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DIABETIC Medicine

COMMENTARY

Lower carbohydrate diets for adults with type 2 diabetes

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1 | BACKGROUND

The terms of reference for the working group were to review the evidence on lower carbohydrate diets (alongside higher fat and/or higher protein) compared with the current government advice for adults with type 2 diabetes (T2D); consider the impact, in adults with T2D, of lower compared with higher carbohydrate diets on markers and clinical outcomes of T2D including any potential adverse effects and make recommendations based on the review of the evidence. Its remit did not include consideration of the wider management of T2D, studies of children, people with pre-diabetes, type 1 diabetes or gestational diabetes.

2 | DIABETES

Diabetes is a condition in which the body does not produce sufficient insulin to regulate blood glucose levels and the insulin produced does not work effectively. This leads to elevated blood glucose concentrations (hyperglycaemia) which causes damage to blood vessels and nerves.

There are two main types of diabetes: type 1 diabetes and T2D. There are also other forms such as gestational diabetes and rare genetic forms such as maturity-onset diabetes of the young. In 2018, an estimated 4·7 million people in the UK had diabetes.[3] This included about 3.8 million people with diagnosed diabetes and an estimated 1 million people who were undiagnosed.

T2D accounts for about 90% of all cases of diabetes in the UK[3–5] and occurs as a result of reduced β-cell insulin secretion and increased insulin resistance.[6] Although several non-modifiable risk factors such as age, family history and ethnicity are associated with increased T2D risk, about 80%–85% of an individual's risk of developing T2D is associated with obesity,[7] a modifiable risk factor.

2.1 | Current UK government advice

Current UK government advice on carbohydrate intake is based on recommendations made by Scientific Advisory Committee on Nutrition (SACN) following its review on carbohydrates and health.[8] The evidence considered in the SACN review on carbohydrates comprised studies in the general population, and recommendations were for the UK general population.

Current UK government advice for the general population is that approximately 50% of total dietary energy should be obtained from carbohydrates, mainly from starchy foods consisting of high fibre or whole-grain food where possible. It is recommended that the average

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population intake of free sugars should not exceed 5% of total dietary energy and that adults should achieve a daily dietary fibre intake of 30 g/day.

There are no separate recommendations on carbohydrate intake for adults with T2D, and the advice for the general UK population thus applies to those with T2D.

In England, the National Institute for Health and Care Excellence has issued guidelines for the identification, diagnosis and management of T2D including dietary advice that is in line with UK government advice for the general population.[9] The Scottish Intercollegiate Guidelines Network has also issued guidelines on the management of diabetes including offering adults with T2D a range of dietary options for achieving weight loss that may also improve glycaemic control.[10]

The ultimate aim of T2D management and treatment is to reduce and maintain glycated haemoglobin (HbA1c) concentration at a value below the cut-off for the definition of T2D. However, any reduction in HbA1c reflects an improvement in the degree of T2D control. Improvement of blood lipids and blood pressure is also an important treatment goal.

Management of T2D usually involves behavioural interventions (including diet, physical activity, smoking cessation and reduced alcohol intake) and/or medications. Treatment may also include bariatric surgery to reduce weight.

A reduction in energy intake is an important part of the behavioural interventions recommended to people with T2D who are living with overweight or obesity. The aim of reducing energy intake is weight loss, which in turn improves glycaemic control. Glycaemic index and glycaemic load are measures of the post-prandial blood glucose response to foods.

Both Diabetes UK and the American Diabetes Association emphasise tailoring advice to the individual, and both note the lack of clear evidence for a specific dietary intake of carbohydrate for those with T2D.[11,12]

2.2 | Purpose of review

SACN initiated this evidence review in response to a request from Public Health England, for a systematic assessment of the scientific evidence on 'low'-carbohydrate diets, in recognition that such diets are gaining attention and increasingly being promoted.

3 | METHODS

SACN's Framework for the Evaluation of Evidence[2] was used as the basis for assessing the evidence. Public Health England conducted a search of key online databases: MEDLINE, Embase, the Cochrane Library (CDSR and DARE), National Institute for Health and Care Excellence evidence, TRIP and Google Scholar to identify relevant English language articles published between 1980 and 30 September 2018, using an agreed list of search terms focusing on lower carbohydrate diets and T2D. There was a particular interest in the following primary outcomes: weight change (≥12 months), glycated Hb (HbA1c), a marker of impaired glycaemic control (≥3 months) and secondary outcomes: body weight (≥3 to <12 months), fasting plasma glucose (≥3 months), blood lipid profiles (≥3 months) and medication use.

TABLE 1 Categories of dietary carbohydrate intakes based on Feinman et al. (2015)[13] and Accurso et al. (2008)[19]

Description	Amount of carbohydrate	
	g/d	% TE (based on 2000 kcal/d)
Very low carbohydrate[a]	20–50	≤10
Low carbohydrate	>50 to <130	>10 to <26
Moderate carbohydrate	130–230	26–45
High carbohydrate	>230	>45

[a]Also referred to as ketogenic diets.

SACN invited interested parties to highlight relevant evidence which satisfied the inclusion criteria for the report through a call for evidence from 9 February to 7 March 2018.

The report included evidence from systematic reviews (SR) and meta-analyses (MA) and pooled analyses of randomised controlled trials (RCT) and prospective cohort studies comparing the impact of lower vs higher carbohydrate diets on markers and clinical outcomes of T2D. It also included RCT published after the most recent SR, MA and pooled analyses of RCT.[2] Only SR that included studies with a minimum duration of 3 months and individuals with pre-diagnosed T2D (as defined in the primary RCT) when they entered the study were considered. Two reviewers independently screened titles and abstracts of the publications identified by the literature search and subsequently assessed full-text articles. Any differences were resolved by consensus.

For the purposes of this report, in order to enable comparisons of carbohydrate intake across the studies under consideration, the classification proposed by Feinman et al.[13] was adopted as the basis for the categorisation of carbohydrate intake (see Table 1).

The quality of included SR and MA was assessed by the approach outlined in the SACN Framework for the Evaluation of Evidence[2] and the AMSTAR 2 tool.[14] Expert judgement, based on pre-specified criteria, was used to grade the strength of the evidence (*adequate*, *moderate*, *limited*, *inconsistent* or *insufficient*) for the primary and secondary outcomes. Only outcomes where the evidence base was graded as *adequate* or *moderate* were used to inform recommendations.

3.1 | Evidence identified

After the removal of duplicates, the online database search identified 3169 abstracts that were screened for eligibility. Full texts of nineteen potentially relevant SR with MA were retrieved and assessed. Out of these, 15 were excluded. Five additional publications that met the inclusion criteria were identified by SACN working group members. In total, nine publications met the criteria and were included for data extraction, including eight SR with MA and one network meta-analysis.

After a detailed assessment, results from four SR with MA[15–18] were used to grade the evidence and draw conclusions. This is because they were more recent, had larger numbers of participants and were considered to be of better quality based on the SACN Framework for the Evaluation of Evidence[2] and AMSTAR 2 criteria.[14] Out of the 36 publications included in the MA, 18 reported outcomes in the shorter term (minimum duration of 3 months) only and 18 reported outcomes in the longer term (minimum duration of 12 months). In this report, *shorter term* refers to studies or assessments that reported at ≥3 to 6 months (since all except 1 of the time points included in shorter-term studies or assessments did not extend beyond 6 months) and *longer term* refers to studies that reported outcomes at ≥12 months.

Body weight

The evidence for lower compared with higher carbohydrate diets on body weight was *inconsistent* in the shorter term (≥3 to 6 months); there was a greater reduction in body weight with lower compared with higher carbohydrate diets at 3 months, but this difference was not observed between 3 and 6 months or at 6 months. There was *adequate* evidence for no difference in effect between lower and higher carbohydrate diets in reducing body weight in the longer term (≥12 months).

HbA1c

There was *adequate* evidence of a greater reduction in HbA1c with lower compared with higher carbohydrate diets in the shorter term (≥3 to 6 months). The evidence was *inconsistent* in longer-term studies with a duration of 12 up to 24 months. There was *adequate* evidence for no difference between lower and higher carbohydrate diets on HbA1c change in longer-term studies at 24 months.

Fasting plasma glucose

There was *moderate* evidence of a greater reduction in fasting plasma glucose with lower compared with the higher carbohydrate diets in the shorter term (≥3 to 6 months). There was *insufficient* evidence to assess if there was a difference between lower and higher carbohydrate diets on fasting plasma glucose in the longer term (≥12 months).

Serum total cholesterol

There was *moderate* evidence for no difference in effect between lower and higher carbohydrate diets in reducing serum total cholesterol in the shorter term (≥3 to 6 months). There was *adequate* evidence for no difference in effect between lower and higher carbohydrate diets in reducing serum total cholesterol in the longer term (≥12 months).

Serum TAG

There was *adequate* evidence of a greater reduction in serum TAG with lower compared with higher carbohydrate diets in the shorter term (≥3 to 6 months). The evidence was *inconsistent* in the longer term (≥12 months).

Serum LDL-cholesterol

There was *adequate* evidence for no difference in effect between lower and higher carbohydrate diets on change in serum LDL-cholesterol in the shorter term (≥3 to 6 months) and in the longer term (≥12 months).

Serum HDL-cholesterol

The evidence on lower compared with higher carbohydrate diets on serum HDL-cholesterol was *inconsistent* in the shorter term (≥3 to 6 months) and longer term (≥12 months).

Changes in medication use

There was *moderate* evidence of a greater reduction in medication use with lower compared with higher carbohydrate diets. This outcome was not assessed according to study duration. It was not possible to assess consistency in effect size.

3.2 | Limitations of the evidence base

The overall quality of the evidence base was limited by a number of uncertainties in the data, including variability in the definition of a low-carbohydrate diet; smaller than prescribed differences in reported carbohydrate intakes between lower and higher carbohydrate diets; inherent inaccuracies in estimates of self-reported dietary intakes and lack of information on adherence to prescribed diets.

An important limitation was that the risk of bias was high or unclear in most of the primary RCT that was included in the MA. This reduces the confidence that can be placed on the estimates of the effects of lower carbohydrate diets on the markers of T2D and clinical outcomes under consideration.

Another important limitation in the evidence base was that shorter-term studies did not assess outcomes beyond 6 months and few longer-term studies assessed outcomes beyond 12 months.

The majority of participants in the primary RCT were living with overweight (BMI ≥ 25 to <30 kg/m^2) or obesity (BMI ≥ 30 kg/m^2). It is not known if reported effects can be generalised to adults with a healthy weight (BMI ≥ 18·5 to <25 kg/m^2).

It is not known if the reported effects of lower carbohydrate diets apply to individuals of different ethnicities since the majority of primary RCT did not report the ethnicity of participants and most were conducted in populations that were predominantly White. In those that were reported ethnicity, none conducted subgroup analyses based on ethnicity.

This report did not assess evidence on the effect of lower carbohydrate diets in the general population without T2D. It is not known if the reported effects of lower carbohydrate diets in adults with T2D apply to the general adult population without T2D.

Several additional gaps were identified in the evidence base:

- No trials provided information about the type of carbohydrate consumed (e.g. wholegrain, refined grain, free sugars, fibre) or considered how this could affect the outcomes of interest;
- The potential impact of increasing the proportions of other macronutrients (usually fats and/or proteins) to compensate for reduced carbohydrate intake in the lower carbohydrate groups, or the type of macronutrient (e.g. saturated or unsaturated fats; plant- or animal-based proteins), on markers and clinical outcomes of T2D was generally not considered; and
- No trials considered clinical endpoints such as diabetes complications, CVD events or mortality.

3.3 | Conclusions

Overall, the evidence suggests beneficial effects of lower carbohydrate diets for some outcomes (HbA1c, fasting plasma glucose, serum TAG) in the shorter term (up to 6 months). Since the shorter-term assessments did not report outcomes between 6 and 12 months, it is uncertain if the suggested benefits are maintained beyond 6 months.

Although there was no consistent evidence of reductions in body weight with lower carbohydrate diets, it is not possible, from the evidence considered, to separate the effects of weight change from effects of change in carbohydrate intake.

Lower carbohydrate diets may allow reductions in diabetes medication, but the interpretation is complicated by inconsistencies in reporting and measurement of changes in medication use.

No differences were observed between higher and lower carbohydrate diets on serum total or LDL-cholesterol either in the shorter (≥3 to 6 months) or longer term (≥12 months). Evidence on HDL-cholesterol was inconsistent in the shorter (≥3 to 6 months) and longer term (≥12 months).

In general, there was no difference in adverse events between lower and higher carbohydrate diets but study duration did not extend beyond 12 months in the majority of primary RCT.

3.4 | Recommendations

The report states that recommendations are applicable to adults living with T2D and overweight or obesity. There was insufficient evidence to make recommendations for adults living with T2D without being overweight or obesity. The report did not assess evidence on the effect of lower carbohydrate diets in the general population without T2D.

The report makes the following recommendations:

- For adults living with T2D and overweight or obesity, a lower carbohydrate diet can be recommended by clinicians as an effective short-term option (up to 6 months) for improving glycaemic control and serum TAG concentrations.
- Individuals living with T2D and overweight or obesity who choose a lower carbohydrate diet should include whole-grain or higher fibre foods, a variety of fruits and vegetables and limit intakes of saturated fats, reflecting current dietary advice for the general population.
- Since the majority of individuals living with T2D have overweight or obesity, weight management remains the primary goal for improving glycaemic control and reducing CVD risk. Health professionals should support any evidence-based dietary approach that helps individuals with T2D to achieve long-term weight reduction.

- Adults living with T2D and overweight or obesity who change to a lower carbohydrate diet and are taking diabetes medication may be at risk of hypoglycaemia. It is recommended that they receive advice and support from their health care team to manage this risk and to make adjustments to their medication as required.

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