Point-of-care testing for Hb A1c in the management of diabetes: a systematic review and metaanalysis

CRD summary
This review concluded that there was an absence of evidence in clinical trial data for the effectiveness of point-of-care testing for glycated haemoglobin (haemoglobin A1c) measurement in the management of diabetes. This conclusion reflects the limited data available and is likely to be reliable.

Authors' objectives
To assess whether point-of-care testing for haemoglobin A1c (glycated haemoglobin) improved glycaemic control compared with laboratory-based testing in patients with diabetes.

Searching
MEDLINE, EMBASE and The Cochrane Library were searched from 1980 to August 2010 and CINAHL was searched from 1982 to August 2010. The search was limited to randomised controlled trials and there were no language restrictions; search terms were reported and the full search strategy was reported in an online appendix. The bibliographies of relevant publications were also screened and experts in the field were contacted for additional studies.

Study selection
Randomised controlled trials that compared point-of-care testing with independent laboratory-based testing for glycated haemoglobin in patients of any age with type 1 or type 2 diabetes, were eligible for inclusion. Studies had to report patient-level outcomes including glycated haemoglobin outcomes (change in glycated haemoglobin level or proportion of patients with glycated haemoglobin of 7.0% or below) and changes in treatment. Additional outcomes sought were emergency admissions, measures of patient satisfaction and costs.

Trials were conducted in ambulatory clinics or primary care settings. Where reported, the mean age of participants in studies of patients with type 2 diabetes or a mixture of type 1 and type 2 diabetes ranged from 49 to 67 years; the study of patients with type 1 diabetes reported a mean participant age of approximately 12.5 years. The proportion of female patients ranged from 41 to 53%. Where reported, the mean duration of diabetes ranged from 4.0 to 8.7 years, study duration ranged from one to 18 months and frequency of testing ranged from one to three months. Most trials used the DCA 2000 (Siemens Healthcare Diagnostics) system for point of care testing measurements.

Three reviewers assessed studies for inclusion.

Assessment of study quality
The risk or bias in included studies was assessed using Cochrane guidelines. Specific criteria considered were: sequence generation; allocation concealment; handling of incomplete outcome data; selective outcome reporting; 'other issues'. Blinding was not assessed due to the nature of the intervention. Studies were classified as 'low' risk of bias if the four specified criteria were met, 'moderate' risk if one or two criteria were partly met, and 'high' risk if no criteria were met.

Two general practitioners and a clinical biochemist independently assessed study quality; any disagreements were resolved by discussion.

Data extraction
For the intervention and comparator groups, data were extracted on: mean and standard deviation change from baseline in glycated haemoglobin; proportion of patients achieving target glycated haemoglobin (7% or below) at the end of the study; the proportion of patients for whom treatment was intensified during the trial. Data were also extracted, as reported, on patient satisfaction and costs.

Data were independently extracted by two general practitioners and a clinical biochemist; any disagreements were resolved by discussion.
Methods of synthesis
Pooled estimates of the difference in change from baseline in mean glycated haemoglobin, between intervention and comparator groups, were calculated using a fixed-effect model, weighted by inverse variance. For the one clustered trial, standard deviations were re-calculated from standard errors corrected for clustering supplied by the authors; number of patients who achieved target glycated haemoglobin (7.0% or below) was also adjusted for clustering.

Between-study heterogeneity was assessed using $\chi^2$ and $I^2$.

Results of the review
Nine articles, reporting seven trials with 11,402 participants (range 201 to 3,953), were included in the review. Three trials included adult only patients with type 2 diabetes, two included adults with type 1 or 2 diabetes, one included only adolescents with type 1 diabetes and one specified only "patients with diabetes". The proportion of patients who did not complete the trial ranged from 1.1% to 34.4%. Studies were rated "low" or "moderate" risk of bias on all criteria, with the exception of one study which was rated as "high" risk of bias for adequacy of sequence generation; full details of the risk of bias assessment were reported in an online appendix.

There was no significant difference between intervention (point of care testing measurement) and comparator (laboratory-based measurement), for the mean change from baseline in glycated haemoglobin, based on three studies. There was no significant between-study heterogeneity.

Four studies reported data on the proportion of patients achieving target glycated haemoglobin at the end of the study. Heterogeneity in study populations and outcome measurement methods precluded meta-analysis. Two studies reported odds ratios favouring rapid testing and three studies reported no significant difference between the two measurement methods.

Four studies, using different outcome measure, reported data on treatment intensification; individual study results were reported in the paper and rates of treatment intensification appeared similar between groups.

Three studies assessed various aspects of patient satisfaction; two reported significant positive results in favour of point of care testing and one reported no significant difference between the testing methods.

Cost information
Three studies reported different measures of costs; all reported slightly lower (not statistically significant) estimates for point-of-care testing.

Authors’ conclusions
There was an absence of evidence in clinical trial data for the effectiveness of point-of-care testing for glycated haemoglobin measurement in the management of diabetes.

CRD commentary
The review stated a clear research objective and reported its inclusion criteria. A range of sources were searched for relevant publications and no language restrictions were applied, minimising the risk of missing relevant publications. Measures to minimise error and/or bias were applied throughout the review process. The risk of bias in included studies was assessed and reported in full online. The methods used to summarise studies were appropriate and the authors cautious conclusions were likely to be reliable.

Implications of the review for practice and research
Practice: The authors did not specify any recommendations for clinical practice.

Research: The authors stated that future trial design should: ensure appropriate selection and stratification of patients (according to baseline glycated haemoglobin); provide clear definition of current process of care and revised process of care using point of care testing; ensure results of point of care testing were discussed with patients when generated and treatment decisions were documented and implemented; ensure that the analytical performance of the point-of-care testing system was adequate.
Funding
NIHR Oxford Biomedical Research.

Bibliographic details

PubMedID
21368238

DOI
10.1373/clinchem.2010.157586

Original Paper URL
http://www.clinchem.org/cgi/content/abstract/57/4/568

Indexing Status
Subject indexing assigned by NLM

MeSH
Blood Glucose /analysis; Diabetes Mellitus /blood /therapy; Hemoglobin A, Glycosylated /analysis; Humans; Patient Satisfaction; Point-of-Care Systems

AccessionNumber
12011003515

Date bibliographic record published
05/10/2011

Date abstract record published
16/05/2012

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.