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Diabetic Diets in South Asia: Recommendations, Adherence, and Outcomes

By

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Global Epidemiology

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Diabetic Diets in South Asia: Recommendations, Adherence, and Outcomes

By

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An abstract of A thesis submitted to the Faculty of the Rollins School of Public Health of Emory University in partial fulfillment of the requirements for the degree of Master of Public Health in Global Epidemiology 2016

ABSTRACT Diabetic Diets in South Asia: Recommendations, Adherence, and Outcomes By Shirin Kasturia

Introduction: Dietary modification is an important aspect of diabetes management that could reduce the burden of diabetes in South Asia by slowing disease progression and lowering the risk of complications. Our study aims to determine how frequently diets are recommended, how well they are followed, and if there are corresponding clinical benefits.

Methods: Cross-sectional data from the Centre for cArdiometabolic Risk Reduction in South-Asia (CARRS) Cohort Study were used to estimate prevalence of following diabetic diets in participants with self-reported diabetes, undiagnosed diabetes, and no diabetes. Participants with self-reported diabetes were divided into four groups based on whether they were prescribed and/or follow diabetic diets. These groups were assessed for differences in socio-demographic characteristics, clinical variables, and dietary intake. Linear and logistic regression models were used to estimate associations between prescription and/or following of diabetic diets with achievement of diabetes care goals (A1c<7.0%, blood pressure<140/90mmHg, and LDL cholesterol<100mg/dl).

Results: 5.65% of all participants reported following diabetic diets. Those with selfreported diabetes were more likely to follow diabetic diets (34.6%) than those with undiagnosed diabetes (4.1%) or no diabetes (1.8%), p<0.001. Of those with reported diabetes, those prescribed diabetic diets were 4.2 (95% CI: 3.27, 5.34) times more likely to follow diabetic diets than those who were not prescribed them. Higher income was associated with diet prescription, while higher education was associated with both prescription and following of diabetic diets(p<0.001). Whole grain intake was greater in those who were prescribed a diet than those who were not prescribed a diet, and, complementary to this, refined grain intake was lower (p<0.0001). Following a diet was associated with lower LDL cholesterol levels, even after adjusting for socio-demographic characteristics; however, the effect was attenuated after adjusting for history of hypertension and hyperlipidemia to the models.

Discussion: Though patients who were prescribed diabetic diets were more likely to follow them, the majority of patients with diabetes in urban South Asia were neither prescribed nor followed such diets. Being prescribed and/or adhering to diabetic diets was associated with positive changes in dietary intake. However, despite differences in diet, there were limited associations with cardio-metabolic outcome variables beyond lower LDL cholesterol.

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Chapter 1: Overview

Background

The prevalence of type 2 diabetes has been rising globally in recent years. The Non-Communicable Diseases Risk Factor Collaboration estimates that there were approximately 422 million people living with diabetes in 2014 [1] and the International Diabetes Federation projects that there may be as many as 592 million by the year 2035[2]. Approximately 65.1 million, or 17%, of people living with diabetes live in India, where the prevalence of diabetes has increased from 5.8% of adults in 2000 to 9.1% in 2013 [2, 3]. This increase is likely due to a combination of genetic susceptibility and lifestyle changes associated with globalization and urbanization [4]. The onset of diabetes may also be occurring at younger and younger ages as there was a noticeable temporal shift in the age of onset of diabetes between the Chennai Urban Rural Epidemiology Study (CURES) conducted in 2004 and the National Urban Diabetes Study (NUDS) conducted in 2000 [5, 6]. Complications of diabetes, which increase with disease duration and poor diabetes management, exacerbate the already substantial social and economic burdens experienced in this rapidly developing country.

Therapeutic Goals

Though the ideal treatment regimen will vary from patient to patient, the ADA recommends targeting lifestyle and pharmacological therapy towards the following goals [7]:

- 1. To reach a healthy weight.
- 2. To reduce glycated hemoglobin A1c (HbA1c, a marker of average blood glucose over the past 3 months) to less than 7%.
- 3. To keep blood pressure below 140/80 mmHg.
- 4. to keep low-density lipoprotein (LDL) cholesterol levels below 100 mg/dl.

Lifestyle Modification and Diabetes

Healthy lifestyle choices are integral components of diabetes management and prevention. The most recent (2016) American Diabetes Association (ADA) guidelines include intensification of lifestyle therapy as the starting point for any diabetes management plan [8]. According to the ADA, healthy lifestyle choices include adopting a healthful diet, regular physical activity, tobacco cessation, weight management, and effective coping [8].

Primary Prevention

Lifestyle interventions including increased physical activity and dietary modification are not only important components of diabetes management, but they are also a cost effective means of reducing the incidence of type 2 diabetes mellitus [9]. A study of 522 overweight subjects in Finland demonstrated that lifestyle changes alone can prevent diabetes from developing in high-risk subjects [10]. Subsequent studies around the world have replicated these findings, including one in India [11-13].

Secondary and Tertiary Prevention

Lifestyle interventions for management of diabetes and its complications focus on improving glycemic control and decreasing cardiovascular risk factors either independently or in addition to pharmacological therapy.

Overweight and obesity are common comorbidities of diabetes that complicate management. Along with diabetes, obesity is a known risk factor for cardiovascular disease that contributes to morbidity and mortality in diabetic patients [14]. Weight loss, through lifestyle interventions including reduced calorie diets and physical activity, can prevent or reduce obesity while also aiding in glycemic control [14]. Physical activity alone, independent of change in BMI, has also been shown to reduce HbA1c, which is directly associated with the microvascular complications of diabetes [15].

In terms of diet alone, there is conflicting evidence regarding whether any specific dietary modification without weight loss reduces morbidity and mortality in diabetes; however, individualized healthy eating plans with a focus on nutrient-dense foods can aid in self-management of diabetes and facilitate glycemic control[8]. In two small studies of 11 and 14 subjects, very low calorie diets were even shown to reverse type 2 diabetes in the short term by normalization of beta cell function and hepatic insulin sensitivity[16, 17]; however, these studies have not been replicated on a larger scale.

The recently released Look AHEAD Trial demonstrated that while there were no changes in cardiovascular mortality, an intensive lifestyle intervention for weight loss that included dietary modification in patients with type 2 diabetes led to significant, long-term improvements in glycemic control, quality-of-life, and healthcare costs [18].

Dietary Modification

With regards to diet, exact recommendations vary by diabetes organization. Up until 1994, the American Diabetes Association (ADA) emphasized limiting carbohydrates and fat in the nutritional management of diabetes [19]. However, beginning in 1994 and continuing to today, the ADA recommends tailoring the macronutrient composition of the diet to individuals' needs [20]. Nonetheless, other groups such as the European Association for the Study of Diabetes (EASD) continue to recommend limiting total carbohydrates and fat [21, 22]. The Indian Council of Medical Research guidelines recommend a composition of 55-60% carbohydrates, 20-25% fat, and 10-15% protein [23]. Despite differences in opinion on the exact macronutrient composition of diets for adults with diabetes, most experts would agree that dietary carbohydrates should come from high-fiber foods including whole grains, fruits, vegetables, legumes, and nuts [20, 21]. Most would also agree on limiting saturated fat intake [<10% [20, 22] or <7% [24]] and eliminating *trans* fats.

Barriers to Dietary Change

While the benefits of 'diabetic diets' are clear, their implementation, particularly in South Asia is more complicated. The multicenter STARCH (Study To Assess the dietary CarboHydrate content of Indian type 2 diabetes population) study involving 796 patients with diabetes found that the percentage of carbohydrate intake was not significantly different between individuals with and without diabetes[25]. Similarly, this percentage was also not significantly different between those who did and did not report adherence to advised diet plans [25]. In a study of 200 patients with diabetes in Tamil Nadu, only 29% demonstrated 'good dietary behavior' (calorie restriction of >75% of meals, diet >50% vegetables and fruit and <25% fats or fried foods, total avoidance of sweets) despite 'reasonably good' access to healthcare [26]. This suggests that factors other than access to care may be influencing adherence to diabetic diets in South Asia.

Nutritional Understanding

Nutrition knowledge among patients with diabetes is low. In a study of 258 patients with diabetes in New Delhi, 26.7% of patients were not sure of the definition of a 'simple carbohydrate' [27]. Among those who felt they knew, in a multiple choice question, 51.9% said that simple carbohydrates were 'those digested quickly that are rapidly converted into sugar' and 48.1% said they were 'those digested slowly that are converted slowly into sugar' – about the proportion you would expect by chance alone [27]. In a survey of 654 patients attending a diabetes clinic in Lucknow, India, only 13.1% of patients recognized that poor diet was a cause of obesity [28]. Many clinically overweight and obese patients in this study also considered their weight to be 'healthy' [28]. A key conclusion in each of these studies was that despite high levels of education and socioeconomic status, knowledge of healthy food choices and nutrition was poor [27-29]. Poor

understanding of nutrition and its importance among patients with diabetes is a substantial barrier to changing dietary behavior in this high-risk group [30].

Physician Recommendations

The few studies that have explored this topic in India have found that few patients with diabetes are prescribed 'diabetic diets' and among those who are prescribed dietary modifications, few adhere to them. The multicenter STARCH study found that only 56.6% of patients with diabetes were advised a diet plan by their physician [25]. Of those who were advised a diet plan, 67.4% reported adhering to the plan [25]. The two most common reasons for non-adherence were 'not being bothered about the suggested diet plan' and 'not liking the advised diet' [25]. In the survey of 654 patients in Lucknow, 13.3% of patients stated that the reason they chose their physician was that he/she did not insist on 'diet restriction and exercise' [28]. For the minority of patients who do report adherence to diets, many do not get adequate diet education or recommendations.

Cultural/Religious Practices

Lack of cultural sensitivity in recommendations and education may underlie the lack of adherence to diabetic diets in South Asia [31]. Many of the Western diet recommendations focus on reading nutrition labels and counting calories of Western foods, which is difficult for most patients to do in India. Many younger patients also find it difficult to follow printed diet charts that do not leave room for variations [30]. In the Lucknow study, most individuals reported sweet tasting fruits, tubers, and milk as prohibited food items and believed bitter vegetables are the most beneficial [28]. Fruit consumption in this population was only 120-140 g/day [28], well below the World Health Organization's recommendation of >400 g/day[32]. Many cultural and religious values for specific foods, particularly Indian sweets, may also hinder adherence to diabetic diets [33].

Limited Access to Dietary Alternatives

White rice is also a dietary staple in South Asia and the lack of complex carbohydrate alternatives makes following diabetic diets challenging [34]. In a study of 703 individuals in a rural village in Tamil Nadu, the majority of adults consumed carbohydrates, primarily white rice, for ~80% of their daily energy intake [35]. The STARCH study found that carbohydrates accounted for ~65% of the total caloric intake. Given the high levels of white rice consumed in South Asia, brown rice may be a simple substitute that could potentially decrease insulin resistance and improve glycemic control[36].

Project Aims

While the STARCH study assessed dietary intake in adults with diabetes who reported adherence or non-adherence to diabetic diets [25], they did not further analyze whether socioeconomic or demographic factors may be associated with adherence or physician prescription of diets. Furthermore, few population-based studies have explored these questions as most prior studies have been in patients attending diabetes clinics. Thus, the objectives of this study were to:

- Determine the prevalence of adults following special diets (including a diabetic diet, low-fat diet, high-fiber diet, and weight-reducing diet) according to diabetes status in a population-based study in South Asia
- 2) To assess differences in socio-demographic characteristics, self-reported diagnosed co-morbidities, and dietary intake among adults with diabetes according to whether they were prescribed and/or adhere to a special diet
- To estimate the associations of being prescribed and/or adhering to a special diet with markers of cardio-metabolic risk

Chapter 2: Manuscript

Diabetic Diets in South Asia: Recommendations, Adherence, and Outcomes

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Abstract

Introduction: Dietary modification is an important aspect of diabetes management that could reduce the burden of diabetes in South Asia by slowing disease progression and lowering the risk of complications. Our study aims to determine how frequently diets are recommended, how well they are followed, and if there are corresponding clinical benefits.

Methods: Cross-sectional data from the Centre for cArdiometabolic Risk Reduction in South-Asia (CARRS) Cohort Study were used to estimate prevalence of following diabetic diets in participants with self-reported diabetes, undiagnosed diabetes, and no diabetes. Participants with self-reported diabetes were divided into four groups based on whether they were prescribed and/or following diabetic diets. These groups were assessed for differences in socio-demographic characteristics, clinical variables, and dietary intake. Linear and logistic regression models were used to estimate associations between prescription and/or following of diabetic diets with achievement of diabetes care goals (A1c<7.0%, blood pressure<140/90mmHg, and LDL cholesterol<100mg/dl).

Results: 5.65% of all participants reported following diabetic diets. Those with selfreported diabetes were more likely to follow diabetic diets (34.6%) than those with undiagnosed diabetes (4.1%) or no diabetes (1.8%), p<0.001. Of those with reported diabetes, those prescribed diabetic diets were 4.2 (95% CI: 3.27, 5.34) times more likely to follow diabetic diets than those who were not prescribed them. Higher income was associated with diet prescription, while higher education was associated with both prescription and following of diabetic diets(p<0.001). Whole grain intake was greater in those who were prescribed a diet than those who were not prescribed a diet, and, complementary to this, refined grain intake was lower (p<0.0001). Following a diet was associated with lower LDL cholesterol levels, even after adjusting for socio-demographic characteristics; however, the effect was attenuated after adjusting for history of hypertension and hyperlipidemia to the models.

Discussion: Though patients who were prescribed diabetic diets were more likely to follow them, the majority of patients with diabetes in urban South Asia were neither prescribed nor followed such diets. Being prescribed and/or adhering to diabetic diets was associated with positive changes in dietary intake. However, despite differences in diet, there were limited associations with cardio-metabolic outcome variables beyond lower LDL cholesterol.

Introduction

The prevalence of type 2 diabetes has been rising globally in recent years, particularly in India, where the prevalence of diabetes has increased from 5.8% of adults in 2000 to 9.1% in 2013 [2, 3]. Today, 17% of people living with diabetes in the world (approximately 65.1 million people) reside in India [2]. The onset of diabetes may also be occurring at younger and younger ages as there was a noticeable temporal shift in the age of onset of diabetes between the Chennai Urban Rural Epidemiology Study (CURES) conducted in 2004 and the National Urban Diabetes Study (NUDS) conducted in 2000 [5, 6]. Complications of diabetes, which increase with disease duration, exacerbate the already substantial social and economic burdens experienced in this rapidly developing region.

The general goals of clinical care for diabetes are: (1) to reach a healthy weight, (2) to reduce glycated hemoglobin A1c (HbA1c) to less than 7%, (3) to keep systolic/diastolic blood pressure below 140/90 mmHg, and (4) to keep low-density lipoprotein (LDL) cholesterol levels below 100 mg/dL [7, 37]. Lifestyle changes including diet, physical activity, and weight management are cost effective approaches to managing diabetes and preventing complications [9, 38, 39]. With regards to diet, exact recommendations vary across diabetes associations [19-23]. However, despite differing opinions on the exact macronutrient composition of diets for adults with diabetes, most experts would agree that carbohydrates should come from high-fiber foods including whole grains, fruits, vegetables, legumes, and nuts [20, 21]. Most would also agree on limiting saturated fat intake [<10% [20, 22] or<7% [24]] and eliminating *trans* fats.

Despite the clear benefits of 'diabetic diets' in improving glycemic control and reducing the need for pharmacologic therapy [18], their implementation, particularly in South Asia, has not been well studied. While there have been a limited number of studies performed in India and Pakistan looking at adherence to diabetic diets and differences in nutrient or food group intake, they have either been restricted to specific states, cities, or hospitals [21, 26, 40-43] or only involved patients admitted to specialized endocrinology clinics where care received may not have been representative of care provided to the general population [25]. There have been no population-based studies looking at these factors or relating them to socio-demographic variables. It is unclear how frequently diets are being recommended by physicians, how well they are adhered to by patients, or if there are corresponding clinical benefits. Thus, the aims of this study were to: (1) determine the prevalence of adults following diabetic diets (including a diabetic diet, low-fat diet, high-fiber diet, and weight-reducing diet) according to diabetes status in a population-based study in South Asia; (2) to assess differences in sociodemographic characteristics, self-reported diagnosed co-morbidities, and dietary intake among adults with diabetes according to whether they were prescribed and/or follow to diabetic diets; and (3) to estimate the association of being prescribed and/or following diabetic diets with markers of cardio-metabolic risk.

Methods

Sample

For this study, we used data from the Centre for cArdiometabolic Risk Reduction in South-Asia (CARRS) Cohort Study. The CARRS Cohort Study used complex, multi-stage, probability-based sampling to select households and individuals that were representative of the cities involved (Chennai and New Delhi in India and Karachi in Pakistan). A total of 16,288 men and non-pregnant women over 20 years old were enrolled in 2010-11 [44]. The baseline study visit involved a comprehensive questionnaire that covered socio-demographics, medical history, diet and other lifestyle behaviors.

Exposure assessment

As part of the medical history, patients were asked whether they had a diagnosis of diabetes. We checked the laboratory values of participants without selfreported diabetes to identify cases of undiagnosed diabetes using standard diagnostic criteria: fasting plasma glucose (FPG) \geq 126 mg/dL or HbA1C \geq 6.5%. We identified participants following diabetic diets by their response to a question that asked if they were on a special diet. Those who responded 'yes' were further asked what diets they followed ('Diabetic diet', 'low fat diet', 'High fiber diet', 'low salt diet', 'weight reducing diet', or 'other'). For this study, we considered 'diabetic diet', 'high-fiber diet', 'low-fat diet', and 'weight-reducing diet' as dietary modifications for diabetes (together referred to as 'diabetic diets'). The study also queried whether or not participants with self-reported diabetes were 'prescribed dietary modifications' as a treatment for diabetes ('yes' or 'no').

We divided participants with self-reported diabetes into four exposure groups based on whether they were prescribed dietary modifications and whether they reported following diabetic diets. The groups were as follows: (1) individuals who follow diabetic diets and report having been prescribed dietary modifications, (2) individuals who follow diabetic diets but do not report being prescribed dietary modifications, (3) individuals who do not follow diabetic diets but were prescribed dietary modifications, and (4) individuals who do not follow diabetic diets and were not prescribed dietary modifications (referent).

Outcome assessment

Dietary Intake: CARRS used a 26-item food propensity questionnaire (FPQ), adapted from the INTERHEART study [45]. The FPQ is semi-quantitative (consume food group never or less than once a month, per month, per week, or per day frequencies), thus, we could not calculate nutrient-level data and were limited to comparisons of the frequency of consumption of food groups. We standardized all frequencies to servings per day and collapsed food groups into 16 categories consistent with previous CARRS analyses [46].

Cardio-metabolic Risk Factors: We evaluated five cardio-metabolic risk factors including, HbA1c, FPG, systolic blood pressure (SBP), diastolic blood pressure (DBP), and body mass index (BMI). HbA1c, FPG, and low-density lipoprotein (LDL) cholesterol were analyzed using standardized laboratory techniques. Trained study staff measured weight, height, and blood pressure using standardized procedures. BMI was calculated as weight (kg) divided by heightsquared (m²). We used these variables as continuous measures for linear models and as dichotomous outcomes for logistical models using the following cut points: HbA1c <7%, FPG <126 mg/dl, SBP <140 mmHg, DBP <90 mmHg, LDL cholesterol <100 mg/dl, BMI <25 kg/m².

Covariates

We identified potential covariates from the CARRS study questionnaire including study site, age, sex, education level, income, alcohol use, tobacco use, oral diabetic medications, history of hyperlipidemia or hypertension, and vegetarianism. We categorized education as up to primary school, high school to secondary school, or graduate school and above; income as <10,000 INR/yr, 10,000-20,000 INR/yr, or >20,000 INR/yr; alcohol use as regular use, past/occasional use, or never use; and tobacco as current use, past use, or never used. We treated age as a continuous variable and medications, hyperlipidemia, hypertension, and vegetarianism as binary ('yes', 'no') categorical variables. For this study, we defined vegetarians as those who eat meat, poultry, and fish never or less than once per month.

Statistical analysis

We used SUDAAN (RTI International, Research Triangle Park, NC) in order to account for complex survey design in our analysis. We reported results as weighted percentage and unweighted counts unless otherwise specified. We used Wald chisquare statistics with Satterthwaite correction to compare the proportions of

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individuals following a special diet according to diabetes status (self-reported diagnosed diabetes, undiagnosed diabetes, and no diabetes)[47]. For these initial prevalence estimates, in order to appropriately compare the participants with undiagnosed diabetes, we excluded participants who were missing values for both HbA1c and FPG. Subsequent analyses included only participants with self-reported diabetes, regardless of missing laboratory values (n=1,850).

In order to assess the association between being prescribed a diabetic diet and adhering to a diabetic diet, we estimated a prevalence ratio and 95% confidence interval (CI) using weighted counts. We used Wald chi-square statistics with Satterthwaite correction to test for statistically significant differences between the four groups defined above with respect to socio-demographic characteristics, selfreported diagnosed co-morbidities, and dietary intake. We used analysis of variance (ANOVA) to test for statistically significant differences in continuous variables including age, BMI, SBP, DBP, LDL cholesterol, HbA1c, and FPG.

We used multivariable linear regression to estimate associations between the four groups with HbA1c, FPG, blood pressure (SBP and DBP), LDL cholesterol, and BMI. We also performed multivariable logistic regression models specifying these variables as dichotomous outcomes to estimate the odds ratio for the higher risk outcome. Separate models were run for each of the linear and logistic regression model outcome variables including (1) an unadjusted model, and models adjusting for (2) socio-demographic variables that were significantly associated with diet group (study site, education, household income, alcohol use, and tobacco use), and (3) the socio-demographic factors from model 2 plus self-reported diagnosis of hyperlipidemia and hypertension.

Results

Among all CARRS participants who were not missing laboratory values for both HbA1c and FPG (n=13676), 5.65% reported following a special diet (**Table 1**). Those with self-reported diabetes were significantly (p<0.001) more likely to report following a special diet (34.7%) than those with undiagnosed diabetes (4.1%) or no diabetes (1.8%). This was true for each specific type of special diet, e.g., diabetic diet, high-fiber diet, low-fat diet, and weight-reducing diet. Among those with selfreported diabetes, the most common diet was a diabetic diet (33.8%) followed by a low-fat diet (6.8%). In those with undiagnosed diabetes or no diabetes, low-fat diets were the most common (2.63% and 1.36%, respectively).

Subsequent results include only participants with self-reported diabetes (n=1,850) and the four special diets for diabetes (diabetic diet, high-fiber diet, low-fat diet, and weight-reducing diet) are referred to together as 'diabetic diets.'

Overall, 24.4% of participants with self-reported diabetes were *both* prescribed a diet for diabetes and reported following one, 10.2% reported following a diabetic diet despite not being prescribed one, 12.1% reported not following a diabetic diet despite being prescribed one, and over half (53.4%) reported not being prescribed or following a diet (**Table 2**). When we assessed the association between having been prescribed a diabetic diet and following a diabetic diet, those who

reported being prescribed a diet were significantly more likely to report following a diabetic diet than those who were not prescribed a diet: prevalence ratio (95% CI), 4.20 (3.27, 5.34).

When we compared socio-demographic variables between the four groups there were significant differences in multiple categories (**Table 3**). Those who were prescribed and follow diabetic diets were more likely to reside in Delhi (70.5%), whereas the majority of those who neither followed a diet nor were prescribed one resided in Chennai (63.1%) (p=<0.0001). Those who followed and were prescribed a diet were also more likely to have received a higher education (p=0.0005) or earn an income >20,000 INR/yr (p<0.001). Those who were not prescribed a diet were more likely to use alcohol regularly and those who did not follow a diet were more likely to be current tobacco users (p<0.01). We noted no significant differences in age (p=0.49) or sex (p=0.09) across the four groups. The only significantly different marker of cardio-metabolic risk was LDL cholesterol: those who did not follow diabetic diets regardless of whether they were prescribed them had higher levels compared to those who did follow diabetic diets (p=0.01). Those who were prescribed a diet had a greater proportion of self-reported hyperlipidemia (p=0.01) and those who were neither prescribed nor followed a diet had the lowest proportion of self-reported hypertension (p=0.02).

There were significant differences in food group intake (servings/day) between the four groups for all food groups except milk and milk products, nuts and seeds, fruit juice, deep-fried foods, and sugar-sweetened beverages, p<0.05 (**Figure 1**). The most significant differences were in meat and organ meats, poultry, fish and shellfish, legumes and pulses, whole grains, refined grains, and coffee and tea (all with p<0.0001). For all meats (meats and organ meats, poultry, and fish and shellfish) the lowest intake was seen in participants who both followed and were prescribed a diet. For the fish and shellfish category those not prescribed a diet ate fish or shellfish almost twice as frequently as those prescribed a diet, with the most frequent consumers being those who do not follow a diabetes diet and were not prescribed one (0.18 servings per day). In the legumes and pulses category there was greater intake in those who follow a diet compared to those who do not. Whole grain intake was greater in those who were prescribed a diet than those who were not prescribed a diet, and, complementary to this, refined grain intake was lower.

In linear regression models (**Table 4**), the only outcome associated with the four groups was LDL cholesterol. In unadjusted linear regression models, both the prescribed/following and the not prescribed/following diet groups were associated with lower cholesterol levels compared to the not following/not prescribed diet group, with mean differences of -6.72 mg/dL(95% CI: -11.28, -2.06) and -10.15 mg/dL (95% CI: -16.89, -3.39), respectively. However, after adjustment for socio-demographic variables, tobacco and alcohol use, and self-reported hypertension and hyperlipidemia, only the not prescribed/following diet group was significantly associated with a lower LDL cholesterol compared to the not prescribed/not following diet group: risk difference of -8.46 (95% CI: -16.40, -0.52). In the logistic regression models (**Table 4**), this diet group was also associated with a lower odds of having LDL cholesterol ≥100 mg/dl, OR of 0.61 (95% CI: 0.39, 0.93); however, this result did not remain significant after adjustment for confounders. There was also

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an association between the prescribed/follow a diet group and having HbA1c \geq 7% in the unadjusted models (OR of 1.62 (95% CI: 1.11, 2.39)), but this result was also attenuated after adjustment for confounders.

Discussion

Approximately one-third of participants with self-reported diabetes in this representative urban South Asian cohort were following diabetic diets. This is consistent with other studies of patients with diabetes conducted in Karachi, Pakistan [42, 43], the southern India regions of Tamil Nadu [26] and Puducherry [21, 40], and the western India city of Ahmedabad [41], which found rates of selfreported adherence to diabetic diets ranging from 29% to 77%. Interestingly, the prevalence of following diabetic diets was greater in those with undiagnosed diabetes than those without diabetes, though low-fat diets, specifically, were more popular in this group. This is a promising finding as lifestyle interventions, particularly weight-loss, have been shown to prevent diabetes progression in individuals with impaired glucose tolerance [9].

Only 36.5% of participants with self-reported diabetes were prescribed dietary modifications by their physicians and of those who were, 67.2% of them were also adherent to diabetic diets. The multicenter STARCH (Study To Assess the dietary CarboHydrate content of Indian type 2 diabetes population) found a similar rate of adherence to physician diet recommendations (67.4%); however, in the STARCH study over half (56.6%) of all patients with type 2 diabetes were recommended a diet by their physician [25]. While the STARCH study was conducted at specialized endocrinology centers, the population of the CARRS cohort most likely received their care at more generalized treatment facilities where adherence to current standards of care is low and resources for providing diabetes education are often limited, particularly in Karachi, Pakistan [42, 48, 49].

While patient adherence to diabetic diets is a complicated issue, physician recommendation of diabetic diets should not be. The recently released Look AHEAD Trial demonstrated that an intensive lifestyle intervention for weight loss that included dietary modification in patients with type 2 diabetes led to significant, long-term improvements in glycemic control, quality-of-life, and healthcare costs [18]. A review article by Rawal et al. in 2012 highlighted that lifestyle interventions in developing countries including China, Thailand, and Korea have also demonstrated reductions of HbA1c in patients with type 2 diabetes mellitus, though not necessarily of the same magnitude as in the developing world where resources are less scarce [39]. Despite the incomplete adherence seen in our study, participants who were prescribed dietary modifications by their physicians were still over four times more likely to report following a diet than those who were not. Thus, simply increasing the frequency that physicians recommend dietary changes to patients may be the most effective initial step to increase rates of dietary adherence.

In our cohort, those who were prescribed a diet were more likely to have higher income levels. This difference could either be due to providers treating patients differently by income/education or patients of different income/education

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levels seeing different providers. It may also be affected by limited access to care for lower income patients. However, those with a high income were not necessarily more likely to follow a diet. This is consistent with several studies in India that demonstrated that despite high socioeconomic status, knowledge of healthy food choices and nutrition is poor [27-29]. In a study of 258 patients with diabetes in New Delhi, 26.7% of patients were not sure of the definition of a 'simple carbohydrate' [27] and in another survey of 654 patients with diabetes in Lucknow, India, only 13.1% of patients recognized that poor diet was a cause of obesity [28]. Poor understanding of nutrition and its importance among patients with diabetes is a substantial barrier to changing dietary behavior in this high-risk group [30]. On the other hand, those who follow a diet and were prescribed one were more likely to have had a graduate level of education or above. It is likely that individuals with graduate level education may have a better understanding of the importance of diet in diabetes self-management.

The four diet groups described in our study were associated with significant changes in food group intake, particularly with respect to refined grains, whole grains, vegetables, and animal-based products (meat, poultry, and fish/shellfish). Those who were prescribed a diet had lower frequencies of refined grain intake and higher frequencies of whole grain intake. This may reflect counseling received from physicians on diabetic diets as the guidelines generally suggest limiting simple carbohydrates in exchange for more complex, high-fiber carbohydrates [19] [21, 22] [23]. For the different meats, those who were following diabetic diets as well as those who were prescribed them ate meat, poultry, eggs, and fish/shellfish less frequently. Vegetables were eaten more often by those following a diet than those not following a diet. These dietary modifications in our study are in contrast to the STARCH study, which found that carbohydrate intake was not significantly different between those who did and did not report adhering to diabetic diets [25]. Unfortunately, as the CARRS FPQ did not include estimates of portion size, we were unable to calculate the macronutrient composition of the diet.

The only cardio-metabolic outcome consistently associated with the four diet groups was LDL cholesterol, which was lower in participants who adhered to diabetic diets. This is a beneficial finding given that LDL cholesterol is a risk factor for cardiovascular disease in patients with diabetes [50]. We did not see any statistically significant associations between diet group and the other outcomes. This may indicate that the diabetic diets followed by CARRS participants with selfreported diabetes are not associated with improved glycemic control or decreased cardio-metabolic risk, or it may be that the dietary modifications we observed were not big enough to produce any meaningful change in health outcomes.

A key limitation of this study was that it was cross-sectional and therefore we cannot rule out reverse causality. Another limitation of this study and previous studies is that 'following a diabetic diet' is a binary variable; however, it would be more informative to have a more sensitive measurement that takes into consideration how the patients was counseled and to what extent they followed recommendations.

Overall, the results of our study indicate that diets are not followed or recommended frequently for patients with diabetes in South Asia. While multiple barriers exist to changing dietary behavior in this high-risk group including poor understanding of nutrition and its importance [27-30]; low rates of physicians prescribing dietary modifications [25]; limited access to diabetes education and counseling [41]; limited access to dietary alternatives [34, 35]; cultural/religious practices [31, 33]; and lack of motivation to change [25, 26, 28], educating patients on diabetic diets and their benefits may lead to increased rates of adherence and dietary changes of greater magnitude than those observed in our study. Given the known benefits of lifestyle changes for the management of diabetes [9, 18, 21, 22, 26, 38], increasing the quality and frequency of diabetes education and counseling, particularly regarding diet, should be a priority in South Asia as the burden of diabetes continues to grow. Prospective studies and clinical trials are needed to improve our understanding of the cardio-metabolic health benefits of such lifestyle interventions in this population.

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Chapter 3: Tables and Figures

Table 1: Percent¹ (and number²) of participants self-reporting following special diets³ according to diabetes status in the CARRS Cohort Study⁴

	No Diabetes	Undiagnosed	Self-reported	Total	
	(n=10091)	Diabetes (n=1927)	Diabetes (n=1658)	(n=13676)	P-value ⁵
Diabetic Diet	0.14% (14)	0.70% (15)	33.78% (561)	3.87% (590)	< 0.0001
High fiber diet	0.21% (21)	0.41% (7)	2.18% (32)	0.45% (60)	0.0009
Low fat diet	1.36% (149)	2.63% (52)	6.82% (113)	2.12% (314)	< 0.0001
Weight reducing diet	0.35% (48)	1.55% (26)	1.99% (30)	0.69% (104)	0.0003
None of the above	98.24% (9894)	95.90% (1845)	65.30% (1084)	94.35% (12823)	< 0.0001

¹ Percentages shown are weighted column percentages

² Numbers shown are unweighted counts

³ Diets are not mutually exclusive, some participants reported following more than one type of diet.

⁴ Participants missing both hemoglobin A1C and fasting blood glucose were excluded from this table

⁵ P-value from satterthwaite-adjusted chi-square tests comparing proportion following a diet between the three groups

	Follow a diabetes diet	Do not follow a diabetes diet	Total
Prescribed a diabetes diet	24.4% (440)	12.1% (221)	36.5% (661)
Not prescribed a diabetes diet	10.2% (201)	53.4% (987)	63.5% (1188)
Total	34.6% (641)	65.4% (1208)	

Table 2: Percentages¹ (and Numbers²) of participants with self-reported diabetes who reported following a diabetes diet or being prescribed a diabetes diet the CARRS Cohort Study (n=1849)

¹Percentages reported are weighted percentages of the total

² Number reported are unweighted counts

	Follow diet		Do not follow diet			
		Not		Not		
	Prescribed	prescribed	Prescribed	prescribed	Total	
	(n=440)	(n=201)	(n=221)	(n=987)	(n=1849)	p-value ²
STUDY SITE						< 0.0001
Chennai	18.8% (91)	48.8% (103)	19.4% (49)	63.1% (637)	45.5% (880)	
New Delhi	70.5% (300)	34.2% (66)	36.4% (74)	17.6% (164)	34.5% (604)	
Karachi	10.7% (49)	17.1% (32)	44.2% (98)	19.3% (186)	20.0% (365)	
CHARACTERISTICS						
Age (years)	52.3 (0.61)	52.8 (0.97)	52.1 (1.11)	51.4 (0.50)	51.9 (0.43)	0.49
Sex						0.0887
Female	53.3% (242)	49.0% (99)	62.8% (139)	50.9% (497)	52.7% (977)	
Male	46.7% (198)	51.0% (102)	37.2% (82)	49.1% (490)	47.3% (872)	
Education						0.0005
Up to primary school High school to	14.7% (78)	20.5% (45)	24.9% (59)	24.3% (254)	21.6% (436)	
secondary school Graduate school and	57.5% (254)	58.9% (126)	59.8% (127)	62.9% (615)	60.8% (1122)	
above	27.8% (108)	20.6% (30)	15.3% (35)	12.9% (118)	17.6% (291)	
Income						< 0.0001
<10,000 INR/yr	37.8% (168)	44.0% (101)	38.6% (83)	62.0% (615)	51.4% (967)	
10,000-20,000 INR/yr	20.4% (101)	25.8% (48)	25.5% (59)	21.7% (210)	22.2% (418)	
>20,000 INR/yr	41.8% (167)	30.3% (50)	35.9% (76)	16.3% (153)	26.4% (446)	

Table 3: Study Site and Socio-demographic characteristics of CARRS Surveillance Study participants with diabetes grouped by diabetes diet (n=1849)¹

Alcohol use						0.0074
Use regularly	3.2% (11)	5.7% (12)	1.0% (2)	6.5% (63)	4.9% (88)	
Past or occasional use	8.9% (40)	8.6% (18)	8.2% (16)	10.3% (100)	9.5% (174)	
Never used alcohol	87.9% (389)	85.7% (171)	90.8% (203)	83.2% (824)	85.5% (1587)	
Tobacco use						0.007
Current User	15.9% (68)	18.7% (34)	24.6% (55)	23.2% (204)	21.1% (361)	
Past User	1.9% (12)	1.2% (3)	6.5% (13)	3.2% (34)	3.1% (62)	
Never Used	82.2% (360)	80.2% (164)	68.9% (152)	73.7% (749)	75.9% (1425)	
BMI (kg/m2)	27.3 (0.37)	27.0 (0.34)	27.9 (0.53)	26.9 (0.26)	27.1 (0.20)	0.22
Systolic blood pressure						
(mmHg)	133.9 (1.46)	134.9(1.63)	133.2 (1.91)	132.3 (1.04)	133.1 (0.72)	0.59
Diastolic blood pressure						
(mmHg)	85.5 (0.66)	86.4 (1.19)	84.7 (0.88)	84.8 (0.54)	85.1 (0.36)	0.5
LDL cholesterol (mg/dl)	105.6 (1.72)	102.2 (3.04)	111.4 (3.26)	112.4 (1.51)	109.6 (1.00)	0.01
HbA1c (%)	8.7 (0.13)	8.7 (0.20)	8.6 (0.22)	8.7 (0.11)	8.7 (0.09)	0.98
Fasting plasma glucose						
(mg/dl)	174.5 (4.45)	169.4 (6.85)	168.7 (6.71)	173.2 (3.60)	172.6 (2.91)	0.82
Prescribed oral diabetic						
medications						0.1485
Yes	89.7% (398)	92.0% (183)	82.5% (184)	89.6% (888)	89.0% (1653)	
No	10.3% (42)	8.0% (18)	17.5% (37)	10.4% (99)	11.0% (196)	
Self Reported						
Hyperlipidemia						0.0102
Yes	13.8% (47)	9.1% (21)	14.1% (31)	7.4% (78)	9.9% (177)	
No	86.2% (391)	90.9% (180)	85.9% (189)	92.6% (904)	90.1% (1664)	

Self Reported Hypertension						0.0244
Yes	42.5% (186)	48.8% (90)	50.4% (118)	37.8% (371)	41.6% (765)	
No	57.5% (253)	51.2% (111)	49.6% (103)	62.2% (611)	58.4% (1078)	
Vegetarian						< 0.0001
Yes	41.8% (187)	25.2% (50)	25.4% (56)	13.5% (126)	23.0% (419)	
No	58.2% (253)	74.8% (151)	74.6% (165)	86.6% (861)	77.0% (1430)	

¹ Values presented are weighted mean (weighted SD) or weighted column % (unweighted n).

² P-value from analysis of covariance (ANOVA) for continuous variables and chi-square tests for categorical variables, comparing socio-demographic and clinical characteristics across the four groups.

³ Vegetarian defined as those who eat meat, poultry, and fish never or less than once per month.

	Linear Regression Models 1			Logistic Regression Models ²		
	Model 1	Model 2	Model 3	Model 4	Model 5	Model 6
HbA1c						
Follow Diet + Prescribed Diet	-0.00 (-0.33, 0.32)	-0.02 (-0.43, 0.38)	-0.03 (-0.42, 0.35)	1.46 (1.00, 2.12)	1.45 (0.98, 2.12)	1.45 (0.97, 2.16)
Follow Diet + Not Prescribed Diet	-0.03 (-0.44, 0.38)	-0.00 (-0.39, 0.39)	0.01 (-0.38, 0.40)	1.04 (0.68, 1.58)	1.05 (0.69, 1.60)	1.05 (0.68, 1.62)
Do Not Follow Diet + Prescribed Diet	-0.08 (-0.49, 0.33)	-0.07 (-0.48, 0.34)	-0.08 (-0.52, 0.35)	0.91 (0.58, 1.45)	0.98 (0.60, 1.62)	0.96 (0.57, 1.62)
Do Not Follow Diet + Not Prescribed Diet	ref	ref	ref	ref	ref	ref
Fasting Plasma Glucose						
Follow Diet + Prescribed Diet	1.40 (-9.57, 12.37)	-7.25 (-22.62, 8.12)	-6.61 (-21.25, 8.02)	1.30 (0.90, 1.84)	1.23 (0.80, 1.90)	1.25 (0.80, 1.95)
Follow Diet + Not Prescribed Diet	-3.75 (-17.15, 9.65)	-6.19 (-20.45, 8.06)	-5.72 (-20.42, 8.98)	0.81 (0.54, 1.22)	0.80 (0.53, 1.21)	0.79 (0.53, 1.20)
Do Not Follow Diet + Prescribed Diet	-4.40 (-17.15, 8.34)	-7.82 (-22.02, 6.39)	-6.28 (-20.55, 7.99)	0.97 (0.66, 1.43)	1.03 (0.66, 1.60)	1.09 (0.69, 1.73)
Do Not Follow Diet + Not Prescribed Diet	ref	ref	ref	ref	ref	ref
Blood Pressure						
SBP						
Follow Diet + Prescribed Diet	1.63 (-1.80, 5.06)	-0.25 (-4.06, 3.57)	0.31 (-3.34, 3.95)	1.34 (0.93, 1.92)	1.12 (0.76, 1.65)	1.17 (0.79, 1.73)
Follow Diet + Not Prescribed Diet	2.56 (-0.90, 6.01)	1.88 (-1.67, 5.44)	1.10 (-2.17, 4.38)	1.43 (0.98, 2.12)	1.38 (0.92, 2.03)	1.30 (0.86, 1.95)
Do Not Follow Diet + Prescribed Diet	0.93 (-3.72, 5.57)	-0.86 (-5.49, 3.77)	-0.37 (-4.65, 3.91)	1.16 (0.83, 1.65)	0.95 (0.65, 1.39)	0.97 (0.66, 1.42)
Do Not Follow Diet + Not Prescribed Diet	ref	ref	ref	ref	ref	ref
DBP						
Follow Diet + Prescribed Diet	0.70 (-1.05, 2.45)	-0.21 (-2.12, 1.70)	0.03 (-1.91, 1.96)	1.21 (0.88, 1.67)	1.08 (0.73, 1.62)	1.16 (0.78, 1.73)
Follow Diet + Not Prescribed Diet	1.67 (-0.82, 4.15)	1.25 (-1.46, 3.96)	0.90 (-1.73, 3.53)	1.20 (0.72, 1.99)	1.14 (0.65, 2.01)	1.09 (0.63, 1.92)
Do Not Follow Diet + Prescribed Diet	-0.10 (-2.32, 2.12)	-0.24 (-2.50, 2.02)	0.00 (-2.08, 2.09)	1.17 (0.79, 1.73)	1.08 (0.68, 1.73)	1.14 (0.72, 1.80)
Do Not Follow Diet + Not Prescribed Diet	ref	ref	ref	ref	ref	ref
LDL Cholesterol						
Follow Diet + Prescribed Diet	-6.72 (-11.38, -2.06)	-5.92 (-11.64, -0.19)	-5.22 (-11.12, 0.67)	0.79 (0.58, 1.11)	0.85 (0.57, 1.26)	0.87 (0.58, 1.30)
Follow Diet + Not Prescribed Diet	-10.14 (-16.89, -3.39)	-9.36 (-16.42, -2.29)	-8.54 (-15.50, -1.58)	0.61 (0.39, 0.93)	0.61 (0.37, 0.99)	0.62 (0.38, 1.02)
Do Not Follow Diet + Prescribed Diet	-0.96 (-8.13, 6.21)	-1.33 (-8.98, 6.33)	-0.10 (-7.62, 7.42)	0.89 (0.54, 1.45)	0.90 (0.51, 1.58)	0.97 (0.55, 1.72)
Do Not Follow Diet + Not Prescribed Diet	ref	ref	ref	ref	ref	ref
BMI						
Follow Diet + Prescribed Diet	0.39 (-0.53, 1.31)	-0.36 (-1.32, 0.61)	-0.36 (-1.32, 0.60)	0.99 (0.73, 1.35)	0.83 (0.59, 1.16)	0.82 (0.58, 1.15)
Follow Diet + Not Prescribed Diet	0.17 (-0.64, 0.98)	-0.17 (-1.03, 0.68)	-0.30 (-1.19, 0.58)	1.04 (0.73, 1.49)	0.94 (0.64, 1.39)	0.90 (0.61, 1.35)
Do Not Follow Diet + Prescribed Diet	1.07 (-0.03, 2.18)	0.47 (-0.61, 1.55)	0.48 (-0.62, 1.58)	1.21 (0.79, 1.82)	1.01 (0.66, 1.54)	1.06 (0.66, 1.72)
Do Not Follow Diet + Not Prescribed Diet	ref	ref	ref	ref	ref	ref

Table 4: Associations of diet group with HbA1c, blood pressure (SBP and DBP), LDL, and BMI CARRS Surveillance Study adjusting for socio-demographic confounders. 3

¹ Values presented are Risk Difference (95% Confidence Interval)

² Values presented are Odds Ratios (95% Confidence Interval) for HgbA1c > 7, FPG>126, SBP>140, DBP>90, LDL Cholesterol>100, and BMI>25

³ Model 1: Unadjusted linear regression model, Model 2: Linear regression model controlling for socio-demographic variables), Model 3: Linear regression model controlling for socio-demographic variables in Model 2 as well as history of hypertension or hyperlipidemia, Model 4: Unadjusted logistic regression model, Model 5: Logistic regression model adjusting for socio-demographic variables, Model 6: Logistic regression model controlling for socio-demographic variables in Model 2 as well as history of hypertension or hyperlipidemia

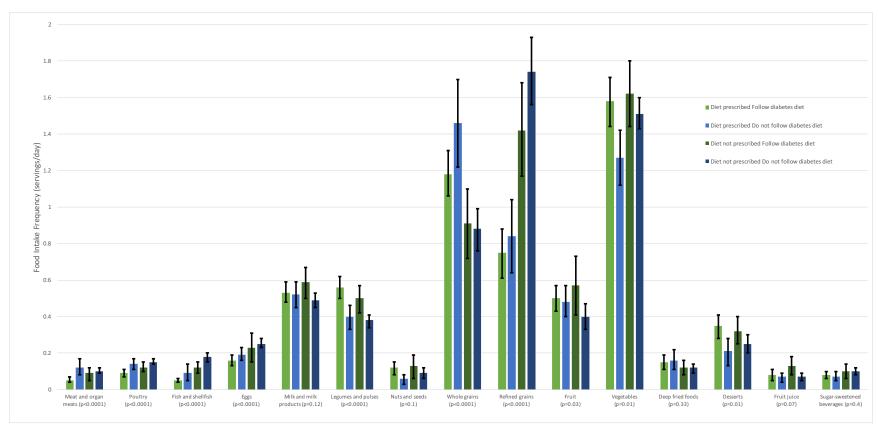


Figure 1: Comparison of food group intake between diet groups among participants with self-reported diabetes in the CARRS Cohort Study.

Colored bars depict estimated mean intake of food group in servings/day with vertical bars depicting 95% confidence limits and p-values corresponding to Satterthwaite-adjusted chi-square tests. Both Western and South Asian desserts were included in the dessert category.

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