Continuous glucose monitoring for patients with diabetes: an evidence-based analysis

Medical Advisory Secretariat

CRD summary
The review found that there was moderate quality evidence that in diabetic individuals with an infusion pump, continuous blood glucose monitoring plus self-monitoring was not more effective in reducing glycosylated haemoglobin, hypoglycaemic events or severe hypoglycaemic events than self-monitoring alone. These conclusions require cautious interpretation, mainly because the review included only two studies and the analysis appeared underpowered.

Authors’ objectives
To compare the effectiveness and cost-effectiveness of continuous blood glucose monitoring plus self-monitoring versus self-monitoring alone for managing insulin-dependent diabetes.

Searching
MEDLINE, EMBASE, CINAHL, The Cochrane Library and IHTA were searched for studies published in English from 2002 to September 2010. Reference lists of retrieved articles were checked. Search terms were reported.

Study selection
Eligible studies were randomised controlled trials (RCTs) that included at least 30 adult or paediatric participants with insulin-dependent diabetes (type 1, type 2 or gestational) and compared continuous blood glucose monitoring plus self-monitoring versus self-monitoring alone. Outcomes of interest were change in glycosylated haemoglobin, frequency or duration of episodes of hypoglycaemia, hyperglycaemia or euglycaemia and adverse effects. Studies were required to report extractable statistical data.

Participants in the two included studies were adults and children (28% and 38% children) with type 1 diabetes, a mean or median baseline glycosylated haemoglobin level of at least 7.5% to 8% and who already used an insulin infusion pump. Both studies compared real-time continuous glucose monitoring versus self-monitoring of blood glucose (plus an insulin infusion pump in both groups). The intervention group was required to wear the continuous glucose monitor at least 70% of the time or for two three-day periods per week. The control group were required to take at least three blood glucose readings daily (where reported). The primary outcome in both studies was change in glycosylated haemoglobin; a wide range of other measures of blood glucose were also reported. Reported adverse events included ketoacidosis, severe hypoglycaemia and skin abscesses. Both studies had a duration of six months.

The initial stages of the search were conducted by a single reviewer. Where study eligibility was unclear, it was determined in consultation with one or more epidemiologists.

Assessment of study quality
The reviewers used GRADE criteria to assess individual study quality (stated to include criteria such as allocation concealment, blinding and follow-up), overall consistency of the evidence, applicability of the evidence to the review question and risk of publication bias. The overall quality of the evidence was graded as high, moderate, low or very low.

The authors did not state how many reviewers performed the assessment.

Data extraction
For continuous outcomes, data on change from baseline in the two groups were extracted with standard deviations and p values for comparisons between the groups. For adverse events, descriptive data were extracted.

The authors did not state how many reviewers performed the data extraction.

Methods of synthesis
For the primary outcome only, data were pooled to calculate the pooled mean difference (MD) between the groups in
change from baseline, with 95% confidence intervals (CIs). The results of $X^2$ and $I^2$ calculations for statistical heterogeneity were displayed on forest plots. Data on other outcomes were not combined.

**Results of the review**

Two studies were included in the review (270 participants, 132 and 138). Neither study described allocation concealment or provided details of any lifestyle changes that could have caused confounding. Other limitations reported by the reviewers included attrition of 15% and poor compliance in 35% of participants (one study) and failure to use intention-to-treat analysis or confirm self-reported hypoglycaemic episodes (the other study). The overall quality of the evidence was rated as moderate.

When the studies were pooled there was no significant difference between the groups in mean change in glycosylated haemoglobin (MD -0.18, 95% CI -0.38 to 0.03; two studies) with no significant heterogeneity.

In one study there was no significant difference in hyperglycaemic or hypoglycaemic episodes per day. In the other study there was no significant difference in the incidence of hyperglycaemia or hypoglycaemia but severe hypoglycaemia was significantly more common ($p=0.04$) in the intervention group (11 events versus three events); it was unclear whether the unit of analysis was per-participant or per-event for this analysis.

One study reported seven serious adverse events in the intervention group and three in the control group. The other study reported 12 serious adverse events in the intervention group and five in the control group (including the episodes of severe hypoglycaemia mentioned above)

**Authors’ conclusions**

There was moderate quality evidence that in diabetic individuals with an infusion pump, continuous blood glucose monitoring plus self-monitoring was not more effective in reducing glycosylated haemoglobin than self-monitoring alone and did not reduce incidences of hypoglycaemic events and severe hypoglycaemic events.

**CRD commentary**

The objectives and inclusion criteria of the review were clear. Relevant sources were searched for studies. The search was limited by language and (apparently) by publication status, so the review was at risk of language and publication biases. There were too few studies to conduct formal assessment for publication bias. It was unclear whether appropriate steps were taken to reduce the risk of reviewer bias and error during quality assessment and data extraction. The initial stages of study selection were performed by a single reviewer. It was unclear why the opening text in the results section of the review referred to four studies as only two were included. The reviewers did not systematically pre-specify criteria used to assess study quality and did not systematically report the quality characteristics of each study. Going by the details reported, the studies appeared to be of questionable quality. All these factors made it difficult to assess the reliability of the review findings.

The methods used to pool data appeared appropriate. Statistical heterogeneity was reported in the forest plot but not mentioned in the text. The forest plot suggested that the meta-analysis was underpowered and that larger studies may well have resulted in statistically significant findings. It was unclear why findings for blood sugar outcomes and adverse effects were not combined statistically or as a narrative synthesis.

The authors’ conclusions require cautious interpretation, mainly because the review included only two studies and the analysis appeared underpowered.

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

The authors did not state any implications for practice and research.

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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.