The effect of continuous subcutaneous glucose monitoring (CGMS) versus intermittent whole blood finger-stick glucose monitoring (SBGM) on hemoglobin A1c (HbA1c) levels in type 1 diabetic patients: a systematic review

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CRD summary
This review indicated that continuous glucose monitoring did not improve glycated haemoglobin compared with whole blood finger-stick self monitoring in type 1 diabetes patients, but suggested possible benefit in children and improved asymptomatic nocturnal hypoglycaemia detection. The conclusion for children should be viewed cautiously given discrepancies in analysis; the evidence does not appear to support the conclusion regarding nocturnal hypoglycaemia.

Authors' objectives
To compare the effects of subcutaneous continuous glucose monitoring (CGMS) with intermittent whole blood finger-stick self blood glucose monitoring (SBGM) on glycated haemoglobin (HbA1c) levels in patients with type 1 diabetes.

Searching
MEDLINE, EMBASE, and the Cochrane Central Registry of Controlled Trials (CENTRAL) were searched for published English language articles (1996 to March 2007). Search terms were reported. Reference lists of relevant systematic reviews and retrieved studies were scanned. Medtronic Canada (the manufacturer of the CGMS sensor) was contacted for additional studies.

Study selection
Randomised controlled trials (RCTs) (parallel or cross-over) of at least 90% participants with type 1 diabetes that compared self blood glucose monitoring with continuous glucose monitoring (using Medtronic devices only) were eligible for inclusion. Eligible trials had to be of at least one month duration, have at least 80% follow-up rate and report glycated haemoglobin (HbA1c) levels. Trials of pregnant women and trials with post-pancreatic/islet cell transplantation patients were excluded.

The primary outcome of interest was reduction in HbA1c. The secondary outcome was frequency of symptomatic hypoglycaemic episodes (defined as a sensor value less than 3.1mmol/L lasting at least 30 minutes) as a result of using continuous glucose monitoring.

Most of the included trials were in children (under 18 years); the remainder were in patients aged 20 to 78 years. Continuous glucose monitoring and self blood glucose monitoring treatment adjustment regimens varied between trials. Included trials were published in the USA, Germany, Spain, Sweden and Australia.

Studies were selected for inclusion independently by two reviewers, and disagreements were resolved through consensus.

Assessment of study quality
Methodological quality was assessed by two reviewers using the Jadad score (that assessed randomisation, blinding, follow-up and withdrawals) to give a score out of a maximum of 5 points. Disagreements were resolved by consensus.

Data extraction
The change from baseline in HbA1c between groups for each treatment group and the frequency of hypoglycaemic episodes with continuous glucose monitoring was extracted independently by two reviewers, and disagreements were resolved by consensus.

Methods of synthesis
The difference in change in HbA1c from baseline between groups appeared to be pooled using a random-effects meta-analysis. Heterogeneity was assessed using the I^2 statistic and χ^2 test.
Sensitivity analyses were performed to assess the effects of trial quality and type of population (paediatric versus adult). A funnel plot was used to assess publication bias.

**Results of the review**

Seven RCTs were included in the review (n=335 patients, 303 patients with type 1 diabetes; range 11 to 97). Three RCTs were deemed high quality (Jadad score of 3 or more); four RCTs did not describe randomisation or allocation concealment, blinding was unclear in three RCTs and two RCTs were cross-over RCTs. Trial duration ranged from 12 to 24 weeks.

Subcutaneous continuous glucose monitoring (CGMS) was associated with a decrease in HbA\(_1c\), although this was not statistically significant (0.22%, 95% CI -0.439 to 0.004; seven RCTs). There was no significant heterogeneity; publication bias was not indicated. Results with high quality trials only were similar. Analysis of the paediatric population only resulted in a significant decrease in HbA\(_1c\) associated with subcutaneous CGMS (0.37% (95% CI -0.71 to -0.02; five RCTs).

There was some indication that nocturnal hypoglycaemia was decreased in the CGMS group.

**Authors' conclusions**

There was not sufficient evidence to support the idea that subcutaneous continuous glucose monitoring was more beneficial than intensive whole blood finger-stick self blood glucose monitoring in improving glycedated haemoglobin in type 1 diabetic patients; there might be a benefit in the paediatric population. There was some evidence of improved detection of asymptomatic nocturnal hypoglycaemia in the continuous glucose monitoring group.

**CRD commentary**

The research question was supported by clear inclusion criteria. Only studies published in English were included, so publication and language bias could not be ruled out (although a test for publication bias found no evidence of this). Study selection, data extraction and validity assessment were performed in duplicate, reducing the risk of error and bias.

Trial quality was assessed using the Jadad scale and taken into consideration in the analysis. Heterogeneity was assessed and meta-analysis appeared to be appropriate. A small number of trials were included and some of the reporting was inconsistent. The sensitivity analysis of paediatric versus adult patients appeared to contain a mixture of both adult and paediatric trials, so the results of this analysis may be incorrect. Details of the analyses performed were also poorly reported.

In view of possible omission of relevant non-English studies and uncertainties around the analysis, the conclusion regarding lack of evidence may not be reliable. The conclusion of possible benefit in children should be viewed with caution due to discrepancies in this analysis. The conclusion regarding nocturnal hypoglycaemia did not appear to be supported by evidence in the review.

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

**Practice**: The authors did not state any implications for practice.

**Research**: The authors stated that longer-term studies may be needed to demonstrate an improvement in HbA\(_1c\) and that large RCTs are needed to determine efficacy in terms of improving diabetes management and patient lifestyle.

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