Study to Assess the Dietary Carbohydrate Content of Indian Type-II Diabetes: The STARCH Study Result

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TITLE PAGE

Title: Study to Assess the Dietary Carbohydrate Content of Indian Type-II Diabetes: The STARCH Study Result

Running title: Study to assess the dietary carbohydrate content of Indian type-2 diabetes

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ABSTRACT

Objective: To assess dietary total and complex carbohydrate (CHO) content of daily diet in type 2 diabetes populations (T2DM) in India. **Setting:** We enrolled total of 796 subjects in this exploratory cross-sectional, single visit, multicenter, two arms (T2DM and non-diabetes group), and epidemiological survey. Participants were from specialty endocrinology/diabetology centers from five regions of India i.e. east, west, north, south and central. **Participants:** Total 796 subjects (Asian) were enrolled into the study, including 385 in type-2 diabetes and 409 non-diabetes groups. Key inclusion criteria were male or female ≥ 18 years, diagnosed with T2DM for at least 12 months for T2DM group & not on any diet plan for non-diabetes group. **Primary & Secondary Outcome Measures:** Primary outcome of interest was % of total energy intake as CHO and % of complex CHO intake from total CHO**.** Secondary outcome were differences in % of total energy intake as CHO, complex CHO content, protein, fats between T2DM and non-diabetes group. Also, % of type-II diabetes population who adhered to diet plan and with glycaemic controls was observed. **Results:** In T2DM group (n=385), mean (SD) % of total energy intake as total CHO was 64.1 (±8.3, 95% CI, 63.3 – 64.9), mean (SD) % of energy intake as complex CHO was 57.0 (±11.0, 95% CI, 55.9 – 58.1) and as simple (non-complex) CHO was 7.1 (±10.8, 95% CI, 6.0 – 8.2). Mean (SD) % of complex CHO intake from total CHO was 89.5 (±15.3, 95% CI, 88.0 – 91.1). **Conclusions:** Data from study confirms that CHO constitute 64.1% of total energy from diet in T2DM group, which is higher than recommended by National Institute of Nutrition, India (between 50-60% of total energy from carbohydrates). **Trial Registration**: ClinicalTrials.gov Identifier: NCT01450592; Clinical Trial Registry of India - CTRI/2012/02/002398.

ARTICLE SUMMARY

Strength and Limitations of this Study

- Study for the first time reports the dietary habits of India T2DM population from across India
- Study neutralizes the myths associated with differences in dietary habits in different regions of India
- Dietary habits of T2DM population is not much different from non-diabetes population
- Possible limitation of the study includes the potential for measurement error of diet and covariates
- More detailed analysis of the diet (qualitative) was not planned in this study, which can provide more useful information about the quality and quantity of CHO consumed at various meals during a typical day
- Population flow was mostly form specialty endocrinology / diabetology centres from urban area

INTRODUCTION

In recent scenario, diabetes is becoming a global public health problem especially in India. Obesity, especially central obesity & increased visceral fat due to physical inactivity, consumption of a high-calorie/ high-fat and high sugar diets are major contributing factors for diabetes (1). In India, as urbanization and economic growth occurs, there are major deviations in the dietary pattern which are influenced by the varied cultural and social customs. Traditional dietary patterns are disappearing as Indians are adapting themselves to living in the more industrialized, urban environments that are brought about by globalization. Environmental and lifestyle changes resulting from industrialization and migration to urban environment from rural settings may be responsible to a large extent, for this epidemic of type-2 diabetes mellitus in Indians (2).

Sparing few smaller studies (3, 4) from Southern part of India, we do not have larger studies which document the dietary contents of type-2 diabetes patients. There was a need to conduct dietary survey considering the diverse dietary food habits in various parts of India. The objective of the present study (STARCH: **S**tudy **T**o **A**ssess the dieta**R**y **C**arbo**H**ydrate content of Indian type-2 diabetes) was to assess the dietary total and complex carbohydrate content of daily diet in type-2 diabetes populations. The study will provide preliminary information on the carbohydrate in diet & how the same can be addressed in future to optimize the management of type-2 diabetes patients with various strategies like diet planning & education and use of drugs which target dietary carbohydrates absorption.

RESEARCH DESIGN AND METHODS

Study Design & Study Subject

Patients ≥18 years of age of either sex, diagnosed with type-2 diabetes for at least 12 months were eligible for this study in diabetes population group while non-diabetes population who were not on any diet plan or dietary advice were included in another group. Patients with specific co-morbidities, which may impact daily diet, or suffering from chronic diseases that might interfere with diet or patients on weight management plan which includes dietary modifications or dietary alterations were excluded from this study.

This was an exploratory cross-sectional, single visit, two arms, multicenter, single country epidemiological survey designed to assess the dietary total and complex carbohydrate content of Indian type-2 diabetes population. The study was conducted at 10 centers across India ensuring population from all zones viz. east, west, north, south and central India between March 2012 and September 2012. For each subject, the treating physician or clinical research coordinator has documented demographics, medical data and treatment. Type-2 diabetes population underwent investigations for fasting blood glucose (FPG), 2-hour post-prandial blood glucose (2hr-PPBG) and hemoglobin A1c (HbA1c). All patients provided written informed consent to participate. The study was conducted in accordance with principles of Good Clinical Practice and was approved by the appropriate institutional review boards / ethical committee and regulatory agencies.

Dietary Survey Methodology

A dietary survey form, 3-day dietary recall and validated Food Frequency Questionnaire (vFFQ) was completed by qualified dietician or trained study coordinator. Dietary assessment included general dietary information (Vegetarian, or Mixed), status of diet plan advised by physician and survey of dietary patterns for both groups with the help of dietary survey form, which included questions about diet consumed during 2-typical working days & during 1-typical weekend day (usually Sunday). The data collection on basic demography, diagnosis, duration of type 2 diabetes, vital signs, family/personal history, concomitant diseases, anti-diabetic medications and other medications were done on case report form which was followed by interview with dieticians or assigned trained study coordinator to complete dietary assessment at each site who were trained before the start of the study & provided with training manual to secure same level of interview.

Primary & Secondary Outcomes

The primary outcome variables were the percentage of total energy intake as carbohydrate and the percentage of complex carbohydrate intake from total carbohydrate in type-2 diabetes group. Percentage of total energy intake from carbohydrate calculated as sum of percentage of energy intake from complex carbohydrate and percentage of energy intake from simple carbohydrate.

The secondary outcome variables include difference in the percentage of total energy intake as total, complex and simple carbohydrate by type-2 diabetes versus non-diabetes population, difference in the percentage of total energy intake as proteins and fats by type-2 diabetes versus non-diabetes population, percentage of type-2 diabetes population who adheres to diet plan, percentage of type-2 diabetes population with glycaemic control (HbA1c < 7%; FBG between 70-130 mg/dL & PPBG < 180 mg/dL), utilization pattern of ant-diabetic drugs.

Statistical Analysis & Evaluations

All analyses were performed on the eligible population. Primary descriptive analysis of the data was performed using basic summary statistics. Further, descriptive measures such as n, mean, median, standard deviation (SD), first quartile (Q1), third quartile (Q3), minimum and maximum were calculated for continuous variables. Percentages were calculated based on non-missing values. Frequency and percentage were calculated for categorical variables. For continuous variables, the mean change was compared statistically between the group of type-2 diabetes and non-diabetes by using either Independent–t test or Mann-Whitney U test based on normality of the data. The tests were done at 5% level of significance and p-value ≤ 0.05 was considered as significant. Other comparisons specified in the secondary variables were analysed similarly. As per recommendation by National Institute of Nutrition and Indian consensus guideline for healthy eating, a balanced diet should provide around 50-60% of total calories from carbohydrates, preferably from complex carbohydrates, about 10-15% from proteins and 20-30% from both visible and invisible fat (5, 6). Data were stratified as per carbohydrate consumption; below National Institute of Nutrition recommendation (<50%), as per National Institute of Nutrition recommendation (50% to 60%) and above National Institute of Nutrition recommendation (> 60%) to capture the natural distribution of patients within those subgroups. For categorical variables, the number and percentage of subjects were presented. Continuous data are presented in this paper as mean and standard deviation (SD). The statistical evaluations were performed using the software SAS version 9.1.3.

RESULTS

Demographics & Lifestyle Characteristics

Total 796 subjects were enrolled into the study, out of those 2 subjects were not considered for final analysis due to non-completion of dietary survey. The remaining 794 subjects (385 type-2 diabetes and 409 non-diabetes group) completed the epidemiological survey. Region-wise recruitment was: north region (n=160), east region (n=180), south region (n=158), west region (n=116), and central India (n=180). The demographic characteristics of the analyzed population are summarized in table 1. The Mean (SD) age of type-2 diabetes group was 53.4 (11.16) years and non-diabetes group was 42.5 (12.55) years. Out of 794 subjects, 195 (50.6 %) and 175 (42.8%) male subjects were from type-2 diabetes and non-diabetes group respectively. 190 (49.4 %) and 234 (57.2%) female subjects were from type-2 diabetes and non- diabetes group respectively. The Mean (SD) duration of diabetes (years) was 8.7 (5.95). The mean (SD) BMI (kg/m^2) in type-2 diabetes and non-diabetes group was 26.4 (4.4) and 26.7 (5.0). The region-wise BMI (kg/m^2, mean (SD)) was 25.06 (3.7) and 25.22 (3.53) for east, 26.15 (4.4) and 30.87 (7.1) for west, 26.79 (4.3) and 25.9 (3.8) for north, 26.61 (3.5) and 25.66 (3.6) for south and 26.87 (5.0) and 26.25 (4.4) for central region in type-2 diabetes and non-diabetes group respectively. The diet in both type-2 diabetes and non-diabetes group was comprised of nearly equal (±5%) distribution of vegetarian and mixed diet (vegetarian plus non-vegetarian). Total 248 (64.4 %) and 176 (43.0 %) subjects were doing exercise in type-2 diabetes (n=385) and non- diabetes group (n=409) respectively. Among them, 228 (91.9%; n=248) & 150 (85.2%; n=176) were reported as doing regular exercise in type-2 diabetes and non-diabetes group respectively. 40.3% (n=155) and 59.2% (n=228, data not available for n=2) in type-2 diabetes group reported active and sedentary life-style respectively.

Table 1: Demographic characteristics of type-2 diabetes and non-diabetes group (n=794)

Parameters	Type-2 diabetes (n=385)	Non-diabetes (n=409)
Age (years)	53.4 (11.16)	42.5 (12.55)
Gender, n (%)		
Male	195 (50.6%)	175 (42.8%)
Female	190 (49.45)	234 (57.2%)
Body weight (kg)	66.45 (11.51)	68.54 (12.89)
Body mass index (kg/m^2)	26.4 (4.4)	26.7 (5.0)
Socio-economic status, n* (%)		
Lower class	8 (2.1%)	1 (0.2%)
Upper lower	64 (16.6%)	12 (2.9%)
Lower Middle	54 (14.0%)	39 (9.5%)
Upper Middle	195 (50.6%)	261 (63.8%)
Upper class	64 (16.6%)	96 (23.5%)
Vegetarian	170 (44.2%)	195 (50.6%)
Mixed Diet	215 (55.8%)	190 (49.4%)

* The Socio-economic status was analyzed using Kuppuswamy's scale which based on three parameters: education of head of family, occupation and family income (per month).(7)

Primary & Secondary Outcomes

In type-2 diabetes group (n=385), the mean (SD) percentage of total energy intake as total carbohydrate (%) was 64.1 (±8.3, 95% CI, 63.3 – 64.9), the mean (SD) percentage of energy intake as complex carbohydrate (%) was 57.0 (±11.0, 95% CI, 55.9 – 58.1) and as simple (non-complex) carbohydrate (%) was 7.1 (±10.8, 95% CI, 6.0 – 8.2). The mean (SD) percentage of complex carbohydrate intake from total carbohydrate (%) was 89.5 (±15.3, 95% CI, 88.0 – 91.1).

The region wise mean carbohydrate intake (in %, mean (SD)) is summarized in table 2. Regions include North, East, West, South and Central India.

Table 2: Region-wise mean (SD) carbohydrate (CHO, % energy and gms/day) intake in type-2 diabetes group

Region	Type-2 diabetes Group				
	n	Simple CHO mean % (SD)	Complex CHO mean % (SD)	Total CHO mean % (SD)	Total CHO (gms/day, SD)
East	90	20.2 (9.9)	45.2 (8.2)	65.4 (6.8)	255 (47)
West	46	0.4 (1.5)	60.5 (7.3)	60.9 (7.3)	225 (59)
North	80	0.9 (1.7)	61.8 (5.6)	62.7 (5.1)	235 (66)
South	79	6.8 (12.4)	55.5 (11.7)	62.3 (12.9)	228 (68)
Central	90	3.1 (4.6)	64.1 (7.7)	67.2 (5.6)	273 (151)
All	385	7.1 (10.8)	57.0 (11.0)	64.1 (8.3)	246 (92)

In non- diabetes group (n=409), the mean (SD) percentage of total energy intake as carbohydrate (%) was 66.8 (9.1, 95% CI,), the mean (SD) percentage of energy intake as complex carbohydrate (%) was 52.9 (13.3, 95% CI, 51.6 – 54.2) and as simple carbohydrate (%) was 13.9 (13.8, 95% CI, 12.6 – 15.2). The region wise carbohydrate intake (in %, mean, SD) is summarized in table 3.

Table 3: Region-wise mean carbohydrate (CHO% energy and gms/day) intake in non-diabetes group

Region	Non-diabetes group				
	n	Simple CHO mean % (SD)	Complex CHO mean % (SD)	Total CHO mean % (SD)	Total CHO (gms/day, SD)
East	90	10.3 (6.3)	54.3 (13.2)	64.6 (9.0)	342 (149)
West	70	22.7 (18.6)	43.7 (16.2)	66.4 (10.8)	523 (520)
North	80	4.4 (2.1)	62.9 (4.9)	67.3 (4.8)	268 (82)
South	79	20.6 (17.3)	45.3 (9.1)	65.9 (13.5)	295 (123)
Central	90	13.4 (10.4)	56.5 (10.8)	69.8 (3.9)	347 (96)
All	409	13.9 (13.9)	52.9 (13.3)	66.8 (9.1)	351 (253)

The mean (SD) of total calorie intake per day (Kcal) were 1547 (610, 95% CI, 1486 – 1608) and 2132 (1892, 95% CI, 1948 – 2316) respectively for type-2 diabetes and non-diabetes group.

The mean (SD) of total carbohydrate intake per day (gm.) were 246 (92, 95% CI, 236 - 255) and 351 (253, 95% CI, 326 – 357), total protein intake per day (gm.) were 57 (74, 95% CI, 49 – 64) and 58 (27, 95% CI, 55 – 60) and total fats intake (gm.) per day were 37 (18, 95% CI, 35 – 39) and 55 (98, 95% CI, 45 – 65) respectively for type-2 diabetes and non-diabetes group.

The mean (SD) of percentage of total energy intake from total carbohydrate (%) were 64.1 (8.2, 95% CI, 63.3 - 64.9) and 66.8 (9.1, 95% CI, 65.9 - 67.7); from protein (%) were 14.3 (4.4, 95% CI, 13.9 – 14.8) and 12.0 (3.2, 95% CI, 11.7 – 12.3) and from fats (%) were 21.5 (7.9, 95% CI, 20.8 – 22.4) and 21.1 (9.0, 95% CI, 20.3 – 22.0) respectively for type-2 diabetes and non-diabetes group.

There was significant difference between type-2 diabetes and non-diabetes group (Δ 2.7%, ±8.7; Δ -2.3%, ±3.9; $p \leq 0.0001$) for total energy intake from total carbohydrates and proteins (% energy) respectively. There was no significant difference between type-2 diabetes and non-diabetes group (Δ -0.4%, ±8.5; $p = 0.0637$) for total energy intake from fats (% energy).

The region-wise mean of percentage of total energy intake from macronutrients (%) in type-2 diabetes and non-diabetes groups is summarized in figure 1 and figure 2 respectively.

Among type-2 diabetes group (n=385), 169 (43.9%) were vegetarian and 216 (56.1%) were mixed diet. Similarly, 194 (47.3 %) were vegetarian and 215 (52.6%) were mixed diet in non-diabetes group (n=409).

In type-2 diabetes group (n=385), 218 (56.6%) subjects were advised for diet plan, while 167 (43.3%) subjects were not provided any diet plan by their physician. From the type-2 diabetes subject who were advised diet plan (n=218), 147 (67.4%) subject self-reported adherence while 71 (32.5%) subjects reported non-adherence to diet plan. The most common reasons for non-adherence (n=71) were not bothered about suggested diet plan (48, 67.6%), not liking the advice diet (13; 18.3%), lack of support to prepare advised diet (4; 5.6 %), and other reasons not specified (6, 8.4 %). The CHO consumption as per diet plan adherence is depicted in table 4.

Table 4: Carbohydrate consumption with respect to diet plan adherence in type-2 diabetes group

CHO Intake	Diet Plan		
	Advised (n=218)		Not Advised (n=167)
	Adherent to Diet (n=147)	Not Adherent to Diet (n=71)	
Total CHO Intake (%, SD)	63.4 (9.3)	60.4 (7.1)	66.2 (6.9)
Complex CHO Intake (%, SD)	54.1 (11.9)	56.1 (9.4)	60.0 (10.1)
Simple CHO intake (%, SD)	9.4 (13.2)	4.3 (7.4)	6.2 (9.3)

In present study, the mean (SD) HbA1c (%, n=299) was 8.2 (2.0), FBG (mg/dl, n=314) was 148.2 (61.0) and 2-h PPBG (mg/dl, n=309) was 220.0 (90.2) in type-2 diabetes group. For glycemic control as per ADA criteria, out of n=299, 33.1% (n=99) had HbA1c <7%, out of n=314, 48.4% (n=152) had FBG between 70-130 mg/dl and out of n=309, 37.5% (n=116) had 2-

h PPBG <180 mg/dl. This means 66.9%, 51.6% and 62.5% subjects had HbA1c, FBG and 2-h PPBG respectively above the recommended target levels.

In type-2 diabetes group, after stratifications as per % energy consumption <50% from carbohydrate, the mean (SD) of 2-h PPBG (mg/dl) was 225.0 (91.8), 50%- 60% from carbohydrate consumption, the mean (SD) of 2-h PPBG (mg/dl) was 206.2 (91.6) and, >60% from carbohydrate consumption the mean (SD) of 2-h PPBG (mg/dl) was 224.5 (89.4). There was a trend toward increasing 2-h PPBG with increasing in CHO consumption (% energy) if we consider subjects with % energy consumption ≥ 50% from CHO (only n=16, consuming <50% of total energy from CHO, hence not considered). The blood glucose level as per stratification of percent energy carbohydrate consumption (<50%, 50-60% and >60%) is summarized in table5.

Table 5: Glycemic level after stratification by percent energy from carbohydrate consumption in type-2 diabetes group

Blood Glucose Parameters	Percentage of total energy intake from carbohydrate stratification		
	< 50%	50% – 60%	> 60%
FPG (mg/dl) mean (SD) (n=314)	150.8 (61.6) n=16	147.0 (65.6) n=76	148.3 (59.6) n=222
PPBG (mg/dl) mean (SD) (n=309)	225.0 (91.8) n=16	206.2 (91.6) n=77	224.5 (89.4) n=216
HbA1c (%) mean (SD) (n=299)	8.2 (1.2) n=16	8.0 (1.8) n=78	8.2 (2.1) n=205

The most commonly used anti-diabetic medications metformin (77.8%; n=298), sulphonylureas (72.6%; n=278), alpha-glucosidase inhibitors (AGIs) (26.4%; n=101), thiazolidinedione (24.0%; n=92), insulin (20.6%; n=79) and dipeptidyl peptidase-IV inhibitors (13.6%, n=52).

DISCUSSION

The present cross-sectional study confirms that the Indian type-2 diabetes belonging to any part of India consumes high CHO in their diet. This further necessitates the need of well-structured, individualized, patient centric approach for patient education and drug therapy to enhance the diabetes management care in India.

Our study showed that 64.1% (±8.3, 95% CI, 63.27 - 64.93) of total calories were come from total CHO (total i.e. simple plus complex) in type-2 diabetes group. This suggest that the CHO consumption by type-2 diabetes in India is higher (Δ4.1% above upper limit of 60%) than as recommended by guidelines. Recently, Sivasankari V et. a1, reported similar dietary pattern of type-2 diabetes from South India (CHO ~ 65%, P ~ 11.5% & F ~ 23.5%) (4). Studies from West, reported just 39-49% energy from CHO in diet which is much lower than that reported in the current study (8). This further confirms that Indians consumes high CHO in their diet. Diabetes population seems to be well aware of restricting the consumption of simple CHO to <10% as per recommendation (7.1% (±10.8, 95% CI, 6.0 - 8.2) energy came from simple CHO). In region-wise analysis, only eastern region reported higher consumption of simple CHO (20.2% (±10.0, 95% CI 18.1 - 22.3)) and subsequently lower consumption of complex CHO (45.2% (±8.2, 95% CI, 43.5 - 47.0)) was observed. This reflects typical dietary pattern of eastern Indian population.

The total calorie intake [1547.5 Kcal (±610.0, 95% CI 1486.3 - 1608.6)] appears in the recommended range of daily allowance in type-2 diabetes group (1329 – 1993 kcal/day, considering mean weight 66.45 kg and caloric requirements as 20-30 kcal/kg/day as per Misra A. et al 2011(6).

In non-diabetes group (n=409), 66.8% (±9.1, 95% CI, 65.9 - 67.7) of total energy came from total CHO (simple plus complex CHO). The difference between type-2 diabetes and non-diabetes group was 2.7% (p <0.001, Mann-Whitney U test used to calculate p-value based on normality assumption). As expected, non-diabetes group consumed simple CHO higher than the recommendation (13.9% (±13.9, 95% CI, 11.1 - 15.3)) and relatively lower consumption of complex CHO (52.9% (±13.3, 95% CI, 51.6 - 54.2)). These findings were similar to earlier reports from Indian study (9).

The comparison of macronutrient i.e. CHO, fat and protein consumption region-wise revealed that there was similar pattern of dietary consumption i.e. high CHO, and lower range of fat & protein across the region (figure 1). This study prevailed the myth that only South Indian population in India consumes high CHO in their diet (rice, idly, etc). Similar dietary pattern was also reported in non-diabetes populations (figure 2).

In the present study, only 38.2% (n=147) of total type-2 diabetes population (n=385) self-reported that they adhere to diet plan advised by their physician. Only 56.6% (n=218) confirmed that they have been provided with diet plan. 43.3% (n=167) self-reported that their physician never advised them any diet plan. Type-2 diabetes population who failed to adhere to diet plan (n=71, 18.4% of total type-2 diabetes population) said that they don't bother about diet plan (67.6%), do not like the suggested diet plan (18.3%), while 5.6% said, no body to take care of them. This data further reinforce the need that all people with type-2 diabetes should receive regular nutritional counseling from a dietician to reinforce importance of diet therapy in type-2 diabetes patients. We suggest people with type-2 diabetes should be encouraged to obtain optimal metabolic control through a balance of food intake, physical activity and medication to avoid long-term complications. Most importantly, specific dietary recommendations should be individualized to accommodate the person's preferences and lifestyle to enhance the acceptance and adherence to diet plan.

In the present study, paradoxically, type-2 diabetes population seems to consume higher CHO in diet (table 4) in category who confirmed adherence to diet plan. In addition, subjects who think they adhere to diet plan, seem to consume highest simple sugar, although, it was within recommended levels (<10% of total energy), however, no explanation can be put for this paradoxical findings. In our study, 67.1% subjects; who were advised diet; reported adherence to diet plan which is little lower than reported by Patel M. et. al. (73%) (10) from a study conducted in western part of India.

This cross-sectional study provided good opportunity to assess the glycemic control in type-2 diabetes population. In our study, 66.9% of type-2 diabetes population has HbA1c above 7% target. Patel M et al (10), reported similar findings in their study recently (35% study subjects has HbA1c <7%). The higher blood sugar levels may reflect poor compliance of type-2 diabetes subjects with therapy, poor physical activity, poor awareness of cut-off points, importance of diet, etc. Engaging the physicians, trained dietician, and people with diabetes for increasing awareness for life-style changes to prevent long-term complications is clearly warranted.

The amount of CHO consumed affects blood glucose levels and insulin responses (6). In our study, there was a trend towards the higher consumption of CHO with high 2h-PPBG levels.

Monabala K et al (11), reported that increase in dietary CHO (% of energy), glycemic load and weighted glycemic index was associated with increase in HbA1c levels. The high CHO consumption & its impact on glycemic control especially on PPBG can be controlled by proper diet advice and implementation of strategies - using AGIs (dietary carbohydrate inhibitors) which delays the digestion and absorption of complex CHO and reduces the post-prandial rise in blood glucose levels (12). AGIs like acarbose seems to be particularly useful in newly diagnosed type 2 diabetes with excessive PPBG, because of their unique mode of action in controlling the release of glucose from complex carbohydrates and disaccharides (13).

In our study majority of type-2 diabetes subjects were treated with multiple antidiabetic drug therapy. The most commonly prescribed antidiabetic drug class was metformin followed by sulphonylurea, alpha-glucosidase inhibitors, thiazolidinedione, insulin and dipeptidyl peptidase-IV inhibitors. Metformin was the most commonly prescribed anti-diabetic drugs. Metformin is hypoglycemic agent widely used in clinical practice for more than half decade to treat diabetes. It is safe and effective as monotherapy or can also be used in combination with any other hypoglycemic agent for treatment of diabetes. Furthermore it is cost-effective, reduces weight or weight neutral. It has less incidence of hypoglycemia as compared to sulfonylurea and insulin, has beneficial effects on lipids (14, 15). Second most commonly used medication was sulphonylurea. Among the sulfonylureas, glimepiride was the most commonly used. The higher usage of sulfonylurea is probably due to the need to rapidly control the glucose levels and the preference for glimepiride could be due to its lower propensity to cause hypoglycemia. Similar pattern of drug utilization was reported earlier in small study from northern India (16). Usage of AGIs seems to be more in our study compared to previously reported data [26.4% our study vs. 7.6% Sultana G et. al.(16)]. Author in his editorial stated that there is a need of therapeutic agents that target the early stages type 2 diabetes, such as the α-glucosidase enzyme inhibitors, like acarbose, which reduces postprandial hyperglycemia and hyperinsulinaemia and increases incretin levels (Glucagon Like Ppetide-1). This strategy may play more prominent role in an Indian setting where the role of AGIs is even more significant as our meal component is carbohydrate rich, which is confirmed by present study.[17] However, to confirm the beneficial role of AGIs in high CHO consuming Indian type-2 diabetes will require a prospective randomized study.

LIMITATION

This study has limitations; the cross-sectional design of the study does not allow making inferences about the cause (consumption of high CHO) and effect (glycemic control, rise on PPBG). Another possible limitation of the study includes the potential for measurement error of diet and covariates. The more detailed analysis of the diet (qualitative) was not planned in this study, which can provide more useful information about the quality and quantity of CHO consumed at various meals during a typical day. We would like to conduct the post-hoc analysis of diet using the 3-day dietary recall data to further enhance the knowledge on this aspect. Population flow was mostly form specialty endocrinology / diabetology centers from urban area.

CONCLUSION

Data from present cross-sectional study confirms that carbohydrate constitute 64.1% of total energy from diet in type-2 diabetes group, which is higher than recommended. There was clear non-adherence to dietary advice in type-2 diabetes group. In type-2 diabetes group, there was trend between CHO intake and post-prandial blood glucose. From data, it may be relevant to use AGIs in most of the diabetes patient with high PPBG. However, studies correlating the CHO content and glycemic control with AGIs in Indian subjects are wanting and warrant further study.

AUTHOR CONTRIBUTIONS

SRJ was involved in study concept; study design, data collection and analysis, manuscript writing, reviewing and finalization. AB, SB, SSB, MD, SG, SM, PRS, RS, and SS were involved in data collection and analysis, and were involved in reviewing the manuscript. SSJ was involved in study design, data analysis related to dietary survey, development & validation of dietary survey and reviewing of manuscript.

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CONFLICT OF INTEREST

No authors report a conflict of interest.

ROLE OF THE FUNDING SOURCE

Study sponsor (Bayer Zydus Pharma, India) was involved in study concept, study design, the collection, analysis and interpretation of data, and in the decision to submit the paper for publication.

REFERENCES

1. Mohan V. Why are Indians more prone to diabetes? J Association Physician India 2004;52:468-474.

2. Gopalan C. Rising Incidence of Obesity, Coronary Heart Disease and Diabetes in the Indian Urban Middle Class Possible Role of Genetic and Environmental Factors. World Rev Nutr Diet 2001;90:127-143.

3. G Radhika, RM Sathya, V Sudha, A Ganesan, V Mohan. Dietary salt intake and hypertension in an urban south Indian population. J Association Physician India 2007;55:405-411.

4. Sivasankari V, Manobala K, Geetha G, Vijayalakshmi P, Sudha V, Anajan RM, et al. Dietary profile of Chennai urban adults with diabetes. Poster at RSSDI 2012 (Abstract)

5. National Institute of Nutrition. Dietary Guideline for Indians- A Manual. 2nd Edition 2010. Available at: http://www.ninindia.org/DietaryguidelinesforIndians-Finaldraft.pdf accessed on 25 March 2013.

6. Misra A, Sharma R, Gulati S, Joshi SR, Sharma V, Ghafoorunissa, et al. Consensus Dietary Guidelines for Healthy Living and Prevention of Obesity, the Metabolic Syndrome, Diabetes, and Related Disorders in Asian Indians. Diabetes Technology & Therapeutics 2011;13(6):683-694.

7. SSL Parashar. Principles of sociology in Health Care, Section 4: Social, Behavioral & Communication Sciences. Textbook on Public Health & Community Medicine. P 608 – 613.

8. Esposito K, Maiorino MI, Palo CD, Giugliano. Dietary glycemic index and glycemic load are associated with metabolic control in type-2 diabetes: The CAPRI Experience. Metabolic Syndrome Related Disorders 2010;8(3):255-261.

9. G Radhika, RM Sathya, V Sudha, A Ganesan, V Mohan. Dietary salt intake and hypertension in an urban south Indian population. J Association Physician India 2007;55:405-411.

10. Patel M, Patel IM, Patel YM, Rathi SK. Factors associated with consumption of diabetic diet among type 2 diabetic subjects from Ahmedabad, Western India. J Health Popul Nutr 2012;30(4):447-55.

11. Manobala K, Lakshmipriya N, Vijayalakshmi P, Geetha G, Sudha V, Anajan RM, et al. Association of dietary carbohydrates and refined cereal consumption with glycemic control among Chennai urban adults with diabetes. Poster at RSSDI 2012. (Abstract)

12. Hanefeld M. Acarbose revisited for efficacy, safety and cardiovascular benefits: a key role for controlling glycemic variability. Expert Rev Endocrinol Metab 2012;7(4):395-405.

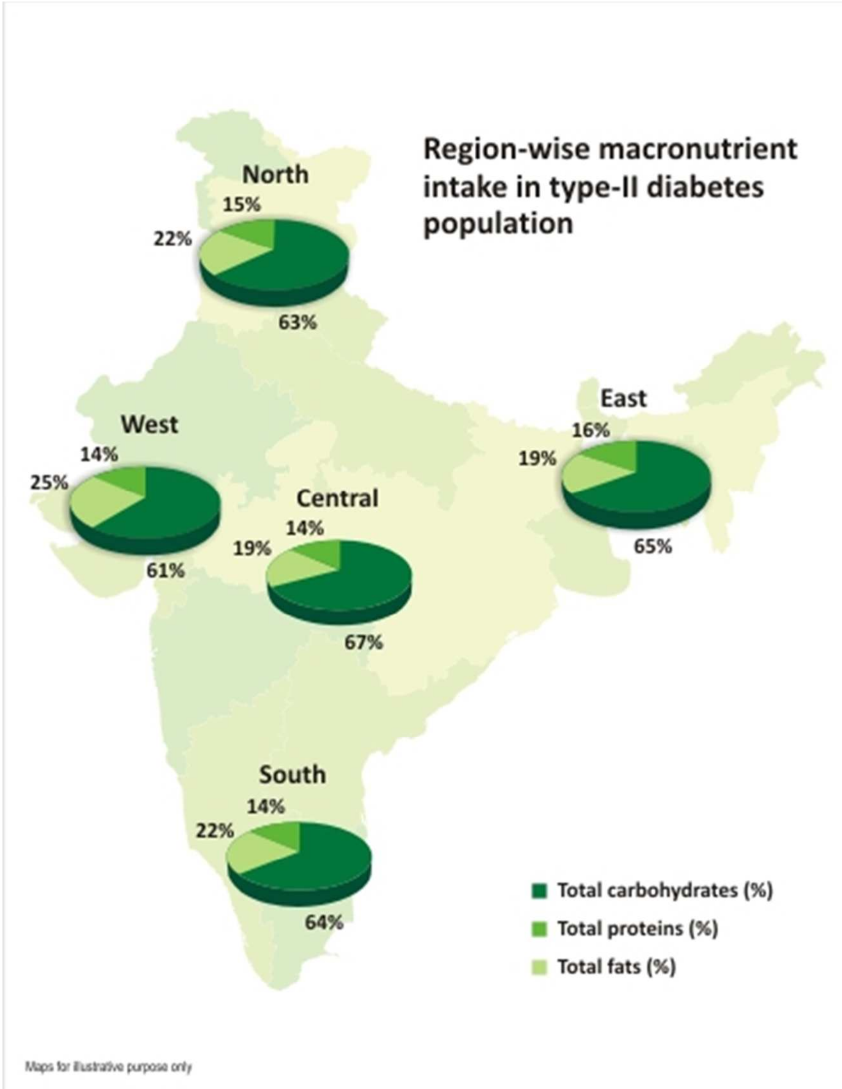
13. Derosa G, Maffioli P. α-Glucosidase inhibitors and their use in clinical practice. Arch Med Sci 2012;8(5): 899-906.

14. Ali S, Fonseca V. Overview of metformin: special focus on metformin extended release. Expert Opin Pharmacother 2012;13(12):1797-1805.

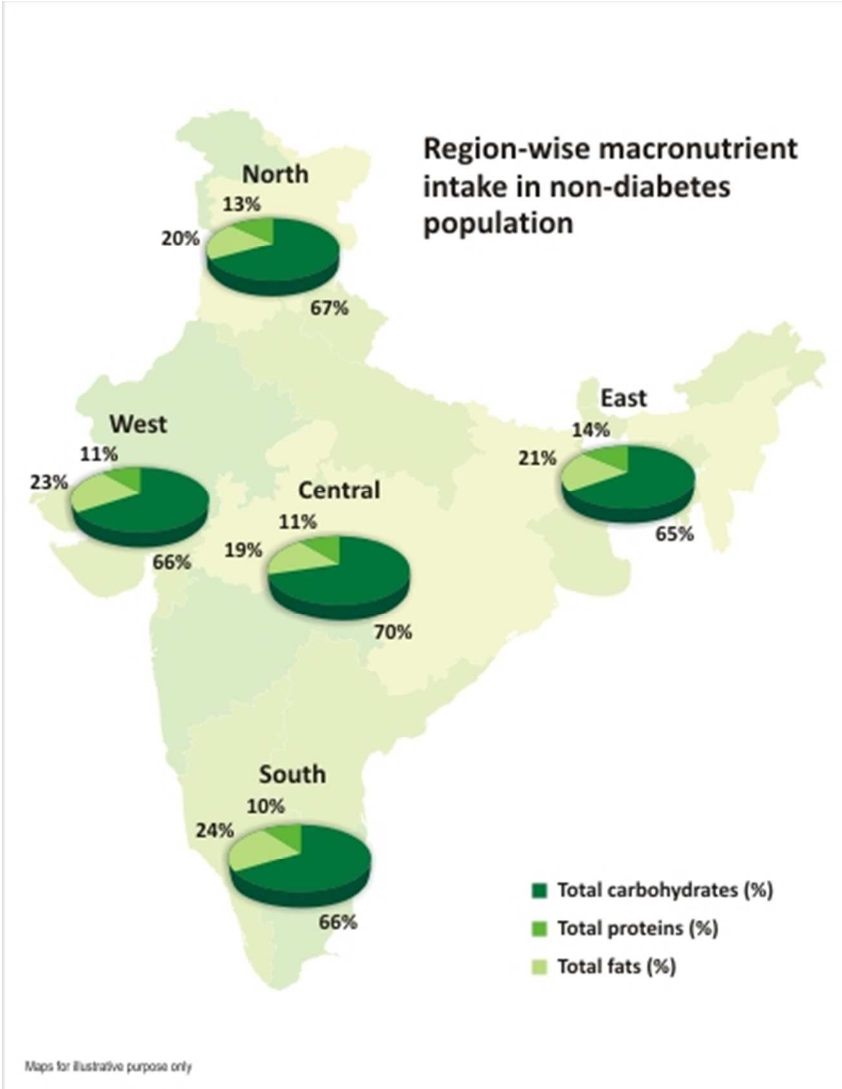
15. Bennett WL, Maruthur NM, Singh S, Segal JB, Wilson LM, Chatterjee R, et al. Comparative effectiveness and safety of medications for type 2 diabetes: an update including new drugs and 2-drug combinations. Ann Intern Med 2011;154(9):602-613.

16. Sultana G, Kapur P, Aqil M, Alam MS, Pillai KK. Drug utilization of oral hypoglycemic agents in a university teaching hospital in India. J Clin Pharm Ther 2010;35(3):267-277.

17. Joshi SR. Editorial: Post-prandial Carbohydrate Modulation via Gut- Indian Perspective. J Association Phy India 2010;58:665.



Regionwise marconutrient composition in type-2 diabetes group (% energy intake)
107x139mm (100 x 100 DPI)



Regionwise marconutrient composition in non-diabetes group (% energy intake)
107x139mm (100 x 100 DPI)

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STARCH Study: Results from dietary survey in Indian T2DM population

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TITLE PAGE

STARCH Study: Results from dietary survey in Indian T2DM population

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Running title: Results from dietary survey in Indian T2DM population

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STARCH Study: Results from dietary survey in Indian T2DM population

ABSTRACT

Objective: To assess the dietary total and complex carbohydrate (CHO) contents in type-2 diabetes mellitus (T2DM) subjects in India. **Setting:** We enrolled 796 subjects in this cross-sectional, single-visit, multicenter, two-arm, single-country survey. Participants were enrolled from 10 specialty endocrinology/dialectology centers from five regions of India. **Participants:** A total of 796 subjects (Asian) were enrolled in study (385, T2DM & 409, non-T2DM). Key inclusion criteria – male or female ≥18 years, diagnosed with T2DM ≥12 months (T2DM), and not on any diet plan (non-T2DM). **Study Outcome:** Primary outcome of interest was percentage of total energy intake as simple and complex CHO from total CHO. Secondary outcomes were differences in percentage of total energy intake as simple CHO, complex CHO, proteins, and fats between T2DM and non-T2DM groups. Also, percentage of T2DM subject who adhered to diet plan and glycemic controls. **Results:** Mean (SD) of total calorie intake per day (Kcal) were 1547 (610, 95% CI, 1486 – 1608) and 2132 (1892, 95% CI, 1948 – 2316) respectively for T2DM and non-T2DM groups. In T2DM group (n=385), mean (SD) percentage of total energy intake as total CHO, complex CHO & simple CHO was 64.1±8.3 (95% CI 63.3 to 64.9), 57.0±11.0 (95% CI 55.9 to 58.1) and 7.1±10.8 (95% CI 6.0 to 8.2) respectively. Mean (SD) percentage of complex CHO intake from total CHO was 89.5±15.3 (95% CI 88.0 to 91.1). Mean (SD) total protein/fat intake per day (gm) was 57.1 (74.0)/ 37.2 (18.6) and 57.9 (27.2)/ 55.3 (98.2) in T2DM and non-T2DM group respectively. **Conclusions:** Our study shows that CHO constitutes 64.1% of total energy from diet in T2DM subjects; higher than recommended in India. However, our findings need to be confirmed in larger epidemiological survey.

ARTICLE SUMMARY

Strength and limitations of this study

- Study for the first time reports the dietary habits of T2DM subjects from across India
- Study neutralizes the myths associated with differences in dietary habits in different regions of India
- Dietary habits of T2DM subjects are not much different from those of non-T2DM subjects
- Possible limitation of the study includes, small sample size and the possibility of measurement error of diet and covariates
- Population flow was mostly form specialty endocrinology/diabetology centers from urban area

INTRODUCTION

In recent scenario, diabetes is becoming a global public health problem, especially in India. Obesity, especially central obesity, and increased visceral fat due to physical inactivity and consumption of a high-calorie/high-fat and high-sugar diets are major contributing factors for it.[1] In India, as urbanization and economic growth occur, there are major deviations in the dietary pattern that are influenced by varied cultural and social customs. Environmental and lifestyle changes resulting from industrialization and migration to urban environment from rural settings may be responsible to a large extent, contributing to the epidemic of type-2 diabetes mellitus (T2DM) in Indians.[2]

Sparing few smaller studies[3,4] from southern part of India, we do not have studies that document the dietary contents of patients with T2DM from across India. There was a need to conduct a dietary survey considering the diverse dietary food habits in various parts of India. The objective of this study (STARCH: **S**tudy **T**o **A**ssess the dieta**R**y **C**arbo**H**ydrate content of Indian type-2 diabetes population) was to assess the total and complex carbohydrate (CHO) contents in the daily diet of T2DM subjects. Our study provides preliminary information on the dietary carbohydrate, fat and proteins contribution in food consumed by T2DM subject and also how it compares with non-T2DM subjects from pan India.

RESEARCH DESIGN AND METHODS

Study design and study subject

Our study was an exploratory cross-sectional, single-visit, two-arm, multicenter, single-country survey. Study subjects were enrolled (from March 2012 to September 2012) from 10 sites across all regions of India, viz; East, North, West, South and Central considering different dietary patterns. Subjects were enrolled from endocrinology / diabetology clinics / hospitals with clinical research facilities during routine out-patient visits. Study subjects were not provided with any incentives for participation in the study. The subject ≥18 years of age of either sex, diagnosed with T2DM for at least 12 months, were eligible in T2DM group whereas subjects not on any diet plan or dietary advice and who visited for acute illnesses / conditions which do not affect inclusion in the survey were included in non-T2DM. Moreover, non-T2DM subjects were matched to T2DM subjects with respect to age, sex and center. Patients with specific comorbidities that may impact daily diet, with chronic diseases, or weight management plan that includes dietary modifications or dietary alterations were excluded from study. . All subjects provided written informed consent. Study was conducted in accordance with principles of Good Clinical Practice and was approved by the institutional review boards/ethics committee.

Dietary survey methodology

A dietary survey form, 3-day dietary recall, and validated Food Frequency Questionnaire (FFQ) were completed by a qualified dietitian or trained study coordinator. Dietary assessment included general dietary information (vegetarian or mixed), status of diet plan advised by physician, and information about dietary patterns for both groups with the help of dietary survey form, which included questions about diet consumed during two typical working days and during one typical weekend day (usually Sunday). The final dietary assessment was done using the 3-day dietary recall data.

Primary and secondary outcomes

Primary outcome variables were the percentage of total energy intake as total CHO and complex CHO intake from total CHO in T2DM group. Percentage of total energy intake from CHO was calculated as sum of percentage of energy intake from complex CHO and simple CHO. Secondary outcome variables include difference in the percentage of total energy intake as total, complex, and simple CHO, proteins and fats between T2DM and non-T2DM subjects, percentage of patients with T2DM who adhere to diet plan, glycemic control as per American Diabetes Association (ADA) criteria[5] (HbA1c < 7%, FBG between 70 and 130 mg/dL, and PPBG < 180 mg/dL), and utilization pattern of antidiabetic drugs.

Statistical analysis and evaluations

It was assumed that, at least 50% of total energy intake comes from CHO and at least 50% complex CHO intake comes from total CHO in T2DM subjects. Thus 385 T2DM subjects were required to achieve an allowable error of 5% where allowable error is half width of 95% confidence interval. Taking missing data into consideration, we planned to conduct the survey with a total of 400 subjects each group. All analyses were performed on the eligible subject.

Primary descriptive analysis of the data was performed using basic summary statistics. Further descriptive measures such as n, mean, median, standard deviation (SD), first quartile (Q1), third quartile (Q3), minimum, and maximum were calculated for continuous variables. Percentages were calculated based on non-missing values. Frequency and percentage were calculated for categorical variables. For continuous variables, the mean change was compared statistically between the T2DM and non-T2DM groups using either independent *t*-test or Mann–Whitney *U*-test based on normality of the data. The tests were carried out at 5% level of significance and p-value ≤ 0.05 was considered as significant. Other comparisons specified in the secondary variables were carried out similarly. As per recommendation by the National Institute of Nutrition[6] (NIN) and Indian Consensus Guideline[7] for Healthy Eating, a balanced diet should provide approximately 50%–60% of total calories from CHO (preferably from complex CHO), approximately 10%–15% calories from proteins, and approximately 20%–30% calories from both visible and invisible fats. Data were stratified as per CHO consumption; below NIN recommendation (<50%), as per recommendation (50%–60%), and above recommendation (>60%) to capture natural distribution of patients within these stratifications. In addition, we also compared the findings with WHO Expert group recommendations i.e. total CHO should provide 55–75% total energy and that free sugars should provide less than 10% energy.[8] For categorical variables, the number and percentage of subjects were considered. Continuous data are presented in this article as mean and SD. The statistical evaluations were performed using the software SAS, version 9.1.3.

RESULTS

Demographics and lifestyle characteristics

A total of 796 subjects were enrolled in the study; of those two subjects were screen failure & no subject declined to participate in our study. The remaining 794 subjects (385 in T2DM and 409 in non-T2DM groups) completed survey. Region-wise recruitment was as follows: north region (n=160), east region (n=180), south region (n=158), west region (n=116), and central India (n=180). The demographic characteristics of the analyzed subjects are summarized in table 1. The mean (SD) age of T2DM group was 53.4 (11.16) years and of non-T2DM subjects was 42.5 (12.55) years. Of 794 subjects, 195 (50.6%) and 175 (42.8%) male subjects were from T2DM and non-T2DM groups, respectively. The mean (SD) duration of diabetes (years) was 8.7 (5.95). The mean (SD) body mass index (BMI; kg/m^{2,} mean (SD)) in T2DM and non-T2DM groups was 26.4 (4.4) and 26.7 (5.0), respectively. The region-wise BMI (kg/m^2, mean (SD)) was 25.06 (3.7) and 25.22 (3.53) for east, 26.15 (4.4) and 30.87 (7.1) for west, 26.79 (4.3) and 25.9 (3.8) for north, 26.61 (3.5) and 25.66 (3.6) for south, and 26.87 (5.0) and 26.25 (4.4) for central region in T2DM and non-T2DM groups, respectively. The diet in both T2DM and non-T2DM groups was composed of nearly equal (±5%) distribution of vegetarian and mixed diet (vegetarian plus non-vegetarian). In T2DM (n=385) and non-T2DM group (n=409), 248 (64.4%) and 176 (43.0%) subjects were doing exercise. Among them, 228 (91.9%; n=248) and 150 (85.2%; n=176) were reported as doing exercise regularly in T2DM and non-T2DM group, respectively; 40.3% (n=155) and 59.2% (n=228, data not available for two participants) in T2DM group reported active and sedentary lifestyle respectively.

Primary and secondary outcomes

In T2DM group (n=385), the mean (SD) percentage of total energy intake as total CHO was 64.1±8.3 (95% CI 63.3 to 64.9), as complex CHO was 57.0±11.0 (95% CI 55.9 to 58.1), and as simple CHO was 7.1±10.8 (95% CI 6.0 to 8.2). The mean (SD) percentage of complex CHO intake from total CHO was 89.5±15.3 (95% CI 88.0 to 91.1). The overall summary and comparative analysis of T2DM & non-T2DM subject is presented in table 2. The region-wise mean carbohydrate intake (%, mean (SD)) is summarized in table 3.

Table 1 Demographic characteristics of T2DM and non-T2DM group (n=794)

Parameters	T2DM (n=385)	Non-T2DM (n=409)
Age (years, mean (SD))	53.4 (11.16)	42.5 (12.55)
Gender, n (%)		
Male	195 (50.6)	175 (42.8)
Female	190 (49.45)	234 (57.2)
Body weight (kg), n (%)	66.45 (11.51)	68.54 (12.89)
Body mass index (kg/m2), n (%)	26.4 (4.4)	26.7 (5.0)
Socioeconomic status, n* (%)		
Lower class	8 (2.1)	1 (0.2)
Upper lower	64 (16.6)	12 (2.9)
Lower middle	54 (14.0)	39 (9.5)
Upper middle	195 (50.6)	261 (63.8)
Upper class	64 (16.6)	96 (23.5)
Diet, n (%)		
Vegetarian	170 (44.2)	195 (50.6)
Mixed diet	215 (55.8)	190 (49.4)

*The socioeconomic status was analyzed using Kuppuswamy's scale which is based on three parameters: education of head of family, occupation, and family income (per month).[9]

Table 2 Secondary Outcome: Summary and comparative analysis of dietary content of T2DM & non-T2DM groups

	T2DM (N=385)	Non-T2DM (N=409)	Mean Diff. between groups	P-Value
Total calorie per day (Kcal)				
Mean (SD)	1547.46 (610.02)	2132.23 (1892.48)	584.77 (1423.17)	<0.0001^
Total simple CHO per day (gm)				
Mean (SD)	28.25 (44.60)	90.867 (149.51)	62.61 (111.71)	<0.0001^
Total complex CHO per day (gm)				
Mean (SD)	217.88 (91.48)	259.85 (136.89)	41.97 (117.09)	<0.0001^
Total CHO per day (gm)				
Mean (SD)	246.13 (91.64)	350.72 (252.95)	104.58 (192.44)	<0.0001^
Total protein per day (gm)				
Mean (SD)	57.11 (74.01)	57.89 (27.23)	0.78 (55.11)	0.0539^
Total fat per day (gm)				
Mean (SD)	37.16 (18.56)	55.30 (98.19)	18.14 (71.65)	<0.0001^
Percentage of total energy simple CHO (%)				
Mean (SD)	7.09 (10.85)	13.91 (13.86)	6.82 (12.49)	<0.0001^
Percentage of total energy complex CHO (%)				
Mean (SD)	57.00 (11.01)	52.92 (13.32)	-4.08 (12.25)	0.0001^
Percentage of total energy total CHO (%)				
Mean (SD)	64.09 (8.28)	66.83 (9.15)	2.74 (8.74)	<0.0001^
Percentage of total energy proteins (%)				
Mean (SD)	14.33 (4.45)	12.01(3.23)	-2.32 (3.87)	<0.0001^
Percentage of total energy fats (%)				
Mean (SD)	21.56 (7.89)	21.15 (9.05)	-0.41 (8.51)	0.0637^

*Independent T-Test/^ Mann-Whitney U test used to calculate p-value based on normality assumption. Test done at 5% Significance level and P <= 0.05 indicates Significance. # Mean Diff. between groups = Mean of non-T2DM group- Mean of T2DM group.

Table 3 Region-wise mean CHO (in %, mean (SD) and g/day) intake in T2DM group

Region	T2DM group				
	n	Simple CHO, mean (SD)	Complex CHO, mean (SD)	Total CHO, mean (SD)	Total CHO, g/day (SD)
East	90	20.2 (9.9)	45.2 (8.2)	65.4 (6.8)	255 (47)
West	46	0.4 (1.5)	60.5 (7.3)	60.9 (7.3)	225 (59)
North	80	0.9 (1.7)	61.8 (5.6)	62.7 (5.1)	235 (66)
South	79	6.8 (12.4)	55.5 (11.7)	62.3 (12.9)	228 (68)
Central	90	3.1 (4.6)	64.1 (7.7)	67.2 (5.6)	273 (151)
All	385	7.1 (10.8)	57.0 (11.0)	64.1 (8.3)	246 (92)

In non-T2DM group (n=409), the mean (SD) percentage of total energy intake as total CHO was 66.8 (9.1, 95% CI), complex CHO was 52.9 (13.3, 95% CI 51.6 to 54.2), and simple CHO was 13.9 (13.8, 95% CI 12.6 to 15.2). The region-wise CHO intake (in %, mean (SD)) is summarized in table 4.

Table 4 Region-wise mean CHO (%, mean (SD) and g/day) intake in non-T2DM group

Region	**Non-T2DM group**				
	n	**Simple CHO, mean (SD)**	**Complex CHO, mean (SD)**	**Total CHO, mean (SD)**	**Total CHO, g/day (SD)**
East	90	10.3 (6.3)	54.3 (13.2)	64.6 (9.0)	342 (149)
West	70	22.7 (18.6)	43.7 (16.2)	66.4 (10.8)	523 (520)
North	80	4.4 (2.1)	62.9 (4.9)	67.3 (4.8)	268 (82)
South	79	20.6 (17.3)	45.3 (9.1)	65.9 (13.5)	295 (123)
Central	90	13.4 (10.4)	56.5 (10.8)	69.8 (3.9)	347 (96)
All	409	13.9 (13.9)	52.9 (13.3)	66.8 (9.1)	351 (253)

The mean (SD) of total calorie intake per day (kcal) were 1547 (610, 95% CI 1486 to 1608) and 2132 (1892, 95% CI 1948 to 2316), respectively, for T2DM and non-T2DM groups. The mean (SD) of total CHO intake per day (g) were 246 (92, 95% CI 236 to 255) and 351 (253, 95% CI 326 to 357); total protein intake per day (g) were 57 (74, 95% CI 49 to 64) and 58 (27, 95% CI

55 to 60); and total fats intake (g) per day were 37 (18, 95% CI 35 to 39) and 55 (98, 95% CI 45 to 65) for T2DM and non-T2DM groups. The mean (SD) of percentage of total energy intake from total CHO were 64.1 (8.2, 95% CI 63.3 to 64.9) and 66.8 (9.1, 95% CI 65.9 to 67.7), from protein were 14.3 (4.4, 95% CI 13.9 to 14.8) and 12.0 (3.2, 95% CI 11.7 to 12.3), and from fats were 21.5 (7.9, 95% CI 20.8 to 22.4) and 21.1 (9.0, 95% CI 20.3 to 22.0), respectively, for T2DM and non-T2DM groups. There was a significant difference between T2DM and non-T2DM groups (Δ 2.7±8.7%, Δ –2.3±3.9%; p≤0.0001) for total energy intake from total CHO and proteins (% energy). There was no significant difference between T2DM and non-T2DM groups (Δ –0.4±8.5%; p=0.0637) for total energy intake from fats (% energy). The region-wise mean percentage of total energy intake from macronutrients in T2DM and non-T2DM groups is summarized in figures 1 and 2, respectively. Among T2DM group (n=385), 169 (43.9%) patients were vegetarian and 216 (56.1%) were mixed diet. Similarly, 194 (47.3 %) participants were vegetarian and 215 (52.6%) were mixed diet in non-T2DM group (n=409).

Figure 1 Regionwise marconutrient composition in T2DM group (% energy intake)

<<Figure 1>>

Figure 2 Regionwise marconutrient composition in non-T2DM group (% energy intake)

<<Figure 2>>

In T2DM group (n=385), 218 (56.6%) subjects were advised for diet plan by their physician. The adherence to prescribed diet was recorded as yes or no outcome by asking subject whether they adhere to diet plan. We considered this approach as appropriate due to cross sectional nature of this survey. From patients with T2DM who were advised diet plan (n=218), 147 (67.4%) self-reported adherence. The most common reasons for non-adherence (n=71) were not bothered about suggested diet plan (48, 67.6%), not liking advised diet (13, 18.3%), lack of support to prepare advised diet (4, 5.6%), and other reasons not specified (6, 8.4%). The CHO consumption & glycaemic parameters as per diet plan adherence is depicted in table 5, however, the relationship between this covariate was not further analyzed.

Table 5 CHO consumption & glycaemic parameters with respect to diet plan adherence in T2DM group

Parameters	Diet plan		
	Advised (n=218)		Not advised (n=167)
	Adherent to diet (n=147)	Not adherent to diet (n=71)	
Total CHO intake (%, SD)	63.4 (9.3)	60.4 (7.1)	66.2 (6.9)
Complex CHO intake (%, SD)	54.1 (11.9)	56.1 (9.4)	60.0 (10.1)
Simple CHO intake (%, SD)	9.4 (13.2)	4.3 (7.4)	6.2 (9.3)
FBG (mg/dl)	n=100	n=61	n=153
mg/dl, mean (SD)	146.1 (62.0)	142.2 (54.4)	151.8 (62.9)
Control level* (70-100 mg/dl) (n, (%))	52 (35.4)	30 (42.3)	70 (41.9)
PPBG (mg/dl)	n=97	n=60	n=153
mg/dl, mean (SD)	220.2 (78.7)	212.1 (100.6)	223.1 (93.0)
Control level* (<180 mg/dl) (n, (%))	34 (23.1)	29 (40.8)	53 (31.7)
HbA1c (%)	n=96	n=59	n=1544
Percent, mean (SD)	8.0 (1.7)	7.8 (1.8)	8.4 (2.2)
Control level* (<7%) (n, (%))	27 (18.4)	26 (36.6)	46 (27.5)

* As per ADA criteria[5] i.e. HbA1c < 7%, FBG between 70 and 130 mg/dL, and PPBG < 180 mg/dL

In our study, the mean (SD) HbA1c (%, n=299) was 8.2 (2.0), FBG (mg/dL, n=314) was 148.2 (61.0), and 2-h PPBG (mg/dL, n=309) was 220.0 (90.2) in T2DM group. For glycemic control as per ADA[6] criteria, out of 299 subjects, 33.1% (n=99) had HbA1c <7%; out of 314, 48.4% (n=152) had FBG between 70 and 130 mg/dL; and out of 309, 37.5% (n=116) had 2-h PPBG <180 mg/dL. This means 66.9%, 51.6%, and 62.5% subjects had HbA1c, FBG, and 2-h PPBG above the recommended levels.

In T2DM group, after stratifications as per percent energy from CHO consumption <50%, 50%-60% & >60%, the mean (SD) of 2-h PPBG (mg/dL) were 225.0 (91.8); 206.2 (91.6); 224.5 (89.4) respectively (table 6). There was a trend toward increasing 2-h PPBG with increase in CHO consumption (% energy) if we consider subjects with percent energy consumption ≥50% from CHO (n=16, consuming <50% of total energy from CHO, hence not considered). However, the current study was not powered to investigate the effect of CHO consumption & relationship with glycemic control. We present here the observations from our study without doing further analysis considering the various confounder factors like age, sex, BMI, drug therapy, duration of disease, etc. We suggest further research to investigate correlation between % CHO consumption & 2h-PPBG & other glycaemic parameters.

Table 6 Glycemic level after stratification by percent energy from CHO consumption in T2DM group (descriptive observation)

Blood glucose parameters	**Percentage of total energy intake from CHO stratification**		
	<50%	**50%–60%**	**>60%**
FBG (mg/dL) mean (SD) (n=314)	150.8 (61.6) n=16	147.0 (65.6) n=76	148.3 (59.6) n=222
PPBG (mg/dL) mean (SD) (n=309)	225.0 (91.8) n=16	206.2 (91.6) n=77	224.5 (89.4) n=216
HbA1c (%) mean (SD) (n=299)	8.2 (1.2) n=16	8.0 (1.8) n=78	8.2 (2.1) n=205

The most commonly used antidiabetic medications were metformin (77.8%, n=298), sulfonylureas (SU) (72.6%, n=278), alpha-glucosidase inhibitors (AGIs) (26.4%, n=101), thiazolidinedione (TZD) (24.0%, n=92), insulin (20.6%, n=79), and dipeptidyl peptidase-IV inhibitors (DPP4-I) (13.6%, n=52).

DISCUSSION

Our study shows that T2DM subject belonging to any part of India consumes high CHO in their diet if we compare with dietary recommendations.[6,7] Our study showed that 64.1±8.3% (95% CI 63.27 to 64.93) of total calories came from total CHO in T2DM group. This suggests that the CHO consumption by T2DM subject in India is higher (Δ4.1% above upper limit of 60%) than that recommended by the guidelines[6,7] & within recommended limits as per WHO expert consensus.[9]. Recently, Sivasankari *et al*[4] reported similar dietary pattern of T2DM subject from south India (CHO ~65%, P~11.5%, and F~23.5%). Studies from West[10] reported just 39%–49% energy intake from CHO in diet, which is much lower than that reported in our study. This further show that our subjects consume high CHO in their diet compared to western population. T2DM subjects seems to be well aware of restricting the consumption of simple CHO to <10% as per recommendation as per NIN[6], Indian consensus statement[7] & WHO expert recommendations[8] (7.1±10.8% (95% CI 6.0 to 8.2) of total energy came from simple CHO). In region-wise analysis, only eastern region reported higher consumption of simple CHO (20.2±10.0%, 95% CI 18.1 to 22.3); subsequently, lower consumption of complex CHO (45.2±8.2%, 95% CI 43.5 to 47.0) was observed. This reflects typical dietary pattern of subjects from eastern India.

Total calorie intake (1547.5±610.0 kcal, 95% CI 1486.3 to 1608.6) appears in the recommended range of daily allowance in T2DM group (1329–1993 kcal/day, considering mean weight (66.45 kg) and caloric requirements (20–30 kcal/kg/day) as per Misra *et al*.[7] In non-T2DM group (n=409), 66.8±9.1% (95% CI 65.9 to 67.7) of total energy came from total CHO. The difference between T2DM and non-T2DM group was 2.7% ($p<0.001$). As expected, non-T2DM group consumed simple CHO higher than the recommended level (13.9±13.9%, 95% CI 11.1 to 15.3) and relatively lower consumption of complex CHO (52.9±13.3%, 95% CI 51.6 to 54.2). These findings were similar to those reported earlier by G. Radhika et al.[11]

The comparison of macronutrient (i.e., region-wise CHO, fat, and protein) revealed a similar pattern of dietary consumption, that is, high CHO and lower range of fat and protein (figure 1). This study neutralizes the myth that only south Indian population consumes high CHO in their diet (rice, idly, and so on). Similar dietary pattern was also reported in non-T2DM subjects (figure 2).

Our study shows that only 38.1% of total T2DM subjects (n=385, ref table-5) adheres to diet. This findings where similar (37%, adherence to diet) to study reported by Shobhana R et al earlier from south India[12]. Moreover, adherence to diet plan was higher (64.4%, n=218, ref table-5) in T2DM subjects who were advised diet plan by their physicians, little lower than that reported by Patel *et al* (73%)[13] study from western India. These data further suggest the need that all people with T2DM should receive regular nutritional counseling from dietitian/physicians. We suggest people with T2DM should be encouraged to achieve optimal metabolic control through a balance of food intake, physical activity, and medication to avoid long-term complications. Most importantly, specific dietary recommendations should be individualized to accommodate the person's preferences and lifestyle to enhance the acceptance and adherence to diet plan.

The cross-sectional study provides a good opportunity to assess glycemic control in T2DM subjects. In our study, 66.9% T2DM subject had HbA1c above target 7% (non-adjusted for co-variables). Patel *at al*[13] reported similar findings in their study (35% had HbA1c <7%). In T2DM subjects, higher blood glucose levels may reflect poor compliance to therapy, poor physical activity, poor awareness of cutoff points, importance of diet, and so on. Engaging the physicians, trained dietician, and people with diabetes for increasing awareness for lifestyle changes to prevent long-term complications is clearly warranted.

The amount of CHO consumed affects blood glucose levels and insulin responses.[7] In our study, there was a trend (non-significant) toward higher consumption of CHO with high 2-h PPBG levels. Manobala *et al*[14] reported that increase in dietary CHO (% of energy), glycemic load, and weighted glycemic index was associated with increase in HbA1c levels.

In our study, most commonly prescribed antidiabetic drug class was metformin (77.8%) followed by sulfonylurea (72.6%), alpha-glucosidase inhibitors (26.4%), thiazolidinedione (24.0%), insulin (20.6%), and dipeptidyl peptidase-IV inhibitors (13.6%). Similar pattern of drug use was reported earlier in a small study from northern India.[15]

Our study shows that T2DM subjects consumes high CHO in their diet, which has direct effect on post-prandial blood glucose and insulin response.[7] In addition to dietary & life-style modifications, multiple therapeutic strategies like AGIs, SU, Insulin, DPP4-I & glucagon-like-peptide – 1 analogues may benefit out T2DM subjects. Metformin was the most commonly used antidiabetic agent in our study. It is hypoglycemic agent widely used in clinical practice for more than half a decade to treat diabetes. It is as safe and effective as monotherapy and can also be used in combination with any other hypoglycemic agent for treatment of diabetes. Furthermore, it is cost-effective, reduces weight, and is weight neutral. It has less incidence of hypoglycemia as compared to sulfonylurea and insulin and exerts beneficial effects on lipids.[16,17] Second most commonly used medication was sulfonylurea. Among the sulfonylureas, glimepiride was the most commonly used. The higher usage of sulfonylurea is probably due to the need to rapidly control the glucose levels and the preference for glimepiride could be due to its lower propensity to cause hypoglycemia. Next commonly used agents were AGIs (acarbose & voglibose) in our study. AGIs such as acarbose seem to be particularly useful in newly diagnosed T2DM with excessive PPBG, because of their unique mode of action that is to delay digestion and absorption of complex CHO and reduce postprandial rise in blood glucose levels.[18,19] Usage of AGIs seems to be more in our study compared to that reported previously (26.4% in our study vs. 7.6% in Sultana *et al*[15]). The author in his editorial stated that there is a need of therapeutic agents that target the early stage T2DM, such as the alpha-glucosidase enzyme inhibitors that reduce postprandial hyperglycemia and hyperinsulinemia and increase incretin levels (glucagon like peptide-1). This strategy have more prominent role in an Indian setting where the role of AGIs is even more significant as our meal component is rich in CHO as seen in our study.[20] However, we need to investigate further the benefit of various therapeutic interventions in high CHO-consuming Indian T2DM subject in a prospective randomized controlled study to assess this hypothesis.

LIMITATION

This study has some limitations; the cross-sectional design of the study does not allow making inferences about the cause (consumption of high CHO) and effect (glycemic control, rise on PPBG). Another possible limitation of the study includes small sample size, the possibility of measurement error of diet and covariates. The more detailed analysis of the diet (qualitative) was not planned in this study, which could provide more useful information about the quality and quantity of CHO consumed at various meals during a typical day. We did not perform repeat studies and so could not verify the accuracy of our findings. We would like to conduct the post hoc analysis of diet using the available data to further enhance the knowledge on this aspect. Subject flow was mostly from specialty endocrinology/diabetology centers from urban area and may not completely represent the actual T2DM subject in India.

CONCLUSION

Data from present cross-sectional study shows that CHO constitutes 64.1% of total energy from diet in T2DM group, which is higher than the recommended level. There was clear non-adherence (self-reported) to dietary advice in T2DM group. Our findings need to be confirmed in larger epidemiological survey.

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AUTHOR CONTRIBUTIONS

SRJ, RR & PM was involved in study concept; study design; data collection and analysis; and manuscript writing, reviewing, and finalization. AB, SB, SSB, MD, SG, SM, PRS, RS, and SS were involved in data collection and analysis, and were involved in reviewing the manuscript. SSJ was involved in study design, data analysis related to dietary survey, development and validation of dietary survey, and review of the manuscript.

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Study sponsor (Bayer Zydus Pharma, India) was involved in study concept; study center selection, study design; the collection, analysis, and interpretation of data; and in the decision to submit the article for publication. Makrocare was contracted by sponsor for data management, statistical analysis and medical writing.

CONFLICT OF INTEREST

SRJ: *Author:* Bayer Zydus Pharma; *Speaker:* Sanofi, Abbott, USV, Franco Indian, Ranbaxy, PHFI, MSD, Novartis, J & J, Roche Diagnostics, Novo Nordisk, Marico, Emcure; *Consultant, Investigator:* Bayer Zydus Pharma; *Research Support:* Bayer Zydus Pharma; AB: *Advisor,* *Author, Speaker, Consultant, Investigator*: SB: *Investigator*: Bayer Zydus Pharma. SSB: *Advisor, Author, Speaker, Consultant, Investigator*: MD: *Research Grant*: Bayer Zydus Pharma. SG: *Advisor, Author, Speaker, Consultant, Investigator*: SM: *Investigator*: Bayer Zydus Pharma. PSR: *Advisor, Author, Speaker, Consultant, Investigator*: RS: *Advisor, Author, Speaker, Consultant, Investigator*: SS: *Author, Consultant, Investigator*: SJS: *Advisor, Author, Speaker, Consultant, Investigator*: Bayer Zydus Pharma, Emcure; RR & PM: *Author, Employee*: Bayer Zydus Pharma, India. Bayer Zydus pharma markets acarbose in India.

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FIGURE LEGENDS

Figure 1 Regionwise marconutrient composition in T2DM group (% energy intake)

Figure 2 Regionwise marconutrient composition in non-T2DM group (% energy intake)

REFERENCES

1. Mohan V. Why are Indians more prone to diabetes? J Assoc Physician India 2004;52:468–74.
2. Gopalan C. Rising incidence of obesity, coronary heart disease and diabetes in the Indian urban middle class possible. Role of genetic and environmental factors. *World Rev Nutr Diet* 2001;90:127–43.
3. G Radhika, RM Sathya, V Sudha, *et al*. Dietary salt intake and hypertension in an urban south Indian population. *J Association Physician India* 2007;55:405–411.
4. Sivasankari V, Manobala K, Geetha G, *et al*. Dietary profile of Chennai urban adults with diabetes. Poster at RSSDI 2012 (Abstract).
5. American Diabetes Association. Standards of Medical Care in Diabetes – 2013. Diabetes Care 2013;36(Suppl 1):S11-S66.

6. National Institute of Nutrition. *Dietary Guideline for Indians – A Manual*. 2nd Edition. 2010. Available at: http://www.ninindia.org/DietaryguidelinesforIndians-Finaldraft.pdf (accessed 25 Mar 2013).

7. Misra A, Sharma R, Gulati S, *et al*. Consensus dietary guidelines for healthy living and prevention of obesity, the metabolic syndrome, diabetes, and related disorders in Asian Indians. Diabetes Technol Ther 2011;13(6):683–94.

8. Mann J. Dietary carbohydrate: relationship to cardiovascular disease and disorders of carbohydrate metabolism. Eur J Clin Nutr 2007;61 (Suppl 1):S100–S111

9. SSL Parashar. Principles of sociology in health care, Section 4: social, behavioral and communication sciences. *Textbook on Public Health and Community Medicine*. p. 608–13.

10. Esposito K, Maiorino MI, Palo CD, *et al*. Dietary glycemic index and glycemic load are associated with metabolic control in type-2 diabetes: the CAPRI experience. Metab Syndr Relat Disord 2010;8(3):255–61.

11. G Radhika, RM Sathya, V Sudha, *et al*. Dietary salt intake and hypertension in an urban south Indian population. J Assoc Physician India 2007;55:405–11.

12. Shobana R, Begum R, Snehalatha C et al. Patient's adherence to diabetes treatment. J Assoc Physicians India 1999;47(12):1173-5.

13. Patel M, Patel IM, Patel YM, *et al*. Factors associated with consumption of diabetic diet among type 2 diabetic subjects from Ahmedabad, western India. J Health Popul Nutr 2012;30(4):447–55.

14. Manobala K, Lakshmipriya N, Vijayalakshmi P, *et al*. Association of dietary carbohydrates and refined cereal consumption with glycemic control among Chennai urban adults with diabetes. Poster at RSSDI 2012 (Abstract).

15. Sultana G, Kapur P, Aqil M, *et al*. Drug utilization of oral hypoglycemic agents in a university teaching hospital in India. J Clin Pharm Ther 2010;35(3):267–77.

16. Ali S, Fonseca V. Overview of metformin: special focus on metformin extended release. Expert Opin Pharmacother 2012;13(12):1797–1805.

17. Bennett WL, Maruthur NM, Singh S, *et al*. Comparative effectiveness and safety of medications for type 2 diabetes: an update including new drugs and 2-drug combinations. Ann Intern Med 2011;154(9):602–13.

18. Hanefeld M. Acarbose revisited for efficacy, safety and cardiovascular benefits: a key role for controlling glycemic variability. Expert Rev Endocrinol Metab 2012;7(4):395–405.

19. Derosa G, Maffioli P. α-Glucosidase inhibitors and their use in clinical practice. Arch Med Sci 2012;8(5):899–906.

20. Joshi SR. Editorial: post-prandial carbohydrate modulation via gut – Indian perspective. J Assoc Physician India 2010;58:665.

TITLE PAGE

STARCH Study: Results from dietary survey in Indian T2DM population

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STARCH Study: Results from dietary survey in Indian T2DM population

ABSTRACT

Objective: To assess the dietary total and complex carbohydrate (CHO) contents in type-2 diabetes mellitus (T2DM) subjects in India. **Setting:** We enrolled 796 subjects in this cross-sectional, single-visit, multicenter, two-arm, single-country survey. Participants were enrolled from 10 specialty endocrinology/dialectology centers from five regions of India. **Participants:** A total of 796 subjects (Asian) were enrolled in study (385, T2DM & 409, non-T2DM). Key inclusion criteria – male or female ≥18 years, diagnosed with T2DM ≥12 months (T2DM), and not on any diet plan (non-T2DM). **Study Outcome:** Primary outcome of interest was percentage of total energy intake as simple and complex CHO from total CHO. Secondary outcomes were differences in percentage of total energy intake as simple CHO, complex CHO, proteins, and fats between T2DM and non-T2DM groups. Also, percentage of T2DM subject who adhered to diet plan and glycemic controls. **Results:** Mean (SD) of total calorie intake per day (Kcal) were 1547 (610, 95% CI, 1486 – 1608) and 2132 (1892, 95% CI, 1948 – 2316) respectively for T2DM and non-T2DM groups. In T2DM group (n=385), mean (SD) percentage of total energy intake as total CHO, complex CHO & simple CHO was 64.1±8.3 (95% CI 63.3 to 64.9), 57.0±11.0 (95% CI 55.9 to 58.1) and 7.1±10.8 (95% CI 6.0 to 8.2) respectively. Mean (SD) percentage of complex CHO intake from total CHO was 89.5±15.3 (95% CI 88.0 to 91.1). Mean (SD) total protein/fat intake per day (gm) was 57.1 (74.0)/ 37.2 (18.6) and 57.9 (27.2)/ 55.3 (98.2) in T2DM and non-T2DM group respectively. **Conclusions:** Our study shows that CHO constitutes 64.1% of total energy from diet in T2DM subjects; higher than recommended in India. However, our findings need to be confirmed in larger epidemiological survey.

ARTICLE SUMMARY

Strength and limitations of this study

- Study for the first time reports the dietary habits of T2DM subjects from across India
- Study neutralizes the myths associated with differences in dietary habits in different regions of India
- Dietary habits of T2DM subjects are not much different from those of non-T2DM subjects
- Possible limitation of the study includes, small sample size and the possibility of measurement error of diet and covariates
- Population flow was mostly form specialty endocrinology/diabetology centers from urban area

INTRODUCTION

In recent scenario, diabetes is becoming a global public health problem, especially in India. Obesity, especially central obesity, and increased visceral fat due to physical inactivity and consumption of a high-calorie/high-fat and high-sugar diets are major contributing factors for it.[1] In India, as urbanization and economic growth occur, there are major deviations in the dietary pattern that are influenced by varied cultural and social customs. Environmental and lifestyle changes resulting from industrialization and migration to urban environment from rural settings may be responsible to a large extent, contributing to the epidemic of type-2 diabetes mellitus (T2DM) in Indians.[2]

Sparing few smaller studies[3,4] from southern part of India, we do not have studies that document the dietary contents of patients with T2DM from across India. There was a need to conduct a dietary survey considering the diverse dietary food habits in various parts of India. The objective of this study (STARCH: **S**tudy **T**o **A**ssess the dieta**R**y **C**arbo**H**ydrate content of Indian type-2 diabetes population) was to assess the total and complex carbohydrate (CHO) contents in the daily diet of T2DM subjects. Our study provides preliminary information on the dietary carbohydrate, fat and proteins contribution in food consumed by T2DM subject and also how it compares with non-T2DM subjects from pan India.

RESEARCH DESIGN AND METHODS

Study design and study subject

Our study was an exploratory cross-sectional, single-visit, two-arm, multicenter, single-country survey. Study subjects were enrolled (from March 2012 to September 2012) from 10 sites across all regions of India, viz; East, North, West, South and Central considering different dietary patterns. Subjects were enrolled from endocrinology / diabetology clinics / hospitals with clinical research facilities during routine out-patient visits. Study subjects were not provided with any incentives for participation in the study. The subject ≥18 years of age of either sex, diagnosed with T2DM for at least 12 months, were eligible in T2DM group whereas subjects not on any diet plan or dietary advice and who visited for acute illnesses / conditions which do not affect inclusion in the survey were included in non-T2DM. Moreover, non-T2DM subjects were matched to T2Dm subjects with respect to age, sex and center. Patients with specific comorbidities that may impact daily diet, with chronic diseases, or weight management plan that includes dietary modifications or dietary alterations were excluded from study. . All subjects provided written informed consent. Study was conducted in accordance with principles of Good Clinical Practice and was approved by the institutional review boards/ethics committee.

Dietary survey methodology

A dietary survey form, 3-day dietary recall, and validated Food Frequency Questionnaire (FFQ) were completed by a qualified dietitian or trained study coordinator. Dietary assessment included general dietary information (vegetarian or mixed), status of diet plan advised by physician, and information about dietary patterns for both groups with the help of dietary survey form, which included questions about diet consumed during two typical working days and during one typical weekend day (usually Sunday). The final dietary assessment was done using the 3-day dietary recall data.

Primary and secondary outcomes

Primary outcome variables were the percentage of total energy intake as total CHO and complex CHO intake from total CHO in T2DM group. Percentage of total energy intake from CHO was calculated as sum of percentage of energy intake from complex CHO and simple CHO. Secondary outcome variables include difference in the percentage of total energy intake as total, complex, and simple CHO, proteins and fats between T2DM and non-T2DM subjects, percentage of patients with T2DM who adhere to diet plan, glycemic control as per American Diabetes Association (ADA) criteria[5] (HbA1c < 7%, FBG between 70 and 130 mg/dL, and PPBG < 180 mg/dL), and utilization pattern of antidiabetic drugs.

Statistical analysis and evaluations

It was assumed that, at least 50% of total energy intake comes from CHO and at least 50% complex CHO intake comes from total CHO in T2DM subjects. Thus 385 T2DM subjects were required to achieve an allowable error of 5% where allowable error is half width of 95% confidence interval. Taking missing data into consideration, we planned to conduct the survey with a total of 400 subjects each group. All analyses were performed on the eligible subject.

Primary descriptive analysis of the data was performed using basic summary statistics. Further descriptive measures such as n, mean, median, standard deviation (SD), first quartile (Q1), third quartile (Q3), minimum, and maximum were calculated for continuous variables. Percentages were calculated based on non-missing values. Frequency and percentage were calculated for categorical variables. For continuous variables, the mean change was compared statistically between the T2DM and non-T2DM groups using either independent *t*-test or Mann–Whitney *U*-test based on normality of the data. The tests were carried out at 5% level of significance and p-value ≤ 0.05 was considered as significant. Other comparisons specified in the secondary variables were carried out similarly. As per recommendation by the National Institute of Nutrition[6] (NIN) and Indian Consensus Guideline[7] for Healthy Eating, a balanced diet should provide approximately 50%–60% of total calories from CHO (preferably from complex CHO), approximately 10%–15% calories from proteins, and approximately 20%–30% calories from both visible and invisible fats. Data were stratified as per CHO consumption; below NIN recommendation (<50%), as per recommendation (50%–60%), and above recommendation (>60%) to capture natural distribution of patients within these stratifications. In addition, we also compared the findings with WHO Expert group recommendations i.e. total CHO should provide 55–75% total energy and that free sugars should provide less than 10% energy.[8] For categorical variables, the number and percentage of subjects were considered. Continuous data are presented in this article as mean and SD. The statistical evaluations were performed using the software SAS, version 9.1.3.

RESULTS

Demographics and lifestyle characteristics

A total of 796 subjects were enrolled in the study; of those two subjects were screen failure & no subject declined to participate in our study. The remaining 794 subjects (385 in T2DM and 409 in non-T2DM groups) completed survey. Region-wise recruitment was as follows: north region (n=160), east region (n=180), south region (n=158), west region (n=116), and central India (n=180). The demographic characteristics of the analyzed subjects are summarized in table 1. The mean (SD) age of T2DM group was 53.4 (11.16) years and of non-T2DM subjects was 42.5 (12.55) years. Of 794 subjects, 195 (50.6%) and 175 (42.8%) male subjects were from T2DM and non-T2DM groups, respectively. The mean (SD) duration of diabetes (years) was 8.7 (5.95). The mean (SD) body mass index (BMI; kg/$m^{2,}$ mean (SD)) in T2DM and non-T2DM groups was 26.4 (4.4) and 26.7 (5.0), respectively. The region-wise BMI (kg/m^2, mean (SD)) was 25.06 (3.7) and 25.22 (3.53) for east, 26.15 (4.4) and 30.87 (7.1) for west, 26.79 (4.3) and 25.9 (3.8) for north, 26.61 (3.5) and 25.66 (3.6) for south, and 26.87 (5.0) and 26.25 (4.4) for central region in T2DM and non-T2DM groups, respectively. The diet in both T2DM and non-T2DM groups was composed of nearly equal (±5%) distribution of vegetarian and mixed diet (vegetarian plus non-vegetarian). In T2DM (n=385) and non-T2DM group (n=409), 248 (64.4%) and 176 (43.0%) subjects were doing exercise. Among them, 228 (91.9%; n=248) and 150 (85.2%; n=176) were reported as doing exercise regularly in T2DM and non-T2DM group, respectively; 40.3% (n=155) and 59.2% (n=228, data not available for two participants) in T2DM group reported active and sedentary lifestyle respectively.

Primary and secondary outcomes

In T2DM group (n=385), the mean (SD) percentage of total energy intake as total CHO was 64.1±8.3 (95% CI 63.3 to 64.9), as complex CHO was 57.0±11.0 (95% CI 55.9 to 58.1), and as simple CHO was 7.1±10.8 (95% CI 6.0 to 8.2). The mean (SD) percentage of complex CHO intake from total CHO was 89.5±15.3 (95% CI 88.0 to 91.1). The overall summary and comparative analysis of T2DM & non-T2DM subject is presented in table 2. The region-wise mean carbohydrate intake (%, mean (SD)) is summarized in table 3.

Table 1 Demographic characteristics of T2DM and non-T2DM group (n=794)

Parameters	T2DM (n=385)	Non-T2DM (n=409)
Age (years, mean (SD))	53.4 (11.16)	42.5 (12.55)
Gender, n (%)		
Male	195 (50.6)	175 (42.8)
Female	190 (49.45)	234 (57.2)
Body weight (kg), n (%)	66.45 (11.51)	68.54 (12.89)
Body mass index (kg/m2), n (%)	26.4 (4.4)	26.7 (5.0)
Socioeconomic status, n* (%)		
Lower class	8 (2.1)	1 (0.2)
Upper lower	64 (16.6)	12 (2.9)
Lower middle	54 (14.0)	39 (9.5)
Upper middle	195 (50.6)	261 (63.8)
Upper class	64 (16.6)	96 (23.5)
Diet, n (%)		
Vegetarian	170 (44.2)	195 (50.6)
Mixed diet	215 (55.8)	190 (49.4)

*The socioeconomic status was analyzed using Kuppuswamy's scale which is based on three parameters: education of head of family, occupation, and family income (per month).[9]

Table 2 Secondary Outcome: Summary and comparative analysis of dietary content of T2DM & non-T2DM groups

	T2DM (N=385)	Non-T2DM (N=409)	Mean Diff. between groups	P-Value
Total calorie per day (Kcal)				
Mean (SD)	1547.46 (610.02)	2132.23 (1892.48)	584.77 (1423.17)	<0.0001^
Total simple CHO per day (gm)				
Mean (SD)	28.25 (44.60)	90.867 (149.51)	62.61 (111.71)	<0.0001^
Total complex CHO per day (gm)				
Mean (SD)	217.88 (91.48)	259.85 (136.89)	41.97 (117.09)	<0.0001^
Total CHO per day (gm)				
Mean (SD)	246.13 (91.64)	350.72 (252.95)	104.58 (192.44)	<0.0001^
Total protein per day (gm)				
Mean (SD)	57.11 (74.01)	57.89 (27.23)	0.78 (55.11)	0.0539^
Total fat per day (gm)				
Mean (SD)	37.16 (18.56)	55.30 (98.19)	18.14 (71.65)	<0.0001^
Percentage of total energy simple CHO (%)				
Mean (SD)	7.09 (10.85)	13.91 (13.86)	6.82 (12.49)	<0.0001^
Percentage of total energy complex CHO (%)				
Mean (SD)	57.00 (11.01)	52.92 (13.32)	-4.08 (12.25)	0.0001^
Percentage of total energy total CHO (%)				
Mean (SD)	64.09 (8.28)	66.83 (9.15)	2.74 (8.74)	<0.0001^
Percentage of total energy proteins (%)				
Mean (SD)	14.33 (4.45)	12.01(3.23)	-2.32 (3.87)	<0.0001^
Percentage of total energy fats (%)				
Mean (SD)	21.56 (7.89)	21.15 (9.05)	-0.41 (8.51)	0.0637^

*Independent T-Test/^ Mann-Whitney U test used to calculate p-value based on normality assumption. Test done at 5% Significance level and P <= 0.05 indicates Significance. # Mean Diff. between groups = Mean of non-T2DM group- Mean of T2DM group.

Table 3 Region-wise mean CHO (in %, mean (SD) and g/day) intake in T2DM group

Region	T2DM group				
	n	Simple CHO, mean (SD)	Complex CHO, mean (SD)	Total CHO, mean (SD)	Total CHO, g/day (SD)
East	90	20.2 (9.9)	45.2 (8.2)	65.4 (6.8)	255 (47)
West	46	0.4 (1.5)	60.5 (7.3)	60.9 (7.3)	225 (59)
North	80	0.9 (1.7)	61.8 (5.6)	62.7 (5.1)	235 (66)
South	79	6.8 (12.4)	55.5 (11.7)	62.3 (12.9)	228 (68)
Central	90	3.1 (4.6)	64.1 (7.7)	67.2 (5.6)	273 (151)
All	385	7.1 (10.8)	57.0 (11.0)	64.1 (8.3)	246 (92)

In non-T2DM group (n=409), the mean (SD) percentage of total energy intake as total CHO was 66.8 (9.1, 95% CI), complex CHO was 52.9 (13.3, 95% CI 51.6 to 54.2), and simple CHO was 13.9 (13.8, 95% CI 12.6 to 15.2). The region-wise CHO intake (in %, mean (SD)) is summarized in table 4.

Table 4 Region-wise mean CHO (%, mean (SD) and g/day) intake in non-T2DM group

Region	Non-T2DM group				
	n	**Simple CHO, mean (SD)**	**Complex CHO, mean (SD)**	**Total CHO, mean (SD)**	**Total CHO, g/day (SD)**
East	90	10.3 (6.3)	54.3 (13.2)	64.6 (9.0)	342 (149)
West	70	22.7 (18.6)	43.7 (16.2)	66.4 (10.8)	523 (520)
North	80	4.4 (2.1)	62.9 (4.9)	67.3 (4.8)	268 (82)
South	79	20.6 (17.3)	45.3 (9.1)	65.9 (13.5)	295 (123)
Central	90	13.4 (10.4)	56.5 (10.8)	69.8 (3.9)	347 (96)
All	409	13.9 (13.9)	52.9 (13.3)	66.8 (9.1)	351 (253)

The mean (SD) of total calorie intake per day (kcal) were 1547 (610, 95% CI 1486 to 1608) and 2132 (1892, 95% CI 1948 to 2316), respectively, for T2DM and non-T2DM groups. The mean (SD) of total CHO intake per day (g) were 246 (92, 95% CI 236 to 255) and 351 (253, 95% CI 326 to 357); total protein intake per day (g) were 57 (74, 95% CI 49 to 64) and 58 (27, 95% CI

55 to 60); and total fats intake (g) per day were 37 (18, 95% CI 35 to 39) and 55 (98, 95% CI 45 to 65) for T2DM and non-T2DM groups. The mean (SD) of percentage of total energy intake from total CHO were 64.1 (8.2, 95% CI 63.3 to 64.9) and 66.8 (9.1, 95% CI 65.9 to 67.7), from protein were 14.3 (4.4, 95% CI 13.9 to 14.8) and 12.0 (3.2, 95% CI 11.7 to 12.3), and from fats were 21.5 (7.9, 95% CI 20.8 to 22.4) and 21.1 (9.0, 95% CI 20.3 to 22.0), respectively, for T2DM and non-T2DM groups. There was a significant difference between T2DM and non-T2DM groups (Δ 2.7±8.7%, Δ −2.3±3.9%; p≤0.0001) for total energy intake from total CHO and proteins (% energy). There was no significant difference between T2DM and non-T2DM groups (Δ −0.4±8.5%; p=0.0637) for total energy intake from fats (% energy). The region-wise mean percentage of total energy intake from macronutrients in T2DM and non-T2DM groups is summarized in figures 1 and 2, respectively. Among T2DM group (n=385), 169 (43.9%) patients were vegetarian and 216 (56.1%) were mixed diet. Similarly, 194 (47.3 %) participants were vegetarian and 215 (52.6%) were mixed diet in non-T2DM group (n=409).

Figure 1 Regionwise marconutrient composition in T2DM group (% energy intake)

<<Figure 1>>

Figure 2 Regionwise marconutrient composition in non-T2DM group (% energy intake)

<<Figure 2>>

In T2DM group (n=385), 218 (56.6%) subjects were advised for diet plan by their physician. The adherence to prescribed diet was recorded as yes or no outcome by asking subject whether they adhere to diet plan. We considered this approach as appropriate due to cross sectional nature of this survey. From patients with T2DM who were advised diet plan (n=218), 147 (67.4%) self-reported adherence. The most common reasons for non-adherence (n=71) were not bothered about suggested diet plan (48, 67.6%), not liking advised diet (13, 18.3%), lack of support to prepare advised diet (4, 5.6%), and other reasons not specified (6, 8.4%). The CHO consumption & glycaemic parameters as per diet plan adherence is depicted in table 5, however, the relationship between this covariate was not further analyzed.

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Table 5 CHO consumption & glycaemic parameters with respect to diet plan adherence in T2DM group

Parameters	**Diet plan**		
	Advised (n=218)		**Not advised (n=167)**
	Adherent to diet (n=147)	**Not adherent to diet (n=71)**	
Total CHO intake (%, SD)	63.4 (9.3)	60.4 (7.1)	66.2 (6.9)
Complex CHO intake (%, SD)	54.1 (11.9)	56.1 (9.4)	60.0 (10.1)
Simple CHO intake (%, SD)	9.4 (13.2)	4.3 (7.4)	6.2 (9.3)
FBG (mg/dl)	n=100	n=61	n=153
mg/dl, mean (SD)	146.1 (62.0)	142.2 (54.4)	151.8 (62.9)
Control level* (70-100 mg/dl) (n, (%))	52 (35.4)	30 (42.3)	70 (41.9)
PPBG (mg/dl)	n=97	n=60	n=153
mg/dl, mean (SD)	220.2 (78.7)	212.1 (100.6)	223.1 (93.0)
Control level* (<180 mg/dl) (n, (%))	34 (23.1)	29 (40.8)	53 (31.7)
HbA1c (%)	n=96	n=59	n=1544
Percent, mean (SD)	8.0 (1.7)	7.8 (1.8)	8.4 (2.2)
Control level* (<7%) (n, (%))	27 (18.4)	26 (36.6)	46 (27.5)

* As per ADA criteria[5] i.e. HbA1c < 7%, FBG between 70 and 130 mg/dL, and PPBG < 180 mg/dL

In our study, the mean (SD) HbA1c (%, n=299) was 8.2 (2.0), FBG (mg/dL, n=314) was 148.2 (61.0), and 2-h PPBG (mg/dL, n=309) was 220.0 (90.2) in T2DM group. For glycemic control as per ADA[6] criteria, out of 299 subjects, 33.1% (n=99) had HbA1c <7%; out of 314, 48.4% (n=152) had FBG between 70 and 130 mg/dL; and out of 309, 37.5% (n=116) had 2-h PPBG <180 mg/dL. This means 66.9%, 51.6%, and 62.5% subjects had HbA1c, FBG, and 2-h PPBG above the recommended levels.

In T2DM group, after stratifications as per percent energy from CHO consumption <50%, 50%-60% & >60%, the mean (SD) of 2-h PPBG (mg/dL) were 225.0 (91.8); 206.2 (91.6); 224.5 (89.4) respectively (table 6). There was a trend toward increasing 2-h PPBG with increase in CHO consumption (% energy) if we consider subjects with percent energy consumption ≥50% from CHO (n=16, consuming <50% of total energy from CHO, hence not considered). However, the current study was not powered to investigate the effect of CHO consumption & relationship with glycemic control. We present here the observations from our study without doing further analysis considering the various confounder factors like age, sex, BMI, drug therapy, duration of disease, etc. We suggest further research to investigate correlation between % CHO consumption & 2h-PPBG & other glycaemic parameters.

Table 6 Glycemic level after stratification by percent energy from CHO consumption in T2DM group (descriptive observation)

Blood glucose parameters	Percentage of total energy intake from CHO stratification		
	<50%	50%–60%	>60%
FBG (mg/dL) mean (SD) (n=314)	150.8 (61.6) n=16	147.0 (65.6) n=76	148.3 (59.6) n=222
PPBG (mg/dL) mean (SD) (n=309)	225.0 (91.8) n=16	206.2 (91.6) n=77	224.5 (89.4) n=216
HbA1c (%) mean (SD) (n=299)	8.2 (1.2) n=16	8.0 (1.8) n=78	8.2 (2.1) n=205

The most commonly used antidiabetic medications were metformin (77.8%, n=298), sulfonylureas (SU) (72.6%, n=278), alpha-glucosidase inhibitors (AGIs) (26.4%, n=101), thiazolidinedione (TZD) (24.0%, n=92), insulin (20.6%, n=79), and dipeptidyl peptidase-IV inhibitors (DPP4-I) (13.6%, n=52).

DISCUSSION

Our study shows that T2DM subject belonging to any part of India consumes high CHO in their diet if we compare with dietary recommendations.[6,7] Our study showed that 64.1±8.3% (95% CI 63.27 to 64.93) of total calories came from total CHO in T2DM group. This suggests that the CHO consumption by T2DM subject in India is higher (Δ4.1% above upper limit of 60%) than that recommended by the guidelines[6,7] & within recommended limits as per WHO expert consensus.[8]. Recently, Sivasankari *et al*[4] reported similar dietary pattern of T2DM subject from south India (CHO ~65%, P~11.5%, and F~23.5%). Studies from West[10] reported just 39%–49% energy intake from CHO in diet, which is much lower than that reported in our study. This further show that our subjects consume high CHO in their diet compared to western population. T2DM subjects seems to be well aware of restricting the consumption of simple CHO to <10% as per recommendation as per NIN[6], Indian consensus statement[7] & WHO expert recommendations[8] (7.1±10.8% (95% CI 6.0 to 8.2) of total energy came from simple CHO). In region-wise analysis, only eastern region reported higher consumption of simple CHO (20.2±10.0%, 95% CI 18.1 to 22.3); subsequently, lower consumption of complex CHO (45.2±8.2%, 95% CI 43.5 to 47.0) was observed. This reflects typical dietary pattern of subjects from eastern India.

Total calorie intake (1547.5±610.0 kcal, 95% CI 1486.3 to 1608.6) appears in the recommended range of daily allowance in T2DM group (1329–1993 kcal/day, considering mean weight (66.45 kg) and caloric requirements (20–30 kcal/kg/day) as per Misra *et al*.[7] In non-T2DM group (n=409), 66.8±9.1% (95% CI 65.9 to 67.7) of total energy came from total CHO. The difference between T2DM and non-T2DM group was 2.7% ($p<0.001$). As expected, non-T2DM group consumed simple CHO higher than the recommended level (13.9±13.9%, 95% CI 11.1 to 15.3) and relatively lower consumption of complex CHO (52.9±13.3%, 95% CI 51.6 to 54.2). These findings were similar to those reported earlier by G. Radhika et al.[11]

The comparison of macronutrient (i.e., region-wise CHO, fat, and protein) revealed a similar pattern of dietary consumption, that is, high CHO and lower range of fat and protein (figure 1). This study neutralizes the myth that only south Indian population consumes high CHO in their diet (rice, idly, and so on). Similar dietary pattern was also reported in non-T2DM subjects (figure 2).

Our study shows that only 38.1% of total T2DM subjects (n=385, ref table-5) adheres to diet. This findings where similar (37%, adherence to diet) to study reported by Shobhana R et al earlier from south India[12]. Moreover, adherence to diet plan was higher (64.4%, n=218, ref table-5) in T2DM subjects who were advised diet plan by their physicians, little lower than that reported by Patel *et al* (73%)[13] study from western India. These data further suggest the need that all people with T2DM should receive regular nutritional counseling from dietitian/physicians. We suggest people with T2DM should be encouraged to achieve optimal metabolic control through a balance of food intake, physical activity, and medication to avoid long-term complications. Most importantly, specific dietary recommendations should be individualized to accommodate the person's preferences and lifestyle to enhance the acceptance and adherence to diet plan.

The cross-sectional study provides a good opportunity to assess glycemic control in T2DM subjects. In our study, 66.9% T2DM subject had HbA1c above target 7% (non-adjusted for co-variables). Patel *at al*[13] reported similar findings in their study (35% had HbA1c <7%). In T2DM subjects, higher blood glucose levels may reflect poor compliance to therapy, poor physical activity, poor awareness of cutoff points, importance of diet, and so on. Engaging the physicians, trained dietician, and people with diabetes for increasing awareness for lifestyle changes to prevent long-term complications is clearly warranted.

The amount of CHO consumed affects blood glucose levels and insulin responses.[7] In our study, there was a trend (non-significant) toward higher consumption of CHO with high 2-h PPBG levels. Manobala *et al*[14] reported that increase in dietary CHO (% of energy), glycemic load, and weighted glycemic index was associated with increase in HbA1c levels.

In our study, most commonly prescribed antidiabetic drug class was metformin (77.8%) followed by sulfonylurea (72.6%), alpha-glucosidase inhibitors (26.4%), thiazolidinedione (24.0%), insulin (20.6%), and dipeptidyl peptidase-IV inhibitors (13.6%). Similar pattern of drug use was reported earlier in a small study from northern India.[15]

Our study shows that T2DM subjects consumes high CHO in their diet, which has direct effect on post-prandial blood glucose and insulin response.[7] In addition to dietary & life-style modifications, multiple therapeutic strategies like AGIs, SU, Insulin, DPP4-I & glucagon-like-peptide – 1 analogues may benefit out T2DM subjects. Metformin was the most commonly used antidiabetic agent in our study. It is hypoglycemic agent widely used in clinical practice for more than half a decade to treat diabetes. It is as safe and effective as monotherapy and can also be used in combination with any other hypoglycemic agent for treatment of diabetes. Furthermore, it is cost-effective, reduces weight, and is weight neutral. It has less incidence of hypoglycemia as compared to sulfonylurea and insulin and exerts beneficial effects on lipids.[16,17] Second most commonly used medication was sulfonylurea. Among the sulfonylureas, glimepiride was the most commonly used. The higher usage of sulfonylurea is probably due to the need to rapidly control the glucose levels and the preference for glimepiride could be due to its lower propensity to cause hypoglycemia. Next commonly used agents were AGIs (acarbose & voglibose) in our study. AGIs such as acarbose seem to be particularly useful in newly diagnosed T2DM with excessive PPBG, because of their unique mode of action that is to delay digestion and absorption of complex CHO and reduce postprandial rise in blood glucose levels.[18,19] Usage of AGIs seems to be more in our study compared to that reported previously (26.4% in our study vs. 7.6% in Sultana *et al*[15]). The author in his editorial stated that there is a need of therapeutic agents that target the early stage T2DM, such as the alpha-glucosidase enzyme inhibitors that reduce postprandial hyperglycemia and hyperinsulinemia and increase incretin levels (glucagon like peptide-1). This strategy have more prominent role in an Indian setting where the role of AGIs is even more significant as our meal component is rich in CHO as seen in our study.[20] However, we need to investigate further the benefit of various therapeutic interventions in high CHO-consuming Indian T2DM subject in a prospective randomized controlled study to assess this hypothesis.

LIMITATION

This study has some limitations; the cross-sectional design of the study does not allow making inferences about the cause (consumption of high CHO) and effect (glycemic control, rise on PPBG). Another possible limitation of the study includes small sample size, the possibility of measurement error of diet and covariates. The more detailed analysis of the diet (qualitative) was not planned in this study, which could provide more useful information about the quality and quantity of CHO consumed at various meals during a typical day. We did not perform repeat studies and so could not verify the accuracy of our findings. We would like to conduct the post hoc analysis of diet using the available data to further enhance the knowledge on this aspect. Subject flow was mostly from specialty endocrinology/diabetology centers from urban area and may not completely represent the actual T2DM subject in India.

CONCLUSION

Data from present cross-sectional study shows that CHO constitutes 64.1% of total energy from diet in T2DM group, which is higher than the recommended level. There was clear non-adherence (self-reported) to dietary advice in T2DM group. Our findings need to be confirmed in larger epidemiological survey.

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AUTHOR CONTRIBUTIONS

SRJ, RR & PM was involved in study concept; study design; data collection and analysis; and manuscript writing, reviewing, and finalization. AB, SB, SSB, MD, SG, SM, PRS, RS, and SS were involved in data collection and analysis, and were involved in reviewing the manuscript. SSJ was involved in study design, data analysis related to dietary survey, development and validation of dietary survey, and review of the manuscript.

FUNDING SOURCE

Study sponsor (Bayer Zydus Pharma, India) was involved in study concept; study center selection, study design; the collection, analysis, and interpretation of data; and in the decision to submit the article for publication. Makrocare was contracted by sponsor for data management, statistical analysis and medical writing.

CONFLICT OF INTEREST

SRJ: *Advisor, Author, Speaker, Consultant, Investigator, Research Support*: AB: *Author, Research Grant*: Bayer Zydus Pharma; SB: *Investigator*: Bayer Zydus Pharma; SSB: *Investigator*: Bayer Zydus Pharma; MD: *Research Grant*: Bayer Zydus Pharma; SG:

Comment [RR1]: Need update

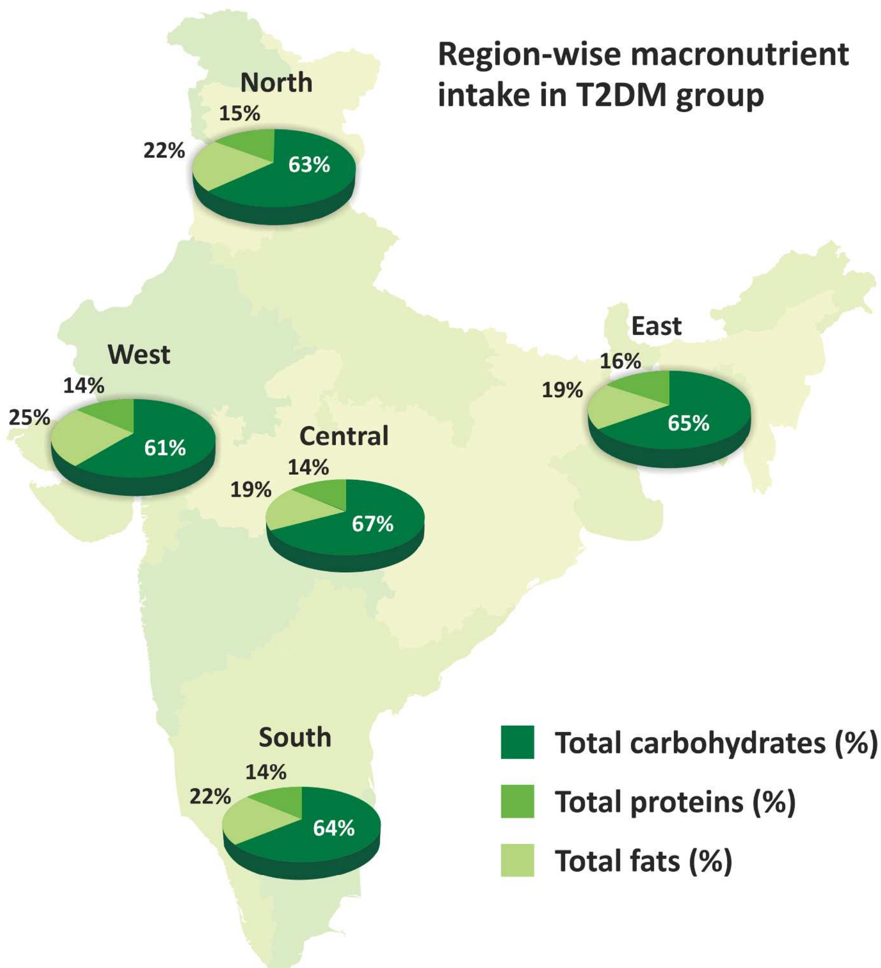
Investigator: Bayer Zydus Pharma; SM: *Investigator*: Bayer Zydus Pharma; PRS: *Advisor, Speaker, Investigator*: Bayer Zydus Pharma; RS: *Author, Investigator*: Bayer Zydus Pharma; *Advisor:* Sanofi, Eli Lily; *Advisor, Author:* Nova Nordisk; *Speaker:* USV India, Alkem; SS: *Investigator*: Bayer Zydus Pharma; SSJ: *Advisor, Author, Speaker, Consultant, Investigator*: RR & PM: *Author,* Employee: Bayer Zydus Pharma, India. Bayer Zydus pharma markets acarbose in India.

Comment [RR2]: Need update

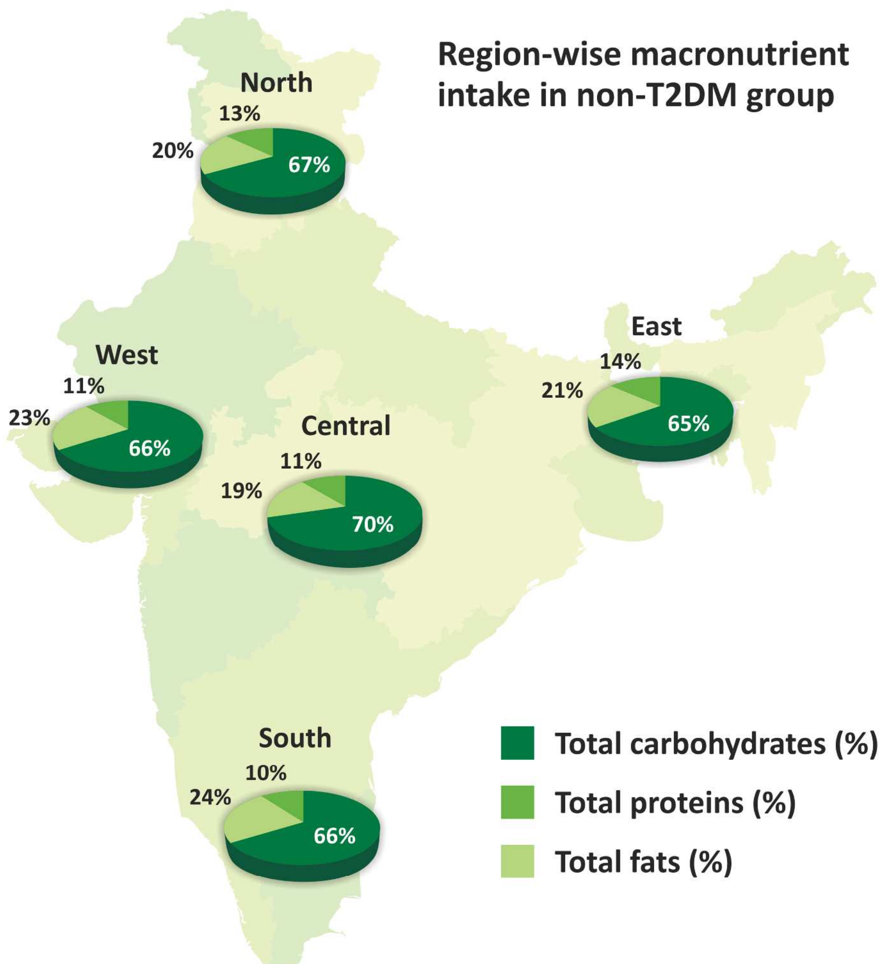
REFERENCES

1. Mohan V. Why are Indians more prone to diabetes? J Assoc Physician India 2004;52:468–74.
2. Gopalan C. Rising incidence of obesity, coronary heart disease and diabetes in the Indian urban middle class possible. Role of genetic and environmental factors. *World Rev Nutr Diet* 2001;90:127–43.
3. G Radhika, RM Sathya, V Sudha, *et al*. Dietary salt intake and hypertension in an urban south Indian population. *J Association Physician India* 2007;55:405–411.
4. Sivasankari V, Manobala K, Geetha G, *et al*. Dietary profile of Chennai urban adults with diabetes. Poster at RSSDI 2012 (Abstract).
5. American Diabetes Association. Standards of Medical Care in Diabetes – 2013. Diabetes Care 2013;36(Suppl 1):S11-S66.
6. National Institute of Nutrition. *Dietary Guideline for Indians – A Manual*. 2nd Edition. 2010. Available at: http://www.ninindia.org/DietaryguidelinesforIndians-Finaldraft.pdf (accessed 25 Mar 2013).
7. Misra A, Sharma R, Gulati S, *et al*. Consensus dietary guidelines for healthy living and prevention of obesity, the metabolic syndrome, diabetes, and related disorders in Asian Indians. Diabetes Technol Ther 2011;13(6):683–94.
8. Mann J. Dietary carbohydrate: relationship to cardiovascular disease and disorders of carbohydrate metabolism. Eur J Clin Nutr 2007;61 (Suppl 1):S100–S111
9. SSL Parashar. Principles of sociology in health care, Section 4: social, behavioral and communication sciences. *Textbook on Public Health and Community Medicine*. p. 608–13.

10. Esposito K, Maiorino MI, Palo CD, *et al*. Dietary glycemic index and glycemic load are associated with metabolic control in type-2 diabetes: the CAPRI experience. Metab Syndr Relat Disord 2010;8(3):255–61.
11. G Radhika, RM Sathya, V Sudha, *et al*. Dietary salt intake and hypertension in an urban south Indian population. J Assoc Physician India 2007;55:405–11.
12. Shobana R, Begum R, Snehalatha C et al. Patient's adherence to diabetes treatment. J Assoc Physicians India 1999;47(12):1173-5.
13. Patel M, Patel IM, Patel YM, *et al*. Factors associated with consumption of diabetic diet among type 2 diabetic subjects from Ahmedabad, western India. J Health Popul Nutr 2012;30(4):447–55.
14. Manobala K, Lakshmipriya N, Vijayalakshmi P, *et al*. Association of dietary carbohydrates and refined cereal consumption with glycemic control among Chennai urban adults with diabetes. Poster at RSSDI 2012 (Abstract).
15. Sultana G, Kapur P, Aqil M, *et al*. Drug utilization of oral hypoglycemic agents in a university teaching hospital in India. J Clin Pharm Ther 2010;35(3):267–77.
16. Ali S, Fonseca V. Overview of metformin: special focus on metformin extended release. Expert Opin Pharmacother 2012;13(12):1797–1805.
17. Bennett WL, Maruthur NM, Singh S, *et al*. Comparative effectiveness and safety of medications for type 2 diabetes: an update including new drugs and 2-drug combinations. Ann Intern Med 2011;154(9):602–13.
18. Hanefeld M. Acarbose revisited for efficacy, safety and cardiovascular benefits: a key role for controlling glycemic variability. Expert Rev Endocrinol Metab 2012;7(4):395–405.
19. Derosa G, Maffioli P. α-Glucosidase inhibitors and their use in clinical practice. Arch Med Sci 2012;8(5):899–906.
20. Joshi SR. Editorial: post-prandial carbohydrate modulation via gut – Indian perspective. J Assoc Physician India 2010;58:665.



Regionwise marconutrient composition in T2DM group (% energy intake)
215x279mm (300 x 300 DPI)



Regionwise marconutrient composition in non-T2DM group (% energy intake)
215x279mm (300 x 300 DPI)

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract -Y
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found -Y
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported - Y
Objectives	3	State specific objectives, including any prespecified hypotheses - Y
Methods		
Study design	4	Present key elements of study design early in the paper - Y
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection - Y
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants - Y
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable -
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group -Y
Bias	9	Describe any efforts to address potential sources of bias - Y
Study size	10	Explain how the study size was arrived at - Y
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why - Y
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding - Y
		(*b*) Describe any methods used to examine subgroups and interactions
		(*c*) Explain how missing data were addressed - Y
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy - Y
		(*e*) Describe any sensitivity analyses

Continued on next page

Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed - Y
		(b) Give reasons for non-participation at each stage - Y
		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders - Y
		(b) Indicate number of participants with missing data for each variable of interest – Y, as applicable
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time
		Case-control study—Report numbers in each exposure category, or summary measures of exposure -
		Cross-sectional study—Report numbers of outcome events or summary measures -Y
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included – Y, as applicable
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives - Y
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias - Y
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence - Y
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based - Y

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.