Monitoring blood glucose control in diabetes mellitus: a systematic review
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Authors' objectives
To carry out a systematic review to evaluate the clinical and cost effectiveness of different methods of monitoring blood glucose control in diabetes mellitus.

Searching
The authors searched MEDLINE from 1976 to 1999, EMBASE from 1980 to 1998, IBSS from 1975 to 1998, and the database of the Diabetes Health Economic Study Group (search dates unclear). The MEDLINE search strategy was provided in full in the report, as were the keywords used to search EMBASE and IBSS. The authors also listed the Science Citation Index and the Social Sciences Citation Index as sources but gave no further details. Additional studies were identified by searching the authors' personal collections of articles, by handsearching Diabetic Medicine and Diabetes Care journals from 1990 to 1999, and by contacting the British Diabetic Association, and Bayer and Roche Diagnostics. The citations in retrieved papers were also examined. Non-English language papers were included as too few articles were retrieved by searches restricted to English language publications only.

Study selection
Study designs of evaluations included in the review
Only randomised controlled trials (RCTs) were included in the analysis of clinical effectiveness.

Specific interventions included in the review
Self-monitoring, near-patient testing, and laboratory testing in health care settings were considered for inclusion.

The included studies of self-monitoring in Type 2 diabetes mellitus examined the following: self-monitoring of blood glucose (SMBG); urine monitoring with or without patient education; patient education and follow-up to reinforce the use of SMBG; feedback of glycated haemoglobin results; SMBG with or without a calorie-controlled diet; and a weight-control programme including SMBG. The duration of the interventions ranged from 4 to 12 months. Comparisons were made between blood testing, urine testing and no testing.

The included studies of self-monitoring in Type 1 diabetes mellitus examined SMBG, urine monitoring, different frequencies of SMBG, and patient education. The duration of the interventions ranged from 26 weeks to 9 months. Comparisons were made between different testing frequencies, blood or urine testing, or blood testing or no testing.

The included studies of self-monitoring in diabetes mellitus during pregnancy examined SMBG, self-monitoring with and without a meter, SMBG at home or with hospital care, and SMBG before or after meals.

The included studies of near-patient and laboratory testing examined the measurement of glycated haemoglobin, fructosamine and blood glucose in the assessment of glycaemic control in people with diabetes.

Participants included in the review
Adults and children with diabetes mellitus Type 1 or 2, and women with gestational diabetes mellitus (GDM) or diabetes in pregnancy. The inclusion criteria, which were tabulated in the report, varied between the included studies.

Outcomes assessed in the review
All the available clinical or patient outcome measures were assessed. These included metabolic, clinical and self-rated measures.

How were decisions on the relevance of primary studies made?
The authors do not state how the papers were selected for the review, or how many of the reviewers performed the selection.
Assessment of study quality

The quality of the primary studies was assessed using a checklist for randomised and non-randomised studies (see Other Publications of Related Interest no.1). The checklist had been modified by adding an additional item concerning the range of outcome measures, and removing the item on power. The modified checklist had 27 items grouped by subscales for reporting external validity and internal validity. The overall quality score ranged from zero (lowest quality) to a maximum of 28 points. The statistical power of each study was assessed separately based on the estimated detectable per cent difference in the mean glycated haemoglobin between the groups. This was scored from 1 (3.00% or less) to 5 (0.25% or less). The quality of the studies was assessed independently by two reviewers using a checklist. Inter-rater reliability was calculated as the mean difference in the score for each subscale of the checklist. The final grading of each item was reached by discussion.

Data extraction

The authors do not state how the data were extracted for the review, or how many of the reviewers performed the data extraction. The following data were extracted from each included study and tabulated in the report: study setting, study design, the number of participants, the characteristics of the participants, intervention groups compared in the study, study duration, outcome measures, drop-outs, and results.

Methods of synthesis

How were the studies combined?

The data were synthesised using a random-effects meta-analysis where possible, or in a narrative summary. Comparisons were made between the effect of any monitoring (blood or glucose) versus no monitoring, and blood monitoring versus urine monitoring, with respect to changes in glycated haemoglobin and weight. Publication bias was explored using funnel plots and associated tests (see Other Publications of Related Interest no.2).

How were differences between studies investigated?

The meta-analyses included a statistical test of heterogeneity. Where a meta-analysis was not possible or was inappropriate, the findings were summarised with a narrative description of the differences between the studies. These included differences in the setting and participants' characteristics, the testing methods and equipment used, the use of treatment protocols, reliability of monitoring, compliance, and confounding interventions.

Results of the review

Eight RCTs, including 734 patients, were included in the evaluation of the effectiveness of self-monitoring in Type 2 diabetes mellitus.

Eight controlled trials were included in the evaluation of the effectiveness of self-monitoring in Type 1 diabetes mellitus: 1 was an RCT (n=39), 1 was an RCT with factorial design (n=37), 3 were randomised crossover trials (n=82), 1 was a crossover trial that did not report the method of allocation (n=16), 1 used a sequential cluster allocation (n=86), and one was a non-randomised controlled trial (n=181).

Five RCTs were included in the evaluation of the effectiveness of self-monitoring of blood and urine glucose in women with GDM or diabetic pregnancy: 4 trials (n=158) were in women with diabetic pregnancy, and only one RCT (n=66) included women with GDM.

The number of studies included in the assessment of near-patient and laboratory testing was not explicit.

Self-monitoring in Type 2 diabetes mellitus.

The mean quality score for the 8 included RCTs was 15.0 (standard deviation 1.7), indicating poor conduct and reporting. All of the trials included too few patients to detect a difference of 0.5% or less in glycated haemoglobin, indicating low statistical power. The interventions were not standardised and the duration of the studies ranged between 4 and 12 months. Compared with no monitoring, there was no evidence that self-monitoring of blood or urine glucose
improves blood glucose control, measured using glycated haemoglobin or fasting plasma glucose; the pooled difference in glycated haemoglobin was -0.25 (95% confidence interval, CI: -0.61, 0.10), based on 4 RCTs (n=285). There was no evidence that blood glucose monitoring was more effective than urine glucose monitoring in improving blood glucose control; the pooled difference in glycated haemoglobin was -0.03 (95% CI: -0.52, 0.47), based on 3 RCTs (n=278). The patients' perception of monitoring was not assessed adequately in the included studies. Urine testing was preferred by approximately 70% of patients in 2 RCTs.

Self-monitoring in Type 1 diabetes mellitus.

The mean quality score for the 8 included controlled trials was 14.4 (standard deviation 1.6), indicating poor conduct and reporting. Only one study had sufficient power to detect a difference in glycated haemoglobin of less than 1%, indicating low statistical power. It was difficult to combine the findings of the studies because of differences in design, participant selection, and the testing modalities compared. The combined treatment effect on glycated haemoglobin from self-monitoring of blood glucose, compared with self-monitoring of urine glucose, was -0.57 (95% CI: -1.07, -0.06), based on 5 studies (n=180, including 18 patients in a crossover study). The statistical significance was sensitive to assumptions regarding the correlation of initial and final measurements. The majority of patients in 6 studies seemed to prefer blood monitoring to urine testing.

GDM and diabetes in pregnancy.

The mean quality score for the 5 RCTs was 12.8 (standard deviation 3.5), indicating poor conduct and reporting. None of the trials had sufficient power to detect differences in less common maternal and foetal outcomes. A meta-analysis was not possible as the trials used different interventions and measured different outcomes. A narrative summary of the findings from the 5 RCTs concluded that women with Type 1 diabetes mellitus managed at home with SMBG, can achieve blood glucose control as good as that achieved by patients who receive intensive control in hospital. Hospital admission was less for women managed at home with SMBG. Maternal and foetal outcomes may be as good with SMBG at home, and this approach was preferred by the patients. In GDM, the monitoring of blood glucose after meals, rather than before, may lead to better metabolic control and foetal outcomes.

Near-patient and laboratory testing.

Indirect evidence from 2 RCTs suggested that the monitoring of glycated haemoglobin in Type 1 and Type 2 diabetes mellitus will be clinically effective. There was no evidence on the effectiveness of different testing frequencies.

Cost information

Yes. In Type 2 diabetes mellitus, urine testing was less costly than blood testing. In Type 1 diabetes mellitus, one study showed that blood testing was more costly than urine testing. With regard to near-patient and laboratory testing, indirect evidence from 2 RCTs suggested that the monitoring of glycated haemoglobin in Type 1 and Type 2 diabetes mellitus will be cost-effective.

Authors' conclusions

The authors concluded that although SMBG is well established in clinical practice, the optimal use of the technique has not been established. Current evidence suggests that it may not be essential for all patients. A protocol should be drawn up for the conducting and reporting of evaluations of blood glucose-monitoring devices.

CRD commentary

The review addressed a clear but broad question resulting in a complex, although well-organised, report. The inclusion criteria were well defined for questions about the effectiveness of self-monitoring, but were less clear for studies of near-patient and laboratory testing. The search for studies was comprehensive and well reported. The quality of the studies of clinical effectiveness was reported as a composite score, derived from a fairly long checklist of features pertaining to the internal and external validity of randomised and non-randomised studies. Although convenient, such checklists have rarely been adequately validated and the composite scores lack transparency. The text did, however, include a useful narrative summary of the key quality features of the included studies. In addition, the quality was
assessed independently by two reviewers. Details of the individual included studies were well presented in tables, except for studies of near-patient and laboratory testing. The findings of the studies were synthesised appropriately, either using a meta-analysis or a narrative summary, with due attention to heterogeneity.

The authors’ conclusions were consistent with the evidence presented and clearly highlight important gaps in current knowledge. This review has also been published as a journal article (see Other Publications of Related Interest no.3).

**Implications of the review for practice and research**

Practice: SMBG may not be essential for all patients, but the optimal use of it has not been established.

Research: There were three recommendations for research.

Randomised studies are needed to determine the clinical and cost-effectiveness of SMBG in Type 2 diabetes mellitus and GDM.

Observational studies in people with Type 1 diabetes mellitus are needed, in order to identify groups of patients for whom blood glucose monitoring is beneficial.

Studies should assess the occurrence of hypoglycaemia, the patient’s satisfaction with care and health-related quality of life. Further research is needed to evaluate the effectiveness of near-patient measurement of glycated haemoglobin in diabetes clinics and in primary care.

**Funding**

NHS R&D Health Technology Assessment (HTA) Programme, project number 96/10/03.

**Bibliographic details**


**Original Paper URL**

http://www.hta.ac.uk/project.asp?PjtId=1015

**Other publications of related interest**


**Indexing Status**

Subject indexing assigned by NLM

**MeSH**

Blood Glucose Self-Monitoring /instrumentation /methods; Diabetes Mellitus, Type 1 /blood; Diabetes Mellitus, Type 2 /blood; Female; Pregnancy; Pregnancy in Diabetics /blood; Randomized Controlled Trials as Topic; Reproducibility of Results

**AccessionNumber**

12000008328

**Date bibliographic record published**

Database of Abstracts of Reviews of Effects (DARE)

Produced by the Centre for Reviews and Dissemination

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Date abstract record published
30/06/2002

Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.