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Low-glycemic Index Diets in the Improvement of HbA1c in Diabetes: A Systematic Review of Randomized Control Trials

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ABSTRACT

There is a controversy around the world about the utility of low-GI diets in diabetes management. The aim of this systematic review is to assess the effect of low-GI diets in the improvement of Hemoglobin A1c (HbA1c) in diabetes in randomized control trials. Literature searches identified 10 Randomized Control Trials (RCT) comprising 630 subjects, that met strict inclusion criteria. All were randomized crossover or parallel experimental design with a diet duration ranging from 4 to 48 weeks. There was a significant difference in HbA1c levels between the low-GI and the high-GI diets in 6 out of 10 studies. Low-GI diets may contribute to improved glycemic control in diabetes, but further research is required to determine the benefit on long-term glycemic control.

INTRODUCTION

World Health Organization (WHO) estimations suggest that, globally, over 422 million adults aged over 18 years old were living with diabetes in 2014 [1]. Therefore, there is an urgent need to identify new therapeutic management strategies. The main goal of these strategies is the optimization of glycemic control since decreased HbA1c levels are associated with a reduction in development and progression of complications [2]. Nutrition therapy is one of the key components of diabetes management; however, there is currently no universal agreement about the optimal diet, specifically with regard to the glycemic index of diet [3].

The Glycemic Index (GI) measures how different carbohydrate foods affect the overall blood glucose levels. Foods can be ranked based on a scale from 0 to 100 according to the extent they raise blood glucose, compared to a reference food, such as glucose or white bread [4]. Meals or foods with relatively low GI (55 or less) are slowly digested, absorbed and metabolized, resulting in reduced and gradual supply of glucose to the bloodstream and decreased postprandial insulin levels [5].

Although it is obvious to suggest that low-GI diets should improve glycemic control, there is a controversy about the utility of these diets in the management for people with diabetes [3,6-8]. The most recent position statement from the American Diabetes Association recommends that substituting low-glycemic load foods for higher-load foods may modestly improve glycemic control, but asserts that there is not sufficient evidence of long-term benefit to recommend their use as primary strategy [3]. Similarly, the Diabetes UK Position Statement suggests the use of individualized education to support people to quantify, monitor and reduce their dietary carbohydrate intake and recognize and encourage low-glycemic index foods, but the strength of the evidence is not rated, which means these recommendations should be individualized by a dietitian or a professional nutritionist [6].

The aim of this systematic review of randomized control trials is to assess the effect of low-GI diets compared with high-GI diets on glycemic control, measured by Hemoglobin A1c (HbA1c) in diabetes and provide a more objective basis to guide the dietary recommendations.

RESEARCH DESIGN AND METHODS

Data Searches

An electronic literature search was conducted to address the question of whether low-GI diets, compared with control, common diabetic or high-GI diets, improved HbA1c in individuals with diabetes type 1 or type 2. The low-GI diets were defined by authors as those containing

low-glycemic index carbohydrates and emphasize at low-glycemic index foods, including peas, beans, lentils, legumes, rye bread, rye pita, pasta, brown rice, large flake oatmeal, quinoa, oat bran, dairy products, vegetables and many fruits. High-GI diets were mainly standard diabetic diets and contained high-glycemic index carbohydrates and foods, including potato, wheat meal, white bread, most breakfast cereals and rice. Relevant studies were identified from Cochrane Library and Medline internet sources using the key words "Glycemic Index, "Diabetes" and "HbA1c" or "(A1c) Glycated Haemoglobin" and using the term Randomized Control Trials (RCT). Hand searches of relevant systematic reviews and meta-analyses, with searching of reference lists from included studies to identify potentially relevant RCTs, were also conducted. Two systematic reviews were identified as relevant [7,8].

Study Selection

From the initial search, 172 records were identified. The first round of study selection was to identify potentially relevant studies by title screening. Studies were excluded if it was immediately apparent that they were not relevant and specifically if glycaemic index was not included in the title; if the study subjects were not patients with diabetes; if the intervention was not low-GI diet; if the intervention included treatment, exercise intervention or low compared to high-carbohydrate diet; if subjects had gestational diabetes.

The second round of study selection was to remove duplicate papers and identify potentially relevant studies by abstract screening. The studies met the following inclusion criteria: randomized control trials with a cross-over or parallel experimental design an intervention, study duration of 4 weeks or longer, subjects with diabetes type 1 or 2, different intervention than control (Difference in the glycemic index of the whole day diet or on at 1 meal with very low-glycemic index), assessment of glycemic control measured by HbA1c. Although this systematic review includes studies with a duration period of 4 weeks or longer, HbA1c will still provide a good measure of glycemic control in these studies. However, it has a greater chance of demonstrating the full effect of the intervention in studies longer than that. Fructosamine levels reflects glycemic control over the past 2-4 weeks, but its clinical meaning and the risk of complications for a specific value is not well known compared to HbA1c, thus HbA1c was selected for primary outcome [8].

From the titles and abstracts of these records, seventeen papers after examination of the full text availability were identified. Studies were excluded if the intervention was not directly supervised or well-documented through the use of dietary assessment methods, food diaries or provision of food; if the glycemic control was already optimal at the start of the study (Subjects had HbA1c levels <6.5%); or if the glycemic index was not measured or the dietary intakes were not quantified. These criteria resulted in 10 RCT studies (Table in the systematic review and process of study selection is presented in Figure 1.

Outcome Measures

The outcome measure that used to assess overall glycemic control in the studies was HbA1c. HbA1c reflects the average glucose levels over the preceding period of 6-12 weeks and it has been correlated with increased risk of macro and microvascular complications both in diabetes type 1 [9] and 2 [10].

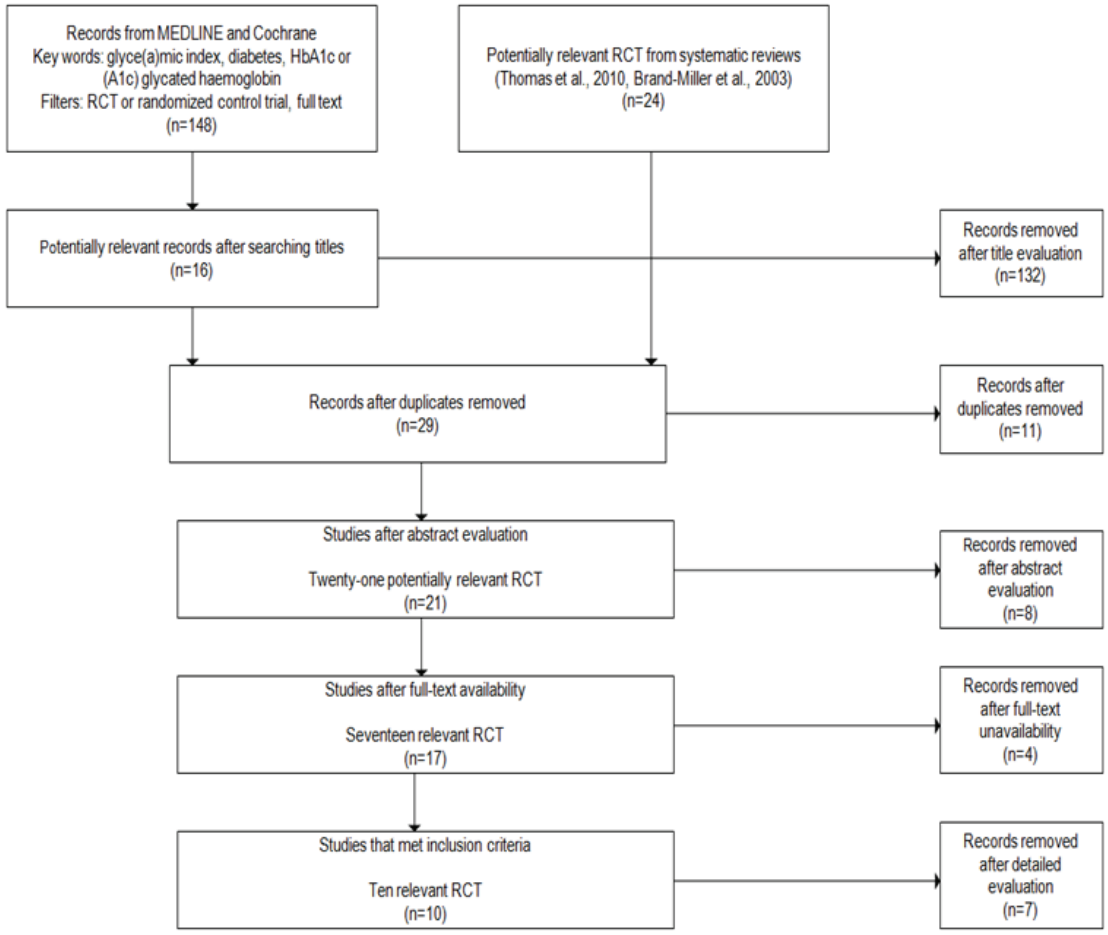

Figure 1: Data searches and study selection flow chart

RESULTS

Description of studies

All ten studies identified for inclusion in this review were RCT, comprising a total of 630 subjects (179 with type 1 diabetes and 451 with type 2 diabetes). The time range of the studies is between January of 1991 and November of 2012, while no records were found after then. The general characteristics and the main outcomes of the studies, including number of participants, duration of each diet, study design, mean GI, mean HbA1c levels and compliance assessment, are shown in Table 1. The average GI of the high-GI diets were 78 and the average GI of the low-GI diets was 58, on the glucose scale. The largest study with diabetes type 1 subjects included 104 children and had a duration of 48 weeks which is one of the largest RCT investigating the effect in glycemic control of low- compared to high-GI diets [11]. The largest study in subjects with type 2 diabetes had 210 subjects with 24-week duration [16]. Two studies had the shortest duration of 4 weeks [13,18], one lasted for 5 weeks [20] and one lasted for 6 weeks [19] while two studies had the longest duration of 48 weeks [11,14]. The studies conducted in USA [14], Canada [15,16], Australia [11,17], Mexico [19], Thailand [13], France [18,20] and Italy [12]. Therefore, the interindividual variability and the diversity in populations may be a potential problem and the generalization in the population of patients with diabetes may be challenging.

Adverse Events

Two studies that reported hypoglycemic events included subjects with diabetes type 1 [11,12]. In one study, episodes of hypoglycemia were significantly fewer by 0.8 per month in the low-GI diet compared to high-GI diet (P<0.01) [12]. In the second study, which compared low-GI diet with CHO exchange diet, there were no differences in hypoglycemic events between the two groups [11].

Interventions

The low-GI diets were achieved by dietary advice in three studies [11,14,18] and by prescribed diet in four studies [13,17,19,20]. In Giacco et al., [12], the low-GI diet was higher in fiber than high-GI diet (15 vs 50 g), in Jenkins et al. [15], the low-GI diet included 190 g or more of legumes per day and in Jenkins et al. [16], the high-GI diet was higher in cereals compared with low-GI diet (6 to 8 servings more depending on calories). All the studies assessed the dietary compliance by a 7-day food record, except 1 that assessed it by a 3-day food record [11] and two that assessed it by 1-day food record [13,19]. Most of the studies didn't report any differences between the two groups in confounding factors, including weight loss, caloric intake and physical activity that could affect the results.

Quality of Studies

The Risk of Bias Tool (RoB) introduced by Cochrane Collaboration was used to assess the quality of studies [21]. All of the studies described the eligibility criteria of the participants and no trial reported any significant difference in the baseline characteristics between low and high-GI group. All of the studies were randomized, but only four of them described the method of randomization. Specifically, one used a computer-generated random numbers of 1 and 2, which assigned to each participant [11], two randomized their

Table 1: Characteristics and outcomes of the studies

Study	n	High-GI	Low-GI	Study design/ Duration of each diet (weeks)	HbA1c			Intervention (Low-GI vs High-GI)	Compliance assessment
					High-GI	Low-GI	P		
Type 1 subjects									
Gilbertson et al. (2003) [11]	104	66	35	Parallel/48	8.61 (1.37)	8.05 (0.95)	0.05*	Dietary advice vs simple CHO measurement	3-day food diary at 1, 3, 6 and 16 month
Giaccco et al. (2000) [12]	63	90	70	Parallel/24	9.1 (1.4)	8.6 (0.9)	<0.05	Fiber content (15 vs. 50 g)	7-day food record/month
Type 2 subjects									
Komindr et al. (2001) [13]	10	100	70	Crossover/ 4	11.15 (2.02)	10.97 (1.55)	>0.05	Prescribed diet of low vs high GI	1-day food record/period
Ma et al. (2008) [14]	40	80	76	Parallel/48	8.39 (0.30)	7.67 (0.28)	0.08	Dietary advice vs ADA diet	7-day food record/month
Jenkins et al. (2012) [15]	121	82	66	Parallel/12	6.9 (1)	6.9 (2)	>0.05	High-legumes (> 190 g/day) vs low legumes diet	7-day food record at week 8, 10 and 12
Jenkins et al. (2008) [16]	210	83	69	Parallel/24	7.14	6.64	<0.01*	Low vs high-cereal diet	7-day food record/month
Brand et al. (1991) [17]	16	90	77	Crossover/ 12	7.9 (0.5)	7.0 (0.3)	<0.05*	Prescribed diet of low vs high GI	4-day weighed food record/ period
Rizkala et al. (2004) [18]	12	71	39	Crossover/ 4	7.57 (0.35)	7.17 (0.39)	<0.01*	Dietary advice of low vs high GI	7-day food record/period
Jimenez-Cruz et al. (2003) [19]	36	56	44	Crossover/ 6	8.6 (0.3)	8.1 (0.24)	0.02*	Prescribed diet of low vs high GI	1-day food record at 1, 4 and 6 week
Type 1 and Type 2 subjects									
Fontvieile et al. (1992) [20]	12 (T1) 6 (T2)	64	38	Crossover/ 5	8.3 (1.5)	8.3 (1.4)	>0.05	Prescribed diet of low vs high GI	7-day food record/period

Data are presented as mean (SD). Mean GI on each diet using glucose as the reference food (GI=100);
HbA1c in % units; n, total number of participants of each study
*Mean HbA1c values between High-GI and Low-GI are significantly different, P<0.05

participants by using an identification number and allocation into groups was performed by a statistician [15,16] and one used a method of randomly permuted blocks [14]. Blinding study participants and investigators is difficult in dietary intervention studies, but blinding of stuff involved in the analysis was assessed as a quality criterion. Only three studies reported that the assessors involved in the analysis were blinded [11,15,16]. Three studies reported that the allocation was concealed [11,15,16]. Seven studies reported a drop out rate less than 15% [11,12,14,15,17,20], two reported higher than 15% [16,19] and in one there were no records [18]. Three studies used intention to treat analysis [12,15,16]. Although all of the studies reported the between-group difference in change in HbA1c and the p values, in one study [16] the standard deviations of the HbA1c and the range of the difference between the groups were not stated. Four studies calculated their sample size based on power calculations [11,12,14,16].

HbA1c

HbA1c measurements after the dietary intervention for the two groups are summarized in Table 1. In six out of 10 studies the overall glycemic control was improved after low-GI diets and HbA1c levels were significantly different ($P<0.05$) between low-GI and high-GI groups [11,12,16-19].

DISCUSSION

A total of 10 randomized controlled trials comprising 630 subjects with diabetes enrolled for each diet period ranging from 4 to 48 weeks were included in this systematic review. This review provides evidence that low-GI diets can improve glycemic control, measured by HbA1c, in patients with diabetes type 1 and 2 who are not optimally controlled. In two studies, the effect of low-GI diets in HbA1c was the largest and specifically Brand et al., [17] found a reduction of 0.9% and Gilbertson et al. 0.6% in HbA1c levels. Others studies demonstrated a significant decrease in HbA1c levels ranging from 0.4% [18] to 0.5% [19]. These findings are supported by two meta-analyses by Brand-Miller et al. (2003) and Thomas et al. (2010), which demonstrated that low-GI diets compared to high-GI diets decreased HbA1c levels by 0.43% (95% CI 0.1-0.7) and 0.4% (95% CI 0.2-0.7 P=0.001), respectively. Improvements of this size have been associated with a reduced risk of complications in patients with diabetes type 2 in UKPDS study. They suggested that every 1% decrease in mean HbA1c levels could result in a reduction in risk of 21% in any diabetes related point, 21% for diabetes related death and 37% for microvascular complications [10]. The improvement in HbA1c levels from low-GI diets can be attributed to slowing the rate of carbohydrate absorption. It has been suggested that low-GI diets can reduce postprandial insulin secretion in type 2 diabetes and reduce insulin requirements in type 1 [3]. It has also been reported that low-GI diets can improve lipid profiles and decrease total fat mass and cause greater weight loss in overweight or obese people compared to control diets [22].

The strengths and the limitations of this systematic review should be considered. The systematic review included trials based on strict criteria, including randomized control design, comparable difference of outcome, quality control data and a control of confounding factors in most studies (Weight loss, energy intake). Although all the included studies were RCT and most of them proved improvement in HbA1c, some had methodological limitation, including small number of participants, lack of outcome assessor blinding, relatively short duration in some studies, failure to report allocation concealment and doubt concerning dietary compliance. Results of other trials may not have been published (Publication bias) and thus be included in the systematic review. Concerning the intervention assessment, the dietary GI of foods can vary largely and depends on food nature, cooking method and duration, extent of starch gelatinization and storage duration [23]. In addition, foods that consumed together can affect the GI of the whole meal [24] and thus the estimation of GI of the diet is potentially prone to measurement error bias. Although, the average low-GI was 58 and high-GI was 78, there was no agreement in the definition of "low-GI" (range 35-77) or "high-GI" (range 56-100) and both ranges were wide. Further research should investigate the effect of low-GI diets in diabetes management and larger studies with longer follow-up periods are required to determine the benefit on long-term glycemic control.

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