

Original Article: Treatment

A low-carbohydrate diet is more effective in reducing body weight than healthy eating in both diabetic and non-diabetic subjects

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Abstract

Background Low-carbohydrate diets are effective for weight reduction in people without diabetes, but there is limited evidence for people with Type 2 diabetes.

Aims To assess the impact of a low-carbohydrate diet on body weight, glycated haemoglobin (HbA_{1c}), ketone and lipid levels in diabetic and non-diabetic subjects.

Methods Thirteen Type 2 diabetic subjects (on diet or metformin) and 13 non-diabetic subjects were randomly allocated to either a low-carbohydrate diet (≤ 40 g carbohydrate/day) or a healthy-eating diet following Diabetes UK nutritional recommendations and were seen monthly for 3 months. Subjects (25% male) were (mean \pm SD) age 52 ± 9 years, weight 96.3 ± 16.6 kg, body mass index 35.1 kg/m², HbA_{1c} $6.6 \pm 1.1\%$, total cholesterol 5.1 ± 1.1 mmol/l, high-density lipoprotein cholesterol 1.3 ± 0.4 mmol/l, low-density lipoprotein cholesterol 3.1 ± 0.9 mmol/l, triglycerides (geometric mean) 1.55 (1.10, 2.35) mmol/l and ketones range 0.0–0.2 mmol/l.

Results Analysis was by intention to treat with last observation carried forward. Twenty-two of the participants (85%) completed the study. Weight loss was greater (6.9 vs. 2.1 kg, $P = 0.003$) in the low-carbohydrate group, with no difference in changes in HbA_{1c}, ketone or lipid levels.

Conclusions The diet was equally effective in those with and without diabetes.

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Keywords diet, ketone levels, obesity treatment, Type 2 diabetes

Abbreviations BMI, body mass index; HbA_{1c}, glycated haemoglobin; HDL, high-density lipoprotein; LDL, low-density lipoprotein

Introduction

There has been a resurgence of interest in the role of low-carbohydrate diets and weight loss over the past few years. These diets have been shown to be effective for weight loss over the short term in people without diabetes [1–3], but the effect appears to be related to reduction in energy rather than carbohydrate intake [4] and concern has been expressed about the long-term effects of these diets [5]. Recently published randomized controlled trials have shown that weight loss is greater with low-carbohydrate diets compared with low-fat

diets over 6 months [6], but the difference disappears at 12 months' follow-up [7]. Concerns about the effects of a relatively high-fat diet on cardiovascular risk factors appear to be unfounded over the short term [8,9], even in individuals with established heart disease [10], but little is known about the long-term effects. Low carbohydrate diets decrease insulin levels and increase ketosis [11,12] and these effects have been noted within 72 h of starting the diet [13]. There is no evidence that ketone production varies between diabetic and non-diabetic subjects, or for the role of ketosis in weight loss.

Although there is now evidence from randomized controlled trials for the effect of low-carbohydrate diets in people without diabetes, there is limited evidence for people with Type 2 diabetes. Previous studies in people with Type 2 diabetes have involved small numbers of subjects, lacked a control group,

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had high attrition rates, had short follow-up periods or used a relatively moderate carbohydrate restriction. An intervention study of a low-carbohydrate diet (< 40 g/day) in 88 Type 2 diabetic patients reported significant reductions in both glycated haemoglobin (HbA_{1c}) and body weight at 1 year [14]. A more recently published intervention study reports improvements in HbA_{1c} and body weight over 16 weeks with a 20 g/day carbohydrate intake in 28 people with Type 2 diabetes [15]. A short-term inpatient study (21 g/day carbohydrate) over 14 days in 10 obese people with Type 2 diabetes reported greater weight loss and significant improvements in glycaemic control and insulin sensitivity [16]. A randomized trial comparing a low-carbohydrate diet (< 30 g/day) with a low-fat diet (< 30% energy as fat) in 54 subjects with Type 2 diabetes (of 132 total subjects with severe obesity) showed a significant trend towards greater decrease in mean HbA_{1c} at both 6 months and 1 year, but did not report weight loss in the diabetic subgroup [6,7]. A randomized study in 31 diabetic subjects compared a 20% carbohydrate diet (equivalent to 85–96 g/day for men and 75–85 g/day for women) to a low-fat diet (25% energy as fat) over 6 months and reported significant changes in weight and fasting blood glucose levels [17]. A 5-week cross-over trial of a eucaloric low-carbohydrate diet (142 g/day) and a low-fat diet (30% energy as fat) in eight men with diet-treated Type 2 diabetes showed a greater improvement in HbA_{1c} with a low carbohydrate intake [18]. A larger-scale randomized trial of 102 patients with Type 2 diabetes compared a prescribed 70 g/day carbohydrate intake (actual reported intake 109.5 g/day) with a low-fat diet (< 35% energy as fat) and showed a significant reduction in body weight and improvement in lipid profile, but no significant change in HbA_{1c} over 3 months [19].

In response to these somewhat contradictory results, this study was designed to determine the effect of a low-carbohydrate diet (40 g/day) on body weight, glycaemic control, ketone production and lipid levels in subjects with and without Type 2 diabetes.

Methods

This study was approved by the local ethics committee and an approved consent form was signed by each subject.

Subjects

Twenty-six (13 subjects with Type 2 diabetes and 13 without) overweight or obese individuals were recruited from a volunteer database held in the research unit at the Oxford Centre for Diabetes, Endocrinology and Metabolism (OCDEM), UK, from direct referral from a physician during attendance at a routine clinic visit or by means of advertisements placed around the hospital. All subjects expressing an interest were invited to attend an appointment at the research unit where the study was explained in detail and they were invited to participate. Inclusion criteria were subjects aged over 18 years of age, body mass index (BMI) > 25 kg/m², without Type 2 diabetes or with Type 2 diabetes treated by diet alone or metformin monotherapy.

Exclusion criteria included individuals with Type 1 or Type 2 diabetes treated by insulin, sulphonylurea or thiazolidinedione therapy, pregnancy or women of childbearing age without adequate contraception, breastfeeding women, major psychiatric disease, including eating disorders, history of alcohol or drug abuse, serum creatinine > 150 µmol/l, abnormal liver function tests (> 1.5 × upper limit of reference interval) or any known malignancy. Subjects were randomly assigned either a low-carbohydrate diet (40 g/day) or healthy-eating advice. All subjects who agreed to take part in the study had not attempted weight loss in the previous 12 months and all non-diabetic subjects had never received formal dietary advice. All subjects with diabetes had received dietary advice in line with Diabetes UK recommendations at diagnosis, but none had had formal dietary intervention in the preceding 12 months.

Randomization

Randomization was undertaken by means of sealed envelopes equivalent to the number of subjects and filled fifty-fifty with an indicator of either a low-carbohydrate diet or healthy-eating advice. Two separate sets of envelopes were prepared for both diabetic and non-diabetic subjects. An independent observer witnessed randomization.

Intervention

The diets were explained to all subjects by a qualified dietitian at an individual randomization visit and written information was provided. Subjects allocated the low-carbohydrate diet were advised to reduce carbohydrate intake to ≤ 40 g/day and were given specific advice to take at least 200 ml of milk daily and include 4–5 portions of fruit and vegetables daily, with an emphasis on low-carbohydrate vegetables such as salads and green leafy vegetables. Concerns have been expressed about saturated fat intakes on low-carbohydrate diets and, as a result, subjects were advised to include lean meats, poultry, fish and game, low-fat dairy products, avoid large amounts of saturated fat and use monounsaturated fat. The subjects in the healthy-eating group were given information in accordance with the dietary guidelines of Diabetes UK. Briefly, subjects were advised to reduce total fat and saturated fat intakes, eat five portions of fruit and vegetables daily and adopt a diet of low glycaemic index. They were advised to reduce total energy intake to produce a 500 kcal/day deficit. All subjects were encouraged to increase physical activity and advised to exercise at moderate intensity for 30 min at least 5 and preferably 7 days per week.

Data collection

The primary outcome measure was body weight and secondary measures included glycated haemoglobin (HbA_{1c}), blood ketone levels, total cholesterol, high-density lipoprotein (HDL) and low-density lipoprotein (LDL) cholesterol levels and triglyceride concentrations. Dietary intake was measured by validated 3-day food diary [20] and analysed by Dietplan5 for Windows [21]. Subjects were seen monthly. All assessments were undertaken at baseline and 3 months after intervention. Body weight and dietary intake were recorded at each monthly interval.

Table 1 Baseline characteristics of 26 diabetic and non-diabetic subjects

Variable	Low carbohydrate (<i>n</i> = 12)	Healthy eating (<i>n</i> = 14)	All subjects (<i>n</i> = 26)
% Male	17	36	23
Age (years)	55 ± 5	50 ± 12	52 ± 9
Weight (kg)	95.6 ± 16.7	97.0 ± 17.2	96.3 ± 16.6
BMI (kg/m ²)	35.1 ± 6.8	35.0 ± 7.4	35.1 ± 7.0
HbA _{1c} (%)	6.7 ± 1.3	6.6 ± 1.0	6.6 ± 1.1
Total cholesterol (mmol/l)	5.1 ± 1.3	5.1 ± 0.8	5.1 ± 1.1
HDL cholesterol (mmol/l)	1.28 ± 0.44	1.37 ± 0.33	1.32 ± 0.38
LDL cholesterol (mmol/l)	3.1 ± 1.1	3.1 ± 0.8	3.1 ± 0.9
Triglycerides (mmol/l)	1.55 (1.01, 2.35)*	1.12 (0.74, 1.72)*	1.48 (0.82, 2.14)*
Ketones (mmol/l)	0.0–0.2†	0.0–0.1†	0.0–0.2†

Mean ± SD.

*Triglyceride concentrations expressed as geometric means.

†Ketone concentrations expressed as ranges.

BMI, body mass index; HbA_{1c}, glycated haemoglobin; HDL, high-density lipoprotein; LDL, low-density lipoprotein; SD, standard deviation.

Table 2 Baseline comparison of diabetic and non-diabetic subjects

Variable	Diabetic subjects (<i>n</i> = 13)	Non-diabetic subjects (<i>n</i> = 13)	<i>P</i> -value
% Male	30	23	
Age (years)	54 ± 9	51 ± 9	0.331
Weight (kg)	99.0 ± 12.9	93.5 ± 19.8	0.412
BMI (kg/m ²)	34.8 ± 4.8	35.8 ± 7.1	0.874
HbA _{1c} (%)	7.3 ± 1.3	6.0 ± 0.3	0.001
Total cholesterol (mmol/l)	4.8 ± 1.2	5.4 ± 0.9	0.184
HDL cholesterol (mmol/l)	1.34 ± 0.5	1.31 ± 0.2	0.837
LDL cholesterol (mmol/l)	2.8 ± 0.9	3.4 ± 0.9	0.090
Triglycerides (mmol/l)	1.51 (0.76, 2.27)*	1.47 (0.57, 2.04)*	0.862

Mean ± SD.

*Triglyceride concentrations expressed as geometric means.

BMI, body mass index; HbA_{1c}, glycated haemoglobin; HDL, high-density lipoprotein; LDL, low-density lipoprotein; SD, standard deviation.

Statistical analysis

Statistical analysis was based upon weight change from baseline. Weight changes from previous studies showed a treatment effect of 3.0 SD. Power calculations indicated that group sizes of nine would give > 90% power at the 0.05 level. The sample size was calculated as 10 in each group and we aimed to recruit 12 to each arm to allow for possible drop out.

All data were analysed using parametric statistics where appropriate. Triglyceride values were log-transformed before analysis, and blood ketone levels were analysed using non-parametric analyses.

Results

Baseline characteristics of the 26 subjects recruited into the study are shown in Table 1. Subjects (25% male) were (mean ± SD) age 52 ± 9 years, weight 96.3 ± 16.6 kg, BMI 35.1 ± 7.0 kg/m², HbA_{1c} 6.6 ± 1.1%, total cholesterol 5.1 ± 1.1 mmol/l, HDL

cholesterol 1.32 ± 0.38 mmol/l, triglycerides 1.55 (1.10, 2.35) mmol/l and ketone concentrations ranged from 0.0 to 0.2 mmol/l. There were no significant differences between the two groups for any of the baseline variables. Table 2 shows a comparison of the characteristics of the diabetic and non-diabetic subjects at baseline. There were no differences for any of these variables with the exception of HbA_{1c}, which was, obviously, significantly higher in the diabetic population (7.3 vs. 6.0%, *P* = 0.001).

Three-month data are presented for 22 (85%) of the 26 patients randomized into the study. Figure 1 shows that 12 subjects were randomized to the low-carbohydrate diet and 14 to healthy-eating advice. Analysis is by last observation carried forward at 1 or 2 months and this applies to one subject allocated to the low-carbohydrate group and one subject allocated healthy-eating advice. There were no drop outs after randomization in the low-carbohydrate group, and this contrasts with four subjects in the healthy-eating

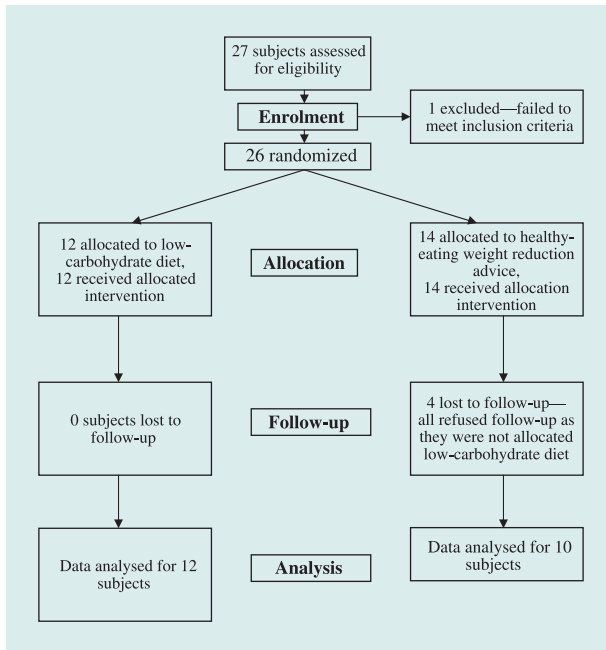


FIGURE 1 Consort flowchart.

Table 3 Absolute changes from baseline at 3 months, low carbohydrate vs. healthy eating

Variable	Low-carbohydrate diet	Healthy eating	P-value
Weight (kg)	-6.9	-2.1	0.003
BMI (kg/m ²)	-2.7	-0.8	0.001
HbA _{1c} (%)	-0.3	-0.2	0.582
Total cholesterol (mmol/l)	0.1	-0.1	0.282
HDL cholesterol (mmol/l)	0.09	-0.06	0.113
LDL cholesterol (mmol/l)	0.2	0	0.126
Triglycerides* (mmol/l)	-0.4	0	0.07
Ketones (mmol/l)	0.1	0	0.055

*Triglyceride concentrations reported as changes in geometric means.
 BMI, body mass index; HbA_{1c}, glycated haemoglobin;
 HDL, high-density lipoprotein; LDL, low-density lipoprotein.

group who refused follow-up after randomization. All four of these subjects expressed disappointment at being allocated to the healthy-eating arm of the study rather than the low-carbohydrate diet.

The differences in the changes between the low carbohydrate and healthy-eating groups at 3 months are shown in Table 3. There was a significant reduction in weight in both groups, but a greater reduction in the low-carbohydrate group compared with the healthy-eating group (6.9 vs. 2.1 kg, $P = 0.003$). Weight loss at 3 months is shown in Fig. 2. There were no differences between the groups for all other measured variables including HbA_{1c} and lipid profile. Ketone production

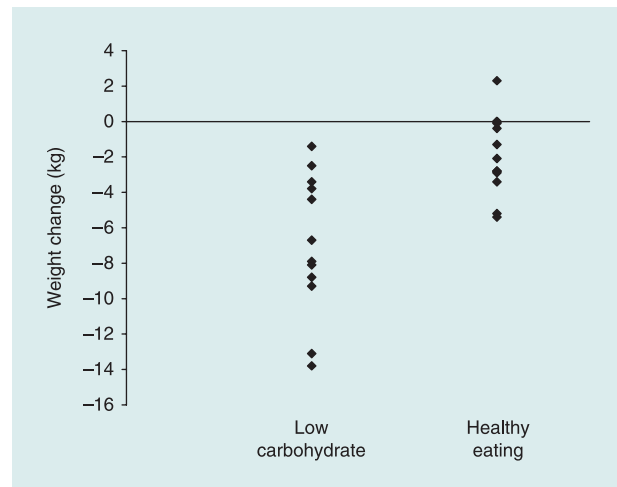


FIGURE 2 Weight loss over 3 months: low carbohydrate vs. healthy eating.

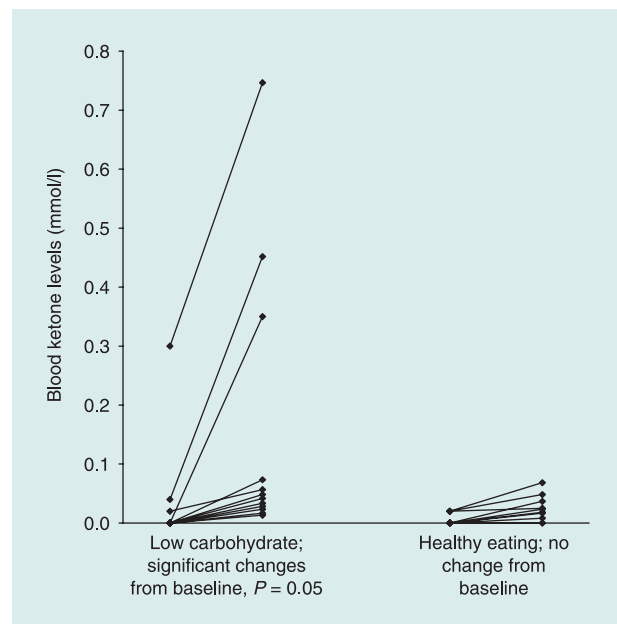


FIGURE 3 Changes in blood ketone levels over 3 months: low carbohydrate vs. healthy eating.

over 3 months was significantly higher in the low-carbohydrate group from baseline ($P = 0.05$), but failed to reach statistical significance when compared with the healthy-eating group (Fig. 3). This can be largely explained by the three outliers in the low-carbohydrate group who showed large increases in blood ketone levels over the course of the study.

Table 4 shows the differences in characteristics at baseline and 3 months and the differences from baseline at 3 months in the diabetic and non-diabetic subjects by dietary allocation.

Dietary intake is shown in Table 5. There were no significant differences in nutrient intake between the two groups at baseline. At the end of the study, dietary analysis showed a

Table 4 Baseline and 3-month characteristics and absolute changes from baseline at 3 months by dietary allocation and diagnosis of diabetes

Variable	Diabetes						Non-diabetes					
	Low carbohydrate (n = 6)			Healthy eating (n = 6)			Low carbohydrate (n = 6)			Healthy eating (n = 4)		
	Baseline	3 months	Change	Baseline	3 months	Change	Baseline	3 months	Change	Baseline	3 months	Change
Weight (kg)	99.7	91.7	-8.0	96.9	96.1	-0.8	91.1	85.3	-5.8	95.7	92.9	-2.8
BMI (kg/m ²)	36.5	33.4	-3.1	33.3	33.0	-0.1	33.7	31.5	2.2	37.3	36.2	-1.1
HbA _{1c} (%)	7.2	6.8	-0.4	7.5	7.3	-0.2	6.1	5.9	-0.2	6.0	5.8	-0.2
Total cholesterol (mmol/l)	4.8	4.8	0	4.7	4.6	-0.1	5.5	5.7	+0.2	5.5	5.4	-0.1
HDL cholesterol (mmol/l)	1.24	1.32	+0.08	1.47	1.34	-0.13	1.32	1.40	+0.08	1.32	1.38	+0.06
LDL cholesterol (mmol/l)	2.70	2.94	+0.24	2.69	2.75	+0.06	3.46	3.60	+0.16	3.57	3.40	-0.17
Triglycerides (mmol/l)	1.8	1.2	-0.6	1.2	1.3	+0.1	1.6	1.5	-0.1	1.4	1.3	-0.1

BMI, body mass index; HbA_{1c}, glycated haemoglobin; HDL, high-density lipoprotein; LDL, low-density lipoprotein.

Table 5 Changes in daily dietary intake over 3 months

Variable	Baseline (n = 26) Mean (SD)	Three months		P-value (changes in low carbohydrate vs. healthy eating)
		Low carbohydrate (n = 11)	Healthy eating (n = 10)	
Energy (kcal)	2130 (457)	1313 (205)	1593 (277)	0.036
Protein (g)	95.2 (18.4)	97.2 (18.9)	79.5 (16.6)	0.113
Fat (g)	92.5 (30.1)	69.3 (25.6)	62.7 (22.4)	0.634
Carbohydrate (g)	223.2 (62.0)	56.8 (26.5)	167.3 (60.4)	0.001
Protein (%energy)	18.4 (3.8)	31.1 (6.9)	19.8 (3.1)	< 0.001
Fat (%energy)	38.6 (7.2)	46.2 (10.6)	34.4 (7.8)	0.033
Carbohydrate (%energy)	39.5 (6.8)	17.3 (9.7)	39.3 (12.8)	< 0.001
Alcohol (%energy)	3.5 (5.0)	6.1 (9.3)	6.6 (6.6)	0.611

SD, standard deviation.

significant reduction in energy intake in both groups, and a greater reduction in calories in the low-carbohydrate group (949 vs. 515 kcal/day, $P = 0.036$). There were no differences in changes in absolute protein and fat intakes between the two groups, but there was a highly significant reduction in carbohydrate intake in the low carbohydrate group to 56.8 g/day. This reduction in carbohydrate intake was reflected in significant changes in %energy from macronutrients.

Discussion

In common with other published work, this study shows a greater reduction in weight over 3 months in subjects allocated a low-carbohydrate diet compared with a healthy-eating regimen. This weight reduction is associated with a significant reduction in energy intake related to decreased carbohydrate intake and is not associated with an absolute increase in either protein or fat intake. Interestingly, subjects in both the healthy-eating and the low-carbohydrate groups reported significant reductions in fat intake over the 3 months of the study, and this suggests that it is possible to adopt a low-carbohydrate

diet without an increase in fat intake. This may reflect the fact that much of the fat eaten today is associated with carbohydrate; for example, in savoury snacks, biscuits, cakes and chocolate, and that eliminating these foods reduces both carbohydrate and fat intake.

Glycaemic control improved in both groups, with no difference between the two groups. This result may reflect the fact that this study included both subjects with and without diabetes. A subanalysis showed that there was a clinical reduction in HbA_{1c} in the subjects with diabetes ($-0.3%$, $P = 0.07$), but this failed to reach statistical significance. However, the non-diabetic subjects also showed a statistically significant reduction in HbA_{1c} ($-0.1%$, $P = 0.038$), although this is unlikely to be of clinical significance. Further analysis of all subjects, regardless of dietary allocation or diagnosis of diabetes, showed a significant improvement in glycaemic control ($-0.3%$ HbA_{1c}, $P = 0.012$) over the 3 months of the study.

There were no significant differences in the changes in lipid levels between the low-carbohydrate and healthy-eating groups, although HDL cholesterol significantly increased and triglyceride levels decreased in the low-carbohydrate group

over 3 months. Lipid levels were relatively low in the subjects with Type 2 diabetes, and this is partly explained by the use of lipid-lowering medication: five of the 13 (38%) diabetic subjects were prescribed statin therapy compared with none of the non-diabetic subjects. There was no evidence of an adverse effect of a low-carbohydrate diet on lipid profiles in either the diabetic or non-diabetic group.

In conclusion, there is evidence to support the hypothesis that low-carbohydrate diets may confer greater benefit in terms of weight loss compared with healthy-eating advice, and are not dangerous in the short term for people with and without Type 2 diabetes. Little is known about the long-term effects of these diets, and this present study is subject to post-study monitoring for 2 years with intention to report annual data.

Competing interests

DRM and PAD have received research funding from the Sugar Bureau. SB has no competing interests to declare.

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