Restricted-carbohydrate diets in patients with type 2 diabetes: a meta-analysis

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CRD summary

The authors concluded that short-term restricted-carbohydrate diets may improve glycaemic control and triglyceride levels in patients with type 2 diabetes, but the long-term effects are unclear. These conclusions appear to be supported by the data presented, but the lack of information about study quality or review methods makes it hard to assess their reliability.

Authors' objectives

To evaluate the effect of a restricted-carbohydrate diet on glycaemia, weight and blood lipids in patients with type 2 diabetes.

Searching

PubMed, CINAHL, the Combined Health Information Database, the Cochrane Library and Web of Science were searched from 1980 to April 2006; the search terms were reported. The references of relevant reviews and studies checked. The search was limited to studies, reported in English and completed in the USA or Canada.

Study selection

The participants in eligible studies were adult in-patients or out-patients with type 2 diabetes, aged 19 years and older. Studies including participants without diabetes were required to report separate results for the two populations. Studies of pre-diabetes and gestational diabetes were excluded. The mean age of the participants in the included studies was 57 (± 6) years (range: 48 to 66). Some studies included participants who were not taking medication for diabetes, while in other studies some participants were taking oral hypoglycaemic agents or insulin (in some cases tailored to blood glucose level). Eligible studies compared a restricted-carbohydrate diet with a non-restricted-carbohydrate diet (controls). A restricted-carbohydrate diet was defined as a diet supplying 45% or less of its total calories from carbohydrates. Eligible studies could use either unregulated or regulated food sources. The diets in the included studies varied from in-patient feeding regimes to outpatient self-selected diets. In the intervention arms, carbohydrates supplied a mean of 29% (± 14) of total daily calories (range: 4 to 45%), while in the control arms, carbohydrates supplied a mean of 55% (± 8) of total daily calories (range: 40 to 70%). The proportion of daily calories supplied by protein and fats ranged from 15 to 45% and 30 to 59%, respectively, in the intervention arms, and from 15 to 20% and 10 to 42% in the control arms. Some studies adjusted protein and fat intake in the intervention arm and/or were designed to be isocaloric (i.e. carbohydrates, protein and fat supplied equal quantities of calories). The duration of the interventions ranged from 1 to 26 weeks. The participants were advised to continue usual physical activities during the study. Eligible studies were required to report one or more of the following criteria: weight loss; blood levels of triglycerides, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol and total cholesterol; and glycaemic control, measured by haemoglobin A_{1c} (HbA_{1c}) or fasting glucose. Dietary compliance was measured by food records, recall and interview, laboratory testing and the monitoring of unused food portions. There were no specific inclusion criteria with respect to the study design.

The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality

The authors did not state that they assessed validity.

Data extraction

All data were continuous. Mean changes from baseline (with standard errors) and percentage changes from baseline were reported. Where the standard error of the mean change was not reported in the primary study, the upper limit was estimated from the standard deviations of the before and after measures. For crossover or paired designs, the data for each phase were extracted separately, provided that baseline values for each phase were available.

The authors did not state how the data were extracted for the review, or how many reviewers performed the data

extraction

Methods of synthesis

The data were pooled in inverse-variance meta-regression analysis, using hierarchical linear mixed models. The percentage reduction in the outcome was used as the dependent variable. Regression models controlled for correlation between observations within the same study and for differences between studies in the duration of the intervention. The restricted maximum likelihood method was used to estimate model parameters, and denominator degrees of freedom were calculated using the method of Berkey et al. (see Other Publications of Related Interest). Some clinical differences between the studies were investigated in single-covariate regression analyses. Further analyses were conducted to investigate the effect of weight change on glycaemia and lipid outcomes.

Results of the review

Thirteen studies (n=263) were included: 6 crossover randomised controlled trials (RCTs; n=91), 3 parallel-group RCTs (n=96), 1 non-randomised controlled trial (n=17) and 3 before-and-after studies (n=59).

The studies were small and short term. Study settings, participants and interventions varied widely. Participant drop-out rates were high and some primary studies reported that long-term dietary adherence was poor.

An investigation of clinical differences between the studies found no significant relationship between any of the outcomes and participant age, inclusion of participants on insulin, or duration of dietary intervention.

Glycaemia.

All 12 studies (n=251) that measured this blood glucose reported a greater reduction in the intervention group than in controls, and 9 studies (out of 11; n=214) that reported HbA_{1c} reported a lower (or more greatly reduced) level in the intervention group. When studies were pooled there was a significantly greater mean reduction in the intervention group in both fasting blood glucose (p=0.013) and HbA_{1c} (p=0.013) than in controls. Interventions with lower levels of carbohydrates resulted in greater reductions in both measures. Regression analyses found that weight change attenuated the effect of the reduction in glycaemia associated with a restricted-carbohydrate diet, though the association remained statistically significant when controlling for weight.

Lipids.

When pooling studies that reported this outcome, there was a strong and statistically significant association between a restricted-carbohydrate diet and lower triglyceride levels (11 studies, n=183; p<0.001). Controlling for weight change did not substantially alter this finding. No statistically significant association was found between the intervention and total, low-density lipoprotein or high-density lipoprotein cholesterol.

Weight change (6 studies, n=139, excluding isocaloric studies).

No statistically significant association was found between the carbohydrate content of the diet and weight.

Authors' conclusions

Short term use of a restricted-carbohydrate diet may improve glycaemic control and triglyceride levels in patients with type 2 diabetes, but the long-term safety and sustainability of such diets is unclear.

CRD commentary

The review objective and inclusion criteria were clear. Relevant sources were searched for literature, but the search string was apparently limited to two Medical Subject Headings, which means that some studies might have been missed. It is unclear whether steps were taken to minimise the risk of error and bias in the review process, such as having more than one reviewer independently select studies and extract the data and there is no indication that study quality was systematically assessed. This makes it difficult to assess the reliability of the findings, especially as the authors noted that there were high losses to follow-up in the primary studies. The methods used to pool the data appear appropriate. The primary studies were heterogeneous, especially with respect to the intensity and duration of the interventions. This

was appropriately addressed by regression analyses, although the authors noted that only a limited number of variables could be analysed because of the small number of studies. The authors' conclusions appear to be supported by the data presented, but the lack of information about review methods and study quality makes it hard to assess their reliability.

Implications of the review for practice and research

Practice: The authors stated that short-term use of a restricted-carbohydrate diet may improve glycaemic control and triglyceride levels in patients with type 2 diabetes. Moderate carbohydrate restriction may also provide some benefit. However, there is currently insufficient evidence to recommend restricted-carbohydrate diets in patients with type 2 diabetes.

Research: The authors stated that RCTs are required to determine the effect of restricted-carbohydrate diets on cardiovascular risk factors (e.g. inflammation, endothelial dysfunction), long-term cardiovascular outcomes and overall safety in patients with type 2 diabetes. Studies should examine not only the effect of specific fats and carbohydrates but also the effect of increased fat or protein intake.

Bibliographic details

Kirk J K, Graves D E, Craven T E, Lipkin E W, Austin M, Margolis K L. Restricted-carbohydrate diets in patients with type 2 diabetes: a meta-analysis. Journal of the American Dietetic Association 2008; 108(1): 91-100

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Other publications of related interest

Berkey CS, Houglin DC, Mosteller F, Colditz GA. A random-effects regression model for meta-analysis. Stat Med 1995;14:395-411.

Indexing Status

Subject indexing assigned by NLM

MeSH

Diabetes Mellitus, Type 2 /blood /diet therapy; Diet, Carbohydrate-Restricted; Dietary Carbohydrates /administration & dosage /metabolism; Female; Hemoglobin A, Glycosylated /metabolism; Humans; Lipid Metabolism /drug effects; Male; Randomized Controlled Trials as Topic; Safety; Treatment Outcome

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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.