: some just about costs, some looking at possible savings and others at cost-effectiveness. Some were funded by the manufacturers of testing strips and meters; these tended to be more favourable by making more generous assumptions on the effect on HbA_{1c} level.

The cost of SMBG in people with T2DM in England is uncertain, but probably around £30M per year, of which at least half could be saved by adhering to previous guidelines and by applying the findings of DiGEM in the sulphonylurea-only group.

The reported costs per annum of SMBG vary amongst studies from £10 to £259, the lowest being an estimate about £10 per year for infrequent testers on diet alone.

Several studies asserted that SMBG can lead to savings that offset testing costs, and some estimated

that SMBG could lead to savings from reduced costs in other health care. These studies tended to have more optimistic assumptions.

However, most of these studies failed to allow for the potentially negative impact of SMBG on aspects of QoL.

The cost-effectiveness analyses vary in their assumptions, with those funded by industry producing lower incremental cost-effectiveness ratios (ICERs). The best analysis to date was that from the DiGEM trial (funded by the UK Health Technology Assessment programme), which, after taking into account all costs, gains and disutilities, concluded that SMBG was not cost-effective.

Conclusions

The current evidence suggests that SMBG is of limited clinical effectiveness in improving glycaemic control in people with T2DM on oral agents, or diet alone, and is therefore unlikely to be cost-effective. There were insufficient data for those on a single basal insulin to reach any conclusion.

No data are available on the possible benefits of SMBG in selected patient subgroups. SMBG can be expected to lead to improved glycaemic control only in the context of appropriate education – both for patients and HCPs – on how to respond to the readings, in terms of lifestyle and treatment adjustment. It may be more effective if patients are able to self-adjust drug treatment.

In the authors' opinion, at a time when funds are scarce, the case for investment in blood glucose monitoring in T2DM, in patients who are not treated with insulin, is not proven. Further research is required on the type of education and feedback that are most helpful, characteristics of patients benefiting most from SMBG, optimal timing and frequency of SMBG, and the circumstances under which SMBG causes anxiety and/or depression.

Publication

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The Health Technology Assessment (HTA) programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

The research findings from the HTA programme directly influence decision-making bodies such as the National Institute for Health and Clinical Excellence (NICE) and the National Screening Committee (NSC). HTA findings also help to improve the quality of clinical practice in the NHS indirectly in that they form a key component of the 'National Knowledge Service'.

The HTA programme is needs led in that it fills gaps in the evidence needed by the NHS. There are three routes to the start of projects.

First is the commissioned route. Suggestions for research are actively sought from people working in the NHS, from the public and consumer groups and from professional bodies such as royal colleges and NHS trusts. These suggestions are carefully prioritised by panels of independent experts (including NHS service users). The HTA programme then commissions the research by competitive tender.

Second, the HTA programme provides grants for clinical trials for researchers who identify research questions. These are assessed for importance to patients and the NHS, and scientific rigour.

Third, through its Technology Assessment Report (TAR) call-off contract, the HTA programme commissions bespoke reports, principally for NICE, but also for other policy-makers. TARs bring together evidence on the value of specific technologies.

Some HTA research projects, including TARs, may take only months, others need several years. They can cost from as little as £40,000 to over £1 million, and may involve synthesising existing evidence, undertaking a trial, or other research collecting new data to answer a research problem.

The final reports from HTA projects are peer reviewed by a number of independent expert referees before publication in the widely read journal series *Health Technology Assessment*.

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Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

The research reported in this issue of the journal was commissioned by the HTA programme on behalf of the Department of Health as project number 09/19/01. The contractual start date was in February 2009. The draft report began editorial review in August 2009 and was accepted for publication in December 2009. As the funder, by devising a commissioning brief, the HTA programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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