

# The application of carbohydrate-reduction in general practice: A medical audit



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**Background:** Carbohydrate-reduction has been used successfully in the management of conditions arising from insulin resistance.

**Aim:** In this audit, the authors report on metabolic outcomes from 72 patients in primary care who have undergone counselling using a low-carbohydrate dietary approach.

**Setting:** This audit took place in a family medical practice located in a relatively affluent suburb in East Auckland, New Zealand.

**Methods:** Patients adopted a carbohydrate reduction diet with regular follow-up and monitoring of health parameters.

**Results:** The mean duration of observation was 21.5 ( $\pm$  10.4) months. On average, patients lost 11 ( $\pm$  8.4) kg, with 17% attaining a healthy body mass index (BMI). Four out of five patients reversed prediabetes over 20.8 ( $\pm$  13.4) months. Twenty-five per cent (28/113) of the practice population with type 2 diabetes (T2DM) participated, of which 64% reversed and 11% remitted T2DM over 20.7 ( $\pm$  11.8) months. Two patients stopped insulin and 10 reduced or stopped other diabetes medications. Nearly 35% (25/72) of participants were initially hypertensive. Thirty-six per cent (9/25) normalised systolic blood pressure (SBP), 28% (7/25) normalised diastolic blood pressure (DBP), and 16% (4/25) normalised both SBP & DBP. Sixty-four per cent reduced or stopped some or all antihypertensive medication. There was a mean reduction in SBP of 10.3 ( $\pm$  17.7) mmHg and DBP of 4.8 ( $\pm$  12.3) mmHg over 23.8 ( $\pm$  9.0) months. Lipid changes were generally favourable, with 52% normalising triglycerides, 61% increasing high density lipoprotein cholesterol (HDL-C) to greater than 1.0 mmol/L, and 39% reducing low density lipoprotein cholesterol (LDL-C).

**Discussion:** This real-world audit aligns with published data on the benefits of carbohydrate reduction.

**Conclusion:** Effective management of prediabetes using CR might represent the biggest 'bang for buck' with a potential reduction in weight and prevention of diseases related to IR.

**Contribution:** A low-carbohydrate dietary approach in primary care may serve as a realistic option for improving multiple health outcomes.

**Keywords:** low-carbohydrate diets; diabetes remission; lifestyle modification; obesity treatment; type 2 diabetes; hypertension reversal; non-alcoholic fatty liver reversal; de-prescribing.

## Background

There is a growing body of literature, in both clinical trials and routine care settings, supporting the return to a less carbohydrate dense diet with demonstrable improvements in a number of important medical conditions and their respective health parameters. These conditions include: obesity, prediabetes, type 2 diabetes (T2DM), hypertension, non-alcoholic fatty liver disease (NAFLD), and polycystic ovarian syndrome (PCOS).

Virta Health, a United States (US)-based company, is at the forefront of combining clinical practice and research in managing prediabetes and/or T2DM using carbohydrate reduction (CR).<sup>1</sup> The company reported 5-year data from an ongoing online clinic programme and clinical trials. The authors concluded that their model of very low carbohydrate intervention with continuous remote care showed excellent retention, sustained clinically significant weight loss, stable glycaemic control, and less dependency on diabetes medication.<sup>2</sup> In the United Kingdom (UK), general practitioner, Dr David Unwin has demonstrated that with using CR, a substantial number

of patients have been able to reverse or remit their T2DM. They were also able to lose weight, reduce antihypertensive medications, improve kidney function,<sup>3</sup> and save a considerable amount of money with less expenditure on medication.<sup>4</sup> Non-alcoholic fatty liver disease has also been shown to improve through CR.<sup>5</sup>

Many other programmes have used CR to obtain positive outcomes in healthcare and well-being.<sup>6,7,8</sup> A 2017 review by Noakes and Windt describes the scientific basis, rationale and practicalities behind CR and gives good advice for health professionals wishing to advocate this therapeutic option.<sup>9</sup> Different health professionals have been increasingly using CR as a therapeutic modality, including the principal author of this audit, and have seen positive health outcomes for a considerable numbers of patients as well as improving career satisfaction.<sup>10</sup> This work profiles a formalised clinical audit of patients with obesity and other insulin resistance (IR)-related co-morbidities after adopting a low-carbohydrate diet. The objective of this audit was to review changes in health parameters relating to these conditions.

## Methods

This audit took place in a family medical practice located in a relatively affluent suburb in East Auckland, New Zealand. The practice has a patient demographic profile representative of other practices within the surrounding suburbs.

### Patient selection and initiation

Exclusion criteria were severe mental illness, terminal illness, pregnancy, and eating disorders. The General Practitioner (GP) took sole responsibility for implementation and management of the dietary intervention. Patients were identified opportunistically by comorbidities (obesity, prediabetes, diabetes, hypertension, NAFLD, PCOS, and migraine) during routine consultations and were asked whether or not they wished to try and make a difference to their health through dietary change. If in agreement, the philosophy of CR was discussed and how it might apply to them. The process involved one-to-one discussion either at the time of the initial suggestion or at a later date.

The first consultation was generally longer than the usual 10–15 min allocated in primary care in New Zealand, and often lasted 20–30 min. This was regarded as an important investment in ‘getting things started’ and often allowed shorter than 15-min follow-up appointments. A double appointment was often allocated to initial consultations, at no extra cost to the patient, as funding was available to cover the cost of longer consultations. Patients were counselled on foods and beverages that were suitable to consume and those recommended to reduce or avoid. They were provided with a handout comprehensively detailing these foodstuffs (Appendix 1). Patients were routinely advised to reduce or avoid ‘junk food’ because of its high carbohydrate density and its overall poor nutritional quality. Subjects were advised to reduce or avoid the foods belonging to the ‘grains’ food group

(bread, pasta, potatoes and rice) and to reduce intake of starchy vegetables and fruit (except berries). General advice was also given in terms of *foods to eat the most* (non-starchy vegetables, nuts, seeds, eggs, fish, meats, tofu/tempeh, full-fat dairy, cooking fats: olive oil, coconut oil, butter), *foods to eat sometimes* (starchy vegetables, fruit, other plant proteins) and *foods to eat least* (ultra-processed packaged foods, seed oils, confectionary, sugary beverages, and refined grains). Subjects were strongly encouraged to become familiar with the carbohydrate content on food labels. They were also recommended reputable online resources such as [www.dietdoctor.com](http://www.dietdoctor.com) to expand their knowledge. Carbohydrate-counting was not considered essential but if individuals wished to do so then two mobile phone apps were recommended (MyFitnessPal<sup>11</sup> and Easy Diet Diary<sup>12</sup>).

Patients were advised that any CR was considered desirable, but that 50 g – 100 g of net carbohydrates (excluding dietary fibre) per day was considered to be within a low carbohydrate range and recommended. The reduction in carbohydrates was initially a matter of personal preference but would subsequently be determined by whether or not the desired health improvements were being achieved. If individuals preferred to venture into the more extreme end of the low carbohydrate spectrum that is the ketogenic range, of less than 20 g carbohydrates per day, there was no routine recommendation to verify a state of ketosis by testing ketones (breath or urine) as it was assumed that this level of CR would be sufficient to achieve ketosis.

Patients were then given a period of time in which to explore this new way of eating, typically 1–2 months, and then reviewed to make sure they were ‘on track’ and to record relevant health parameters. There was a wide variation in the timing of follow-up consultations. Some required weekly review for 1–2 months to ensure compliance and offer encouragement and support, especially when complex psychosocial issues were involved. Others were more independent and required review at only 3–4 monthly intervals.

Dietary data were not collected as this is not routine within the GP clinical practice. Patients were however questioned at follow-up visits about their macronutrient consumption and specifically in terms of grams of carbohydrates consumed. They were also routinely asked about what they had eaten in the last 24 h. It was equally important to address the possibility of de-prescribing medication at these visits.

### Data collection

Data were recorded between September 2018 and November 2021. Baseline parameters were as follows: *demographics* (age, gender, duration of observation in months), *morbidity* (overweight and/or obesity, prediabetes, diabetes, hypertension, abnormal liver function tests [LFTs], PCOS, migraine) and *biometrics* (height, weight, body mass index [BMI], thyroid stimulating hormone [TSH], glycosylated haemoglobin [HbA1c], LFTs ( $\gamma$ -glutamyl transferase [GGT]), alanine aminotransferase [ALT]), lipid profile (total cholesterol

**TABLE 1:** Initial and final parameters.

Variable†	Baseline measure median (IQR)	Latest follow up median (IQR)	Difference mean (s.d.)	P value	Matched pairs n (%)
Age (years)	55 (46, 63)	-	-	-	-
Weight (kg)	99 (88, 111)	90 (77,101)	11 (8.4)	< 0.0001	72
BMI (kg/m <sup>2</sup> )	33 (29, 37)	30 (26, 34)	3.5 (2.7)	< 0.0001	72
HbA1c (mmol/mol)	40 (36, 58)	38 (36, 45)	7.9 (14)	< 0.0001	68
GGT (U/L)	28 (19, 48)	27 (17, 36)	14 (39)	0.0003	63
ALT (U/L)	30 (23, 38)	23 (17, 32)	16 (30)	< 0.0001	63
SBP (mmHg)	135 (126, 143)	128 (120, 138)	8.6 (16)	< 0.0001	68
DBP (mmHg)	84 (74, 87)	77 (70, 83)	4.7 (11)	0.0009	68
TG (mmol/L)	1.7 (1.4, 2.6)	1.6 (1.1, 2.3)	0.3 (1.0)	0.0025	69
TC (mmol/L)	5.0 (4.2, 6.1)	5.0 (4.2, 6.1)	-0.2 (1.6)	0.5892	69
HDL-C (mmol/L)	1.2 (0.9, 1.4)	1.2 (1.1,1.5)	-0.1 (0.2)	< 0.0001	69
LDL-C (mmol/L)	3.0 (2.2, 4.0)	3.1 (2.2, 3.9)	-0.2 (1.5)	0.8495	65
TC/HDL	4.5 (3.6, 5.2)	4.2 (3.1, 5.0)	0.3 (1.2)	0.0058	69
TG/HDL	1.5 (1.1, 2.7)	1.3 (0.8, 2.0)	0.4 (1.3)	0.0003	69

Note: Ethnicity; NZ European = 87.5% - Other = 12.5% (NZ Maori [2], SE Asian [2], Chinese [2], Other Asian [1], Other European [1], Samoan [1]).

†, Cohort of 72 participants, 24 females (33%).

BMI, body mass index, HbA1c, glycosylated haemoglobin; GGT,  $\gamma$ -glutamyl transferase; ALT, alanine aminotransferase; SBP, systolic blood pressure; DBP, diastolic blood pressure; TG, triglyceride; TC, total cholesterol; HDL-C, high density lipoprotein cholesterol; LDL-C, low density lipoprotein cholesterol.

[TC]), triglyceride ([TG], high density lipoprotein cholesterol (HDL-C), low density lipoprotein cholesterol (LDL-C), TC/HDL-C ratio, serum creatinine and estimated glomerular filtration rate (eGFR), systolic blood pressure (SBP) and diastolic blood pressure (DBP).

All heights, weights and blood pressures were recorded at the practice. All subsequent data were then collected sequentially as per routine or necessary reviews and entered into an Excel spreadsheet. At the end of the observation period, patients' most recent parameters were used for comparative analysis, and this was also taken as the endpoint to mark their duration of observation. The spreadsheet was checked twice by the same person to ensure data integrity.

### Statistical analysis

Statistical analyses were performed with R version 4.0.2. Summaries of baseline and follow-up data are shown as median and the interquartile range (IQR, 25th percentile, 75th percentile) for non-normally distributed continuous variables that is, age, weight, HbA1c, lipid profile, and blood pressure. Normally distributed continuous variables are presented as median (standard deviation-[s.d.]) that is duration of diet. Comparisons between baseline and latest follow-up continuous variables were made using the Wilcoxon signed-rank test for paired samples. A  $p < 0.05$  was considered statistically significant. The Bonferroni correction was also applied, for 17 outcome variables measured (13 variables presented in Table 1, data not shown for four variables) and for the 6 cohorts (whole cohort, cohorts with overweight and obesity, pre-diabetes, diabetes, hypertension, and with abnormal liver enzymes). After Bonferroni correction the  $p$ -value was considered statistically significant at 0.00049. Baseline and latest follow-up distributions of data are presented as jitter plots, with a black line representing the median value and a red dot indicating the mean, the  $p$ -value comparing the baseline and follow-up populations is shown.

### Ethical considerations

It was not considered necessary to seek formal ethical approval as this was an audit of service. It was also not a prerequisite to seek consent from patients to share their anonymised data, as per the New Zealand Privacy Commissioner's Office Code of Practice.<sup>13</sup> The views expressed in this article are those of the authors and not an official position of any of their affiliated institutions and the publisher.

### Results

Table 1 presents the baseline and final mean data values for the sample of patients. A total of 72 patients agreed to be counselled in a low-carbohydrate dietary approach; they had a mean age of  $54.4 \pm 13$  years and 33% of them (24) were female. The majority were New Zealand Europeans (87.5%). Data were collected for a mean duration of 21.5 ( $\pm 10.4$ ) months. All were initially judged to be clinically euthyroid. In 7% (5/72) of the patients, initial thyroid function as assessed by TSH was not known. In the remainder, thyroid function was normal. No patients developed hyper- or hypo-thyroidism during their period of observation. One patient was needle-phobic and thus did not do blood tests. Over 98% (71/72) of the patients recorded an initial normal eGFR.

### Overweight and obesity

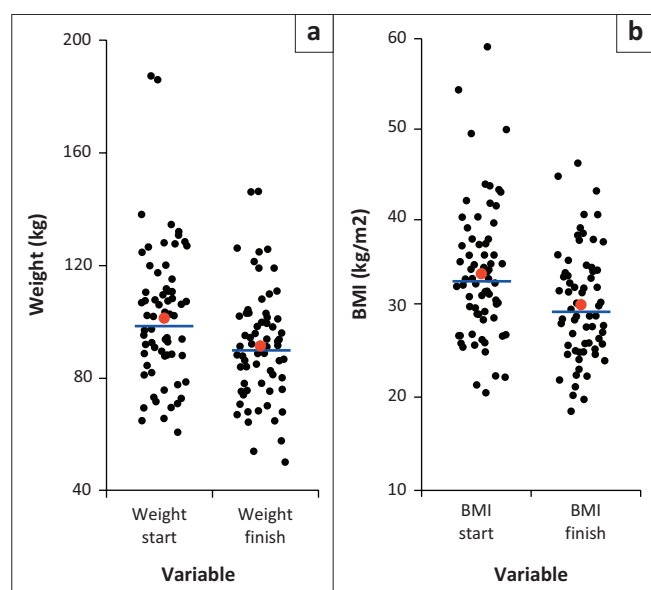
In all, 94% (68/72) of the patients were initially overweight or obese, with a starting BMI greater than 25 kg/m<sup>2</sup>. A total of 99% (71/72) lost weight, with a mean duration of observation of nearly 2 years ( $21.5 \pm 10.4$  months). A total of 13% (9/68) achieved a normal BMI. The average starting weight in the overweight patients was 103.4 kg (107 kg in males, 95 kg in females) and the finishing weight 92.4 kg (96 kg in males and 85 kg in females), with a mean weight loss of 11.0 ( $\pm 8.3$ ) kg ( $11.2 \pm 9.0$  in males,  $10.5 \pm 6.8$  in females). Figure 1 shows statistically significant weight reduction.

## Prediabetes

In New Zealand, prediabetes is defined as an HbA1c in the range of 41–49 mmol/mol (6.0% – 6.5%). There were five patients with prediabetes in this audit; the mean age was 63 years, and one was female. The mean duration of observation was 20.8 ( $\pm$  13.4) months. Four reversed prediabetes (HbA1c below 41 mmol/mol; < 6%). All of them were initially overweight or obese and all reduced their weight with one normalising BMI.

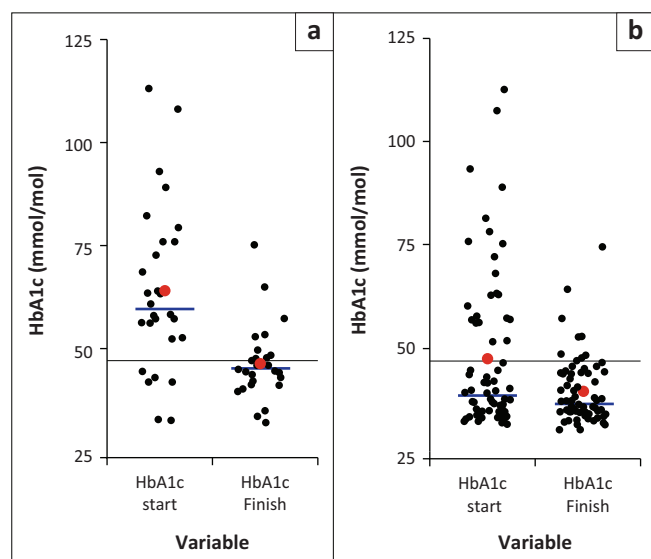
## Diabetes

Twenty-eight patients with T2DM trialed CR. This was just over 25% of the practice population with known T2DM. The mean age was 58 ( $\pm$  14.8) years and 6 (21%) were female.



$p < 0.001$ .

**FIGURE 1:** Change in (a) body weight and (b) body mass index for 72 participants.



$p < 0.001$ .

**FIGURE 2:** Change in glycosylated haemoglobin (a) change in 28 diabetic patients, (b) change in glycosylated haemoglobin in all 72 patients.

Mean CR duration was 20.7 ( $\pm$  11.8) months. A total of 64% (18/28) reversed T2DM, where reversal is defined as achieving an HbA1c < 48 mmol/mol with or without metformin as the only diabetic medication.<sup>14</sup> Eleven per cent (3/28) remitted T2DM, where remission is defined as achieving an HbA1c < 48 mmol/mol without any diabetic medication and that persists for at least 3 months.<sup>15</sup> Two patients were able to stop insulin and two reduced insulin doses while 10 either reduced and/or stopped oral hypoglycaemic agents. A statistically significant reduction in HbA1c is shown in Figure 2a (mean reduction of 17.4 mmol/mol  $\pm$  18.5; 3.7%). Of interest, Figure 2b shows a statistically significant reduction in HbA1c for the cohort of 71 patients who had given blood samples. The mean weight loss was 8.8 ( $\pm$  8.2) kg. A total of 93% were initially overweight/obese; all of these patients lost weight and one attained a normal BMI.

## Hypertension

Thirty-five per cent (25/72) of the total audit group were recorded as taking antihypertensive medication at the initial consultation. The mean age was 55.5 ( $\pm$  9.7) years and 10 (40%) were female. The mean duration of observation was just under 2 years (23.8  $\pm$  9.0 months). Systolic blood pressure and DBP were accepted as normal if below 130 mmHg and 80 mmHg, respectively, as per New Zealand guidelines.<sup>16</sup> A total of 52% (13/25) had an initial SBP above the target level of which 10 (77%) normalised SBP (although one person in the healthy range became hypertensive). The mean final SBP was 130 mmHg and the mean reduction was 10.3 ( $\pm$  17.7) mmHg, ( $p = 0.011$ ). In all, 48% (12/25) had an initial DBP  $\geq$  80 mmHg – DBP in this group did not change significantly. A total of 44% (7/16) normalised DBP, but 3 patients in the healthy range increased DBP. The mean final DBP was 81 mmHg and the mean reduction was 4.8 ( $\pm$  12.3) mmHg, ( $p = 0.075$ ). Four patients (16%) normalised both SBP and DBP having initially high measurements of both.

Sixty-four per cent (16/25) were able to reduce or stop some or all hypertensive medication. Ninety-six per cent (24/25) were initially overweight and/or obese. The mean weight loss was 10.9 kg. Figure 3 demonstrates statistically significant reductions in SBP and DBP. Of note, Figure 3a, c demonstrates a statistically significant reduction in both SBP and DBP for the whole cohort. Figure 3b and Figure 3d shows changes in the 25 hypertensive patients.

## Abnormal liver function tests

Baseline and final data for GGT and ALT were available for 63 patients. Thirty-two per cent (20/63) started with one or more elevated LFTs (GGT > 60 U/L or ALT > 45 U/L). Of the six patients with baseline-only data and the one patient with final-only data, all had normal LFTs; two patients had no LFT data. In the 20 patients with elevated LFTs duration of observation was 21.7 ( $\pm$  8.8) months, three were female and the number of patients with either elevated GGT, elevated ALT or elevated levels of both was 12 (60%), 16 (80%) and 8 (40%), respectively. In those with initial raised GGT, 58%

(7/12) normalised GGT. In those with initial raised ALT, 75% (12/16) normalised ALT, although ALT increased from 38 to 45 in one patient, therefore the overall reduction in high ALT was 69% (11/16). In those with both initial raised GGT and raised ALT, 38% (3/8) were able to normalise both parameters. In the group of 20 patients with at least one elevated LFT, the mean reduction in GGT was 42 U/L and in ALT was 45 U/L. Mean weight loss was 12.9 ( $\pm$  10) kg; all patients initially had high BMI and four patients normalised their BMI. One individual was shown to resolve NAFLD on a subsequent ultrasound examination. Figure 4 demonstrates statistically significant reductions in both ALT and GGT.

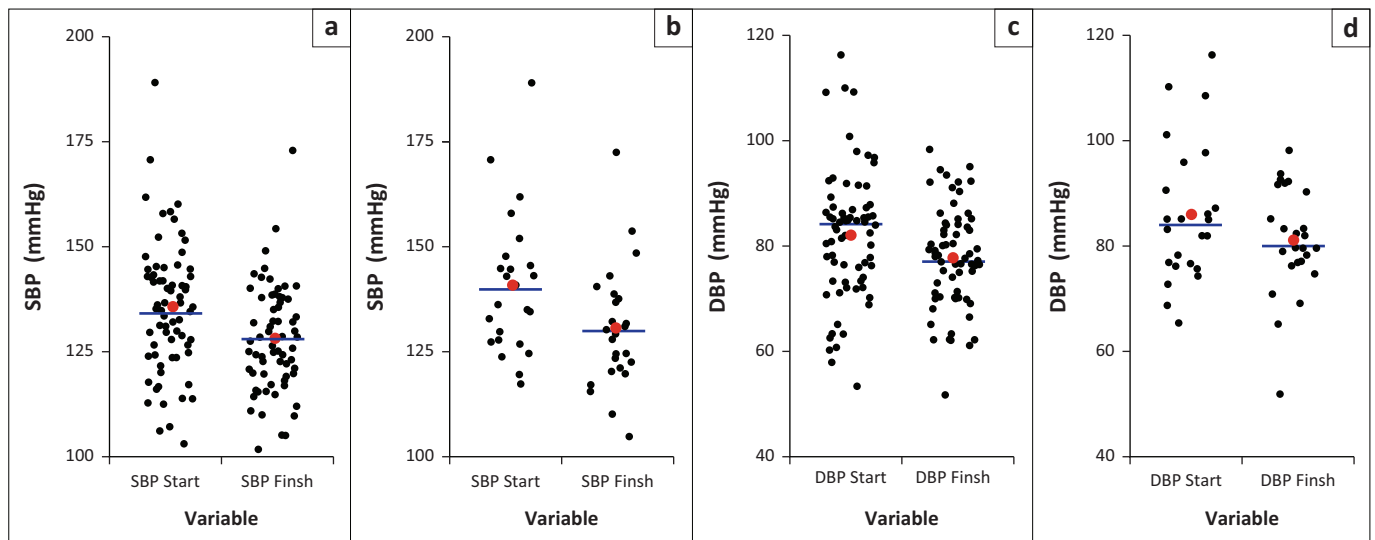
## Lipid profiles

Four per cent (3/72) of the patients did not have final blood lipid results recorded and a further four were missing LDL-C

data as it could not be calculated because of significantly elevated TGs.

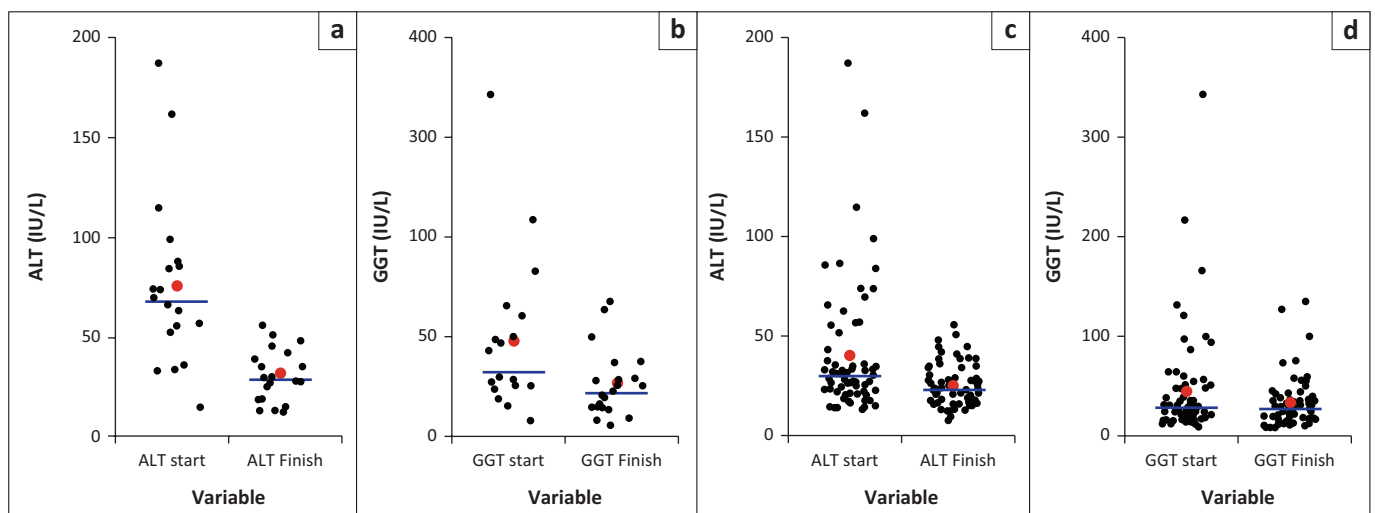
Overall, there was no significant change in TC (Figure 5a). There was a mean reduction in TGs of 0.3 mmol/L with 52% normalisation. Figure 5b shows a statistically significant reduction in TG and there was a significant increase in HDL-C (Figure 5c); LDL-C did not change significantly (Figure 5d).

The ratio of TC to HDL-C was statistically significantly reduced by 0.26 (Figure 5E). Of those starting with a high TC/HDL-C ratio, 38% (13/34) normalised this parameter. Forty-three per cent of those with an initially high TG/HDL-C ratio achieved a desirable ratio of  $<$  1.7 by the end of the period of observation. The ratio of TGs to HDL-C reduced by 0.45 mmol/L and the reduction was statistically significant (Figure 5f).



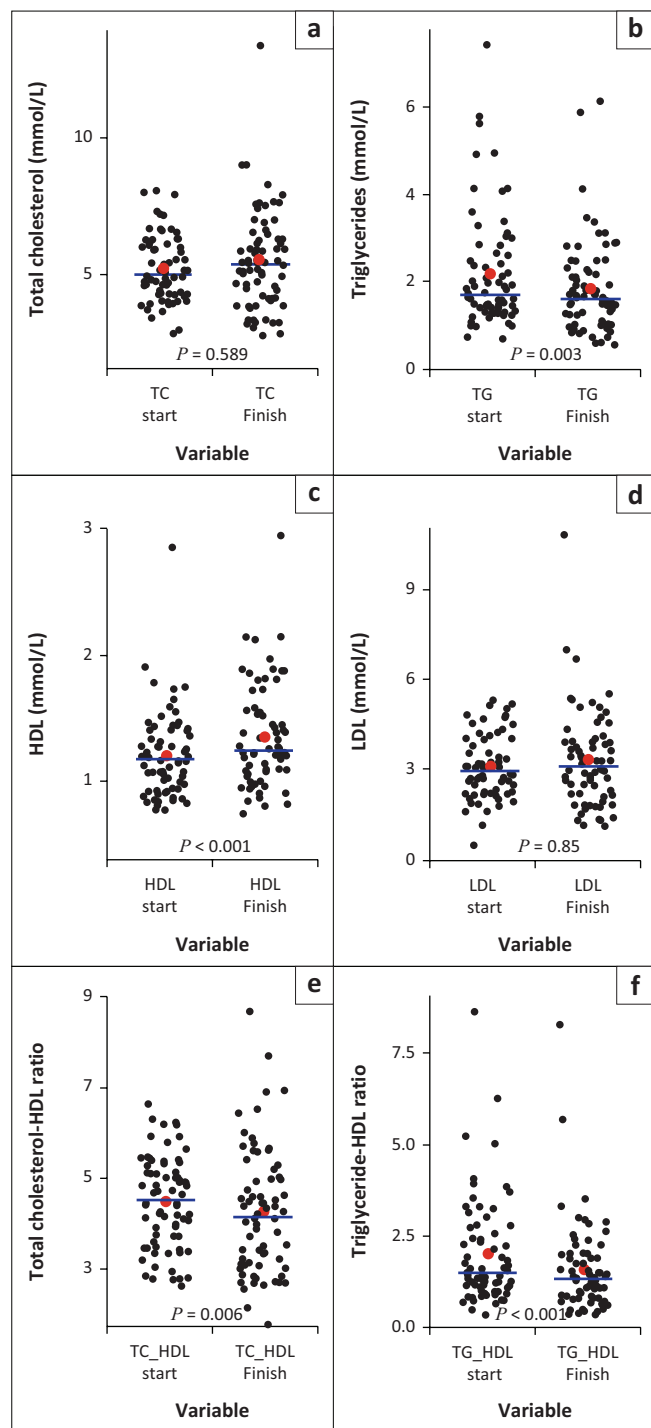
Note: Figure 3a and c,  $p < 0.001$ ; Figure 3b,  $p < 0.011$ ; Figure 3d,  $p < 0.075$ .

**FIGURE 3:** Changes (a) systolic blood pressure and (c) systolic blood pressure in the total cohort of 72 patients. Changes in (b) systolic blood pressure and (d) diastolic blood pressure in the 25 hypertensive patients.



$p < 0.001$ .

**FIGURE 4:** (a,b) Changes in alanine aminotransferase and  $\gamma$ -glutamyl transferase for the 20 patients with elevated alanine aminotransferase and  $\gamma$ -glutamyl transferase levels at start. (c,d) Changes in ALT and GGT for the 70 patients with start and/or finish for ALT and GGT.



**FIGURE 5:** Changes in lipid subfractions between start and finish. 5a. Change in TC 5b. Change in TG 5c. Change in HDL-C 5d. Change in LDL-C 5e. Change in TC/HDL-C 5f. Change in TG/HDL-C.

Six subjects (8%) were able to either reduce or stop lipid-lowering therapies (statins, fibrates); reasons included a reduced cardiovascular risk assessment, significant reduction in TGs, and personal choice. Only one patient increased their statin dose.

### Other conditions

Polycystic ovarian syndrome – the single patient with PCOS lost 8.1 kg within 6 months; her testosterone level normalised and her menstrual periods were restored.

Migraine – in the single patient with a history of frequent migraine attacks there was a dramatic reduction in frequency of episodes and a reduced number of dispensed medications persisting as far as 33 months.

Renal function – all but one patient had a documented initial eGFR, of which 14 (19.4%) were elevated. Seven patients did not have a recorded follow-up eGFR. Of those who did, and had an initial high eGFR, 93% (13/14) improved values, of which 62% (8/13) were normalised. Only one patient demonstrated a deterioration in eGFR falling from 51 to 47 mL/min/1.73 m<sup>2</sup>.

## Discussion

In this article, we present a real-world audit of work undertaken by a single practitioner who has in a little over 3 years supported patients to implement a dietary approach underpinned by CR with the objective of improving their health. What follows, is a discussion of how our observations relate to other data reported from clinical practice, using CR to manage conditions attributed to IR.

### Obesity

Ninety-four per cent of our patients were initially overweight and/or obese. Ninety-nine per cent of these lost a statistically significant amount of weight with 13% achieving a normal BMI.

Noakes reported successful weight loss by way of a low-carbohydrate approach with unsupervised and self-reported observations.<sup>17</sup> We report solely in-practice measurements of weight and height. These data indicate that convincing change can be made in the management of overweight and/or obesity using CR and that these changes can be sustained, as ours were, in 99% for nearly 2 years.

Obesity and its related diseases continue to increase globally,<sup>18</sup> and we would submit that adherence and success of current dietary guidelines is questionable. Other studies have looked at real-world management of overweight and/or obesity using CR and similarly report significant improvements in weight reduction.<sup>19,20</sup> It is often argued that a CR approach is not sustainable for weight loss but it should be noted that other weight loss approaches do not appear to be any more sustainable than CR.<sup>21,22</sup> What is clear, however, is that this approach will often work for those who *can* adopt it.

### Prediabetes

Within the whole practice population, just under 10% (~200) had documented prediabetes. There were only five prediabetic patients in this audit. Four reversed prediabetes for a mean duration of over 20 months. Ten per cent of the practice population with prediabetes is not an insubstantial number and is likely to be an underestimate. Prediabetes presages the approaching ‘tidal wave’ of IR and its sequelae. It should also not be forgotten that an HbA1c in the prediabetic range is still associated with pathological change.<sup>23</sup> There appears to be a

paucity of evidence in the literature on the effect of CR on prediabetes.<sup>24</sup> Unwin has reported a 93% remission rate using CR in prediabetic patients.<sup>4</sup> McKenzie et al. reported that their programme normalised blood sugar in over 50% of those with prediabetes.<sup>25</sup> It would be anticipated that improvement or reversal of prediabetes would match that relating to the management of T2DM with CR, as both are on the spectrum of IR.

## Diabetes

Nearly 40% of the audit group was initially documented as having T2DM; 64% reversed diabetes and 11% remitted diabetes. Therefore, 75% who adopted CR reversed diabetes. This equates to nearly 19% (21/109) of the practice population with T2DM.

These data reflect the results of numerous studies that now demonstrate a significant improvement in diabetes management and cardiovascular risk factors with CR.<sup>26,27,28,29,30,31,32</sup> Studies have shown the safety and sustainability of CR in T2DM.<sup>33</sup> Virta Health investigated the efficacy of CR on T2D outcomes using dietary and lifestyle support by way of telemedicine and health coaching. Twenty per cent completed 5 years of treatment and saw full remission. One-third achieved HbA1c below 48 mmol/mol without any diabetes medications or only metformin. Inflammatory markers, TGs, and HDL-C all improved significantly. Nearly 50% reversed T2DM for up to 5 years.<sup>34</sup> British GP, Dr David Unwin has demonstrated that substantial numbers of patients have been able to reverse and remit T2DM and reduce medications in general with CR. He has also described how CR can have an impact on the public health budget with significant reductions in medication expenditure.<sup>4</sup> This should also translate into reduced expenditure in managing the morbidities associated with diabetes. As a result of this previous work, we did not see the need to undertake a financial analysis. However, undertaking a cost analysis of the current and future practice would be useful to assess the financial savings in a local context.

## Hypertension

A total of 25 patients were initially treated for hypertension. Nearly 60% normalised their SBP and four normalised both SBP and DBP together. In all 64%, were able to stop some or all medication. There was substantial weight loss in this subgroup.

Hypertension is tightly related to body weight and metabolic syndrome.<sup>35</sup> When significant weight loss occurs, hypertension may be improved or reversed and this can be enhanced with CR. Unwin and Hite have previously reported substantial and sustained improvements in blood pressure by using CR.<sup>26,27</sup> It has been postulated that IR leads to renal sodium reabsorption and thus contributes to the pathophysiology of hypertension.<sup>4</sup> Hence, CR may be expected to reduce blood pressure.

## Abnormal liver function tests

Thirty-two per cent of the audit population with data started with elevated LFTs as represented by elevation of either one or both of GGT and ALT. They were assumed to have NAFLD; however, we did not have the resources to routinely organise an ultrasound scan to confirm NAFLD. Fifty-eight per cent (7/12) normalised GGT and 75% (12/16) normalised ALT. Nearly 38% (3/8) were able to completely normalise LFTs.

Abnormal LFTs are a very common finding in affluent societies and most often relate to visceral obesity and IR.<sup>36</sup> Liu et al. concluded that obesity, IR, and elevated liver enzymes appear to be closely related.<sup>37</sup> Non-alcoholic fatty liver disease is highly likely to be associated with carbohydrate exposure. The hepatic metabolism of fructose, a monosaccharide found in fruit and alongside glucose, a 50% component of sucrose (table sugar) is highly implicated in the development of NAFLD.<sup>38</sup> Low-carbohydrate diets have been associated with improvement and resolution of NAFLD.<sup>5,39</sup>

## Other conditions

It was particularly rewarding in the case of a young woman with PCOS, who was able to see a return of her menstrual periods after adopting CR and losing a considerable amount of weight. At the time of this audit, she was planning for pregnancy.

Polycystic ovarian syndrome is a relatively common condition whose pathophysiology relates to obesity and IR.<sup>40</sup> Carbohydrate reduction has been shown to assist in weight loss and reduction of IR in PCOS.<sup>41,42,43</sup>

Our one patient anecdotally reported a reduction in migraine frequency and the number of drugs and doses prescribed.

The common neurological affliction of migraine may also be amenable to CR. This phenomenon is also described in the literature, as early as 1928.<sup>44,45</sup> It has been postulated that the mechanism whereby migraine attacks are improved might be associated with reduced cerebral hyperresponsivity. Ketone bodies might also influence the brain's mitochondrial energy metabolism, which is known to be impaired in migraine.<sup>46</sup>

## Lipid profile

The anticipated improvement in lipid profile with CR as described elsewhere is reflected in our data.<sup>27</sup> We observed no significant change in LDL-C, improvement in HDL-C, substantial reduction in TGs, favourable changes in the TC to HDL-C ratio and TGs to HDL-C ratio.

Elevation in LDL-C may occur with CR and is most often because of an increase in the large buoyant LDL-C subclasses. It is the small dense LDL subclasses that are associated with atherogenesis. Hence, total LDL-C increases but might not

necessarily impart risk of coronary heart disease because there is no increase in small dense LDL particles. Large buoyant LDL-C subclasses are not associated with cardiovascular disease.<sup>47</sup> In contrast, a low-fat, high-carbohydrate diet is more often associated with small dense LDL-C subclasses, which is potentially more harmful.<sup>27,48,49</sup> The TG to HDL-C ratio can be used as a surrogate to reflect the amount of small dense LDL-C particles, with a ratio above 1.7 being regarded as an atherogenic profile.<sup>50</sup> Some patients show a reduction in LDL-C with CR.<sup>51</sup> It should be noticed that LDL-C is calculated using the Friedewald equation and that values can be inaccurate when TG levels are less than 1.13 mmol/L, such that the calculated LDL-C levels would be overestimated. This is of particular relevance to CR when TG levels typically reduce and LDL-C can therefore 'increase', thus showing a falsely elevated LDL-C. There is however no major difference between calculated and measured LDL-C with TG levels between 1.69 mmol/L and 3.39 mmol/L.<sup>52</sup> In a number of lean individuals there can arise an LDL-C hyper-response, which is associated with high HDL-C and low TGs. These are referred to as lean mass hyper-responders.<sup>53</sup> The reason for this phenomenon and its significance and clinical consequences remains as yet unknown.

## Commentary

### Obesity: The pandemic

Obesity is a scourge of modern-day Western societies. The implementation of the nutritional guidelines for a low-fat high carbohydrate (LFHC) diet over the last 50 years has paralleled a significant rise in obesity. The increased use of carbohydrates and the reduction in dietary fat, with imposed saturated fat limits, has also paralleled the global increase in obesity-related morbidity and mortality. At the time of introduction of these guidelines, the scientific rigour of the available evidence to support the guidelines was questionable, and at subsequent review, has come under heavy scrutiny.<sup>54</sup> Obesity is often associated with diabetes, and with this, comes further complications such as ischaemic heart disease, stroke, renal failure, peripheral neuropathy, peripheral vascular disease, and blindness. The cost to society of the complications of obesity and/or diabetes is becoming prohibitive and unsustainable. Furthermore, as humans are living longer, with more obesity-related comorbidities, they will require increasing numbers of medications, technologies, surgeries, care, and clinical time to manage them.

### Carbohydrate-restricted eating

In their narrative review, Noakes and Windt outline the basis for adopting CR and how it can safely and effectively benefit several medical conditions.<sup>9</sup> They offer advice on how medical practitioners might proceed to manage patients in this way. There is now an increasing body of knowledge regarding CR, especially when it comes to refined carbohydrates and how CR can benefit chronic conditions relating to IR.<sup>55,56,57,58</sup> Exogenous carbohydrates

in amounts currently recommended are not necessarily required for a healthy existence.<sup>59</sup> With CR there is an increase in overall fat intake, often with a higher saturated fat intake, and this is cited as a concern by those who argue against this dietary pattern. It is becoming clear however, that this does not usually produce an adverse effect on the overall lipid profile, especially with the more protective marker of HDL-C, increasing, and the more harmful marker of TGs, reducing. A well-formulated low-carbohydrate diet is associated with a replete fibre and micronutrient status.<sup>60</sup> It has also been established that there is a negligible increase in financial expenditure when comparing a LFHC diet with CR diets.<sup>61</sup> Concerning prediabetes and T2DM, there are at least 30 controlled trials; 10 systematic reviews (9 with meta-analyses),<sup>62</sup> such that CR has been endorsed by the American Diabetes Association (ADA),<sup>63</sup> Diabetes UK, Diabetes Canada, and Diabetes Australia. The ADA states:

Reducing overall carbohydrate intake for individuals with diabetes has demonstrated the most evidence for improving glycemia and may be applied in a variety of eating patterns that meet individual needs and preferences.<sup>59</sup>

### Patient and doctor implications

Patients have benefitted from this work in terms of improved health markers, disease reversal and/or remission, reduced medication doses and/or number of medications prescribed, lower medical costs, and an improved sense of well-being. There was also a benefit for the health professional with the accompanying satisfaction of achieving improved patient outcomes and reducing medication prescriptions. The latter appears counterintuitive with so-called 'progressive' diseases such as T2DM (which is likely true with continued recommended levels of carbohydrate exposure). With CR there is regular positive feedback in a speciality that is more often than not picking up the pieces from 'the bottom of the cliff'. There is a significant increase in job satisfaction in the practice of primary care in the current context of a declining workforce and an ever-more demanding workplace.

### The future

It is anticipated that this model of care could be extended to the wider healthcare team thereby potentially maximising efficiency and enhancing patient care. If one GP can show beneficial outcomes in 72 patients to the degree described above, then with additional staff input, the benefits could potentially be a lot more substantial. Carbohydrate reduction is not routinely applied in primary care, as evidence supporting its efficacy has only recently resulted in endorsements and guideline changes. Dr Unwin outlines the clinical practice management guidelines and suggests that CR should be more widely supported by healthcare professionals.<sup>60</sup> Implementing CR in a well-supported manner is relatively straightforward, with a little upskilling in the nutrition field and a few necessary safeguards such as medication reduction in diabetes and hypertension.



We would envisage groups managed by doctors and nurses and individual support aided by health coaches. Unfortunately, our current health service configuration in New Zealand (and further afield) does not provide community dietetic services except for specific disorders such as renal failure, diabetes and heart failure. It would be unwise not to re-orient the health system to incorporate dietitians and/or nutritionists into this area of therapeutic nutrition using CR. They possess the expertise in terms of nutrition knowledge and communication skills, which would be valuable for both patient care and training of the healthcare team.

## Conclusion

Most of the morbidities covered in this audit can be considered under the final common pathway of IR. It has been established that health parameters can be favourably altered in many patients, just by a change to a dietary approach, based on eating whole foods and total CR. Such a pattern resembles the dominant dietary approach before the US guidelines of 1977 and arguably a pattern of eating that was the norm for humans for hundreds of thousands of years. We believe a re-evaluation of the current dietary guidelines is required to stem the tide of morbidities and premature death relating to obesity and/or IR. In the meantime, at least an openness to adopting this approach should be considered more widely in the primary care setting. It is often claimed that dietary changes such as low carbohydrate diets are not sustainable. We would argue, however, that CR leading to some positive change resulting in potentially reduced morbidity, mortality and health expenditure must be worth utilising in those who can adopt it long term. We cannot see, however, that the current national, evidence-based, overweight and/or obesity and cardiovascular guidelines are any more effective at improving health and appear no more sustainable. If anything, they appear to exacerbate the tendency to obesity (and its complications). Like any other dietary change, maintenance persists for only as long as the individual continues to follow the advice. For those who are motivated to change their diet, and who consider this a lifestyle change rather than a temporary diet, it can and does work and can be regarded as safe. Importantly, CR often allows de-prescribing medication rather than the more common pattern of escalation seen with many chronic diseases. There is a way forward in this approach and we remain hopeful that there will be a sea change in medical practice but this will require political willpower and a change from well-established dogma. Effective management of prediabetes using CR might represent the biggest 'bang for buck' with a potential reduction in weight and prevention of diseases related to IR.

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## Authors' contributions

M.H. initiated, gathered and analysed data for the audit. C.Z. contributed to the text, verified statements. C.D. undertook statistical analysis and made suggestions to the text. All authors discussed the results and contributed to the final manuscript.

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## Data availability

The data that support the findings of this study are not openly available because of reasons of patient confidentiality but are available from the corresponding author, M.H., upon reasonable request.

## Disclaimer

The views expressed in this article are those of the authors and not an official position of any of their affiliated institutions and the publisher.

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Appendix 1 starts on the next page →

## Appendix 1

### Patient handout

Meat	Beef	Lamb	Pork	Sausages	Offal
	Chicken	Turkey	Duck	Game	-
	Cured meat	Broths	-	-	-
Seafood	All seafood	Fatty fish: Salmon, mackerel, sardines, herring			
Eggs	Boiled	Fried	Poached	Scrambled	Baked
	Omelette	-	-	-	-
Dairy	Cream cheese	Cottage cheese	Fatty cheese	Full cream	Butter
	Greek yoghurt	Full-cream milk	-	-	-
Vegetables that grow above the ground	Asparagus	Aubergine	Broccoli	Brussels sprouts	Cabbage
	Celery	Capsicum	Cauliflower	Cucumber	Avocado
	Green beans	Kale	Leek	Lettuce	Zucchini
	Olives	Pumpkin	Spinach	Sugar snap peas	Tomato
	Radish	Spring onion	Onion	Mushrooms	Turnip
Berries	Strawberries	Blackberries	Raspberries	-	-
Fats	Olive oil	Avocado oil	Macadamia oil	Mayonnaise	Lard
	Butter	Ghee	Coconut oil	-	-
Nuts and Seeds	Almonds	Brazil nuts	Coconut	Macadamia	Pistachio nuts
	Walnuts	Sunflower	Sesame seed	Pine nuts	Pecan nuts
Drinks	Coffee	Tea	Green tea	Water	Diet drinks

**FIGURE 1-A1:** Foods to eat with reduced carbohydrate eating.

Carbs and sugar dense sugars	Soft drinks	Juices	Sports drinks	Chocolate	Sweets
	Cakes	Buns	Pastries	Ice cream	Breakfast cereal
	Bread	Pasta	Rice	Potatoes	Kumara
	French fries	Potato chips	Couscous	Muesli	Couscous
	Lentils	Polenta	Semolina	Breaded or battered foods	
Fruit	Contains a lot of sugar so eat in its natural form as a treat; Coconut, citrus and melon contain fewer carbohydrates than bananas or grapes				
Dried fruit	All				
Fats and oils	Margarine	Corn oil	Grapeseed oil	Soybean oil	Sunflower oil
	Canola oil	Fat spreads	-	-	-
Drinks	Beer	Dry wine	Champagne	Dessert wine	Dark spirits
	Cider	Liquours	Cordials	-	-
Dairy	Low fat and fat-free	Cheese – spreads and processed		Tinned cream	Condensed milk
	Custard	Yoghurt	Soy milk	Powdered milk	Flavoured milk
Meat/fish	Corned	Battered	Crumbed	Marinated	Sugar cured
	Chicken nuggets	Meat pies	Ready-meals	Meat-free	Tuna in veg oil
Fast food	Burgers	Hot dogs	Spare ribs	Wraps	Pizza
Sauces	Bought sauces	BBQ sauce	Cook-in sauce	Marinades	Pasta sauce
	Salad creams	Salad dressings	Tomato sauce	-	-
Other	Peanuts	Corn syrup	Maple syrup	Table sugar	Treacle
	Fructose	Glucose	Dextrose	Peas	Corn
	Chickpeas	-	-	-	-

**FIGURE 2-A1:** Foods to avoid with reduced carbohydrate eating.