Acarbose: its role in the treatment of diabetes mellitus  
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Authors' objectives
To review the role of acarbose in the pharmacotherapy of diabetes mellitus.

Searching
MEDLINE was searched for articles and reviews (no search strategy or restrictions provided), and Bayer Pharmaceuticals (drug manufacturer) was contacted.

Study selection
Study designs of evaluations included in the review
Clinical trials adhering to the following criteria: (1) randomised, double-blind, placebo-controlled, parallel group study design; (2) minimum of 25 patients enrolled per treatment arm; (3) treatment duration of 90 days or more; and (4) adherence to Food and Drug Administration Good Clinical Practice guidelines.

Specific interventions included in the review
Acarbose (alpha-glucosidase inhibitor), tolbutamide, combined acarbose and tolbutamide, metformin, sulfonylurea, insulin and placebo.

Participants included in the review
Patients with non insulin-dependent diabetes mellitus (NIDDM) were included.

Outcomes assessed in the review
The outcomes assessed were haemoglobin A1c levels, fasting blood glucose levels, postprandial blood glucose (PPG) levels, postprandial triglyceride, and adverse effects (weight gain).

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 authors performed the selection.

Assessment of study quality
The authors do not report the criteria used to assess validity, or how the validity assessment was performed.

Data extraction
The authors do not state how the data were extracted for the review, or how many of the authors performed the data extraction.

Methods of synthesis
How were the studies combined?
The studies were combined through a narrative description, though there was no discussion of the weighting of the studies for factors such as quality or sample size.

How were differences between studies investigated?
Descriptions of characteristics of the studies, such as drug treatment, dosage regimen, duration of the phases of the study and patient characteristics, were provided. No measure of heterogeneity was presented.
Results of the review

Five studies (1,083 patients) were included in the review: 3 (512 patients) focusing on patients on diet alone, and 2 (571 patients) on diet and oral antidiabetic medications.

Patients on diet alone: 3 studies assessed the effects of acarbose treatment on patients on diet alone. Mean haemoglobin A1c levels decreased from baseline for patients on acarbose, compared to an increase for the placebo group. Acarbose treatment improved glycaemic control, reducing postprandial hyperglycaemia. In addition, one study found there was no significant weight change for patients on acarbose or placebo.

Patients on diet and oral antidiabetic medications: 2 studies analysed the effects of acarbose treatment on patients on diet and oral antidiabetic medications (tolbutamide, metformin, sulfonylurea or insulin). Haemoglobin A1c and mean PPG levels declined from baseline for acarbose and acarbose in combination with other oral antidiabetic medications, but increased for placebo.

Other factors: serum insulin concentrations were decreased with placebo and acarbose groups but increased with tolbutamide and combined groups; patients receiving tolbutamide, whether singly or combined, suffered weight gain, whilst those on placebo or acarbose had weight reduction.

Safety: side-effects are relatively mild for acarbose, limited to flatulence, meteorism, borborygmus, abdominal pain and diarrhoea, which tend to resolve several weeks into treatment. Dosages of acarbose above 100 mg three times daily may increase serum transaminases, but these appear controllable through changes in dosage.

Drug interactions: though concern has occurred about the additive hypoglycaemic effects of acarbose and another antidiabetic agent, limited evidence was presented with regard to the influence on bioavailability.

Cost information

The review presents average wholesale prices for acarbose, US$45.61 for one hundred 50-mg tablets and US$58.80 for one hundred 100-mg tablets. The author estimates that the monthly cost of acarbose per patient would be more expensive than generic sulfonylurea therapy but less expensive than metformin monotherapy. No published studies evaluated the pharmacoeconomics of acarbose at time of publication.

Authors’ conclusions

Acarbose is a reasonable choice as a monotherapy or adjunct therapy for patients with poorly-controlled NIDDM. It delays dietary sugar absorption in the small intestine, lowering PPG levels, serum insulin concentrations and triglycerides. Adverse effects are limited to flatulence, abdominal pain and diarrhoea.

CRD commentary

This review fails to include information that is crucial to a good quality systematic review. There is no mention of the criteria used to assess the validity of the primary studies included in the review. Similarly, the review does not discuss the methods by which decisions of relevance, judgements of validity, and data extraction were undertaken. The search strategy did not provide any restriction criteria, whether language or dates, and no keywords were used to assess the completeness. The review does not discuss the weighting of studies for quality or sample size, as part of the process of combining the studies through narrative description. In addition, no measure of heterogeneity or subgroup analysis is undertaken. It should be noted that the study does specify appropriate inclusion criteria for the review.

The exclusion of such information concerning the methodology of the review and the potential bias in selecting the primary studies, brings into question the strength of the evidence and necessitates caution when interpreting the authors’ conclusions.

Bibliographic details

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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.