BMJ Open

Results from a dietary survey in an Indian T2DM population: a STARCH study

Shashank R Joshi,[1] Anil Bhansali,[2] Sarita Bajaj,[3] Subodh S Banzal,[4] Mala Dharmalingam,[5] Shachin Gupta,[6] Satinath Mukhopadhyay,[7] Parag R Shah,[8] Rakesh Sahay,[9] Swapan Sarkar,[10] Pravin V Manjrekar,[11] Rahul T Rathod,[11] Shilpa S Joshi[12]

For numbered affiliations see end of article.

Correspondence to
Dr Shashank R Joshi; shashank.sr@gmail.com

ABSTRACT

Objective: To assess the dietary total and complex carbohydrate (CHO) contents in type-2 diabetes mellitus (T2DM) participants in India.

Setting: We enrolled 796 participants in this cross-sectional, single-visit, multicentre, two-arm, single-country survey. Participants were enrolled from 10 specialty endocrinology/dialectology centres from five regions of India.

Participants: A total of 796 participants (Asian) were enrolled in this study (385, T2DM and 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 was to find out the percentage of total energy intake as simple and complex CHO from total CHO. Secondary outcomes were to find the differences in percentage of total energy intake as simple CHO, complex CHO, proteins and fats between T2DM and non-T2DM groups. The percentage of T2DM participants adhering to diet plan and showing glycaemic controls were also examined.

Results: The mean (SD) of total calorie intake per day (Kcal) was 1547 (610, 95% CI 1486 to 1608) and 2132 (1892, 95% CI 1948 to 2316), respectively, for T2DM and non-T2DM groups. In the T2DM group (n=385), the mean (SD) percentage of total energy intake as total CHO, complex CHO and 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. The mean (SD) percentage of complex CHO intake from total CHO was 89.5±15.3 (95% CI 88.0 to 91.1). The mean (SD) total protein/fat intake per day (g) was 57.1 (74.0)/37.2 (18.6) and 57.9 (27.2)/55.3 (98.2) in T2DM and non-T2DM groups, respectively.

Conclusions: Our study shows that CHO constitutes 64.1% of total energy from diet in T2DM participants, higher than that recommended in India. However, our findings need to be confirmed in a larger epidemiological survey.

Trial registration number: NCT01450592 & Clinical Trial Registry of India: CTRI/2012/02/002398.

Strength and limitations of this study

- The study for the first time reports the dietary habits of type-2 diabetes mellitus (T2DM) participants from across India.
- The study neutralises the myths associated with differences in dietary habits in different regions of India.
- The dietary habits of T2DM participants are not much different from those of non-T2DM participants.
- A possible limitation of the study includes the small sample size and the possibility of measurement error of diet and covariates.
- Population flow was mostly from specialty endocrinology/diabetology centres from urban areas.

especially in India. Obesity, especially central obesity, and increased visceral fat due to physical inactivity and consumption of high-calorie/high-fat and high-sugar diets are major contributing factors for it.[1] In India, as urbanisation 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 industrialisation and migration to an urban environment from rural settings may be responsible to a large extent in contributing to the epidemic of type-2 diabetes mellitus (T2DM) in Indians.[2]

Barring a few smaller studies[3][4] from the southern part of India, we do not have any 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: Study To Assess the dietaRy CarboHydrate content of Indian type-2 diabetes population) was to assess the total and complex carbohydrate (CHO) contents in the daily diet of T2DM participants. Our study not only provides preliminary information on the dietary carbohydrate, fat and

INTRODUCTION

According to a recent scenario, diabetes is becoming a global public health problem,

protein contribution in food consumed by T2DM participants but also shows how it compares with non-T2DM participants from pan India.

RESEARCH DESIGN AND METHODS
Study design and study participants
Our study was an exploratory cross-sectional, single-visit, two-arm, multicentre, single-country survey. Study participants 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. Participants were enrolled from endocrinology/diabetology clinics/hospitals with clinical research facilities during routine outpatient visits. Study participants were not provided with any incentives for participation in the study. Participants aged ≥18 years of either sex, diagnosed with T2DM for at least 12 months, were eligible in the T2DM group, whereas participants not on any diet plan or dietary advice and who visited for acute illnesses/conditions that do not affect inclusion in the survey were included in the non-T2DM group. Moreover, non-T2DM participants were matched to T2DM participants with respect to age, sex and centre. Patients with specific comorbidities that may impact daily diet, with chronic diseases, or a weight management plan that includes dietary modifications or dietary alterations were excluded from the study. All participants provided written informed consent.

Dietary survey methodology
A dietary survey form, a 3-day dietary recall, and a 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 the physician, and information about dietary patterns for both groups with the help of the dietary survey form, which included questions about the 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 the T2DM group. The percentage of total energy intake from CHO was calculated as the sum of percentage of energy intake from complex CHO and simple CHO. Secondary outcome variables include the difference in the percentage of total energy intake as total, complex and simple CHO, proteins and fats between T2DM and non-T2DM participants, percentage of patients with T2DM who adhere to the diet plan, glycaemic control as per American Diabetes Association (ADA) criteria[5] (glycated hemoglobin (HbA1c) <7%, fasting blood glucose (FBG) between 70 and 130 mg/dL, postprandial blood glucose (PPBG) <180 mg/dL) and the utilisation pattern of antidiabetic drugs.

Statistical analysis and evaluations
It was assumed that at least 50% of the total energy intake comes from CHO and at least 50% of the complex CHO intake comes from total CHO in T2DM participants. Thus, 385 T2DM participants were required to achieve an allowable error of 5% where the allowable error is half the width of a 95% CI. Taking missing data into consideration, we planned to conduct the survey with a total of 400 participants in each group. All analyses were performed on the eligible participants. The primary descriptive analysis of the data was performed using basic summary statistics. Further descriptive measures such as n, mean, median, 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 T2DM and non-T2DM groups using either the independent t test or the Mann-Whitney U test based on normality of the data. The tests were carried out at a 5% level of significance and a p value ≤0.05 was considered as significant. Other comparisons specified in the secondary variables were carried out similarly. As per recommendations of 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 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 the natural distribution of patients within these stratifications. In addition, we also compared the findings with the WHO Expert group recommendations, that is, 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 participants were considered. Continuous data are presented in this article as the mean and SD. Statistical evaluations were performed using the software SAS, V.9.1.3.

RESULTS
Demographics and lifestyle characteristics
A total of 796 participants were enrolled in the study; of those, two were screen failures and no participant declined to participate in our study. The remaining 794 participants (385 in the T2DM group and 409 in the non-T2DM group) completed the 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 region (n=180). The demographic characteristics of the analysed participants are summarised in table 1. The mean (SD) age of the T2DM group was 53.4 (11.16) years and of the non-T2DM group was 42.5 (12.55) years. Of the 794 participants, 195 (50.6%) and 175 (42.8%) male participants 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), respectively. The region-wise BMI (kg/m^2, mean (SD)) was 25.06 (3.7) and 25.22 (3.53) for the east region, 26.15 (4.4) and 30.87 (7.1) for the west region, 26.79 (4.3) and 25.9 (3.8) for the north region, 26.61 (3.5) and 25.66 (3.6) for the south region, and 26.87 (5.0) and 26.25 (4.4) for the central region in the T2DM and non-T2DM groups, respectively. The diet in 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 groups (n=409), 248 (64.4%) and 176 (43%) participants were doing exercise. Among them, 228 (91.9%; n=248) and 150 (85.2%; n=176) were reported to be doing exercise regularly in T2DM and non-T2DM groups, respectively; 40.3% (n=155) and 59.2% (n=228, data not available for two participants) in the T2DM group reported active and sedentary lifestyles, respectively.

Primary and secondary outcomes

In the 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 and non-T2DM participants is presented in table 2. The region-wise mean CHO intake (%, mean (SD)) is summarised in table 3.

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

The mean (SD) of total calorie intake per day (kcal) was 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) was 246 (92, 95% CI 236 to 255) and 351 (253, 95% CI 326 to 357); total protein intake per day (g) was 57 (74, 95% CI 49 to 64) and 58 (27, 95% CI 55 to 60); and total fat intake (g) per day was 37 (18, 95% CI 35 to 39) and 55 (98, 95% CI 45 to 65), respectively, for T2DM and non-T2DM groups. The mean (SD) of percentage of total energy intake from total CHO was 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 was 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 was 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 summarised in figures 1 and 2, respectively. Among the T2DM group (n=385), 169 (43.9%) patients were vegetarian and 216 (56.1%) were on a mixed diet. Similarly, 194 (47.3%) participants were vegetarian and 215 (52.6%) were on a mixed diet in the non-T2DM group (n=409).

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

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/m^2), 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)

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

*The socioeconomic status was analysed using Kuppuswamy's scale, which is based on three parameters: education of head of family, occupation and family income (per month).[9]
T2DM, type-2 diabetes mellitus; non-T2DM, non-type-2 diabetes mellitus.

Table 2 Secondary outcome: summary and comparative analysis of dietary content of T2DM and non-T2DM groups

	T2DM (N=385)	Non-T2DM (N=409)	Mean difference between groups‡	p Value
Total calories per day (kcal)				
Mean (SD)	1547.46 (610.02)	2132.23 (1892.48)	584.77 (1423.17)	<0.0001†
Total simple CHO per day (g)				
Mean (SD)	28.25 (44.60)	90.867 (149.51)	62.61 (111.71)	<0.0001†
Total complex CHO per day (g)				
Mean (SD)	217.88 (91.48)	259.85 (136.89)	41.97 (117.09)	<0.0001†
Total CHO per day (g)				
Mean (SD)	246.13 (91.64)	350.72 (252.95)	104.58 (192.44)	<0.0001†
Total proteins per day (g)				
Mean (SD)	57.11 (74.01)	57.89 (27.23)	0.78 (55.11)	0.0539†
Total fat per day (g)				
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†

†Mann-Whitney U test used to calculate the p-value based on the normality assumption. Test performed at 5% significance level and p≤0.05 indicates significance.
‡Mean difference between groups=mean of the non-T2DM group-mean of the T2DM group.
CHO, carbohydrate; T2DM, type-2 diabetes mellitus; non-T2DM, non-type-2 diabetes mellitus.

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 the T2DM group. For glycaemic control as per the ADA[6] criteria, of the 299 participants, 33.1% (n=99) had HbA1c <7%; of the 314 participants, 48.4% (n=152) had FBG between 70 and 130 mg/dL; and of the 309 participants, 37.5% (n=116) had 2 h PPBG <180 mg/dL. This means 66.9%, 51.6% and 62.5% of the participants had HbA1c, FBG and 2 h PPBG above the recommended levels.

In the T2DM group, after stratifications as per per cent energy from CHO consumption <50%, 50–60% and >60%, the mean (SD) of 2 h PPBG (mg/dL) was 225.0 (91.8), 206.2 (91.6) and 224.5 (89.4), respectively (table 6). There was a trend towards increasing 2 h

PPBG with an increase in CHO consumption (% energy) if we consider participants with per cent 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 and relationship with glycaemic control. We present 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 and 2 h-PPBG and other glycaemic parameters.

The most commonly used antidiabetic medications were metformin (77.8%, n=298), sulfonylureas (SU)
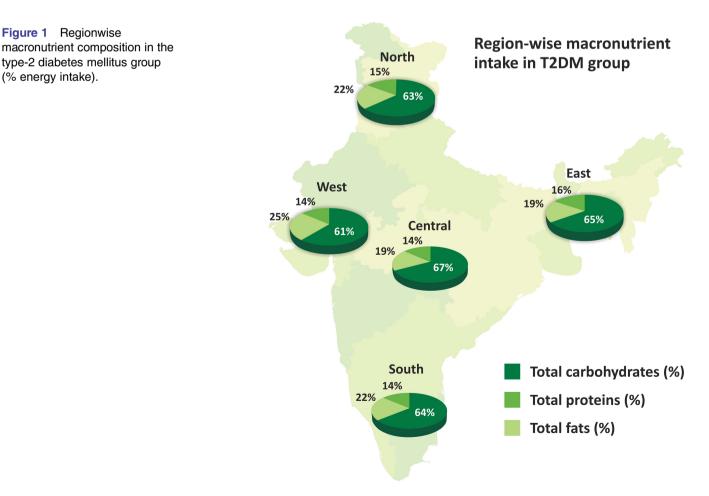
Table 3 Region-wise mean CHO (in %, mean (SD) and g/day) intake in the T2DM group

	T2DM group				
Region	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)

CHO, carbohydrate; T2DM, type-2 diabetes mellitus.

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

| Region | n | Non-T2DM group | | | |
		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)

CHO, carbohydrate; non-T2DM, non-type-2 diabetes mellitus.

(72.6%, n=278), α-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 participants belonging to any part of India consume 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 the T2DM group. This suggests that CHO consumption by T2DM participants in India is higher (Δ4.1% above the upper limit of 60%) than that recommended by the guidelines[6] [7] and within

the recommended limits as per the WHO expert consensus.[9] Recently, Sivasankari et al[4] reported a similar dietary pattern of T2DM participants from south India (CHO ~65%, P~11.5%, and F~23.5%). Studies from the West[10] reported just 39–49% energy intake from CHO in the diet, which is much lower than that reported in our study. This further shows that our participants consume high CHO in their diet compared to the western population. T2DM participants seem to be well aware of the importance of restricting the consumption of simple CHO to <10% as per the recommendations of NIN,[6] the Indian consensus statement,[7] and the 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 the eastern region reported a
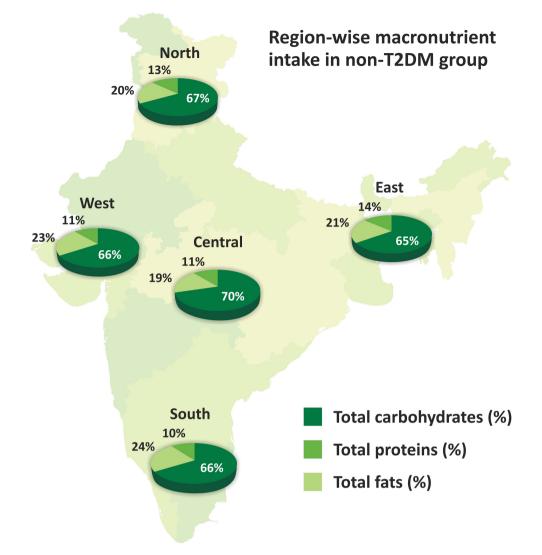
Figure 1 Regionwise macronutrient composition in the type-2 diabetes mellitus group (% energy intake).

Region-wise macronutrient intake in T2DM group

North 15% 22% 63%

West 14% 25% 61%

Central 14% 19% 67%

East 16% 19% 65%

South 14% 22% 64%

Total carbohydrates (%)
Total proteins (%)
Total fats (%)

Figure 2 Regionwise macronutrient composition in the non- type-2 diabetes mellitus group (% energy intake).

higher consumption of simple CHO (20.2±10.0%, 95% CI 18.1 to 22.3); subsequently, a lower consumption of complex CHO (45.2±8.2%, 95% CI 43.5 to 47.0) was observed. This reflects the typical dietary pattern of participants 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 the 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 the 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 groups was 2.7% (p<0.001). As expected, the non-T2DM group consumed simple CHO at a higher level than the recommended level (13.9±13.9%, 95% CI 11.1 to 15.3) and had a 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 Radhika et al.[11]

The comparison of macronutrients (ie, region-wise CHO, fat and protein) revealed a similar pattern of dietary consumption, that is, high CHO and a lower range of fat and protein (figure 1). This study neutralises the myth that only the south Indian population consumes high CHO in their diet (rice, idli and so on). A similar dietary pattern was also reported in non-T2DM participants (figure 2).

Our study shows that only 38.1% of total T2DM participants (n=385, refer table 5) adhere to a diet. This finding is similar (37%, adherence to diet) to that in a study reported by Shobana et al[12] earlier from south India. Moreover, adherence to the diet plan was higher (64.4%, n=218, refer table 5) in T2DM participants who were advised a diet plan by their physicians, but a little lower than that reported by Patel et al[13] (73%) in a study from western India. These data further suggest the need for all people with T2DM to receive regular nutritional counselling from a dietitian/physicians. We suggest that 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 individualised to accommodate the person's

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

Parameters	Diet plan		Not advised (n=167)
	Advised (n=218)		
	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
Per cent, 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] that is, HbA1c < 7%, FBG between 70 and 130 mg/dL, and PPBG <180 mg/dL.
ADA, American Diabetes Association; CHO, carbohydrate; FBG, fasting blood glucose; HbA1c, glycated hemoglobin; PPBG, postprandial blood glucose; T2DM, type-2 diabetes mellitus.

preferences and lifestyle to enhance the acceptance and adherence to the diet plan.

The cross-sectional study provides a good opportunity to assess glycaemic control in T2DM participants. In our study, 66.9% of T2DM participants had HbA1c above the targeted 7% (non-adjusted for co-variables). Patel et al[13] reported similar findings in their study (35% had HbA1c <7%). In T2DM participants, higher blood glucose levels may reflect poor compliance to therapy, poor physical activity, poor awareness of cut-off points, importance of diet and so on. Engaging the physicians, trained dietician and people with diabetes for increasing awareness of 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) towards higher consumption of CHO with high 2 h PPBG levels. Manobala et al[14] reported that an increase in dietary CHO (% of

Table 6 Glycaemic level after stratification by per cent energy from CHO consumption in the 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

CHO, carbohydrate; FBG, fasting blood glucose; HbA1c, glycated hemoglobin; PPBG, postprandial blood glucose; T2DM, type-2 diabetes mellitus.

energy), glycaemic load and weighted glycaemic index was associated with an increase in HbA1c levels.

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

Our study shows that T2DM participants consume high CHO in their diet, which has a direct effect on postprandial blood glucose and insulin response.[7] In addition to dietary and lifestyle modifications, multiple therapeutic strategies like AGIs, SU, Insulin, DPP4-I and glucagon-like-peptide—1 analogues may benefit T2DM participants. Metformin was the most commonly used antidiabetic agent in our study. It is a hypoglycaemic agent that has been 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 hypoglycaemic agent for treatment of diabetes. Furthermore, it is cost-effective, reduces weight and is weight neutral. It has less incidence of hypoglycaemia as compared to sulfonylurea and insulin and exerts beneficial effects on lipids.[16 17] The second most commonly used medication was sulfonylurea. Among sulfonylureas, glimepiride was the one 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 hypoglycaemia. The next commonly used agents were AGIs (acarbose and 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]). In an editorial published in the November 2010 issue of the Journal of Association of Physicians of India,[20] the author expressed the need for therapeutic agents like AGIs that reduce postprandial hyperglycaemia and hyperinsulinaemia and also increase incretin levels (glucagon-like peptide-1) early in the course of T2DM. This strategy may have a more prominent role in an Indian setting where the role of AGIs is even more significant as meal component is rich in CHO as seen in this study.[20] However, we need to investigate further the benefit of various therapeutic interventions in high CHO-consuming Indian T2DM participants in a prospective randomised controlled study to examine this hypothesis.

LIMITATION

This study has some limitations; the cross-sectional design of the study does not allow us to make inferences about the cause (consumption of high CHO) and effect (glycaemic control, rise in PPBG). Another possible limitation of the study includes the small sample size, the possibility of measurement error of diet and covariates. A 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 therefore 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 centres from urban areas and may not completely represent the actual T2DM participants in India.

CONCLUSION

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

Author affiliations
[1]Joshi Clinic, Mumbai, Maharashtra, India
[2]Postgraduate Institute of Medical Education and Research, Chandigarh, India
[3]MLN Medical College, Allahabad, Uttar Pradesh, India
[4]Subodh Banzal's Clinic, Indore, Madhya Pradesh, India
[5]Bangalore Endocrinology and Diabetes Research Center Pvt Ltd, Bangalore, Karnataka, India
[6]Krishna Diabetes Clinic and Educational Research Centre, Bhopal, Madhya Pradesh, India
[7]Institute of Post Graduate Medical Education and Research, Kolkata, West Bengal, India
[8]Gujarat Endocrine Centre, Ahmedabad, Gujarat, India
[9]Sahay's Endocrine and Diabetes Clinic, Hyderabad, Andhra Pradesh, India
[10]Sarkar's Diabetes Nutrition Clinic and Research Center, Agartala, Tripura, India
[11]Department of Medical Affairs, Bayer Zydus Pharma Private Limited, Thane, Maharashtra, India
[12]Mumbai Diet and Health Center, Mumbai, Maharashtra, India

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. Radhika G, Sathya RM, Sudha V, *et al.* Dietary salt intake and hypertension in an urban south Indian population. *J Assoc Physician India* 2007;55:405–11.
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):S11–66.
6. National Institute of Nutrition. *Dietary guideline for Indians—a manual.* 2nd edn. 2010. 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;13:683–94.
8. Mann J. Dietary carbohydrate: relationship to cardiovascular disease and disorders of carbohydrate metabolism. *Eur J Clin Nutr* 2007;61 (Suppl 1):S100–11.
9. SSL Parashar. Principles of sociology in health care, section 4: social, behavioral and communication sciences. In: Bhalwar R ed. *Textbook on public health and community medicine.* New Delhi, India: Department of Community Medicine Armed Forces Medical College Pune in collaboration with WHO India, 2009:608–13.

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;8:255–61.
11. Radhika G, Sathya RM, Sudha V, *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;47:1173–5.
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; 30:447–55.
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;35:267–77.
16. Ali S, Fonseca V. Overview of metformin: special focus on metformin extended release. *Expert Opin Pharmacother* 2012;13:1797–805.
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;154:602–13.
18. Hanefeld M. Acarbose revisited for efficacy, safety and cardiovascular benefits: a key role for controlling glycemic variability. *Expert Rev Endocrinol Metab* 2012;7:395–405.
19. Derosa G, Maffioli P. α-Glucosidase inhibitors and their use in clinical practice. *Arch Med Sci* 2012;8:899–906.
20. Joshi SR. Editorial: post-prandial carbohydrate modulation via gut—Indian perspective. *J Assoc Physician India* 2010;58:665.